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CORRIGENDUM
This document corrects document SWD(2019) 264 final of 25.6.2019.
The watermark "DRAFT" visible from page 6 onwards has been removed.
The text shall read as follows:

COMMISSION STAFF WORKING DOCUMENT

FITNESS CHECK
of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses

{COM(2019) 264 final}

TABLE OF CONTENTS

1 INTRODUCTION

Chemicals are everywhere in our modern society. They are an integral part of most human activities and production processes and they are present in most consumer products, be it for food, electronics, toys, clothes or industrial machines. They have contributed to the improvement of human health and life expectancy, and to our societal comfort and wellbeing. They play an important role in the EU industrial competitiveness and creating jobs. On the flipside, however, are the potential and actual human health and environment risks that result from exposures to hazardous chemicals. The overall aim of 50 years of EU policy on chemicals is to promote their safe use with a view to improving their overall sustainability including human health and environment protection, competitiveness, innovation, internal market, growth and jobs. To do so the EU chemicals legislation (what we call today, 'the European Union chemicals *acquis*') identifies hazardous chemicals and, for those chemicals where the human health and environmental risks require action, establishes measures to manage these risks.

The Commission decided to undertake this Fitness Check of chemicals legislation other than REACH[1] ('the Fitness Check') to see what elements of the European chemicals *acquis* work well and what needs to be improved, both in terms of meeting the policy objectives and in terms of reducing regulatory burden. Unlike most evaluations, the Fitness Check is not an evaluation of one piece of legislation[2] but covers more than 40 different pieces of legislation (see Annex 4 Table 1). It covers legislation that addresses chemical hazard identification, assessment classification and labelling, risk assessment, and risk management, including worker safety, transport, environmental protection, chemical-specific and product-specific legislation.

This Fitness Check focuses on how the chemical risk assessment and management processes work across the EU chemicals *acquis*. This means that in some cases, the focus is on the entire piece of legislation as all of its requirements and, hence, associated regulatory costs relates to chemical hazard/risk assessment and risk management. Examples include the CLP Regulation, the Plant Protection Products Regulation, the Residues of Pesticides Regulation, the Biocidal Products Regulation, the Cosmetics Products Regulation, the Detergents Regulation, the Chemical Agents Directive, and the Carcinogens and Mutagens Directive. For many of the other pieces of legislation only certain requirements were relevant for the purposes of this Fitness Check, for example: the Toy Safety Directive, the water and water-related legislation, the Waste Shipments Directive, the Industrial Emissions Directive and the Seveso III Directive (see Annex 8).

To assess this, the Fitness Check has:

- Mapped out links between hazard identification and consequent risk management in downstream legislation on the basis of generic risk considerations (GRC).
- Mapped out the links between specific risk assessments (SRA) and the consequent risk management.

[1] Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
[2] Section 2.1.3 sets out ongoing evaluations of specific legislation also covered under this Fitness Check

- Examined the overall effectiveness, efficiency, relevance, coherence and EU added value of the two risk management approaches (GRC and SRA), on their own but also compared to one another, as adopted in the chemicals legislation.

Moreover, as announced in the Circular Economy Action Plan, the Commission has assessed the interface between waste, products and chemicals legislations. The Fitness Check takes into consideration the findings presented in the related 'Interface' Communication.[3]

This Fitness Check complements the REACH Evaluation[4]. Together, they cover the core EU legislative framework for the risk management of chemicals. The interface between REACH and other legislation is covered by the REACH review. Some REACH-related aspects are also covered under this Fitness Check in particular where REACH is a central consideration in assessing the coherence of different pieces of chemicals legislation (e.g. the identification, assessment and classification of persistent, bioaccumulative and toxic and very persistent, very bioaccumulative substances (PBTs/vPvBs)).

Figure 1 presents the intervention logic of the chemicals legislation covered by this Fitness Check. It summarises how the EU chemicals *acquis* is envisaged to lead to positive impacts on health, the environment and the functioning of the internal market as well as to enhanced competitiveness and innovation. It presents the links between the needs, the objectives, and the actions taken by different actors for each of the key steps in the hazard and risk assessment processes. It also sets out the related output of all these actions and general outcomes of the implementation and application of the EU chemicals *acquis* (e.g. improved knowledge on substances, hazardous substances identified, etc.).

[3] Communication on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation; COM(2018) 32 final

[4] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions; 5 March 2018; COM(2018) 116 final and SWD(2018) 58 final

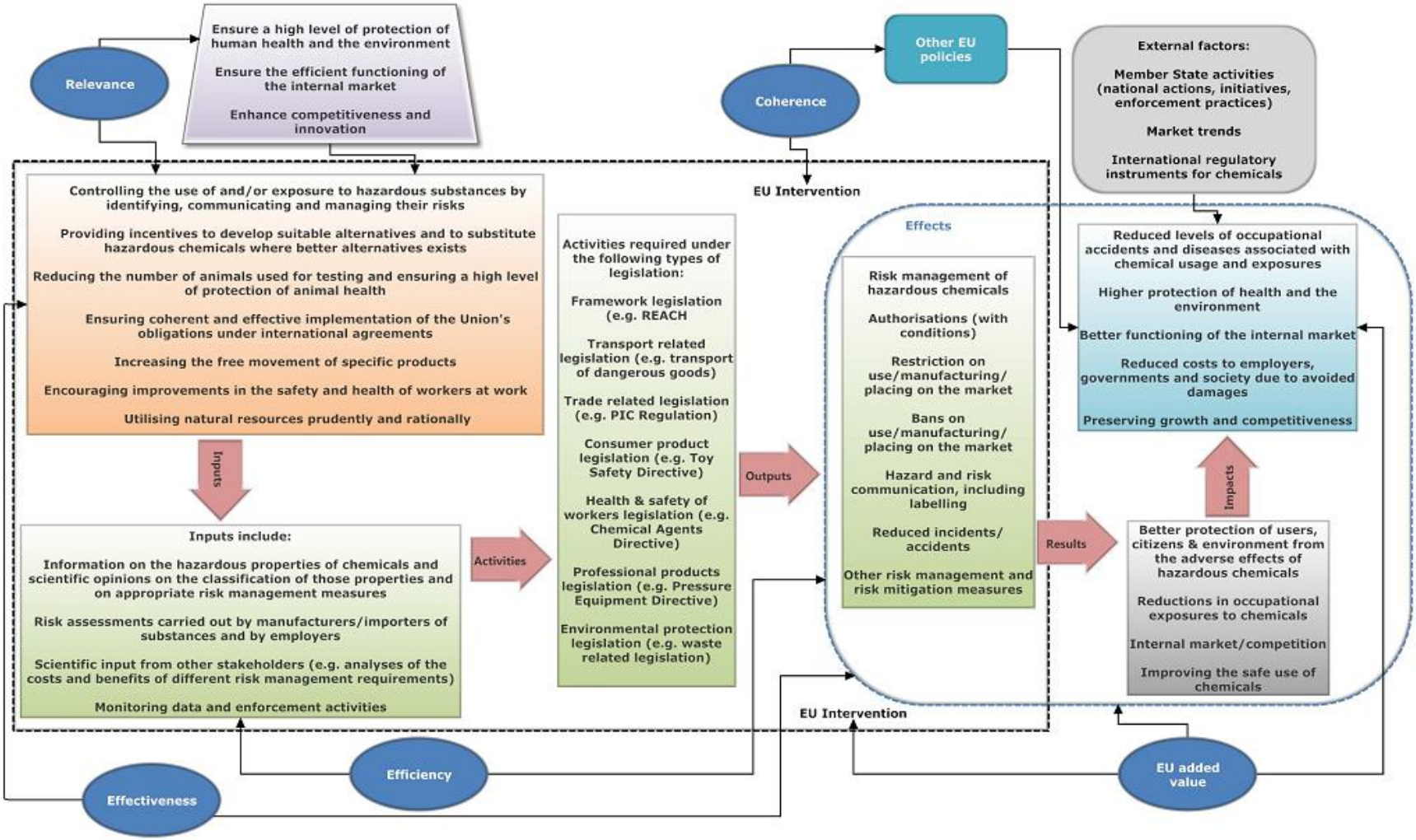


Figure 1 The intervention logic evaluated in this Fitness Check

2 BACKGROUND TO THE INTERVENTION

2.1 Description of the initiative

2.1.1 Objectives of EU chemicals legislation

The primary objectives of EU chemicals *acquis* are:

1. Ensuring a high level of protection of human health from the adverse effects of hazardous chemicals.
2. Ensuring a high level of protection of the environment from the adverse effects of hazardous chemicals.
3. Supporting and enhancing the efficient functioning of the internal market for chemicals and the competitiveness and innovativness of EU industry and business.

Specific pieces of legislation may have more specific objectives related to chemicals (see Annex 4 Table 1), such as protecting selected vulnerable groups (e.g. children), encouraging substitution to less hazardous alternatives, reducing the number of animals used for testing chemicals, ensuring the free movement of specific products or encouraging improvements in the occupational safety and health of workers. It is also a general, if not always explicitly stated, objective of the EU chemicals legislation to improve the knowledge of chemical hazards and risks. Furthermore, some of the legislation within the scope of this Fitness Check may also include objectives that concern other policy areas, such as ensuring agricultural productivity and sustainability or promoting products that have a high level of environmental performance.

The EU has also played a leading role in the development of, and is committed to, several global objectives related to chemicals. The EU and its Member States, committed to the UN objective of a sound management of chemicals throughout their life cycle in 2002, often referred to as the 'World Summit of Sustainable Development (WSSD) 2020 goal'[5]. In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM[6]) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals and waste.[7] In 2015, the EU committed[8] to the United Nations' 2030 Agenda for Sustainable Development including the Sustainable Development Goals (SDGs) (UN, 2015)[9]. Several of the SDGs relate directly or indirectly to chemicals and chemical policy (in particular SDGs 3.9, 6.3, 12.4). It should be noted, however, that apart from some international competitiveness assessment aspects, the Fitness Check scope did not include a detailed assessment of performance against the abovementioned international objectives and commitments. The focus was on the performance of the EU chemicals *acquis* in delivering against the core policy objectives within the EU context.

[5] It was expanded upon in paragraph 23 of the Johannesburg Plan of Implementation (JPOI) (UN, 2002).
[6] http://www.saicm.org/
[7] mainstreamed into the Europe 2020 Strategy (COM(2010) 2020 final)
[8] COM(2016) 739 final
[9] https://www.un.org/sustainabledevelopment/sustainable-development-goals/

2.1.2 The Framework of EU Chemicals Legislation

The EU legal framework for chemicals comprises not only chemicals legislation in the strict sense of the word – directly regulating chemical substances and mixtures – but also legislation regulating conditions under which chemicals are manufactured, treated or used (e.g. occupational health and safety or environmental legislation) or regulating products, in which chemicals are used (e.g. toys, medical devices and food contact materials). Furthermore, there are chemicals-related provisions in several pieces of environmental protection legislation such as the Water Framework Directive, the Waste Framework Directive and the Industrial Emission Directive.

The development of EU legislation on chemicals started in 1967 with the adoption of a Directive[10] that harmonised the Member States' rules for the classification, packaging and labelling of chemical substances across the then European Economic Community. Since then a multitude of different pieces of legislation have been adopted (see Figure 2; see also Annex 4 Table 2) that, to a greater or lesser degree, address the risk management of hazardous chemicals. In 2001 the European Commission adopted a White Paper setting out the strategy for a future chemicals policy, ultimately leading to the adoption of REACH in 2006, the Classification, Labelling and Packaging Regulation ('the CLP Regulation' which repealed the Dangerous Substances and Dangerous Preparations Directives in 2008), and to the establishment of the European Chemicals Agency in Helsinki (ECHA) in June 2007.

The EU has also committed to a number of legally binding international agreements related to chemicals, which are implemented through EU chemicals-related legislation, for example, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the Basel, Minamata, Rotterdam, and Stockholm Conventions as well as the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) (see Annex 8 Section 8.1.1 for further detail).

[10] Dangerous Substances Directive 67/548/EEC

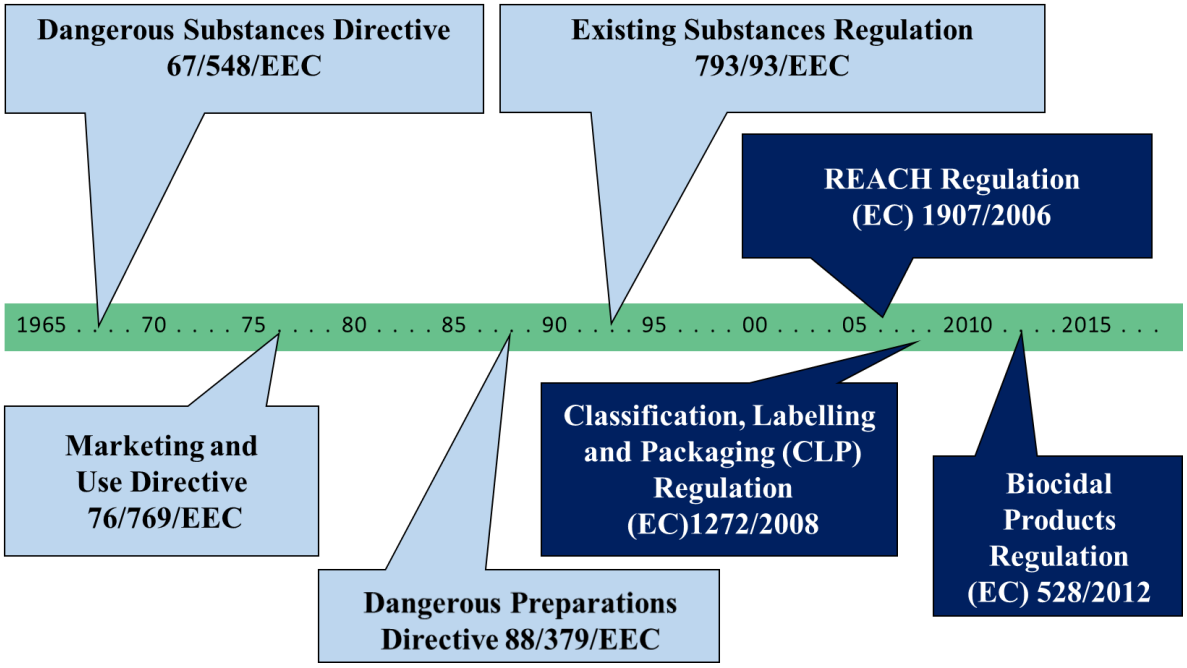


Figure 2 Some key pieces of EU chemicals legislation adopted since 1967

The EU chemicals legislation has been a model for policy development in other parts of the world.[11] The knowledge base resulting from the implementation of different pieces of EU legislation is, in many instances, made available to government, industry and stakeholders beyond the EU.

2.1.3 Scope of the Fitness Check

This Fitness Check focuses on more than 40 pieces of legislation (see Annex 4 Table 1). Those, together with REACH (which is outside the scope of this exercise) form the core of the EU framework of chemicals and chemicals-related legislation. The primary criteria for determining which pieces of legislation to include within the scope of the Fitness Check was the existence of requirements in the legislation relating to hazard/risk assessment and risk management of chemicals. This meant including horizontal legislation that supports the overall process of chemical hazard and risk assessment such as the Test Methods Regulation (440/2008/EC) and the Good Laboratory Practice Directives (2004/9/EC and 2004/10/EC).

A meaningful way to categorise these pieces of legislation, given the risk management focus of this Fitness Check, is as follows (see also Annex 8 section 8.1.2):

1) Legislation covering chemical hazard identification and classification[12]: Chemical Agents Directive (98/24/EC), Carcinogens and Mutagens at Work Directive (2004/37/EC), CLP Regulation (1272/2008/EC), Plant Protection Products Regulation

[11] Study on the cumulative health and environmental benefits of chemicals legislation p. 324
[12] sometimes together with risk assessment and risk management measures

(1107/2009/EC), Asbestos Directive (2009/148/EC) and Biocidal Products Regulation (528/2012/EU).

2) Legislation covering chemical risk assessment and risk management measures:

a) Worker safety and transport legislation: Pregnant Workers Directive (1992/85/EEC), Young People at Work Directive (1994/33/EC), the Chemical Agents Directive (1998/24/EC) and Carcinogens and Mutagens at Work Directive (2004/37/EC).

b) Environmental protection legislation: the Urban Waste Water Directive (91/271/EEC), Water Framework Directive (2000/60/EC) and Industrial emissions (integrated pollution prevention and control) Directive (2010/75/EU).

c) Chemicals control legislation: Contaminants in Food and Feed Regulation (315/93/EEC), Persistent Organic Pollutants Regulation (850/2004/EC), and Directive (2002/32/EC), Residues of Pesticides Regulation (396/2005/EC), Plant Protection Products Regulation (1107/2009/EC), Biocidal Products Regulation (528/2012/EU) and Export and Import of Hazardous Chemicals Regulation (649/2012/EU).

d) Products control legislation: Medical Devices Directives (93/42/EEC; 90/385/EEC; 98/79/EC)[13], Drinking Water Directive (98/83/EC), General Product Safety Directive (2001/95/EC), Detergents Regulation (648/2004/EC), Toy Safety Directive (2009/48/EC), Cosmetic Products Regulation (1223/2009/EC), Food Contact Materials Regulations (10/2011/EC and 450/2009/EC) and Pressure Equipment Directive (2014/68/EU).

3) Supporting and horizontal legislation: Good Laboratory Practice Directives (2004/9/EC and 2004/10/EC), Test Methods Regulation (440/2008/EC), and Protection of Animals Used For Scientific Purposes Directive (2010/63/EU).

This Fitness Check is not an in-depth evaluation of each individual piece of legislation within its scope. Instead, it aims to assess the functioning, performance and coherence of the overall framework with a particular focus on the hazard/risk assessment and risk management of chemicals. In addition and in parallel, the Commission is conducting targeted Better Regulation evaluations of a number of pieces of chemicals legislation within the scope of the Fitness Check, including the Plant Protection Products and the Residues of Pesticides Regulations, the Urban Waste Water Treatment Directive, the Water Framework Directive, the Food Contact Materials legislation and the Detergents Regulation (see Annex 4 Table 4).

At the margins, there is some additional legislation that this Fitness Check could have covered e.g. pharmaceuticals legislation (human[14] and veterinary products[15]) and food additives[16] legislation. It was, however, considered that the risk and hazard assessments performed under these pieces of legislation are used slightly differently compared with those performed under

[13] To be repealed (subject to exceptions) on 26 May 2020 and 26 May 2022 respectively by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 which entered into force on 25 May 2017

[14] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

[15] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

[16] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

the main body of EU chemicals legislation (e.g. an assessment of the risk trade-offs between the health benefits of the medical product versus potential undesired side-effects). REACH is generally outside the scope of this exercise. It is subject to its own legal review deadlines. While the first evaluation of REACH was finished in 2013, the second evaluation had already started when this Fitness Check was launched and was completed by the time that this Fitness Check entered its finalisation phase. Nevertheless, given the importance of hazard identification and classification criteria under this Fitness Check, Annex XIII to REACH covering persistent, bioaccumulative, toxic (PBT) and very persistent and very bioaccumulative (vPvB) criteria was included in the scope of this exercise. In general, where considered relevant from a comparative perspective, links to these pieces of legislation are covered as part of the coherence analysis.

2.1.4 Main steps: from hazard identification to risk management measure

Chemical risk assessment involves the analysis of the inherent hazardous properties of a substance or a mixture and the extent of exposure to that substance or mixture. The human health and environmental risks related to exposure to hazardous chemicals are addressed via the hazard and risk assessment procedures and requirements set out in the different key pieces of the EU chemicals legislation such as the CLP, the Plant Protection Products and Biocidal Products Regulations, etc. The main steps of these procedures involve:

- hazard identification (based on toxicity tests and other relevant information);
- dose (concentration) – response (effect) assessment;
- exposure assessment – exposure scenarios (based on models and measurements of the occurrence of the chemical);
- risk characterisation; and
- risk estimation.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

2.1.5 Risk management approaches

There are two basic approaches to risk management often used in combination, in the EU chemicals *acquis:* one based on specific risk assessment (SRA) and the other one based on generic risk considerations (GRC) (see Annex 8 Section 8.2.1).

The main difference between these two approaches is the point in time when the exposure assessment is considered and the specificity of the exposure assessment. For risk management based on GRC, the potential exposures and risks are considered generically, prior to the adoption of legislation. The GRC-based approach is built into the legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of the chemical, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. For example, under the Cosmetic Products Regulation any substance classified as carcinogenic, mutagenic or toxic for reproduction (CMR)

categories 1A/B and 2, shall be banned from use in cosmetics (subject to strict derogations), given the fact that direct exposure of humans is taking place through the application of a cosmetic product on the external parts of the human body (or teeth or mucous membranes of the oral cavity). Similar approaches have been taken for active ingredients in plant protection products and biocides, for substances in toys, etc.

The decision to link particular hazard properties (e.g. CMR, persistent bioaccumulative and toxic substances (PBTs), endocrine disruptors (EDs)) to automatic risk management measures without the intervening step of a specific risk assessment is done on the basis of generic risk consideration without prejudice to performing also a full risk assessment for the other properties of the substances which are not linked to the related hazard properties. In the legislation evaluated in this Fitness Check, the generic risk consideration approach is typically applied for the following use applications and the following substances:

Use applications:

- when there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management (e.g. labelling obligations under the CLP, labelling requirements and use instructions under the Plant Protection Products and the Biocidal Products Regulations).
- for use in widely dispersive or open applications which result in a significant exposure of humans or the environment (e.g. plant protection products).
- for use in applications where the exposure is considered to be more difficult to control and monitor (e.g. plant protection products).
- for use in applications resulting in exposure of vulnerable groups (e.g. children).
- for use to prioritise the risk assessment of certain chemicals and under certain conditions (e.g. food contact materials)

Substances:

- for substances with hazard properties that result in severe adverse effects on human health or the environment should exposures occur (e.g. CMRs, PBTs, EDs, chemicals with Single Target Organ Toxicity (STOT) properties); and
- for substances where it is difficult/impossible to identify a safe threshold and, therefore, where most specific risk assessments are likely to identify risks that lead to a need for risk management measures (e.g. PBTs, vPvBs, respiratory sensitisers).

On the other hand, in the case of the specific risk assessment approach, the exposure assessment is performed on a case-by-case basis when each substance is risk assessed under a specific legal framework. The risk management measures are triggered based on the outcomes of the specific risk assessment which considers the use of the substances and in which both the hazards and the potential specific exposure scenarios for humans and the environment to the hazardous substance or mixture in question are assessed at the same time.

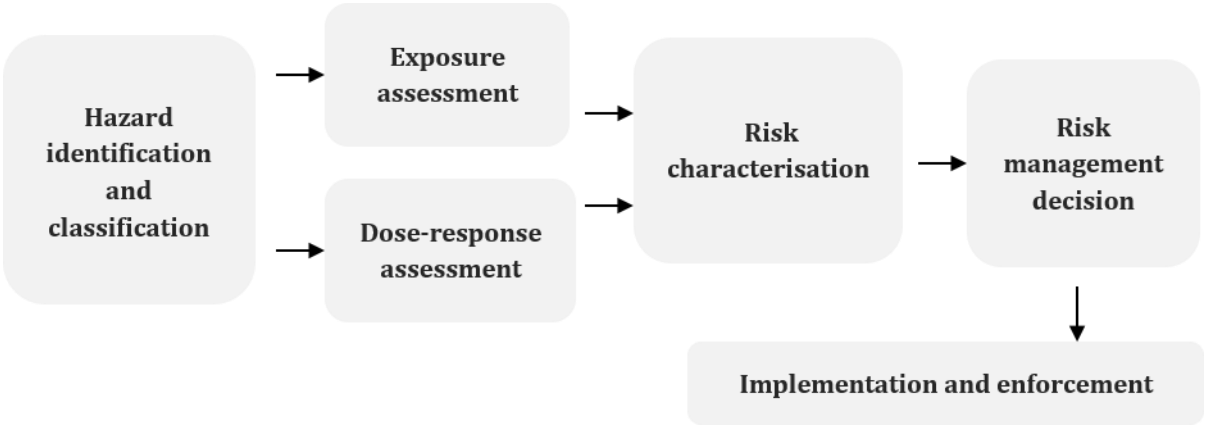
The specific risk assessment approach is used more widely for uses which are not necessarily or obviously going to lead to widespread and difficult to control exposures and/or where the hazard properties of a substance are of less concern.

In many instances, individual pieces of chemicals legislation use a combination of both of these approaches. For example, the Cosmetic Products Regulation applies the specific risk

management approach to establish lists of authorised substances as well as, where necessary, restrictions on the use of certain substances in certain situations. In addition, for substances identified and classified as a CMRs categories 1A/B and 2, the generic risk management approach is applied (such substances shall be banned and cannot, therefore, be used in cosmetic products subject to strict derogations).

2.1.6 Risk assessment and risk management processes and bodies involved

The human health and environmental risks from the exposure to hazardous chemicals are addressed via hazard and risk assessment procedures prescribed in the EU chemicals legislation. The main steps of the chemicals risk assessment and management process (i.e. decision making and implementation and enforcement) usually involve:



The necessary hazard identification, exposure assessment and risk assessment of chemicals are undertaken through a number of separate (but closely aligned) processes involving EU expert committees/bodies associated (see Annex 8 Section 8.2.2). These committees/expert groups are mainly established in association with different pieces or groups of legislation. Examples include:

- the European Chemicals Agency (ECHA): covering the CLP, the Export and import of hazardous chemicals (PIC) Regulation, the Biocidal Products Regulations) and REACH;
- the European Food Safety Authority (EFSA): covering the Plant Protection Products and Residues of Pesticides Regulations as well as the Food Contact Materials and the Contaminants in Food and Feed legislation;
- the Scientific Committee on Consumer Safety (SCCS): covering the Cosmetic Products Regulation, the Toy Safety Directive and the General Product Safety Directive (GPSD)
- the Scientific Committed on Occupational Exposure Limits (SCOEL): previously covering occupational safety and health legislation[17]; and
- the Scientific Committee on Health, Environment and Emerging Risks (SCHEER): covering health, environmental and emerging risks and broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer

[17] SCOEL's competences in terms of occupational exposure to hazardous chemicals have been transferred since 2019 to the Risk Assessment Committee (RAC) of ECHA.

safety or public health and related issues not covered by other European Union risk assessment bodies.

2.2 An overview of the EU chemicals industry and related sectors

The chemicals industry covers five main sectors (petrochemicals, polymers, basic inorganics, specialties and consumer chemicals) broken down into 16 subsectors. Five of these subsectors (paints, varnishes and similar coatings; printing ink and mastics; soap and detergents, and cleaning and polishing preparations; perfumes and toilet preparations; plastics in primary forms; and other organic basic chemicals) account for over 65% of EU chemical companies[18].

The chemicals industry is also characterised by geographical concentration with 85% of the EU turnover in the chemical industry concentrated in seven countries — Germany (30%), France (14%), the Netherlands (10%), Italy (10%), Spain (7%), the United Kingdom (7%), and Belgium (7%).[19]

As an "enabling industry", the chemical industry is at the heart of the EU manufacturing industry, supplying two-thirds of its production to other industry sectors. Thus, a large range of downstream sectors rely on the use of chemicals in their everyday activities, such as the automotive and aerospace sectors, the paper and pulp sector, as well as the manufacture of everyday goods such as textiles, cosmetics, toys, etc. Other important links exist with agriculture activities and services.

The chemical manufacturing industry is the fifth largest in the EU, accounting for 7% of the EU's industrial production. With annual EU chemicals sales of EUR 507 billion[20], the sector comprises over 28 000 companies and it directly employs around 1.2 million people as well as generating additional estimated 3.6 million indirect jobs. SMEs account for around 96% of the number of companies in the sector[21], approximately one third of the direct employment and one third of the sector's value-added. The EU chemical sector generated a value-added of approximately EUR 115 billion[22] in 2014 representing about 0.8% of EU GDP. In 2016, extra-EU chemicals exports amounted to EUR 146.2 billion and extra-EU imports reached EUR 99 billion (the EU chemicals trade surplus outside the EU being valued at EUR 47.2).[23] In 2017, there was an increase in both exports and imports compared to 2016 (+ 6.5% and + 8.3%).[24]

In terms of chemicals sales, the EU chemicals industry represented in 2016 15.1% of the global market, behind China (39.6%) ahead of the United States (14.2%)[25]. EU chemical sales increased by more than 50% in 20 years, while its world market share halved (down from 32.5% in 1996 to 15.1% in 2016) due to strong chemical demand growth in China, and other

[18] CCA1 Study p. 26
[19] CCA Study p. 7 quoting Eurostat, Structural Business Statistics, Annual detailed statistics on industry, (sbs_na_ind), September 2015
[20] CEFIC Facts and Figures Report, CEFIC, 2017, p. 5
[21] CCA1 Study, p. 27
[22] Eurostat 2014 figure for NACE 20
[23] CEFIC Facts and Figures Report, CEFIC, 2017, p.15
[24] Monthly summary of the Chemicals Trends Report; CEFIC; 20 April 2018
[25] CEFIC Facts and Figures Report, CEFIC, 2017, p. 8

emerging countries and low growth in Europe and North America, where Europe sells most of its chemicals.[26]

The main competitive advantage of the EU chemicals manufacturing industry is the high level of technological development, skilled workforce and strong research base. The EU chemicals industry is one of the most research and development intensive manufacturing sectors within advanced economies (behind US and China only). As an input provider for other industries, the chemicals industry is also considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges, with chemical technological breakthroughs spilling over its downstream sectors.

The total sold production of chemicals, including pharmaceuticals in the EU in terms of value increased moderately from 2007 to 2016 with an average annual growth of 0.6%[27]. The production of industrial chemicals in the EU-28, increased each year between 2004 and 2007, rising overall by 4.5 % to peak at 371 million tonnes in 2007. The EU chemicals industry was strongly affected by the economic and financial crisis of 2007-2009. In 2009, total sales revenue in the EU chemicals sector lost more than one fifth of its original value compared to 2008[28]. The recovery trend started in 2010 and peaked in 2012 before declining slightly in line with the global economy. It remained relatively stable during the period 2013–2016 but, in production terms, still 40–50 million tonnes below the pre-crisis peak in 2007.[29] In 2017, and especially if compared to the 2012-2016 period, the EU chemical industry resumed strong growth (+7.9%)[30] which continued in first quarter of 2018[31].

2.3 Baseline

This is a first comprehensive and cross-cutting assessment of the EU chemicals legislation over its 50 years of existence and the progress made towards the achievement of its core objectives. There was no pre-existing assessment that could have been used as a baseline.

The wide scope of the Fitness Check and the selective focus on the hazard and risk assessment and management elements, together with the data limitations and the continuous evolution of EU chemicals legislation led to using for the assessment purposes a number of different points of reference.

For the assessment of the effectiveness the following points of reference were used:

- Achieving human health and environmental protection was measured by looking at the achieved exposure reductions since 1970s through implementation of risk management measures such as bans, restrictions, emission limits, concentration limits, etc. In this regard, a range of different timeframes were considered thus reflecting the fact that different pieces of legislation were adopted at different moments in time (see

[26] Ibidem
[27] Eurostat, Production and international trade in chemicals http://ec.europa.eu/eurostat/statistics-explained/index.php/Production_and_international_trade_in_chemicals
[28] CEFIC Facts and Figures Report, CEFIC, 2017, p. 11
[29] Eurostat Chemicals production and consumption statistics, http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics
[30] Monthly summary of the Chemicals Trends Report; CEFIC; 20 April 2018
[31] Monthly summary of the Chemicals Trends Report; CEFIC; 2 July 2018

Annex 4 Table 2). The ‘present’ (at the time the studies were undertaken i.e. between 2015-2017) was also a frequently used reference point for assessing the effectiveness of certain processes and aspects of the EU framework of chemical legislation (e.g. communication of chemical hazards and risks to consumers and workers). In terms of on-going exposures and predicted future health and environmental impacts e.g. future cancer fatalities linked to past, present and future exposures, the timeframes used went as far as 2100.

- In terms of meeting the internal market objective, the most practical way to measure change was the level of harmonisation and the growth in intra-EU trade of chemicals. Although there is good data on trade, it is difficult to know what proportion of the growth in intra-EU trade is due to chemicals legislation versus other market forces. Trade was used as a performance indicator but this was not explicitly compared to what might have happened in the absence of EU chemicals legislation given the difficulty of estimating what this baseline might have been. The timeframe considered for this part of the assessment was 2006-2016.
- Eurostat data on the volumes of hazardous chemicals produced and consumed in the EU during the 2004-2016 period was used to provide a rather general point of reference for assessing the progress made in terms of substitution of the most hazardous chemicals. However, lack of clear link between competitiveness and innovativeness and the EU regulatory intervention, as well as lack of specific performance criteria or meaningful points of reference made the assessment difficult.

The coherence of the EU chemicals legislation was assessed by comparing different pieces of legislation e.g. are the cut-off criteria under the Plant Protection Products Regulation coherent with the cut-off criteria set out in the Biocidal Products Regulation.

For the assessment of costs and benefits, setting a baseline reflecting what would have been the legislation in place in Member State in the absence of the EU legislation since 1970s was not possible. Therefore, a baseline of no legislation in place at the EU or Member State level was used, even though such an assumption also seems hypothetical. For both cost and benefit assessments, the ‘zero counterfactual’ baseline was used except where the costs of transition from older EU legislation to current EU legislation were assessed (for the CLP Regulation). In this case, the counterfactual used for regulatory costs was the pre-existing legislation. The assessed costs represent therefore total costs and not the additional costs of implementing EU legislation i.e. costs above and beyond the costs of assumed Member State legislation that might have already been in place.

Even though the ‘zero counterfactual’ baseline was used in a consistent way, cost and benefit figures used are difficult to compare because of the timelines not lining up. As explained above the benefit assessment was backwards looking, i.e. what are the specific exposure level reductions that we can observe 'today’ that can be reasonably attributable to the pieces of legislation within the scope of this Fitness Check and/or other pieces of legislation considered as chemicals related. The cost assessment was limited in time (2004-2016 period). It does not look at what were the costs to achieve the specific exposure level reductions. It looks at what were the costs that specific sub-sectors of the chemicals industry had to bear in order to comply with the legislation existing at that time.

3 STATE OF PLAY

This section describes the state of play of the EU chemicals legislation and the factors affecting its implementation and enforcement. The following conclusions should be seen as a collection of issues identified under the Fitness Check and related evaluations, without being complete for each of the pieces of legislation within its scope. Moreover, it should be noted that under a number of pieces of the EU chemicals legislation Member States are not required to report information on enforcement or information provided is of poor quality. This was a significant obstacle for the assessment carried out for the purposes of this Fitness Check. The situation is however expected to improve as several of the individual pieces of legislation within the scope of this Fitness Check are currently undergoing their own evaluations (see the list of ongoing evaluation in Annex 4 Table 4). The follow up to the Fitness Check of monitoring and reporting of environmental policy will also contribute to improving the current state of knowledge.[32]

3.1 Implementation of the EU chemicals legislation

3.1.1 Main actors and roles of each

The implementation of the EU chemicals legislation relies increasingly on European harmonised processes in which Member States alone or in cooperation with others and the Commission play important roles. The Commission has been granted delegated and implementing powers, the latter being executed via comitology. Approximately 20 different committees assist the Commission in the chemicals legislation area.[33]

Member States are responsible for the correct application of the *acquis* and the timely and correct transposition of Directives. Regulations do not need to be transposed i.e. they are directly applicable and legally binding across the EU. In the area of chemicals legislation, the use of Regulations over Directives has increased over the past 10-20 years. Directives are mainly used in the occupational safety and health (OSH) legislation and environmental policy (water and waste) areas. For the OSH legislation this reflects the willingness to provide on the one hand a level playing field for business operating within the internal market and on the other, to leave room for Member States to adopt more stringent protective measures when transposing EU Directives into national law. For environmental policies, this allows taking into account the diversity of environmental situations in the various regions of the EU.

The implementation of the EU chemicals legislation relies also on the activities of different EU agencies (collection of data, scientific opinions, guidance, helpdesks etc.) such as ECHA or EFSA, and scientific committees providing scientific opinions.

3.1.2 State of play

The EU chemicals legislation is relatively mature (2nd or 3rd generation). Some transposition issues related to chemicals legislation (hazard/risk assessment and management aspects) have occurred in the past but the great majority of these have been identified and resolved since

[32] "Actions to streamline Environmental Reporting" COM (2017) 312

[33] Report from the Commission on the working of Committees during 2016 (COM(2017) 594 final; 16 October 2017; SWD(2017) 337 final)

then. Moreover, the increasing replacement of Directives by Regulations has contributed to this.

Certain stakeholder groups have expressed concern about the Commission's capacity to make risk management decisions in a timely manner. Particular areas of concern include the review programme for the approval of existing active substances under the Biocides Regulation which is closely interlinked with Member States' capacity to carry out assessments, and up in the chain linked to the capacity of industry to deliver good quality dossiers, and authorisation of the use of recycled plastics in food contact materials[34].

3.2 Enforcement of the EU chemicals legislation

3.2.1 Main actors and roles of each

The Member States, EU Agencies and the Commission all play a role in enforcement.

The Member States have the legal powers and obligation to enforce against duty holders. Enforcement activities cover all activities aimed at promoting compliance and achieving general and specific legal objectives e.g. allowing free movement of goods, lowering risks to safety, health and the environment, etc. These activities may include enforcement activities in a broader sense such as providing information, guidance and prevention or in a narrower sense such as data collection and analysis, inspections, warnings, improvement notices, fines, prosecutions, legal actions in case of infringement etc.

The Commission's enforcement role is to check the proper application of the legislation. This includes the resort to formal infringement procedures e.g. in case of non-conformity of national transposition law with EU directives or incorrect application of the EU law. The Commission also provides assistance to national authorities through guidance documents, clarifications on interpretation of legal provisions, etc. Some pieces of legislation delegated certain 'enforcement powers' to ECHA or EFSA, for example, in the case of risk assessment dossier evaluation. Guidance to assist national authorities and industry has improved the clarity and consistency of interpretation of legal requirements. National helpdesks for CLP co-operate through the ECHA Helpnet[35] to support companies in understanding their obligations. Although much still needs to be done, networks such as the FORUM[36] and RAPEX[37] and other legislation specific enforcement networks have significantly contributed to improved coherence of enforcement.

[34] The EU Strategy for Plastics SWD(2018) 16 final; 16 January 2018; p. 40

[35] The HelpNet is a network made up of ECHA and the national BPR, CLP and REACH helpdesks. The network was created to improve cooperation on issues of common interest. The benefits of this cooperation are the achievement of a common understanding on the legal requirements under the BPR, CLP and REACH regulations and the provision of consistent and harmonised advice to stakeholders. For more information please visit https://echa.europa.eu/about-us/partners-and-networks/helpnet

[36] The Forum for Exchange of Information on Enforcement is an ECHA body which coordinates a network of authorities responsible for the enforcement of REACH, the CLP and PIC regulations in the EU, Norway, Iceland and Liechtenstein.

[37] The Rapid Alert System enables quick exchange of information between 31 European countries and the European Commission about dangerous non-food products posing a risk to health and safety of consumers.

3.2.2 State of play

The Member States have the legal powers to enforce against duty holders. At Member State level, resource (both financial and human) capacity and expertise constraints, particularly following the financial crisis, are resulting in a number of enforcement challenges:

- Capacity of national competent authorities to conduct the necessary market surveillance activities in respect to consumer goods. The General Product Safety Directive (GPSD) created a horizontal framework ensuring the safety of consumer products. To this end, it sets out a number of obligations for manufacturers, importers and distributors as well as certain obligations for Member States as regards the organisation of market surveillance. The GPSD also established a network of authorities of the Member States competent for product safety aimed at facilitating operational collaboration on market surveillance and other enforcement activities. The GPSD applies to all consumer products including the harmonised sectors like toys, cosmetics, etc., in so far as the relevant harmonisation legislation has not itself provided for specific rules with regards to specific safety aspects. While the GPSD contains an obligation for Member States to take part in the cooperation mechanism, the performance of the obligations it imposes on Member States to organise and perform market surveillance depends on the resources available. For this reason differences in the various Member States still continue to persist, leading to a different level of protection and enforcement within the EU.[38]
- In the case of plant protection products, even though controls on retailers were reported to be generally satisfactory, the majority of Member States do not conduct controls on plant protection products stated to be for use in other Member States or in non-European Union countries. This weakness in control systems can be easily exploited to place non-compliant products on the market.[39]
- Capacity to undertake routine inspections and other compliance and enforcement activities, including monitoring and reporting.
- For example, the need to invest additional resources on enforcement activities is recognised in order to ensure that no biocidal product is illegally placed on the market at national level and that these products are properly labelled.[40]
- Regarding the Toy Safety Directive, Member States considered that the low consistency of national approaches to enforcement (both in terms of the number and the type of control procedures) creates a trade barrier. Limited testing capacity of some Member States was also deplored.[41]
- Another example is non-harmonised food contact materials (FCMs) – i.e. specific food contact materials such as inks, adhesives, or paper for which at EU level no harmonised rules exist[42]. Member States highlighted the lack of resources needed for controls (personnel for the inspections, analytical equipment, facilities, etc.). They also

[38] 'The Goods Package: Reinforcing trust in the single market'; SWD(2017) 469 final; 19 December 2017; p. 11
[39] DG Health and Food Safety 'Overview Report: controls on the marketing and Use of Plant Protection Products'; 2017
[40] Report from the Commission to the European Parliament and the Council on the sustainable use of biocides 17 March 2017 COM(2016)151
[41] Evaluation of Directive 2009/48/EC on the Safety of Toys; Final report; December 2015
[42] https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/non_harmonised_en

reported that local inspection is not adequate for checking compliance with a supply chain spread throughout the world.[43]

- Regarding online chemicals sales, several enforcement surveys show that various non-authorised chemicals and related products are increasingly being offered for sale via the Internet. As chemicals legislation does not distinguish between different types of trade, all provisions regulating chemicals apply in principle also to Internet trade. Currently, however, access to websites and relevant information on transactions, vendors or service providers for monitoring authorities is difficult and therefore hampers their investigations.[44]

Verification of compliance with and enforcement of chemicals legislation is in many cases complex and resource-intensive. Some of the differences in the level of enforcement are due to differences in the resources allocated and made available by Member States. Other factors, leading to non-uniform application of the EU law include the national control set ups (planning and frequency of controls, number of inspectors, training and other professional qualifications, etc.), differences in the interpretation of the EU law, differences in or lack of standards, lack of harmonised requirements and guidelines, etc. The following specific examples illustrate these observations:

- Differences in administrative organisation of Member States create differences regarding the frequency of controls and inspections. These differences are notable regarding in particular the occupational safety and health (OSH) legislation and the CLP Regulation.
- Different interpretation by Member States of the legislation and lack of guidance documents and/or harmonised analytical methods for testing impact the implementation of the EU chemicals legislation. This was indicated in particular for the CLP, the FCMs, the Plant Protection Products Regulations, and the Toy Safety Directive.

Even though the principle of mutual recognition is one of the means of ensuring the free movement of goods within the EU, whether it is effective in doing so, depends on if and how Member States apply it. In cases where there is an absence of mutual recognition, this leads to duplication of efforts between Member States and exacerbates the existing resource limitations. Because mutual recognition is currently underutilised for plant protection products authorisation, risk assessments are sometimes partially or fully repeated by other Member States thus creating additional costs. The main reasons for this are related to lack of information on how the first Member State reached its conclusion, leading to a lack of confidence. The other major reason is the age of the data, noting that some time may have passed between the first and subsequent assessments.

Where technical standards or detailed harmonised requirements are lacking or are incomplete, or where technical standards do exist but there is no EU-wide shared methodology for assessing them, this can undermine the quality and completeness of the exposure assessments

[43] Joint Research Centre (JRC), Non-harmonised food contact materials in the EU: regulatory and market situation, 2016, p. 111

[44] Erdmann et al (2016): Project e-commerce II, Final Report to the Chemical Legislation European Enforcement Network (CLEEN), Germany.

that are needed for conducting the required risk assessments. This issue was highlighted by several Member States regarding the 'safety' (i.e. risk) assessments of toys and their constituent substances, as well as assessing health risks associated with their use.[45] In general, the performance of risk assessment is easier to quality control where there is a requirement to not only document it but also communicate its outcome to the public authorities.

[45] Member States' report on the Toy Safety Directive 2015

4 METHODOLOGY

4.1 Description of methodology: quantification and data collection

A roadmap[46] was published in 2015 presenting the scope and the key evaluation questions to be addressed by the Fitness Check, as well as a consultation strategy to ensure stakeholders' engagement in the process (see below and the Annex 2). The Fitness Check was accompanied by an interservice steering group covering all Commission services in charge of the legislation under scrutiny plus horizontal services.

Priorities for assessment were established on the basis of the main areas of improvement identified by the key studies supporting the Fitness Check[47], considering the concerns raised by stakeholders.

4.1.1 Studies

Two key studies and two related studies, carried out by external consultants for the Commission, provide an important part of the evidence base for the Fitness Check.[48]

A. Complementarity of the Fitness Check core studies

The 1st Fitness Check study[49] (1st FC Study) was completed in January 2017. It focuses on the CLP Regulation and related legislation governing hazard identification, communication and risk management of chemicals. This includes an assessment of costs and benefits associated with the CLP Regulation. The on going costs of the CLP are estimated as 'present day' costs generated at the time of the study (2015-2016) using a 'zero counterfactual' as the point of reference i.e. against a situation where there is no legislation in place at Member State or the EU level. The transition costs from the previsious Dangerous Substances Directive (DSD) and Dangerous Preparations Directive (DPD) to the CLP Regulation cover the time period from 2009 (when the CLP first came into force) to the 2015 deadline for meeting the CLP requirements applicable to mixtures. The (partial) assessment of human health and environmental benefits of classification, labelling and packaging of chemicals was examined across a timeframe of 2000-2016. This allowed a comparison between the partial estimation of benefits accrued under the pre-CLP legislative situation (the DSD and the DPD) against partial estimation of benefits accrued following implementation of the CLP Regulation. The benefits assessment was also done using a zero counterfactual baseline.

The 1st FC Study was complemented by a second study[50] (FC+ study) completed in November 2017. Its focus was pieces of legislation that operate independently of the CLP for chemical hazard identification and classification and pieces of legislation where specific risk assessment procedures form the core part of the risk management process (this was not

[46] http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf
[47] See Section D.5 of the Fitness Check roadmap
[48] For more information regarding the studies please see Section 2.3 Baseline as well as Annex 3 and Annex 4 (Table 1, Table 2, Table 3 and study 'fiches')
[49] Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation
[50] Study supporting the Fitness Check on the most relevant chemicals legislation

covered by the 1st FC Study). For the great majority of assessment aspects, including the analysis of cost drivers, the time reference of the FC+ Study was the 'present day' situation i.e. situation at the time the study was undertaken (2017). The cost driver analysis was done using a zero counterfactual (i.e. no chemicals legislation in place at Member State and the EU level) as the point of reference.

Because in many cases, the EU chemicals legislation is based on the use of both generic and specific risk assessment and more or less direct link to the CLP Regulation (see Annex 4 Table 1), a number of pieces of legislation were covered by both core studies. Examples include the Toy Safety Directive, the Cosmetic Products Regulation, the Plant Protection and the Biocidal Products Regulations, the Industrial Emissions Directive, the Water Framework Directive, the Detergents Regulation, the Food Contact Materials Regulation (Table 1). The REACH Annex XIII and the CLP Regulation were however exclusively covered by the 1st FC study.

In line with the Fitness Check methodology, the studies respond to the evaluation criteria and evaluation questions from the roadmap, while also providing a more detailed analysis of relevant themes through study tasks and case studies.

B. Additional Fitness Check supporting studies

The findings of the two core Fitness Check studies were complemented by a cumulative cost assessment of the chemical industry (CCA1) and a study on the cumulative health and environmental benefits of chemicals legislation (CuBA Study). The CCA1 study provides an estimate of total regulatory costs (i.e. it uses a zero counterfactual as a point of reference which assumes no chemicals legislation at Member State level in the absence of EU chemicals legislation) of the most relevant EU legislation with a bearing on the chemical industry (excluding downstream sectors) during the period 2004-2014.

The CuBA study draws together a large body of evidence on the health and environmental improvements achieved since 1970s as a result of hazardous chemical exposure reductions linked to EU chemicals legislation. The CuBA study also assesses the health and environmental impacts and costs associated with on-going exposures to chemical risks. Again, the benefits are estimated using a zero counterfactual as the point of reference.

C. Methodology, time and legal scope, and topics covered

The main methodologies applied in the context of the abovementioned studies can be described as follows:

- Development of an intervention logic underpinning the rationale for chemicals legislation and the CLP Regulation more specifically, including legal mapping to identify relevant legislation and specific provisions within this. This was then supported by a legal analysis to identify the nature of the obligations for different economic operators, how the legislation was implemented in practice, and areas where there appeared to be inconsistencies, overlaps and incoherence.
- A literature review to pull key information from impact assessments, position papers, academic and scientific research, papers and reports prepared by the relevant scientific bodies, regulatory submissions and other 'grey' literature.
- Development of evaluation questions (see Annex 10) and stakeholder consultation activities (see Annex 2).

- Case study research, which involved a more in-depth examination of some of the most pertinent issues identified as part of initial research (e.g. metals classification and the CLP Regulation, parallel hazard assessments, persistent, bioaccumulative and toxic (PBTs) / very persistent and very Bioaccumulative (vPvBs) substances, carcinogenic, mutagenic or toxic for reproduction substances (CMRs), linkages between the CLP and the occupational safety and health (OSH) legislation and several others), either directly linked to the interface between the CLP and other legislation, the functioning of specific legislation, or examining tools or measures needed to support the legislation.
- Comparative analysis of approaches based on specific risk assessments and generic risk considerations.

More generally, the studies have applied the tools set out in the Better Regulation Toolbox[51] in assessing costs and benefits.

Figure 3 illustrates the time period covered by each of the Fitness Check studies.

Figure 3 Time period covered by the Fitness Check studies

Table 1 illustrates the legal scope covered by studies.

COVERED BY:	LEGISLATION
1st FC FC+ CCA1 CuBA	Industrial Emissions Directive Water Framework Directive Biocidal Products Regulation Plant Protection Products Regulation Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Food contact materials Regulations
1st FC CCA1 CuBA	CLP Regulation REACH Annex XIII[52] Inland transport of dangerous goods Directive Carcinogens and mutagens at work Directive Chemicals Agents Directive Young People at Work

[51] http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf
[52] CCA1 and CuBA cover entire REACH

	Pregnant Workers Directive Seveso III Directive Waste Framework Directive End of Life Vehicles Directive Fertilisers Regulation
1st FC FC+ CuBA	Waste shipments Regulation EU Ecolabel Regulation Pressure equipment Directive General Product Safety Directive
FC+ CCA1 CuBA	RoHS 2 Directive Batteries Directive Packaging and Packaging Waste Directive Export and import of hazardous chemicals (PIC) Regulation POPs Regulation Explosives Directive
1st FC CCA1	Signs at work Directive
FC+ CuBA	Asbestos Directive Urban Waste Water Directive Marine Strategy Framework Directive Contaminants in food and feed Regulation and Directive Drinking Water Directive Medical Devices Directives Protection of animals used for scientific purposes Directive
1st FC	Aerosol dispensers Directive Test methods Regulation Good Laboratory Practice Directives
FC+	Residues of pesticides Regulation

Table 1 Pieces of legislation covered by the Fitness Check Studies

Annex 4 Table 1 and Table 3 provides more detailed information about how the Fitness Check supporting studies cover the topics discussed in the remainder of this document.

The studies provide evidence for the full scope to a large extent. However, either because of methodological challenges and lack of data or peculiarities of this Fitness Check i.e. focusing on the framework-wide issues rather than on legislation specific issues, some aspects were not assessed in-depth. In order to fill such gaps, other available sources of information were used, including other REFIT supporting studies or interim reports, EU Agencies' and the Commission's reports, as well as the other recent chemicals related initiatives and actions (see Annex 4 Table 3).

Annex 4 Table 4 provides a list of finished or still ongoing individual evaluations and how these different sources of information were used for the purposes of this Fitness Check (mainly concerning occupational safety legislation, plant protection products legislation, detergents and waste legislation). It should be noted however that where there is no specific reference to these individual evaluations, it is either because they were already used and refered to in the Fitness Check Studies or because the evaluation has just started and therefore evidence is not yet available.

4.1.2 Data collection and stakeholder consultation

Given the wide scope of the whole exercise and, in some cases, the lack of data (costs, benefits, enforcement, performance monitoring, etc.) on individual pieces of legislation, this

Fitness Check put a particular emphasis on stakeholder and expert input. Therefore, some of the issues identified may require further assessment as part of a dedicated evaluation of a specific piece of legislation, as mentioned above.

The stakeholder consultation strategy developed for the purpose of this Fitness Check[53] comprised an public consultation (from 4 March to 27 May 2016), an SME panel through the Enterprise Europe Network (from 30 May to 18 July 2016), targeted interviews, stakeholder workshops conducted as part of the two main Fitness Check studies as well as the CCA1 and CuBA studies, and two Eurobarometer surveys (see Annex 2 for more details).[54]

In line with the consultation strategy, input from a wide range of stakeholders was collected:

- public authorities, notably competent authorities responsible for the implementation and enforcement activities;
- industry associations covering both the chemicals industry and downstream sectors (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators);
- companies in both the chemicals industry and downstream sectors, focusing in particular on Small and Medium-sized Enterprises (SMEs) (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators);
- civil society organisations – NGOs (e.g. environmental, health, animal welfare);
- consumer associations;
- trade unions
- other interested groups such as academics / research institutes; and
- consumers / workers /citizens.

The online public consultation was conducted in English, German and French. The SME panel and the two Eurobarometer surveys were conducted in all EU languages.

These different consultation activities and tools allowed receiving feedback from all stakeholder groups. A summary of these views is provided in Annex 2.[55]

Information on the Fitness Check is published on the websites of DG GROW[56] and DG ENV[57].

4.1.3 Use of findings from studies and stakeholder views for the purposes of this Fitness Check

The two core Fitness Check studies and the two additional Fitness Check studies provide the main evidence for the assessment presented in the remainder of this document. The evidence that these studies provide was used in a combined and complementary way. Each study

[53] Consultation strategy for the fitness check on chemicals legislation (excluding REACH) http://ec.europa.eu/DocsRoom/documents/17109/attachments/1/translations
[54] Special Eurobarometer 456 November-December 2016 and Special Eurobarometer 468 September-November 2017
[55] See also 1st FC Study, Annex V
[56] http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm
[57] http://ec.europa.eu/environment/chemicals/better_regulation/index_en.htm

corresponds to a different evidence gathering phase which was followed by an assessment phase.

The 1st FC Study corresponds to the first evidence-gathering phase (March 2015-October 2016; see Figure 4) which started with the publication of the Roadmap. It was preceded by the launch of the CCA1 Study. The assessment done during this phase was based on desk research and was followed and complemented by an extensive stakeholder consultation process. This first phase of the assessment provided useful and meaningful input and allowed to identify additional needs in order to cover the full scope of this Fitness Check.

	1ST PHASE							
May 2014	**March 2015**	**July 2015**	**September 2015**	**January 2016**	**March 2016**	**June 2016**	**July 2016**	**October 2016**
Launch of the CCA1 Study	Publication of the Roadmap	Launch of the 1st FC Study	CCA1 workshop	Launch of CuBA Study	Launch of the Open Public Consulation	SME Panel consultation	1st FC Study workshop CCA1 Study Final report	1st FC Study final report

Figure 4 First evidence gathering phase done for the purposes of the Fitness Check

The second evidence gathering phase started with the launch of the FC+ Study (see Figure 5). Similarly to the 1st FC Study, it also included targeted interviews with stakeholders as well as a stakeholder workshop.

2ND PHASE				
October 2016	**December 2016**	**May 2017**	**August 2017**	**November 2017**
Launch of the FC+ Study	Eurobarometer 456	FC+ workshop	CuBA Study final report	FC+ Study final report Eurobarometer 468

Figure 5 Second phase of the assessment done for the purposes of the Fitness Check

During the assessment phase (starting in December 2017), all the evidence and stakeholder input gathered went through a thorough selection process. The purpose was to select those elements that affect (positively or negatively) the functioning of the framework and to identify those aspects that were only affecting the functioning of a specific piece of legislation. Therefore, not all of the findings gathered found their way in the final report. This assessment phase was also necessary in order to reality check the findings and to ensure that the Fitness Check supporting studies were used and combined to their utmost potential.

Annex 4 (Table 1 and Table 3) provides more detailed information about how the Fitness Check supporting studies cover the topics discussed in the remainder of this document.

4.2 Limitations and robustness of findings

Given the wide scope of the exercise and the impacts of chemicals legislation, there were numerous challenges in gathering the data needed to provide a robust evidence base, as well as in providing quantitative estimates of impacts. As far as possible, data was triangulated with evidence collected from multiple sources e.g. literature review, qualitative assessment based on expert input (e.g. Member State Competent Authorities), stakeholder consultation etc. to provide as robust a picture of the evidence as possible. Nevertheless, whilst some

legislation and risk assessment processes are well covered by multiple different stakeholder groups and literature/data sources, other pieces of legislation are less well covered.

Where specific obstacles and challenges were encountered, limitations are mentioned and explained in the relevant sections. The evidence and study limitations presented particular challenges with respect to the Fitness Check findings in the following areas:

- Determining and comparing framework-wide costs and benefits and, therefore, assessing the proportionality of the EU chemicals legislation at the framework level.
- Enforcement and implementation of the EU chemicals legislation.
- Determining the actual significance, in practical terms, of some of the coherence issues identified. It was beyond the scope and resources of the Fitness Check to seek primary evidence in order to test the real life significance of coherence issues flagged by one or more stakeholder groups.

Care was taken to accurately report different opinions and findings while also ensuring that the evidence and sources can be traced back and that therefore the reliability and robustness are ensured.

4.2.1 The First Fitness Check Study ('1st FC Study')

The key limitations of the 1st FC Study can be described as follows:

- The broad scope of the study and the number of pieces of legislation to be considered.
- The lack of available information on the scale of issues identified (both positive and negative) and the subsequent need to rely on information provided by stakeholders.
- The limited response received from civil society stakeholders. However, further desk-based research of published information from NGOs was undertaken to inform the study.
- The lack of available data to assist in determining the effectiveness and efficiency of the legislative framework (particularly in quantitative terms).
- The inability or unwillingness of companies to provide certain data creating difficulties in quantifying the impacts of the CLP Regulation and other legislation.
- The lack of up-to-date information regarding the effect of the CLP Regulation on consumer behaviour.

4.2.2 The Second Fitness Check Study ('FC+ Study')

The key limitations of the FC+ Study can be described as follows:

- Stakeholders were identified based on their active engagement with specific pieces of legislation. However, involvement in the study was on a voluntary basis. Therefore, those who felt strongly about particular processes or pieces of legislation were more likely to take part. To offset this possible limitation stakeholders included regulators, industry and NGOs, as well as officers of the European Commission and EU agencies responsible for chemicals legislation.
- In a limited number of cases particular stakeholder groups (e.g. industry, regulators, NGOs) dominated the responses for certain aspects of legislation. The study report states where this is the case.
- The stakeholders engaged, while broadly diverse, could still be argued to be a relatively small sub-set compared to the size and scale of the EU chemicals industry.

To offset this limitation the work completed under the FC+ Study included a review of the findings of the 1st FC Study to enable a more complete analysis, and evidence was sought wherever possible to back up opinions. Findings from the 1st FC Study (including its public consultation and SME panel) were used to help corroborate findings in the FC+ Study where appropriate.

- The available economic data on costs and efficiency reported in a quantitative fashion was very limited. Literature data, and two stakeholder engagements were used to gather quantitative and qualitative information on the functioning and efficiency aspects of the risk assessment and risk management processes used under the EU legislation. However, it was not possible to provide extensive costed examples related to efficiency.
- The available information on specific pieces of legislation varied, with some legislation and risk assessment processes well covered by multiple different stakeholder groups and literature/data sources. Other pieces of legislation were not as well covered and the analysis relied more on policy guidance documents and review of the legislation to ascertain how the processes function and what potential issues may exist (see Annex 3 Table 6 for a summary of data availability per piece of legislation).
- The FC+ Study also undertook a semi-quantitative assessment of the key cost drivers for six pieces of legislation.[58]

4.2.3 The Study on the Cumualative Health and Environmental Benefits of Chemicals Legislation ('CuBA Study')

With respect to the CuBA Study, key limitations can be described as follows:

- The study focused on "cumulative" health and environmental benefits delivered through the cumulative effect (accumulation) of various different pieces of legislation, each addressing a risk or group of risks. It did not, however, seek to attribute specific impacts to every individual piece of legislation. The study presents a combination of qualitative, quantitative and monetary estimates of these benefits. Neither the socio-economic benefits of chemicals legislation (in terms of accelerated innovation) nor of chemicals themselves (facilitating efficiencies or technologies for example) were part of the study scope.
- It is important to note that this is the first time a study on this scale and scope has been attempted. The work is based on drawing together existing information, though a number of calculations/interpretations were done to derive some of the quantitative figures in the report. In some cases the estimates provided are associated with significant uncertainties. These are discussed at length, but are provided as a starting point for additional research and discussion. Where benefits relate to productivity and/or healthcare treatment ("direct financial") costs, these are compared to GDP in national accounts to provide context on their significance; others reflect "personal valuation" (willingness to pay to avoid certain medical ailments or for ecosystem services, for example). These costs are no less real than those that are linked to GDP:

[58] The Plant Protection Products Regulation, the Residues of Pesticides Regulation, the Biocidal Products Regulation, the Medical Devices Directive, the Toy Safety Directive, and the Cosmetic Products Regulation.

society places a high value on having a long, healthy and fulfilled life. Where appropriate, they are expressed in monetary terms.

4.2.4 The Cumulative Costs Assessment Study ('CCA1 Study')

The cost estimates provided by the CCA1 Study have to be treated with caution due to differences in scope and in the methodology applied. Firstly, the period covered by the CCA1 Study i.e. 2004-2014, only partially corresponds to the one covered by this Fitness Check. Secondly, the estimated costs relate only to certain subsectors of the EU chemicals industry and not to all the downstream sectors that are also considered by this Fitness Check. Furthermore, regulatory costs were estimated and included in the overall CCA1 estimates for several pieces of legislation that are not in the scope of this Fitness Check while, at the same time, several other pieces of legislation although within the scope of this Fitness Check, were not covered. Finally, the sample size and coverage did not allow for statistically accurate analysis and conclusions. Therefore, additional cost elements were gathered where possible and qualitative assessment is presented instead.

ANSWERS TO THE EVALUATION QUESTIONS

The following sections answer the evaluation questions concerning the five central evaluation criteria of effectiveness, efficiency, relevance, coherence and EU added value. A more detailed analysis of effectiveness, efficiency and coherence related issues can be found in annex (Annex 5, Annex 6 and Annex 7 respectively) as well as in the underlying Fitness Check studies.

Many of the factors that affect the effectiveness of EU chemicals legislation are also closely linked to its efficiency, coherence, relevance and implementation. Issues identified in the effectiveness section are, therefore, sometimes referred to in other sections where they are evaluated in more detail.

5 EFFECTIVENESS

5.1 Evaluation question: to what extent does the EU legislative framework for the risk management of chemicals meet its objectives?

This section analyses the progress made towards achieving the three core objectives that are shared by nearly all pieces of EU chemicals legislation:

1. Ensuring a high level of protection of human health from the adverse effects of hazardous chemicals.
2. Ensuring a high level of protection of the environment from the adverse effects of hazardous chemicals.
3. Supporting the efficient functioning of the internal market for chemicals and enhancing the competitiveness and innovation of EU industry and business.

As the first two objectives are rather different in their nature from the third objective and, therefore, have a different set of performance indicators, they are assessed separately.

5.1.1 The objectives of high level of protection of human health and environment

A. What's the issue?

EU chemicals legislation aims to achieve a high level of protection of human health and the environment by minimising exposures to hazardous chemicals and by stimulating substitution of hazardous substances by less hazardous chemicals (or alternative non-chemical solutions). The effectiveness of the EU chemicals *acquis* in achieving these objectives can be assessed by analysing the trends in:

- the production and use of hazardous substances;
- the human and environmental exposures to hazardous chemicals; and, ultimately
- the impacts in the form of the main health and environmental impact parameters associated with exposures to hazardous chemicals, such as trends in the EU incidence rates of certain human diseases, trends in animal population levels, trends in eco-system health/resilience.

B. What are the findings?

Conclusions

For the specific hazardous substances that have been targeted over the last 3-4 decades, the EU chemicals *acquis* has been quite effective in reducing and minimising human and environmental exposures. This includes some notable reductions in exposures to problematic substances such as lead, mercury, benzene, asbestos, polychlorinated biphenyls (PCBs), and a range of other chemicals with carcinogenic, mutagenic or toxic for reproduction (CMR) and persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB) hazard characteristics. However, a range of on-going and emerging health and environmental concerns related to the exposure to hazardous chemicals remain and require further attention.

The analysis finds little evidence of a general shift towards production and/or consumption of less hazardous substances although there are some preliminary positive indications of substitution with respect to substances hazardous to the environment. This may, in part, reflect the effectiveness of risk management measures in reducing exposures and risks, therefore reducing the incentive to substitute to less hazardous substances. Essentially, the share of industrial chemicals hazardous to health and the environment in the total chemicals production has remained relatively unchanged over the last decade.

Trends in endpoint human health and environmental impacts (cancers, reproductive diseases, respiratory sensitization, insect and bird populations, etc.) point to a mixed picture but are difficult to use as direct indicators of chemicals policy performance because of the attribution challenge. Most of these trends are linked to multiple causal factors of which exposure to hazardous chemicals might be just one. Moreover, data is generated, including through the regulatory framework, based on substance-by-substance approach. It is therefore difficult to use it to give a picture of the overall level of protection of human health and the environment. The current approach and indicators used in monitoring and assessing human health and environmental impacts could benefit from being more holistic. On a positive note, the reduction in the incidence rates of workplace-related cancers and in lead-related health impacts are good examples of improvements that can be linked to the EU interventions. There are, however, a few trends such as breast cancer, certain reproductive diseases, and decline of insect and bird populations that are a cause for concern. Further research and a strengthened science-policy interface are needed.

1) Production and consumption of hazardous substances

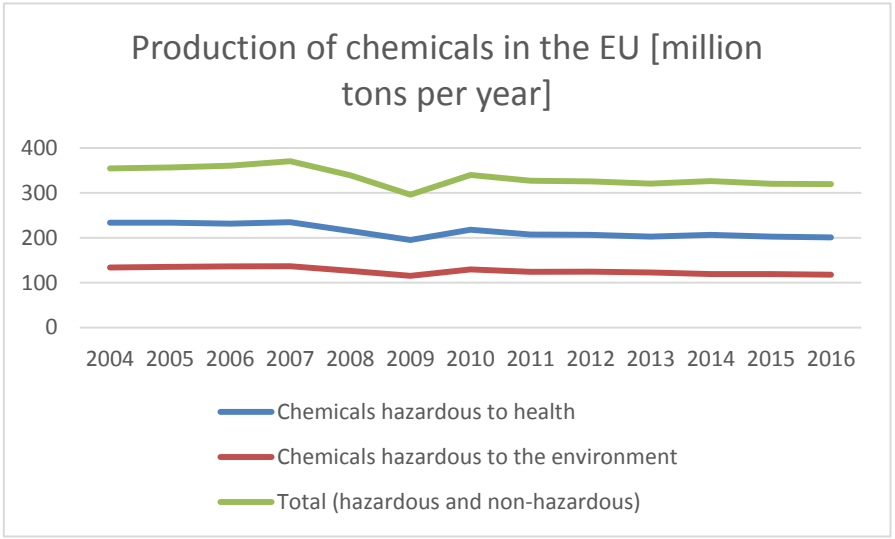
Trends in the production and consumption of hazardous substances, either expressed in absolute terms or relative to overall chemicals production and consumption, are one potential indicator of the substitution of hazardous substances by less hazardous substances. While not shared by all the pieces of legislation within the scope, it remains one of the goals of some of them e.g. the Plant Protection Products Regulation and the Biocidal Products Regulation. Eurostat has been producing since 2014 relevant data sets regarding substitution trends for industrial chemicals (please see also Annex 5 Section 5.1.1 A)).

The findings of the latest analysis[59] for EU-28 published in December 2017 are:

- The trend in the production of chemicals hazardous to health[60] and the environment[61] followed the trend for the overall chemicals production (Figure 6), reaching a peak in

[59] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics

2007, after which there was a significant decline in production during the financial and economic crisis in 2008, followed by a strong rebound between 2009 and 2010 and a subsequent more stable phase.



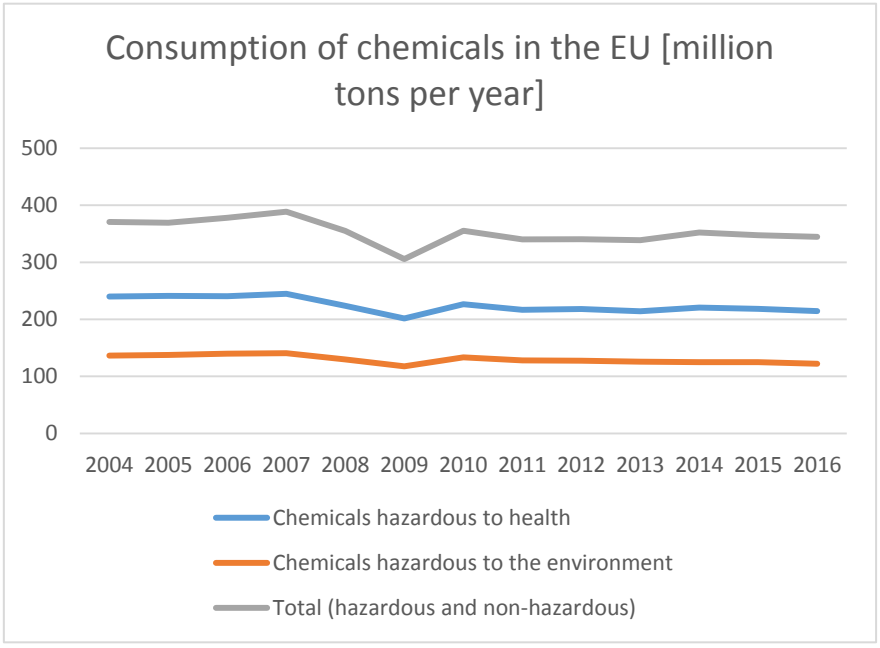


Figure 6 Production and consumption of chemicals, EU-28, 2004-2016. Source: Eurostat (online data codes: env_chmhaz) Note: some chemicals are hazardous to both the environment and human health therefore adding these

[60] Hazardous to health covers the following 5 classes: (1) Harmful to health hazard, (2) Toxic health hazard, (3) Very toxic to health hazard, (4) Chronic toxic health hazard, (5) Carcinogenic, mutagenic and reprotixic (CMR) health hazard. The indicator on chemicals hazardous to health is a sustainable development indicator within the theme for public health.

[61] Hazardous to the environment chemicals covers the following 5 classes: (1) Significant acute environmental hazard, (2) Chronic environmental hazard, (3) Moderate chronic environmental hazard, (4) Significant chronic environmental hazard, (5) Severe chronic environmental hazard. This division is based on their hazard on the aquatic environment

total together and subtracting the result from the total production or consumption volume to determine the volume of non-hazardous chemicals cannot be done.

- The share of chemicals hazardous to health and the environment was relatively unchanged over the period 2004–2016. The share of chemicals hazardous to the environment fluctuated between 37% and 39%, while the share of chemicals hazardous to health fell from about 66% in 2004 to 62% in 2016.

The analysis shows substitution of hazardous substances by less hazardous substances has not yet occurred to any notable extent. Essentially, the share of industrial chemicals hazardous to health and the environment in the total chemicals production has remained relatively unchanged over last decade. This may, in part, reflect the effectiveness of risk management measures in reducing exposures and risks, therefore reducing the incentive to substitute to less hazardous substances. The analysis also shows what might be the beginning of a positive substitution trend. The largest overall decrease in EU-28 production between 2004 and 2016 was recorded for chemicals with severe chronic environmental hazard and for chemicals with significant acute environmental hazard (as the production volume was reduced by about 18 % for both classes over the period under consideration). This may indicate that the substitution for these groups to less hazardous chemicals has started to happen (while it does not seem to be the case yet for chemicals hazardous to health). One could also note that no legislation-specific information is available which could allow the assessment of the pace of substitution once such a need is identified and eventually compare across the legislation. These statistics do not allow to link changes in the share of chemicals hazardous to health and the environment to the EU intervention. In order to do so, more in-depth analysis would be required.

Respondents to the public consultation[62] were asked to assign a score of between 1 (no contribution) to 5 (large contribution) to the role of the EU legislative framework in reducing the use of hazardous chemicals and/or substitution with safer alternatives. Scores assigned showed considerable variation among the four groups of respondents. Industry and public authority groups[63] considered the EU chemicals framework to have made the largest contribution to a reduction in number or use of hazardous chemicals and/or an increase in substitution to safer alternatives. In contrast, NGOs and other civil society organisations were considerably less positive.

2) Human and environmental exposures to hazardous chemicals

There is clear evidence that, where targeted EU policy and regulatory action has been taken, human and environmental exposures to a number of well-known individual hazardous chemicals have been successfully reduced or in many cases, minimised. As one example, consumer exposure to lead e.g. in petrol, paints, toys, drinking water, etc., has been reduced by an estimated 89% in the EU between 1990 and 2011, following a variety of risk management measures implemented by Member States, at least in part due to EU

[62] 1st FC Study, Annex V, p. 149; public consultation Question 23
[63] Weighted scores of 3.4 and 3.5 respectively

legislation.[64] This has resulted in a sustained and significant reduction, on average, in measured levels of lead in blood[65] (see Figure 7).

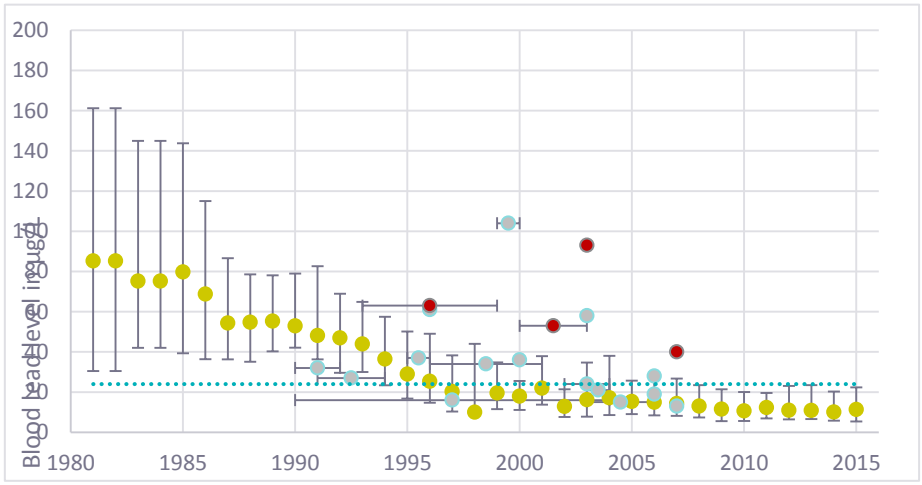


Figure 7 Medians (green dots) and 5th to 95th interval of the distribution of lead levels in the blood of German students from 1981 to 2015, along with levels of lead in blood of children from various European cohorts included in the WHO ENHIS database in grey (no known large lead pollution sources) and red (in the vicinity of known lead pollution sources). Dotted line represents the threshold implied by the WHO IQ loss model.[66]

From the environmental perspective, similar outcomes have been achieved in the EU between 1990 and 2011 for a number of heavy metals such as mercury (66% emissions reduction), cadmium (64% emission reduction) and arsenic (78% emissions reduction)[67] (see Figure 8). Reductions in the concentration of a number of other hazardous chemicals in the environment such as tributyltin, PCBs, dioxins, dichlorodiphenyltrichloroethane (DDT), have also been achieved following EU policy.

[64] CuBA Study p. 373
[65] Ibidem p. 78
[66] Ibidem p. 75
[67] Ibidem p. 89

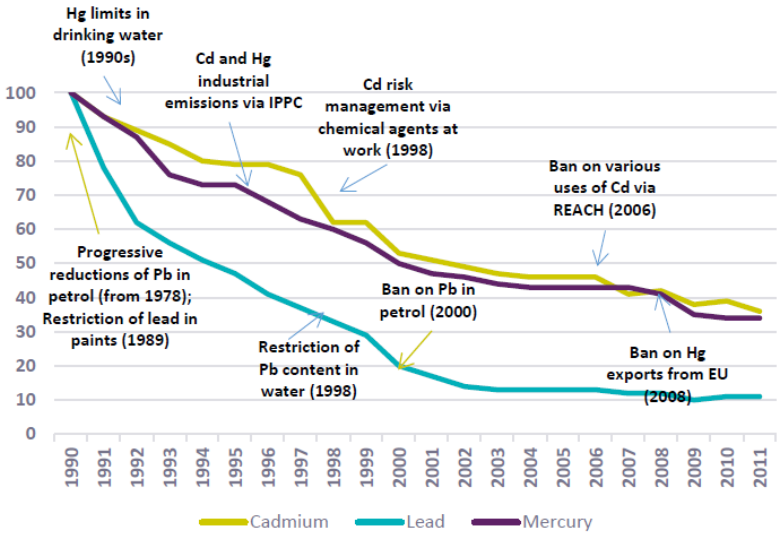


Figure 8 Mercury, Cadmium and Lead emissions (indexed, 1990-2011) alongside selected regulatory action[68]

There are, however, a number of on-going exposure situations that give cause for concern and which point to some shortcomings in meeting the objectives of protecting human health. These reflect both new, emerging issues, as well as existing ones that require further attention in terms of exposure reduction and control. Based on the current evidence[69], some of the more notable on-going exposure issues in the EU are exposures (see also Annex 5 Section 5.1.1. B)) to:

- carcinogenic substances at the workplace for which occupational exposure limits (OELs) have not yet been set[70];
- neurotoxic substances;
- chemicals linked to cardiovascular and respiratory (CVR) disease; and
- endocrine disrupting chemicals.

On-going environmental exposure situations also give cause for concern, the most notable being:

- Hazardous chemical exposures affecting the quality of surface and ground waters, including marine waters, with implications for their ecosystems (and indirectly for human health via seafood and drinking water consumption), despite considerable progress made in reducing the discharge of pollutants such as nutrients, pesticides, industrial chemicals, and household chemicals into Europe's waters over recent decades. Concern has grown regarding, for example, the widespread occurrence of persistent harmful substances such as polybrominated diphenyl ethers, which pose a

[68] CuBA Study p. 101 Table 6.8
[69] Ibidem, Part A: Protecting Human Health
[70] The European Agency for Safety and Health at Work (EU-OSHA) estimated in 2017 that cancer is the main cause of work-related deaths with 106,307 fatal cases per year in the EU-28 (source: EU OSH (2017): What are the main work-related illnesses and injuries resulting in death and in DALY: https://visualisation.osha.europa.eu/osh-costs). Many cases of occupation cancers are due to past exposures. It is estimated in the recent proposal to introduce EU-wide OELs for beryllium, cadmium, arsenic, formaldehyde and MOCA (COM(2018) 171 final) that when adopted, in the longer term it would prevent over 22 000 cases of work-related ill-health (cancers and non-cancers)

risk even at very low concentrations. New (stricter) environmental quality standards have been set for these substances and for some others such as fluoranthene, and these are due to be met by 2021. The results from some Member States, e.g. Sweden, Luxembourg and the Netherlands, indicates the new standard will be difficult to achieve.[71] Concern is also growing that the toxicity of mixtures of chemicals is not sufficiently addressed by the legislation, which focuses largely on individual substances (or small groups).[72]

- Hazardous chemical exposures affecting terrestrial eco-system health/resilience such as neonicotinoid pesticides representing a risk to wild bees and honeybees[73].

Respondents to the public consultation[74] from industry and companies as well as those representing public authorities were overall the most positive about the extent to which the EU legislative framework sufficiently addresses emerging areas of concern while civil society representatives and citizens assigned the lowest scores.

3) Human health and environmental impact evidence and indicators

The trends in the main health and environmental impact parameters that are known, or strongly suspected, to be associated with exposures to hazardous chemicals (e.g. trends in the incidence rates of certain cancers, reproductive diseases, sperm count and quality and trends in animal populations and eco-system health/resilience) are important to consider when examining the effectiveness of EU chemicals policy. However, using human health and environmental adverse effects as direct and reliable indicators of chemicals policy performance needs to be treated with caution because of the attribution challenge: many of the observed health and environmental adverse effects may derive from multiple causes (life-style, genetics, habitat destruction/degradation, etc.) and it is difficult to determine to what extent exposure to hazardous chemicals contributes to the observed adverse effects. Complicating things further is the fact that observable adverse effects in human health and the environment often do not materialise immediately after exposure. For example, the latency between exposure to carcinogens and the development of cancer can often be as much as 20 years or more.

The available evidence regarding the trends in the main health and environmental impact parameters points to a mixed picture. Some clear improvements have been achieved, for example, in the reduction of cancers related to workplace exposure to a number of targeted carcinogens which has resulted in the estimated prevention of 1 million new cancer cases in the EU over the last 20 years partly through the implementation of the occupational safety and health (OSH) legislation[75]. However, a number of other trends suggest there is still cause for concern, for example:

[71] EEA Report 'European Waters- Assessment of status and pressures 2018 (July 2018) p. 47
[72] Ibidem
[73] such as clothianidin, imidacloprid and thiamethoxam. It was recently confirmed by EFSA that most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees (Source: https://www.efsa.europa.eu/en/press/news/180228)
[74] 1st FC Study, Annex V, p. 151; public consultation Question 24
[75] Carcinogens and Mutagens at Work Directive (2004/37/EC)

- The health burdens resulting from most cancers continue to rise in the EU (except for lung cancer) (see Figure 9 for trends for breast cancer). For many cancers, the contributing role of chemical exposures is not yet well understood and defined while at the same time suspected to play a role. As a result, it is often unclear which specific chemical exposures should be targeted by legislation, in an attempt to eliminate preventable disease causes.

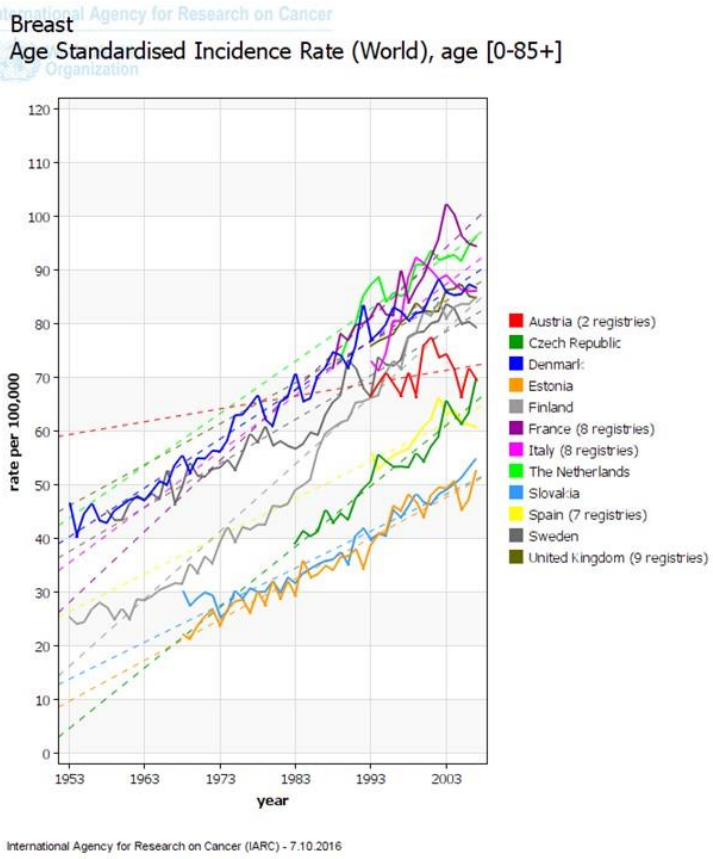


Figure 9 Age-standardised incidence rate trends for breast cancer in several European countries

- The same is true for neurodevelopment and reproductive health. While both male and female fertility rates are decreasing in Europe[76] [77] and while some neurodevelopmental disorders (e.g. autism) increase[78], there is no data on how many of these cases are attributable to exposure to hazardous chemicals. However, it is likely that hazardous chemicals play a role in these adverse health outcomes.[79] Substance categories of concern include certain phthalates, dioxins, perfluorinated chemicals, analgesics, etc.

[76] Temporal trends in sperm count: a systematic review and meta-regression analysis, *Hagai Levine et al, Human* Reproduction Update, p. 1-14, 2017

[77] Male reproductive disorders and fertility trends: influences of environment and genetic susceptibility Skakkebaek NE, Rajpert-De Meyts E, Buck Louis GM, Toppari J, Andersson AM, Eisenberg ML, Jensen TK, Jorgensen N, Swan SH, Sapra KJ et al. Physiol Rev 2016; 96:55–97

[78] CuBA Study, p. 60

[79] CuBA Study p. 329

These issues are more generally linked to the need to obtain better information about the spectrum of chemicals with relevance to human exposures and diseases. Achieving this include improvments regarding data requirements, toxicological testing and screening methods human biomonitoring, as well as better predictive and prioritisation approaches.

In the area of the environment, the observed trends also point to a mixed picture:

- Improvements in water quality[80] in some areas may have contributed to some recovery of aquatic ecosystems[81] and the restriction on the use of tributyltin (TBT) as an antifoulant in marine paints has resulted in the recovery of mollusc populations in many ports and coastal areas in Europe[82].
- Major declines (as high as 50-75%) in the populations of a number of animal species in the EU have been observed over the past 3-4 decades including pollinators, other flying insects[83] (see Figure 10), amphibians, and birds. Europe's wild bee population is in decline with nearly one in ten species facing the threat of extinction and more than a quarter of bumblebee species being currently at risk of dying out[84]. The populations of over 20% of bird species in the EU are in significant decline[85] [86], with the largest declines (46% between 1990 and 2014) for common farmland birds. The causes of these declines requires further research but are likely to be multiple including exposure to hazardous chemicals, changes in agricultural practices, habitat degradation, climate change, etc.

[80] CuBA Study, p. 185
[81] https://www.eea.europa.eu/publications/state-of-water, p. 32
[82] CuBA Study, p. 204
[83] CuBA Study, p. 387
[84] CuBA Study, p. 387
[85] Inger, R., Gregory, R., Duffy, J. P., *et al*. (2014). Common European birds are declining rapidly while less abundant species' numbers are rising *Ecology Letters*, DOI:10.1111/ele.12387
[86] The State of Nature in the EU, Reporting under the EU Habitats and Birds Directives 2007–2012 European Union, 2015

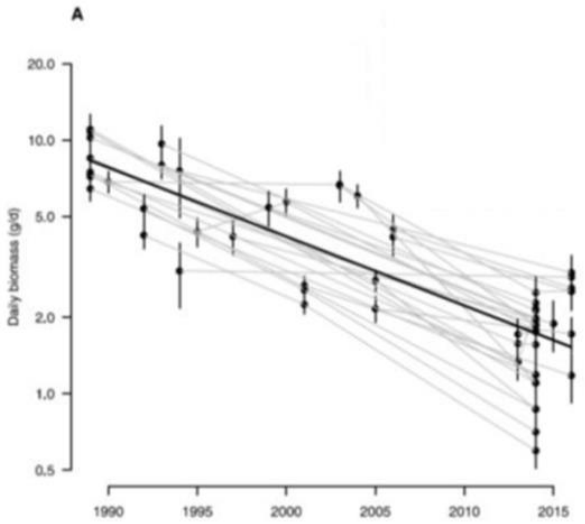


Figure 10 Temporal distribution of insect biomass at selected locations in Germany. Daily biomass across 26 locations in multiple years

The current approach and indicators used in monitoring and assessing human health and environmental impacts could benefit from being more holistic. For instance, such more holistic impact assessments could feed into exposure indicators (e.g. passive sampling, representative mixtures, human biomonitoring) as well as impact indicators (e.g. (eco)epidemiology, effect based methods as proposed in the Water Framework Directive).

5.1.2 The objective of ensuring the efficient functioning of the internal market and of enhancing competitiveness and innovation

A. What's the issue?

The EU chemicals legislation aims to ensure the efficient functioning of the internal market and to enhance competitiveness and innovation. The effectiveness of the EU chemicals legislation in achieving these objectives can therefore be measured by analysing:

- trends in the development of intra-EU sales of chemicals compared to domestic sales;
- trends in the EU export of chemicals and global market share;
- the role that the legislation plays in boosting the competitiveness of the EU chemicals industry and innovation.

B. What are the findings?

Conclusions

EU chemicals legislation has been instrumental in ensuring the free circulation of chemicals and products within the internal market through the harmonisation of requirements, standards, risk management measures, labelling, and mutual recognition approach that reduce barriers for intra-EU trade. To a large degree, there is a level playing field in Europe, and chemicals legislation has strengthened the internal market and enhanced the competitiveness of EU industry, this being reflected in the growth in intra EU trade. The EU remains the largest chemicals exporting region in the world and, despite the decline of the share (although absolute sales levels have increased) in the global market the EU chemicals industry remains

internationally competitive. However, some interpretation, implementation and enforcement issues at Member States level leave room for further improvements.

While the EU chemicals industry is often seen as a frontrunner in terms of innovation, there is no evidence that the EU chemicals legislation, as such, is either a major trigger of, or barrier to, innovation for companies in general.

EU chemicals legislation has been instrumental in ensuring free circulation of substances, mixtures and articles within the internal market through harmonisation of standards and requirements that reduced barriers for intra-EU trade. There has been a continuous increase of the share of the intra-EU trade of chemicals i.e. EU companies selling in the EU single market rather than in their home country market, in the total sold production of chemicals (from 43% in 2006 to 55% in 2016)[87]. For example, the CLP Regulation provides the basis for consistently identifying properties of concern, with this information then used in hazard communication to workers, downstream users and consumers of chemicals. Similar trends have been observed in the fields of cosmetics, detergents, fertilisers, etc., where EU product specific legislation has been adopted. The fact that many Directives have become Regulations contributed to harmonisation across the EU and therefore a better functioning internal market. Nevertheless, there are still areas where divergences in interpretation, implementation and enforcement continue to persist potentially leading to fragmentation of the European market and creating burden and barriers for businesses (see Annex 5 Section 5.1.2).

In terms of international competitiveness, the EU chemical industry in 2016 represented 15.1% of the global market, behind China (39.6%) but ahead of the United States (14.2%)[88]. Although the European share of global sales has decreased (32.5% in 1996) the EU chemicals industry remains internationally competitive as evidenced by the trade surplus of EUR 47.2 billion (exports EUR 146.2 billion, imports EUR 99 billion)[89]. The decrease in the share of global sales is mainly due to relative growth in other parts of the world, such as China and India, served by their own domestic production. Other potential reasons given for this are high energy prices, currency appreciation, high labour costs, regulatory and tax burdens.[90] Yet the EU remains the largest chemicals exporting region in the world[91]. The main competitive advantage of the EU chemical industry is the high level of technological development, skilled workforce and strong research base.

As an input provider for other industries, the chemicals industry is also considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges, with chemical technological breakthroughs spilling over into downstream sectors[92]. As mentioned above, the beginnings of a possible positive trend can be observed

[87] The intra-EU sales increased from EUR 219 billion in 2006 to EUR 280 billion in 2016 (+28%). Domestic sales (sales in the home country) dropped from EUR 184 billion in 2006 to EUR 81 billion in 2016 (-56%). Extra-EU exports increased from EUR 102 billion in 2006 to EUR 146.2 billion in 2016 (+43%). Source: CEFIC Facts and Figures Report, CEFIC, 2017

[88] Ibidem

[89] Ibidem

[90] Ibidem

[91] CEFIC Facts and Figures Report, CEFIC, 2017, p. 21

[92] CEFIC (2015): Competitiveness of the European Chemicals Industry: How to regain ground in the global market. Available at: http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Competitiveness-of-the-European-chemical-industry-2014.pdf quoted in the 1st FC Study Annex IV p. 54

concerning substitution to less hazardous or non-hazardous substances[93] for substances hazardous to the environment. In many cases, hazard classification under the CLP alone for example is an incentive for substitution as it triggers a number of legal obligations, including labelling and communication to downstream users as well as consumers. Indeed, increasing consumer awareness of the health risks associated with certain hazard classifications (most notably carcinogens) is a powerful trigger for substitution in the supply chain.[94] In other cases, risk management measures (such as bans and restrictions) triggered by a certain hazard classification provide such incentives[95]. Innovation and substitution are encouraged by many pieces of legislation acting in concert and supported by drivers, such as consumer demands, market circumstances and initiatives such as e.g. the Substitution Support Portal (SUBSPORT) under the European Union's Life programme[96]. Overall impacts of chemicals legislation on innovation are, however, more complex, as described in the REACH Evaluation[97]. As no specific indicators exist for assessing these and also given that many other factors play a role e.g. intention to develop new applications in order to conquer new markets, it is currently not possible to know whether the EU chemicals legislation has been a major trigger of innovation.

The EU chemicals legislation was considered by citizens, industry and companies and public authorities as mostly effective in ensuring a well-functioning internal market while civil society considered it to be moderately effective.[98] Regarding this particular aspect, SME Panel results showed that the EU chemicals legislation is considered to be sufficiently harmonised across Member States for the proper functioning of the European single market. While citizens, industry and companies and civil society considered the legislation moderately effective in stimulating competitiveness and innovation, public authorities were of an opinion that it is mostly effective in reaching this objective.[99]

5.2 Evaluation question: what factors affect (either positively or negatively) the correct functioning of the EU legislative framework for the hazard identification and risk management of chemicals? What are the consequences or effects that were not originally planned for?

An effective framework of chemicals legislation ensures the timely and sound identification of chemical hazards and risks, the appropriate control of human and environmental exposures to hazardous chemicals and, for hazardous chemicals where the exposures cannot be reliably controlled, a progressive shift towards the use of less hazardous chemicals (substitution) including non-chemical solutions.

The basic steps of the risk management procedures and processes applied to chemicals within the EU framework of chemicals legislation (see Section 2.1 and Annex 8 for further detail) are:

[93] 1st FC Study Annex IV p. 55
[94] 1st FC Study, Annex IV, p. 56
[95] Ibidem
[96] https://www.subsport.eu/
[97] REACH Evaluation SWD, chapter 6.1.1.3.3, p. 51 ff.
[98] 1st FC Study, Annex V, p. 32-38; public consultation Question 10
[99] Ibidem

- hazard identification (based on toxicity tests and other relevant information);
- dose (concentration) – response (effect) assessment;
- exposure assessment – exposure scenarios for relevant uses of the chemical (based on models and measurements of the occurrence of the chemical);
- risk characterisation; and
- risk estimation.

The correct functioning of each of these risk management steps can be affected by one or more key performance factors, including:

- Whether the necessary scientific knowledge (including recognised and accepted test methodologies for hazard identification) and data/information (e.g. on chemical uses and exposure scenarios) are available, are used appropriately and can be shared between different risk assessment regimes to ensure the coherence of findings and to avoid duplication of effort.
- Whether and how the hazard identification and risk assessment process is triggered.
- Whether the overall 'speed' of the hazard identification and classification and risk assessment processes can handle the quantity of existing and newly designed hazardous chemicals placed on the market. This is not simply a question of efficiency but, fundamentally, of effectiveness. If the framework fails to identify and address the hazards and risks of chemicals in a timely manner, its effectiveness is reduced. This also requires further discussion on how to better prioritise and in which areas and/or for which substances such prioritisation would be necessary.
- Whether the necessary competences and resources are available at EU and Member State level to ensure robust and timely hazard identification/assessment/classification, risk assessment and risk management decision-making.
- Whether the use of generic risk considerations (GRC) and specific risk assessment (SRA) based approaches is appropriate and balanced.
- Whether the desired transition to non-animal test methods is happening and is effective.

These different factors can affect the performance of one or more of the risk management steps outlined above. For example, poor quality or missing data affects the ability to correctly identify and classify hazards, to determine reliable exposure scenarios, and, therefore, to arrive at a robust risk assessment. The assessment of the effectiveness of the framework of EU chemicals legislation has, therefore, been structured and presented according to these factors.

5.2.1 Data, knowledge and information

A. What's the issue?

Scientific understanding and the availability of good-quality, reliable data underpins the effective functioning of EU chemicals legislation. It includes, among other things, knowledge and information on chemical properties, data on eco-toxicity of chemicals and on chemical uses and exposures to chemicals (including occurrence in, and release from, articles (consumer products)).

Please refer to Annex 5 Section 5.2.1 for a more detailed description of data, knowledge and information related aspects.

B. What are the findings?

Conclusions

Enormous efforts have been made at the EU and Member State level to ensure that the necessary data to take effective chemical risk management decisions is available, comparable and of good quality. Likewise, the scientific understanding of how hazardous chemicals impact human health and the environment has improved significantly over the last two decades. Much of this effort has been resourced and underpinned by industry assuming the responsibility of ensuring the safe use of chemicals placed on the market. This has been helped by significant investment in EU-level capacity for supporting the risk assessment processes under the various chemicals legislation regimes (ECHA, EFSA, and a number of scientific committees).

While the existing test guidelines cover the majority of known adverse effects on human health and the environment, they can be further improved. Standardised and internationally recognized test guidelines still need to be developed and/or validated. This is the case for certain environmental adverse effects such as the terrestrial compartments and some specific terrestrial species. This is also the case for neurotoxicity, immunotoxicity and some endocrine disruptors related aspects.

The EU has put considerable efforts and resources in promoting the avoidance or reduced use of animal testing. However, there are still barriers to the use and acceptance of alternative (non-animal) test methods for regulatory purposes, partially linked to lack of test guidelines for certain effects or to gaps in the current knowledge.

The current state of knowledge regarding exposure scenarios i.e. knowledge of which chemicals and their combinations, and at what concentrations, humans and the environment are being exposed to, needs further attention.

The scientific understanding of mechanisms and pathways of how hazardous chemicals interact with organisms has improved considerably over the last two decades with, for example, the support of the Commission's research framework programmes.

Much has also been done to improve the quality, reliability and reproducibility of hazard and risk assessment studies and data. Quality standards are prescribed for how hazard and risk analysis is to be conducted, including the testing methodologies. Toxicity studies submitted by chemicals producers or importers need to be performed according to validated test methods and guidelines. In addition, the laboratories that perform chemical hazard and risk assessment studies must comply with the GLP requirements[100]. During the workshops, there was general agreement amongst participants that the GLP requirements help to ensure that the rigorous documentation about how a study was conducted is made available. This is, good to have as it allows comparability and reproducibility but they are not sufficient to ensure high scientific quality.[101]

Validated test methods and guidelines help to ensure comparability and reproducibility of data produced and thus increase the reliability and quality of data. International agreement on test

[100] http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en

[101] See 1st FC Study Workshop report p. 15-18. See also FC+ Study p. 43 and onwards

guidelines (under OECD) ensures the mutual acceptance of the data among countries and regions, which lowers the technical barriers to trade and reduces also the number of animals used for testing. The existing test guidelines cover the majority of known adverse effects on human health and the environment. However, standardised test methods and guidelines are lacking for certain environmental adverse effects (soil biota, reptiles, and other terrestrial animal species).[102] There is also a need to further improve the existing test methods and guidelines regarding neurotoxicity, immunotoxicity, epigenetics, endocrine disruption as well as how to capture peculiarities of nanomaterials.[103]

The policy on the protection of animals used for scientific purposes[104] has streamlined resources and efforts towards the development of alternative methods to replace, reduce, and refine animal testing.[105] To date, this focus has been successful for five human health endpoints[106], for which tests have been validated and recognised internationally[107]. However, there are still barriers to the use and acceptance of alternative test methods, and no methods are available yet to fully evaluate complex systemic endpoints.[108] The identified gaps in existing test guidelines for endpoints relevant for human health and the environment call for development of new test methods and adequate funding is required for both approaches, non-animal and animal. In addition, there is a need to accelerate the regulatory acceptance of alternative test methods[109] (see also Annex 5 Section 5.2.2).

The EU chemicals legislation requires in principle the use of 'all available information'. A number of stakeholders, however, expressed concern that potentially relevant and useful peer-reviewed scientific studies and data were being ignored or overlooked during regulatory hazard and risk assessments because they are not GLP-compliant[110]. This warrants some attention and action because the peer-reviewed studies may use test designs, test species and test endpoints that are more sensitive and relevant than those used in standardised studies and can, therefore, be an important complement to the standardised studies provided that they are reliable and properly documented. Moreover, lack of awareness of authorities regarding the availability of relevant or new information and data for hazard and risk assessment contributes to a situation where it can take several years[111] between the first concerns and evidence being

[102] CuBA study p. 368. Regarding in particular endocrine disruptors see COM(2018) 734 final p. 3-4

[103] Epigenetics literally means "above" or "on top of" genetics. It refers to external modifications to DNA that turn genes "on" or "off." These modifications do not change the DNA sequence, but instead, they affect how cells "read" genes. Epigenetic changes alter the physical structure of DNA. Epigenetic changes can be heritable to the next cell generations (mitotic) but also to the next generation of an organism (meiotic).

[104] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

[105] REACH Evaluation SWD(2018) 58 final, Annex IV

[106] Skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation

[107] Some testing strategies have been developed, also leading to an overall reduction of the use of animals. See for example the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) Strategy to replace, reduce and refine the use of fish in aquatic toxicity and bioaccumulation testing available at https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eurl-ecvam-strategy-replace-reduce-and-refine-use-fish-aquatic-toxicity-and-bioaccumulation

[108] Regulatory fitness check of CLP and related legislation - Case study 4, p. 9-12

[109] Regulatory fitness check of CLP and related legislation - Case study 4, p. 19-20

[110] FC+ Study p. 45 and onwards

[111] Polychlorinated Biphenyls (PCBs) are among a group of man-made chemicals that are known as Persistent Organic Pollutants (POPs). PCBs were commercially produced world-wide on a large scale between the 1930s

published in the academic journals and the regulatory hazard and risk assessments being triggered. Tools are currently lacking to ensure continuous monitoring of scientific papers and publications and mechanism for the identification of, and reaction to, early warning signals.

As regards exposure data in particular, there continue to be significant gaps in our knowledge of which chemicals and their combinations, and at what concentrations, humans and the environment are being exposed to. These gaps have an impact on determining realistic, acceptable and robust exposure scenarios. The main difficulties can be summarised as follows:

- Exposure assessments typically make use of a combination of models, laboratory data and monitoring to calculate the potential exposure within a given scenario. In order to successfully conduct exposure assessments, the models in use have to be underpinned by data, and likewise real world analysis is needed to validate results. Additional monitoring to validate models is often a step that is overlooked in the EU risk assessment processes and this undermines the quality of the results.[112]
- Exposure scenarios used in setting 'safe' exposure limits, are established based on intended, normal, reasonable and/or foreseeable use of a product (e.g. cosmetic, plant protection, biocidal, detergent products) or foreseeable/predictable situation (e.g. occupational or industrial settings). There is evidence that for hazardous chemicals with a broad range of applications in a myriad of different consumer products, industry and public authorities may be unaware of many uses.[113] In addition, there are no requirements on producers of hazardous chemicals for example to make available substance-specific information on actual amounts marketed. As an initial step, the Commission recently began to tackle this issue for veterinary antibiotics where reporting obligations on volumes used have been introduced.[114]
- Yet, even when all uses and amounts are known, determining realistic exposure scenarios can still be problematic where consumer behaviour is difficult to predict. Determining and characterising exposure in an occupational setting by way of comparison is relatively more straightforward, as the exposure scenario is more controlled and predictable.[115]

To address the issue of human health exposure data, the EU Commission has funded the European Human Biomonitoring Initiative (HBM4EU).[116] However, a similar holistic

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and 1980s. In the 1970s, owing to severe concerns pertaining to their human toxicity, suspected carcinogenicity, and environmental persistence, several countries limited the use of PCBs. Finally in 1985, the use and marketing of PCBs in the European Community were very heavily restricted. Measures regarding the disposal of PCBs and PCTs and equipment containing PCBs were taken in 1996. In 2001, the Commission adopted a Community Strategy on Dioxins, Furans and PCBs aimed at reducing as far as possible the release of these substances in the environment and their introduction in the food chains.

[112] FC+ Study p. 51

[113] Market survey on articles treated with biocides, KEMI PM 6/16

[114] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jp . It should be however noted that medicinal products legislation is not in the scope of this Fitness Check.

[115] FC+ Study p. 68

[116] The EU contribution amounts to around EUR 50 million. See https://cordis.europa.eu/project/rcn/207219_en.html

initiative for animals, plants and eco-systems is currently lacking[117] [118]. The screening of 'unknowns' (i.e. sampling and testing designed to detect unsuspected hazardous chemicals) in humans and the environment is also missing.

5.2.2 Hazard and risk (re-)assessment

A. What's the issue?

The obligation to perform hazard and risk assessments or re-assessment sits primarily with industry, in line with the principle of reverse burden of proof[119]. Public authorities (national or EU) intervene only in a limited number of cases (in areas of the highest potential risks to human health and/or the environment).

Please refer to Annex 5 Section 5.2.3 for more detailed description of how hazard/risk assessment is triggered.

B. What are the findings?

Conclusions

Where the initiative to trigger the hazard/risk assessment sits with industry and there is a positive incentive to do the assessment (e.g. seeking authorisation to place a product on the market), the quality of the risk assessment dossiers tend to be good. For the pieces of legislation where the underpinning mechanism relies on the presumption of conformity with the existing rules, information is scarce and therefore does not allow to conclude on the quality of conformity assessments carried out. It appears however clearly that the capacity and resources of the EU and/or Member State authorities to check the quality of these self-assessments are paramount but are often constrained.

The obligation to perform risk assessments sits primarily with the industry in line with the principle of reverse burden of proof. Risk assessment can also be initiated by public authorities, both at the EU and MS level e.g. the Commission will trigger risk assessment under the Water Framework Directive and Industrial Emissions Directive.

The effectiveness of the obligation for industry to carry out a risk assessment, i.e. whether risk assessments are done and to what quality, is influenced by the following aspects:

- existence of a commercial interest to gain approval/authorization,

[117] However the monitoring of emerging pollutants is carried out since 2011 by the Network of reference laboratories for monitoring emerging environmental pollutants (NORMAN Association) together with the Commission to support the Common Implementation Strategy of the Water Framework Directive. More information is available at https://ec.europa.eu/jrc/en/publication/norman-interlaboratory-study-ils-passive-sampling-emerging-pollutants

[118] SOLUTIONS is a project funded by the EU aiming at searching for new and improved tools, models, and methods to support decisions in environmental and water policies. The overall goal of the project is to produce consistent solutions for the large number of legacy, present and future emerging chemicals posing a risk to European water bodies with respect to ecosystems and human health. More information available at https://www.solutions-project.eu/project/#article-24

[119] Reverse burden of proof means that industry is responsible for ensuring the safe use of their chemicals and therefore carrying out the risk assessment and ensuring the risk management of their chemicals, including testing. Public authorities are responsible for checking if this obligation is properly implemented and, where not, to quickly and efficiently propose measures to manage potential risks appropriately.

- existence of a prescription for how the risk assessment should be performed and documented, and
- existence of an obligation to communicate the outcome of the assessment to public authorities and/or downstream users.

Systematic checks by EU and/or national public authorities of the risk assessment done by industry are legally required only for certain pieces of legislation where authorisation/approval/permit is needed before the substance/product can be placed on the market (e.g. plant protection products, biocidal products) or activity can be carried out (e.g. industrial activities, including waste management activities). In such cases, the quality of dossiers submitted by industry and the robustness of the overall assessment are generally good.[120]

Under other product related legislation (e.g. the Cosmetic Products Regulation, the RoHS Directive, the Toy Safety Directive, the Detergents Regulation) and the occupational safety and health (OSH) legislation, the underpinning mechanism is based on conformity/safety assessment done by economic operators themselves and the presumption of conformity with the existing rules.[121] In these cases, assessments carried out are not systematically checked by public authorities. Therefore, ensuring that only safe products are placed on the market or that worker safety rules are complied with, relies primarily on economic operators, including importers, who can be held responsible for non compliance. This approach reduces the administrative burden for public authorities. However, ensuring that this obligation is actually complied with still relies on Member States and depends in particular on market surveillance activities and inspections carried out at national level which requires considerable resources. The recent ECHA report has shown that the compliance with the general safety obligation is challenging[122] but more evidence and information, including data from regular market surveillance or other similar or equal mechanisms, need to be gathered to conclude on the level of compliance of self-assessments (and thus on the level of enforcement).

The EU chemicals legislation requires risk assessments to be updated. However, there are some differences in the level of stringency of the legal provisions. In some cases, the legislation will specify the frequency or conditions that will trigger a re-assessment e.g. the Biocidal Products Regulation, the Plant Protection Products Regulation, the Ecolabel Regulation, the Industrial Emissions Directive and the Water Framework Directive. In most cases however re-assessment is required if and when new scientific knowledge and/or evidence emerge.[123] All the factors identified above for the initial assessment are also valid for re-assessments. Re-assessments seem to be more effective when there is an automatic trigger in the legislation such as expiration of the approval of active substances for plant protection products (usually 10-15 years). More evidence needs to be gathered to conclude on the effectiveness of re-assessments in cases where they are to be triggered by new scientific knowledge.

[120] FC+ Study p. 58-66
[121] In this case, the economic operator declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.
[122] https://echa.europa.eu/-/inspectors-find-phthalates-in-toys-and-asbestos-in-second-hand-products
[123] FC+ study p. 64

Respondents to the public consultation were asked to indicate their satisfaction with risk assessment and characterisation[124] which received the lowest weighted score from Citizens and NGOs and others but was scored relatively highly by industry associations and public authorities.

5.2.3 Hazard classification

A. What's the issue?

The communication of chemical hazard properties to downstream users is an important risk management measure that helps ensure the safe handling of chemicals and mixtures. It needs to be underpinned by reliable, robust hazard classification. Hazard classification is also crucial for other risk management processes within the framework of EU chemicals legislation, such as restrictions or authorisations.

Please refer to Annex 5 Section 5.2.4 for more detailed description of how hazards are classified under the EU chemicals legislation.

B. What are the findings?

Conclusions

As the primary basis for most chemical hazard assessment and classification in the EU, the CLP Regulation is effective and is considered by the majority of stakeholders as an improvement over the earlier Directives that it replaced. Some issues, however, were identified with respect to the pace and focus of harmonised classifications, the classification of mixtures, and inconsistencies in industry self-classifications.

Two processes are available for classification:

- For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH). Harmonised classifications are listed in Annex VI to the CLP Regulation.
- Under the CLP, a substance must be self-classified by manufacturers, importers or downstream users when it has no harmonised classification in Annex VI to the CLP and it presents hazardous properties. This classification and labelling information for the substances to be placed on the market is then notified by manufacturers and importers to the Classification and Labelling Inventory (CLI) held by ECHA. Mixtures must always be self-classified before being placed on the market, as they are not subject to CLH.

The harmonised classification is an important instrument for achieving the safe use and enhancing the substitution of hazardous chemicals. It is also linked with the approval process for plant protection product and biocidal product active substances.

[124] 1st FC Study, Annex V p. 122; public consultation Question 17

According to ECHA the number of assessments for harmonised classifications under the CLP Regulation is relatively low compared to the likely number of chemicals which merit a harmonised classification.[125] During the public consultation, citizens and civil society organisation considered the speed of the procedures for CLH slightly satisfactory, industry considered it to be moderately satisfactory and public authorities considered the speed to be mostly satisfactory.[126] The main consequence of this 'slow' pace is that not all of the potentially hazardous chemicals which would therefore merit a harmonised classification are dealt with thus potentially prolonging exposure of EU citizens to such hazardous chemicals.

It seems to be due to the following capacity constraints:

- Currently, the main focus is on active substances used in plant protection and biocidal products. This explains the fact that relatively few harmonised classifications are being done for industrial chemicals.
- Much of the current situation is a reflection of the high resource needs (staff/expert capacity) at Member State level for preparing a classification dossier, combined with reductions in resources and budgets allocated for this work in many Member States, in particular following the 2008 financial crisis. There is also considerable variation between Member States in their capacity and willingness to initiate harmonised classification dossiers with just a few Member States carrying the majority of the burden.[127]
- The current speed also reflects the need to ensure that all the relevant opinions, including stakeholder views are taken into account.
- In many cases, the process is slowed down and there is some reticence because of the consequences that the harmonised classification may trigger in downstream legislation e.g. ban of CMRs under the Cosmetic Products Regulation or cut-off criteria under the Plant Protection Products Regulation.[128] In this regard, it should be noted that efforts have already been made in order to speed up the CLH process. A fast track procedure was introduced by ECHA for discussing non- controversial endpoints. ECHA indicated that in the RAC meeting where this was introduced, 65% of classification proposals for such endpoints went through without discussion.[129]
- Currently, there is no quantified objective or a point of reference to compare with to evaluate the speed of the classification and to know how many substances and by when these need to have a harmonised classification. In addition, the Commission lacks the legal basis for initiating the harmonised classification process or to ask ECHA to develop dossiers while industry can initiate and submit harmonised classification dossiers only for a limited number of substances. Regarding classification of active substances for plant protection and biocidal products and revision of the existing entries, only Member State Competent Authorities can submit proposals, but, according to industry, they are difficult to approach or not always cooperative.

[125] ECHA Report on the Operation of REACH and CLP 2016 p. 117
[126] 1st FC Study Annex V, p. 204 and onwards, question 34
[127] 1st FC Study Annex II, p. 47-48
[128] 1st FC Study Workshop report p. 19
[129] 1st FC Study Annex II, p. 43

As regards self-classifications by industry under the CLP Regulation, there are often multiple classifications for the same substance submitted to be registered in the CLI because different notifiers fail to arrive at an agreed entry despite the legal obligation to make every effort to do so. Furthermore, there are concerns about the reliability of some of the self-classifications which is exacerbated by the lack of legal basis for ECHA to correct or delete obvious mistakes, to remove entries by companies which have ceased to exist or for substances which are no longer placed on the market (especially below 1t/y) and to get in direct contact with notifiers/registrants, in order to initiate a correction or obligation for manufacturer/importer to check the quality of the information being notified.[130] This affects the value of the CLI as a hazard communication tool. The Commission and ECHA are actively looking into a number of ways to improve the situation.[131]

The lowering of generic concentration limits for some hazard classifications under the CLP compared to the levels prescribed under the previous regime (i.e. the Directive which the CLP Regulation replaced), in particular for skin and eye irritation or corrosion, has resulted in more stringent classifications when classifying mixtures using the 'calculation method'. Stakeholders representing the detergent sector stated that it leads to over-classifications. Similarly, because SMEs are more likely to depend on the calculation methods to classify mixtures (due to cost considerations), they are also more likely to place more conservative hazard classifications on their products than companies that can do the necessary testing. In principle, the bridging principle[132] classification method could address this issue. Bridging principles are basic principles used to classify un-tested mixtures under the CLP Regulation and the UN Global Harmonised System (GHS). However, the lack of clarity with respect to how to apply these principles hampers the effectiveness of this method.[133] It also leads to discrepancies in interpretation and acceptance of classification by Member States. The Commission is now taking steps to address this issue, including guidance on the harmonised application of the legal requirements.

Issues with mixture classification have also been raised by metal industry stakeholders in relation to metals and metal alloys e.g. the alloy used in Euro coins and the stainless steel-nickel-cobalt alloys used as medical implants.[134] While the metal alloys are to be classified following the CLP chemical mixtures classification rules, this stakeholder group believes that it leads to metallic alloys receiving classifications that do not match their real hazard properties. They also believe that this situation could have negative consequences on metals recycling and thus on the realisation of circular economy with some unintended consequences in downstream legislation (e.g. the Toy Safety Directive, the Transport of Dangerous Goods Directive, the Industrial Emissions Directive). It should be noted that the Commission has already been made aware of these concerns and has started to address them, in particular

[130] 1st FC Study Annex II p. 130-135
[131] 1st FC Study p. 25
[132] ECHA Guidance on the Application of the CLP Criteria Version 5.0 – July 2017, p. 68-72
[133] 1st FC Study p. 15-16, p. 41-42; see also Annex II p. 20 and onwards
[134] 1st FC Study, Annex II p.27 and onwards. See also 1st FC Study Annex VI Case Study 2. This issue was also brought up and discussed more recently by the Federation of Finnish Technology Industries at the REFIT Platform. This stakeholder group called upon the Commission to review the current classification rules for metallic alloys and issue a guidance on the interpretation of article 1.3.4 of the CLP in the context of the circular economy, as well as to support the efforts of the metal industry in developing a new test method in order to improve the classification of metallic alloys to be based on their intrinsic properties.

through the bio-elution project [135] [136] (involving industry stakeholders) which is reviewing possible test methods for assessing the bioavailability/exposure to metals in alloys. Whether, and how, several other hazard classes such as persistent, bioaccumulative and toxic/very persistent and very bioaccumlative substances (PBTs/vPvBs), endocrine disruptors (EDs), and neurotoxicity are addressed by the EU chemicals legislation is further discussed in the Section 7 Coherence (for more details on specific substances, i.e. CMRs, PBTs/vPvBs, EDs please refer to Annex 7).

5.2.4 Communication of hazards and risks to consumers and professional users and public authorities

A. What's the issue?

Communication of hazard, risk and safety information about chemical substances and mixtures to users, consumers, workers and public authorities is a key measure to promote the safe use of chemicals, to mitigate risks and to help users make informed product/substance related choices. Various communication measures exist across the legislative framework. Their effectiveness has a direct impact on the correct functioning of the EU chemicals framework and on achieving its objectives.

Please refer to Annex 5 Section 5.2.5 for more detailed description of rules regarding communication of hazards and risks and the related aspects.

B. What are the findings?

Conclusions

The requirements to communicate chemical hazards and risks to consumers, workers, and professional users via hazard pictograms, labels and safety data sheets is considered by most stakeholders to be generally effective and important. Some concerns have been raised by industry stakeholders that labels are becoming overloaded with information making it difficult for consumers to focus on the essential hazard information. A recent Eurobarometer survey suggests that one or two of the hazard pictograms are not well recognised or understood by a majority of consumers.

Within the framework of EU chemicals legislation, one of the primary mechanisms of hazard and risk communication is via pictograms and product labels for hazardous chemicals and mixtures, as prescribed by the CLP Regulation (and in line with the UN Global Harmonised System (GHS)). This means that that any changes agreed to at the GHS level (e.g. refinements to the wording of the hazard statements required on labels) are transposed into EU law via the CLP Regulation. There are also a small number of additional sector-specific labelling requirements (e.g. for cosmetics, toys, and detergents). In addition, the EU Ecolabel Regulation sets out rules for a voluntary labelling scheme.

[135] Biological availability in the context of Art. 12(B) CLP, 19th Meeting of Competent Authorities for REACH and CLP (CARACAL), 12 – 13 November 2015, Brussels, 03/11/2015, Doc. CA/90/2015

[136] Bioaccessibility testing (Bioelution) of metals, inorganic metals compounds and metals-containing materials: simulated gastric fluid, Joint Research Centre, European Commission 2016 https://tsar.jrc.ec.europa.eu/test-method/tm2016-02

A recent Eurobarometer survey[137] indicated that 70% of EU citizens find information on the hazards of chemicals on the label useful. It also showed that there are varying levels of awareness and comprehension of the four (out of a total of nine) chemical hazard pictograms that were examined by the survey. While 'flammability' is well recognised and understood (92% of respondents have seen it before and 96% could correctly state its meaning), it is less the case for the 'environmental' hazard pictograms (47% of respondents have seen it before and 83% could correctly state its meaning), 'serious health hazard' pictograms (20% of respondents have seen it before and 69% could correctly state its meaning), and 'exclamation mark' pictograms (63% of respondents have seen it before and 17% could correctly state its meaning). Nevertheless, when they see one of the chemical hazard pictogram on an unfamiliar product, most respondents (76%) read the safety instructions (57% read the safety instructions on the product label, while 19% say they go further by reading the safety instructions on the product label and then trying to find further information from other sources). The Eurobarometer Survey also found that even in Member States where understanding of the issues surrounding chemical products is high, the comprehension of some of the hazard pictograms is relatively low.

At a more general level, another recent Eurobarometer survey[138] found that less than half of the respondents (45%) feel well informed about the potential dangers of the chemicals contained in consumer products. However, again, this proportion varies considerably between Member States.

Respondents to SME Panel consultation[139] expressed the following views:

- 76% of respondents agreed or strongly agreed that the information currently required to be included on labels is necessary and appropriate.
- 78% of respondents agreed or strongly agreed that the CLP hazard pictograms are generally representative of the actual hazard.
- 63% of respondents agreed that consumers generally do not look beyond the label for hazard information and information on safe use.
- 29% of respondents agreed or strongly agreed that consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (against 41% disagreeing or strongly disagreeing and 31% neither agreeing nor disagreeing).
- 65% of respondents agreed or strongly agreed that employers and workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals.

In part, this is an issue of citizen education and awareness raising by Member States. Hazard communication to workers and professional users is considered to be more effective with a higher level of awareness, recognition and understanding of the pictograms than consumers; in part due to employee training.[140]

[137] Special Eurobarometer 456
[138] Special Eurobarometer 468
[139] 1st FC Study, Annex V, p. 39 and onwards, question 11, table 2-19
[140] 1st FC Study p. 70; see also1st FC Study workshop report p. 12-13

Evidence also indicates that labels can become overloaded with information e.g. too much text, too long and not meaningful chemical names to non-professional users making it difficult for downstream users and consumers to focus on the essential hazard information, thus reducing the effectiveness of hazard communication. Too much text included on labels, especially when this is required to appear in multiple languages, thus restricting the understandability of the information.[141] This could be overcome by increasing the use of digital tools to communication hazard information. 61% of respondents to SME panel consultation[142] agreed or strongly agreed that providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites. Currently, however the legal (mandatory) requirements do not incentivise the use of more innovative techniques and digital tools and when it happens, industry is using digital tools on voluntary basis. While this may improve the understanding and management of hazards and risks, it can also lead to confusion between the CLP-required and the sector-initiated pictograms and labels.

Complementing product labelling, Safety Data Sheets (SDS) are a key communication tool for downstream industry users of hazardous substances and mixtures towards workers. Even though the CLP criteria are used to trigger the obligation to develop a SDS, provisions are in REACH. A SDS must provide information on all hazards covered by the CLP Regulation, as well as on whether a substance or mixture meets the criteria of persistent, bioaccumulative, toxic or very persistent and very bioaccumulative (PBT/vPvB) substances or on substances included in the Candidate List of substances of very high concern (SVHCs). These provisions were evaluated as part of the REACH evaluation which showed that there has been a continued increase in the information passed through the supply chain. However, the evaluation also pointed out a relatively high level of non-compliance and highlighted the potential for clarification and simplification especially for SMEs.[143] Another factor to consider is the capacity of SMEs to perform the risk assessment at the workplace based on the exposure scenarios provided in the safety data sheets (SDS) due to the limited resources and expertise. ECHA together with industry organisations developed a set of tools to simplify and harmonise the elaboration of exposure scenarios for the chemical safety report and their incorporation in the SDSs.[144]

The EU has established two alert systems to enable rapid exchange of information between Member States and the EU authorities in emergency situations when products, food or feed pose an immediate risk to health and safety of consumers. The Rapid Alert System for non-food dangerous products (RAPEX)[145] is an effective tool for allowing public authorities to rapidly take appropriate risk mitigation measures for consumer goods (toys, textiles, cosmetics, etc.). Nevertheless, there is still room for further co-ordination of national market

[141] 1st FC Study p. 24 and p. 70; see also Annex III, Section 7.3; Case Study 5; see also1st FC Study workshop report p. 12-13; see also Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) p. 77-79, p.106

[142]

[143] REACH Evaluation SWD(2018) 58 final p. 14-15, 28-29, 104, 131

[144] Many guideline documents are available on https://echa.europa.eu/safety-data-sheets

[145] See for example the DMF case (FC+ Study p. 105). DMF is a carcinogen antifungal agent used for furniture in South East Asia and included in furniture in small sachets placed on the EU market. DMF was identified as causing problems, signalled by a number of countries through RAPEX and ended up with a specific prohibition. See also 1st FC Study Annex VI Case Study 8 p. 11 and onwards for notifications regarding toys

surveillance activities and authorities (i.e. customs), which could benefit from the measures included in the 'Goods Package'[146]. In a similar way, the Rapid Alert System for Food and Feed (RASFF) provides food and feed national control authorities with an effective tool to exchange information about e.g. undesirable chemicals in food causing food poisoning, not labelled allergens, migration of chemicals from the food contact material into food such as formaldehyde, plasticizers, volatile organic compounds etc.[147]

5.2.5 Legislative gaps affecting the effectiveness

The evaluation found a number of legislative gaps that affect the effectiveness of the chemical legislation. A more detailed assessment is provided in the relevant sections in the remained of this document as well in the Annexes Section 5.2.6:

- combination effects (Relevance Section 8.1.2 1));
- exposure to substances in articles (Relevance Section 8.1.2 3));
- protection of vulnerable groups (Coherence Section 7.2.B) 2) b));
- endocrine disruptors (Coherence Sections 7.2. B) 1) b) and 7.2. B) 2) a) ii) as well as Annex 7.3).

5.2.6 Application of the Precautionary Principle

A. What's the issue?

The precautionary principle is one of the three principles guiding environmental policy under the Treaty (article 191(2) of the TFEU). It allows for taking action when there is still a degree of scientific uncertainty about the risk. Whilst the precautionary principle has not been explicitly defined in EU legislation, the Commission Communication on the precautionary principle[148] sets out steps to be followed in the decision making process. When applied in the chemicals policy area, this mechanism has two steps:

1. A scientific step, where the responsible scientific body (Agency or Committee) assesses if the uncertainties are bigger than those inherent to risk assessment of chemicals and if the consequences of those uncertainties could lead to a significant undesirable impact.
2. A risk management step, where the responsible risk management body (the Commission and the associated committees) decide what action, if any, is required. Options range from taking no action to precautious and/or restrictive (e.g. a ban of further use of a substance) measure, including gathering more data in order to reduce the level of scientific and risk assessment uncertainty.

The precautionary principle enables a rapid response to be given in the face of potential significant impacts to human, animal or plant health, and to the environment. In particular, where scientific data do not permit a complete evaluation of the risk, recourse to this principle

[146] (COM(2017)795). Proposed measures include: fostering cooperation among national market surveillance authorities, sharing information about illegal / non-compliant products and ongoing investigations, reinforced inspections of ports and external borders.
[147] https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2016.pdf
[148] COM/2000/0001 final

may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous.

Whereas both the precautionary and prevention principles can be strictly divided conceptually, it is not always straightforward to separate them as clearly in their application. Some legal instruments based on a general preventive approach nonetheless integrate a precautionary approach for specific substances where risks to health and the environment or the thresholds needed to limit hazards are not identifiable (e.g. the Seveso III Directive aims at prevention, preparedness and response to accidents involving dangerous substances in industry in the EU, the Industrial Emissions Directive takes into account the whole environmental performance of a plant through granting a permit).[149] The precautionary principle should not be confused with the element of caution that scientists apply in their assessment of scientific data e.g. generic risk management approach based measures and application of safety factors are examples of preventative action and not the application of precautionary principle.

Where scientific uncertainty is encountered, the challenge is in finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken. Proportionality also covers examination of the benefits and costs of action/inaction. It is a question of how effectively the EU chemical risk assessment and management processes are working in terms of detecting and acting upon early warnings and avoiding late lessons versus taking over-precautious, unnecessarily restrictive measures and unwarranted recourse to the precautionary principle, as a disguised form of protectionism. Whatever is the measure decided, it remains subject to review, in light of new scientific data, and should allow assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

B. What are the findings?

Conclusions

The inherent uncertainty created by the difficulty in determining the exact level to which exposures to hazardous chemicals can be attributed to human health and environmental impacts (when this is just one factor amongst a number of confounding factors (lifestyles, genetic predisposition, habitat degradation, climate change, etc.)) presents particular challenges for the chemical risk management decision makers. Although the precautionary principle is explicitly taken into account in the design of various pieces of chemicals legislation, to date, it has actually been applied in very few instances in the chemicals policy area. Whilst it does not mean that actions must be taken systematically, a number of stakeholder groups expressed concerns that risk management decision makers err towards a wait-and-see approach whilst more data is gathered to reduce the level of uncertainty. The Bisphenol A case shows, however, that this is not always the case.

The precautionary principle is explicitly taken into account in the design of various pieces of chemicals legislation (e.g. those requiring safety assessments such as the Biocidal Products Regulation and the Plant Protection Products Regulation, the Water Framework Directive, the Persistent Organic Pollutants (POPs) Regulation and the Restriction of Hazardous Substances

[149] The precautionary principle in EU environmental policies; Final Report, November 2017; Milieu Ltd; p. 93

in Electrical and Electronic Equipment (RoHS Directive), as well as REACH (many persistent, bioaccumulative and toxic/very persistent and very bioaccumlative substances (PBTs/)vPvBs are regulated on precautionary basis)).

The following examples show cases where the precautionary principle was applied (non exhaustive):

- The "Community strategy for endocrine disruptors" adopted in 1999 and updated in 2001, 2004 and 2007.
- Ban of Bisphenol A (BPA) in polycarbonate infant feeding bottles in 2011.
- Setting lower specific migration limit for Bisphenol A for varnishes or coatings applied to materials and articles intended to come into contact with food in 2018.[150]

A number of stakeholder groups including NGOs, trade unions, and some Member State Competent Authorities have raised concerns that in the assessment of chemicals, authorities often hesitate to introduce risk management measures in situations where the precautionary principle applies and prefer to wait and request additional data to reduce the level of uncertainty.[151] The BPA case shows however that this not always the case. Indeed, while still facing uncertainties including about the potential replacement substances and their safety and effectiveness, the Commission has mandated EFSA to undertake a full re-evaluation of BPA on the basis of the results of anticipated new studies and scientific data. Following the principles established in the 2000 Communication mentioned above, the Commission will then decide what and if any further action is necessary to protect consumers.

5.2.7 Balance and Mix Between the Risk Management Measures based on 'Generic' and 'Specific' Risk Considerations

A. What's the issue?

Risk management measures in the EU chemicals legislation are taken based on an assessment of the risks to human health or the environment associated with the exposures to hazardous chemicals. As described in more depth in Section 2.1.5 and Annex 8 Section 8.2.1, there are two basic approaches to risk management used, often in combination, in the EU chemicals *acquis*: one based on specific risk assessment (SRA) approach and one based on generic risk consideration (GRC). Under the GRC approach, exposure scenarios are assessed generically based on the hazard of a substance or mixture without considering specific exposure situations. Under the SRA both the hazard of and the potential specific exposure scenarios of humans and the environment to the substance or mixture in question are assessed at the same time.

[150] Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials; applicable as of 6 September 2018

[151] This situation is illustrated by the outcome of risk assessment carried out in 2001 and 2003 for penta-brominated diphenyl ether (PBDE) and octa-brominated diphenyil ether (OBDE) which led to a ban in 2004 (under the legislation preceding REACH though). At the same time, for deca-BDE it was decided to proceed with the scientific research required to resolve the uncertainty, rather than take a precautionary approach. However, on the basis of the evidence gathered after the additional testing, it was decided to ban deca-BDE in 2008. Source: The precautionary principle in EU environmental policies; Final Report, November 2017; Milieu Ltd; p. 50

B. What are the findings?

Conclusions

Generic and specific risk management approaches both have their role to play within the framework of EU chemicals legislation but the application of both approaches has room for improvement.

Findings of this Fitness Check show that both the GRC and SRA have their role to play in the EU chemical legislative framework and that the current balance between the use of generic and specific risk management approaches works well, each under particular circumstances.

	Advantages	**Drawbacks**
Generic Risk Considerations (GRC)	Provide a clear signal to all the actors involved (enforcement authorities, industry and downstream users) on the types of hazardous substances which should be avoided	Automatically triggered risk management measures may lead to disproportionate outcomes and unintended (legal and/or socio-economic) consequences if a mechanism for derogation is absent or not appropriate
	The outcome of the risk management decision making process is more predictable (compared to SRA)	Potential consequences of automatically triggered measures in downstream legislation might influence the upstream scientific debate leading to the classification
	Might be more appropriate for substances of higher concern and where vulnerable populations are at risk and/or cannot be protected through e.g. training or protection equipment (e.g. children under the Toy Safety Directive)	Less appropriate where exposures are minimal or would not occur through the route of exposure of concern and therefore can lead to over-regulation for non-relevant routes of exposure
Specific Risk Assessments (SRA)	Allow more targeted and differentiated consideration of exposures and thus risks and therefore more appropriate identification of actual risks and of risk management measures	The process might be slower compared to GRC and often more costly
	Allow more targeted consideration of costs and benefits of various risk management options	Predictability of risk management decisions can be more difficult

Table 2 Main comments received from stakeholders regarding the GRC and SRA application

Where a derogation mechanism is connected to the GRC approach (i.e. a derogation from e.g. an automatic restriction or ban if certain conditions are fulfilled, such as demonstration of negligible exposure), industry stakeholders stated that it helps to ensure that the risk management measure stipulated will not lead to disproportionate costs or unintended effects e.g. regrettable substitutions. The process of issuing derogations, including their specified

limitations, requirements and justifications, was considered useful by various industry stakeholders as the flexibility is necessary to the implementation of legislation.[152]

Respondents to the public consultation[153] were invited to indicate to what extent they find that the chemicals legislation framework overall should be more oriented towards SRA, GRC or should remain as it is. The preferences of the different groups varied quite considerably. Industry and in particular bigger companies tended to prefer a more extensive use of SRA approaches while NGOs tended to have a higher preference for more GRC approaches. The most common response among Member State competent authorities was that the current application of GRC and SRA approaches within the framework of the EU chemicals legislation is well balanced and should remain as it is. Responses from citizens were mixed, providing equal support for more SRA and for more GRC approaches, but a majority of citizens (ca. 60%) did not know how to answer or did not provide an answer to the question. Respondents were also asked to provide comments on, or arguments for, their preference; these are summarised in Annex 5 Section 2.8.

During the FC+ Study workshop, participants agreed that both approaches have their merits depending on the case at hand. There was no conclusive agreement on which one is to be preferred[154].

During the 1st FC study workshop, one of the topics discussed was the appropriatness and impacts on the existing linkages between the CLP and the relevant pieces of downstream legislation affected by harmonised classifications under CLP and that trigger risk management requirements. The following views were expressed[155]:

- Automatic triggers provide legal certainty and a quick, high level of protection (particularly for cumulative risks). The focus should be on when the use of hazardous chemicals should be allowed (for example, when exposure is controlled), rather than the other way around, meaning an automatic ban with possible derogations is preferable. Another participant noted that for some classifications there should be no derogation.
- Other participants, however, expressed severe criticism against hazard-based risk management measures, which was seen as giving the European industry a competitive disadvantage vis-à-vis the rest of the world. In this respect, some argued that any hazard should only trigger risk assessment, with risk management measures (RMMs) then identified based on this. Consequently, if there is a change in the hazard classification the RMM currently required should be re-assessed.
- There are also arguments in favour of a more mixed approach, which would allow for automatic triggers appropriate under some legislation (where justified) but not under other legislation.

[152] FC+ Study p. 96
[153] 1st FC Study, Annex V, p. 94-102; public consultation Question 14
[154] FC+ Study workshop report p. 18
[155] 1st FC Study workshop report p.18

6 EFFICIENCY

6.1 Evaluation question: what are the costs and benefits associated with the implementation of the legislative framework for chemicals? What are the key drivers for those costs and benefits? To what extent are the costs proportionate to the benefits?

In addition to examining the costs and benefits associated with the implementation of the EU legislative framework for chemicals, the analysis provided below also looks at whether the costs are proportionate to the benefits. Annex 6 and Annex 11 provide a more detailed overview of the costs and benefits identified by the Fitness Check.

6.1.1 Costs and cost drivers

A. What's the issue?

The efficiency of the EU chemicals legislation in achieving its three core objectives is examined by analysing:

- the direct regulatory costs and the enforcement costs;
- drivers for these costs; and
- who is facing these costs.

Indirect costs and the costs of risk management measures triggered under the downstream legislation are not assessed here, but the Fitness Check does consider those processes and whether they are working properly (see Section 5 Effectiveness). Given the differences in the organisation of public administrations across the EU, enforcement costs imposed on public authorities at national level are analysed from a cost drivers' perspective (i.e. not providing monetised and quantified figures).

B. What are the findings?

Conclusions

The methodological, counterfactual and data challenges make it unfeasible to provide a quantified estimate of the overall costs of the EU chemicals legislation. However, an assessment of the CLP Regulation indicates the on-going annual regulatory costs to industry in the EU range from EUR 0.97 to 1.7 billion. Similarly, the annual regulatory costs for industry due to the Plant Protection Products Regulation are estimated at EUR 122-189 million. The annual regulatory costs for industry due to the Detergents Regulation are estimated at EUR 63.7-149 million). This would suggest that the overall regulatory costs of the EU chemicals legislation for EU industry are several billion euros per year. Quantitative and qualitative analysis suggests that regulatory costs have remained relatively stable over the last decade.

Depending on the piece of legislation, the main cost drivers are data generation (hazards, chemical uses, exposures, etc.), staff and worker occupational hygiene monitoring and control costs, as well as enforcement and monitoring costs for public authorities. SMEs are more affected than bigger companies by certain aspects of the EU chemicals legislation such as understanding and compliance with legal obligations. The overall pace of the risk assessment

and risk management processes can also have significant implications for the costs borne by both industry and the public authorities (at both the EU and at Member States levels).

The regulatory costs assessed for the purposes of this Fitness Check cover:

- Direct regulatory costs affecting the EU chemicals industry, downstream users and, which may end up being passed onto consumers to greater or lesser extent. These costs correspond to regulatory charges, substantive compliance costs and administrative costs.
- Implementation and enforcement costs affecting public authorities both at the EU and Member State level.

The baseline used is a simple counterfactual of no EU or Member State chemicals legislation. As explained above (Section 4.2), it was challenging to quantify the overall cumulative costs of the EU chemicals legislation.

1) Direct regulatory costs

a) Overview

All stakeholders recognise that the costs of the chemicals legislation are significant, especially for SMEs[156] with a perception of costs that varies depending on the stakeholder group i.e. industry, NGOs, public authorities, citizens[157].

An estimate was made of the cost of the EU legislation with a bearing six subsectors of the chemical industry during the period 2004-2014 (see Annex 6 Section 6.1.2 Table 12 for the list of pieces of legislation covered). When added up, the estimated average annual total direct cost borne was around EUR 8 billion, representing around 1.7% of their turnover and 9% of the value added.[158]

Among the legislation packages, the emissions and industrial processes package represents approximately 33% of the regulatory cost (4% of the subsectors' value added), the chemicals package (including REACH) 29% (3.5% of value added) and workers' safety 24% (2.9% of value added).[159] Whilst there are different estimates, quantitative and qualitative analysis suggests that regulatory costs have remained relatively stable over the last decade.[160]

However, the figure of EUR 8 billion cannot be considered as an entirely accurate estimate of the cost of the chemicals *acquis* due differences of scope and in the methodology applied:

[156] 1st FC Study, Annex V, p. 138; public consultation Question 20

[157] Among the most significant costs, industry considers costs of understanding and keeping up to date with changes in legal requirements as particularly significant, whereas other stakeholder groups consider this to be a less significant part of overall costs. Similarly, training, inspections and administrative requirements are perceived as more significant by industry compared to other stakeholder groups. Risk management measures, and to a slightly lower degree labelling and packaging requirements are considered of high cost significance by all actors. Classification requirements are perceived to be relatively significant by industry and public authorities but to a lesser degree by NGOs/others.

[158] CCA1 Study p. 8-12

[159] Annex 6 Table 1 provides a list of pieces of legislation per legislative package

[160] CCA1 Study p. 114

- The period covered (2004-2014) corresponds only partly to the one covered by this Fitness Check.
- Costs correspond to only six subsectors (organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) and not all the industry and companies.
- Costs presented above also include regulatory costs for several pieces of legislation that are not in the scope of this Fitness Check. In addition, several other pieces of legislation although within the scope of this Fitness Check, were not covered by the abovementioned cumulative cost assessment attempt. Please see Annex 6 Section 6.1.2 Figure 13 for a full list of pieces of legislation covered.
- While the occupation safety and health (OSH) Framework Directive, *per se*, is not in the scope of this Fitness Check, it can be reasonably assumed that the costs related to occupational health and safety legislation in the chemicals sector derive primarily from the daughter regulations (the Chemical Agents Directive, the Carcinogens and Mutagens Directive, etc.) which are within the scope of the Fitness Check. That said, it should also be noted that the estimated occupational health and safety costs probably include costs of worker safety protection beyond specific risks posed by exposure to hazardous chemicals(e.g. falls from heights, electrocution, burns, etc.) which are substantive but are not within the scope of the Fitness Check.
- Regarding the emissions and industrial processes legislative package, it should be noted that the EU Emission Trading System (ETS) related legislation is not in the scope of this Fitness Check. In this legislative package, most of the monetary obligations are due to ETS. Therefore, the regulatory costs of emissions and industrial processes legislative package as assessed for the purposes of this Fitness Check can be estimated to represent EUR 2.6 billion (instead of EUR 3.1 billion).

Therefore, additional cost elements were gathered where possible and qualitative assessment is presented where providing reliable quantified figures was considered to be impossible.

b) Regulatory charges

Regulatory charges are the fees, levies or taxes imposed by the legislation, primarily faced by industry (see Annex 6 Section 6.1.2. A) table 13 providing a list of regulatory charges by piece of legislation). Fees and charges are, in general, set using the cost recovery principle i.e. they correspond to the actual cost of the work involved and services delivered.

While creating business opportunities for innovative and specialised SMEs, understanding and complying with the chemicals legislation remains a key challenge for them.[161] Therefore, mitigating measures such as reduced fees have been introduced under some pieces of legislation (the CLP Regulation, the Biocidal Products Regulation). However, the SMEs fee reduction mechanism does not exist under all pieces of legislation (e.g. the Plant Protection Product Regulation, the Waste legislation, the Residues of Pesticides Regulation, the Export

[161] In the Commission Communication "Commission follow-up to the 'TOP TEN' Consultation of SMEs on EU Regulation", SMEs were reported to "have concerns about the complexity and cost of information obligations, inconsistent application by Member States and a lack of coherence with specific chemicals legislation". See COM(2013) 446 final, 18 June 2013

and Import of Hazardous Chemicals Regulation, the Detergents Regulation and the Fertilizers Regulation). The use of this tool remains uneven across the EU where it can be applied as in most cases it is up to Member States to define the level of fee reduction[162].

c) Substantive compliance costs

Substantive compliance costs can be divided into:

- One-off costs that are often borne by a particular regulated group e.g. manufacturers, having to adjust and adapt to the changes in legal rules. The transition from the Dangerous Substances Directive (DSD) and Dangerous Preparations Directive (DPD) to the CLP Regulation generated one-off costs estimated ex-post to range from EUR 0.9 - 2.2 billion.[163] Such costs were generated mainly by the (re-)classification obligation and changes to be made in order to comply with the new labelling and safety data sheet requirements. Transition costs can also occur where substance specific risk management measures are taken e.g. a ban of a substance that is classified as carcinogenic, mutagenic or toxic for reproduction (CMR) which requires manufacturers to reformulate and, in some instances, to stop the manufacture of a particular product line altogether. Costs can be very low, for example, where a substitute is readily available, and significantly higher, where it is not, or where reformulation involves significant change to the production process[164].
- Recurrent costs that are sustained by the regulated stakeholders on regular basis. The importance of these costs depends on the overall complexity of legislation. The main cost drivers for recurrent costs are the obligation to generate and provide data for chemical hazard classification (including testing), the risk assessment step, in particular the exposure assessment element, as well as the implementation of risk management measures e.g. hazard communication through labelling[165]. The costs of the classification of a substance are driven mainly by the CLP Regulation. Annual costs arising from the CLP Regulation are estimated to amount to EUR 1.3 billion (EUR 0.97-1.7 billion).[166] Costs are often dependent on data availability and usability[167]. Costs of data generation and risk and exposure assessment are often related to an authorisation/approval/renewal process e.g. under the Plant Protection Products and Biocidal Products Regulations and can be significant cost drivers. The total costs for the pesticides industry are estimated at approx. EUR 122-189 million

[162] The level of fee reduction should still reflect the cost recovery principle, i.e. the fee or charge need to correspond to the actual cost of the work involved, and to cover the cost of the services delivered.
[163] Estimates based on the number of substances (over 99 000) and the number of mixtures (2 – 2.5 million) subject to reclassification, labelling and safety data sheets preparation. Source: 1st FC Study p. 45 and Annex II p. 58-85
[164] 1st FC Study p. 49-51
[165] FC+ Study p. 79-84
[166] 1st FC Study, p. 48. It was not possible to identify what is the share of classification, as the EUR 1.3 billion figure includes direct costs for industry from hazard identification, classification, labelling and packaging, annual up-dates to IT systems in line with adaptations to CLP and new harmonised classifications (CLH), staff training costs, ongoing compliance activities, hassle costs and packaging related costs. (Source: 1st FC STUDY Annex II, p. 95)
[167] In general, when data are publicly available, the risk/hazard assessment process overall is easier. Similarly, low data access and usability affects costs upward. (Source: FC+ Study p. 79-84).

per year. The regulatory charges (fees) represent a small share of the total costs for the industry Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) p.126; not yet publicly available.[168] The costs for pesticides maximum residue level (MRLs) procedures are estimated at around EUR 55 million per year for the industry[169]. Annual costs that the detergents industry has incurred as a direct result of the Detergents Regulation are estimated to range between EUR 63.7 – EUR 149 million (appr. EUR 764 million – EUR 1.8 billion in total since 2005).[170] Depending on the sector, compliance with occupational health and safety legislation, e.g. investments in workers' health protection equipment, can also lead to significant costs.

"Understanding and keeping up-to-date with changes in legal requirements" was identified during the public consultation and the SME Panel Survey as a significant driver of costs by the highest number of companies (84% (147) of companies for the former and 45% of SME respondents for the latter), with the costs of risk management under the different legislation ranked second (73% or 127).[171] Training staff to ensure compliance with legal requirements was also identified as important cost driver (61% (106) by respondents from Industry association and companies).

SME stakeholders underlined the fact that SME specific challenges are often linked to the availability of resources. For SMEs, it is difficult to find the time and money to attend workshops, webinars, conferences, etc. (especially if information is only available in English), and to find the necessary time to track, understand and implement the many and often complex requirements of the EU chemicals legislation and to keep up-to-date with changes to the requirements. From an authority and industry association perspective, it can be difficult to reach smaller companies. There are also differences in the support to SMEs provided by Member States. There was a general view amongst the SME stakeholders consulted that Member States need to do more.[172]

d) Administrative costs

Administrative costs are those borne by businesses, citizens, civil society organisations and public authorities in complying with information obligations. They include[173]:

- the obligation of reporting; and
- retrieving data on applications from downstream users and labelling (also discussed under the section on substantive regulatory costs above).

[168] Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) p.126; not yet publicly available
[169] Ibidem
[170] The largest costs are calculated to have arisen as a result of the need to use different raw materials in place of phosphorus, from having to provide ingredient datasheets to poison centres and from the research and development necessary for reformulation (to reduce the total phosphorus content of consumer laundry detergents and consumer automatic dishwasher detergents (CADD)). (Source: Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation), p. 157)
[171] 1st FC study p. 48
[172] 1st FC Study workshop report p. 19-21
[173] CCA1 Study p.110

Estimates of the costs of reporting by Member States to the EU level were made as part of the "Fitness Check of Reporting and Monitoring of EU Environment Policy".[174] These varied by piece of legislation: for example, the CLP Regulation and the Asbestos Directive were between EUR 30 000 and 100 000 per annum; the Persistent Organic Pollutants (POPs) Regulation and the Regulation on Export and Import of Hazardous Chemicals were under EUR 30 000 per annum.

Another factor that could increase the administrative costs is the pace of the processes for the specific risk assessments. Under the EU chemicals legislation, the expected duration of the risk assessment procedure ranges between several months and several years e.g. the risk assessment and authorisation procedure for active substances in plant protection products and products lasts at least 12 months[175]. The longest average duration of a risk assessment is attributed, according to the stakeholders consulted, to the Biocidal Products Regulation and to the Plant Protection Products Regulation. According to these stakeholders, the process of regulatory validation can take up to 10-15 years[176], due to delays both from the industry applicant in submitting missing data and from the evaluating authorities. For the Biocidal Products Regulation, one could note however that, in most cases, industry can place their substances/products on the market during the assessment period by authorities, which also allows them to recover some costs during that period.

2) Enforcement costs

Legal rules have to be monitored and enforced by public authorities to be effective which implies costs. It is not possible to provide quantified figures for costs of enforcement of the EU chemicals legislation at national level. These costs will vary across legislation and also depend on the regulatory option chosen (e.g. self-regulation, providing information and guidelines, market-based instruments, more or less stringent and prescriptive regulatory actions). Enforcement costs will also vary across Member States depending on the national administrative choices and the related functional costs.[177]

The costs for public authorities[178] include costs associated with:

- Implementation activities: participation in expert groups and scientific bodies, research and regulatory proposals, risk assessments, etc. is time- and resource-intensive. Therefore, the fact that many Member States are lacking resources leads to differences in their involvement in bringing forward harmonised hazard classification dossiers under the CLP Regulation, for example.
- Compliance monitoring and enforcement activities: costs will depend on the way in which this is organised at the national level. For example, data available from the REACH-EN-FORCE[179] projects indicate that on average over 2 000 inspectors are

[174] SWD(2017)230 p.26-27
[175] https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowpesticidesnasub.pdf
[176] FC+ Study p. 82
[177] Quantification of costs incurred in the EU were carried out only in respect to the CLP Regulation. See 1st FC Study Annex II p. 211
[178] 1st FC Study p. 51
[179] https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

trained on REACH and the CLP per annum in the EU, at an annual cost of around EUR 1.7 million.[180]

For illustrative purposes, the overall costs for Member States generated by the Plant Protection Products Regulation for the approval and authorisation procedures are estimated at approx. EUR 44 million annually. The costs for the Residues of Pesticides Regulation (which sets maximum residues levels (MRLs) of pesticides on food products) procedures are estimated at around EUR 5 million annually for the 28 Member States.[181]

At the EU level, the average annual costs to ECHA associated with implementing the CLP are approximately EUR 2.57 million[182]. This figure is the cost of providing guidance, running helpdesks, overseeing committees and forums, etc. The total cost to ECHA of implementing the CLP over the period 2010 to 2016 was over EUR 22.8 million, equivalent to 17% of the combined REACH and the CLP budget.[183] The total capital costs to ECHA of developing the Classification and Labelling Inventory (CLI) were around EUR 1 million, with an annual operating expenditure of around EUR 0.2 million.[184]

The costs for MRLs procedures are estimated at around EUR 3 million for EFSA and the Commission.

6.1.2 Benefits

A. What's the issue?

The efficiency of the EU chemicals legislation is the ratio of the benefits to the costs. Having looked at the costs, this section looks in a similar way at:

- What are the benefits of the EU chemicals legislation?
- How significant are these benefits and what are the key drivers?
- To whom do the benefits accrue?

Data, knowledge and methodological gaps mean it was not possible to arrive at a cumulative 'monetised' benefit estimate for the whole framework of the EU chemicals legislation. Nevertheless, certain components of the broader picture are presented below. It is important to recognise, however, that these benefit estimates represent just a portion of the overall health and environmental benefits of the EU chemicals *acquis*.

B. What are the findings?

Conclusions

The EU chemicals legislation has clearly led to significant benefits in terms of avoided health and environmental impacts. Some of the most notable benefits relate to reduced exposure to hazardous chemicals at the workplace known to increase the risk of cancer and cardiovascular disease. Key benefit drivers include avoided healthcare costs, avoided productivity losses (due

[180] 1st FC Study p. 88
[181] European Chemicals Agency, Budget 2018
[182] European Chemicals Agency, Budget 2018
[183] 1st FC Study p. 52
[184] 1st FC Study p. 46

to avoided lost working hours as a result of illness or premature death), avoided suffering and premature deaths, avoided remediation costs (including wastewater and drinking water treatment costs) and avoided degradation of environmental/eco-system services costs.

Significant benefits in terms of protecting human health and safeguarding the environment have been delivered over the last 50 years by the EU chemicals legislation to industry, to public authorities and regulators as well as to consumers and citizens and to society and the economy more generally. Table 3 provides a list of the main categories of benefits and direct beneficiaries.

Benefits		Direct beneficiaries	
Health	**'Physical' benefits**	Workers, consumers and citizens	Reduced morbidity and mortality health impacts (e.g. reduced number of cancers, cardiovascular diseases, allergies, reproductive illnesses, neurological diseases, etc.) from reduced exposures to hazardous chemicals. This includes avoided suffering and health effects through higher income (due to avoided lost earnings as a result of avoided illness) and longer life expectancy
	Monetised benefits	Consumers and citizens	Avoided healthcare costs, avoided suffering (assessed through willingness to pay techniques), value of avoided life years lost due to premature death, productivity losses due to lost work hours as a result of illness and/or premature death
		Industry	Avoided health costs and productivity losses; a less hazardous working environment can reduce the costs that companies face (healthcare costs, insurance costs, lost productivity, fines, etc.)
		Member States	Reductions in the damage costs associated with chemical exposures (healthcare costs, environmental clean ups, etc.)
Avoided environmental damage		Society	Various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs
		Industry	Reductions in the costs associated with environmental remediation and clean ups. Improved access to and reduced costs of clean water, etc.
		Members States	Reductions in the costs associated with environmental remediation and clean ups.
Regulatory		Member States	Reductions of some of the burden faced by Member States, by enabling them to share efforts (and hence resources) at the European level in the implementation of the legislative framework

Table 3 Benefits of the EU chemicals legislative framework and direct beneficiaries

Some of the biggest, currently measurable, health benefits of the EU chemicals legislation are associated with reductions in the exposure to carcinogenic substances. However, one should keep in mind that, while the extent of cancer incidence due to occupational exposure has been extensively studied, the impacts from environmental exposure to carcinogens are harder to estimate. It is in an occupational setting where the link between exposure to certain chemicals

and cancer is the most clear[185]. Based on reductions in exposure to a group of 13 carcinogens since 1995 that have been targeted by EU occupational health and safety legislation, the total number of cancer deaths avoided across the EU is estimated to be around 1.4 million.[186] Other examples include the estimated benefits from a reduced exposure to hexavalent chromium, phthalates, to pesticides and polychlorinated biphenyls (PCBs) (see Table 4 below as well as Annex 6 Section 6.1.3. B) Table 15 for additional examples).

Benefits	Estimated Benefit Value (€) for the EU	What's Included?	Time period	Legislation
Reduced **poisoning incidents, occupational skin and respiratory diseases and occupational cancers**[187]	**EUR 391 – 512 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income)	2000-2008	• The Dangerous Substances and Preparations Directives
	EUR 217 – 338 million/yr		Since 2008	• The CLP
Reduced exposures to **hexavalent chromium** at workplace[188]	**EUR 100 million/yr EUR 4 billion in total**	**Avoided cancers:** • Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death[189]	1995 - 2010	• The Carcinogens and Mutagens at Work Directive • The Chemical Agents Directive
Reduced exposure to **phthalates (DEHP; DBP)** via a variety of consumer products[190]	**DEHP: EUR 7 billion** cumulatively from (i.e. approx. **EUR 580 million/yr**)	**Reduced female/male reproductive disease:** • Avoided healthcare costs • Avoided productivity losses (lost working hours and income)	1996 - 2008	• Legislation on consumer products (cosmetics (since 2005), food contact materials (2007), electrical equipment (2015), medical devices) • The Water Framework Directive (priority
	DBP: EUR 6.7 billion cumulatively **(**i.e. approx. **EUR 560 million/yr)**			

[185] CuBA Study, p. 45
[186] CuBA Study p. 18 and p. 57
[187] 1st FC Study p. 58
[188] CuBA Study p. 18, 36 and 54
[189] measured by willingness-to-pay to avoid it
[190] CuBA Study p. 114-115; p. 131-14 (in particular 142-144)

Benefits	Estimated Benefit Value (€) for the EU	What's Included?	Time period	Legislation
				substance since 2001) • Pre-REACH Regulation (the Existing Substances Regulation) 1994-2006
Better control and management of **plant protection products** [191]	**EUR 15 – 50 billion/yr**	**Reduced environmental and pollination impacts:** • Value of eco system services • Agricultural value of pollination services provided by pollinating insects	**Since late 70s (legislation on water 1975 and 1979 legislation on pesticides)**	The Plant Protection Products Regulation **(PPPR)**
Reduced **pesticide contamination** of surface and groundwater reserves[192]	**EUR 500 million/yr**	**Avoided drinking water treatment costs:** • Avoided cost of removing pesticides from water treated for drinking water supply	**Since late 1970s (legislation on water 1975 and 1979 legislation on pesticides)**	• The Plant Protection Products Regulation **(PPPR)** • The **Water Framework Directive** and the EQS Directive • The **Drinking Water Directive**
Reduced **contamination** by PCBs[193]	**Cumulative cost of EUR 0.4 - 1.9 billion/yr** (EUR 20 – 90 billion in total)	**Avoided clean-up costs association with PCB use in the past:** • Remediation and waste management costs excluding any health and	1971 to 2018	• Classified under the **CLP** • Directive 96/59/EC on the **disposal of PCBs and PCTs** (not within the

[191] CuBA Study p. 255
[192] CuBA Study p. 215-217
[193] CuBA Stuy p. 267 These clean-up costs are associated with polychlorinated biphenyl (PCBs) use and waste management (remediation and waste management costs; but not including any health and environmental impact costs) caused by the contamination that has been avoided.

Benefits	Estimated Benefit Value (€) for the EU	What's Included?	Time period	Legislation
		environmental impact costs		scope) • The **POPs** Regulation (2004) • **Hazardous Waste List**

Table 4 Selected monetised environmental and health benefits of reduced hazardous chemical exposures[194]

Regarding enhancement of the internal market, competitiveness and innovation objectives, these benefits are examined in Sections 5. Effectiveness and 9. EU added value. There have been positive impacts of the EU chemicals legislation in terms of an efficiently functioning internal market. Benefits in terms of innovation and positive impact on the EU industry's competitiveness are more complex.

More generally speaking, the EU chemicals legislation plays an important role in the shift towards a more circular economy.[195] It also contributes directly to the achievement of the 2030 UN Sustainable Development Goals (SDGs[196]).

Respondents to the public consultation agreed that the EU chemicals legislation and chemical-related legislation generate benefits from reducing the exposure of consumers and citizens to toxic chemicals, reducing the exposure of workers to toxic chemicals and reducing damage to the environment and ecosystems (see Table 5).[197]

Group	Benefits identified by largest proportion of respondents by group		
	Top ranked	Second ranked	Third ranked
Group 1 (citizens)	Reducing the damage to the environment and to eco-systems (58%)	Reducing the exposure of consumers and citizens in general to toxic chemicals (54%)	Reducing the exposure of workers to toxic chemicals (54%) [equal second ranked]
Group 2 (industry)	Reducing the exposure of workers to toxic chemicals (85%)	Reducing the damage to the environment and to eco-systems (84%)	Reducing the exposure of consumers and citizens in general to toxic chemicals (79%)
Group 3 (public authority)	Reducing the exposure of consumers and citizens in general to toxic chemicals (95%)	Reducing the exposure of workers to toxic chemicals (92%)	Reducing the damage to the environment and to eco-systems (89%)
Group 4 (NGO/	Reducing the exposure of workers to toxic chemicals	Reducing the exposure of consumers and citizens in	Reducing the damage to the environment and to eco-

[194] CuBA Study
[195] For example, see the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); 16 January 2018
[196] https://www.un.org/sustainabledevelopment/sustainable-development-goals/
[197] 1st FC Study, Annex V, p.136, question 19

Group	Benefits identified by largest proportion of respondents by group		
	Top ranked	Second ranked	Third ranked
others)	(91%)	general to toxic chemicals (80%)	systems (70%) = encouraging research and innovation, generating jobs and improving competitiveness (70%)

Table 5 Summary of the views of respondents by group to public consultation

Respondents to the public consultation also indicated additional benefits that are generated from:

- encouraging research and innovation, generating new jobs and improving competitiveness;
- stimulating competition and trade within the EU single market; and
- stimulating international trade between the EU and other countries.

Results of the SME Panel consultation suggest the impact of the CLP Regulation (and other EU hazard communication requirements) has been overall positive (increased access to classification data for substances and more consistent classification, safe use of chemicals by workers and consumers, preparedness for industrial accidents, increased awareness of the potential health and environmental impacts). The only exception is "changes in packaging requirements" where proportion of 'neutral/no change' responses was higher compared with proportion of responses suggesting positive impact (40% and 35% respectively; 10% negative impacts; 15% "Don't know").[198]

6.1.3 Are costs and benefits proportionate?

A. What's the issue?

Answering this evaluation question requires the assessment of the framework-wide costs and benefits (environmental, health, internal market, etc.) of the EU chemicals *acquis* to determine whether the costs are proportionate.

B. What are the findings?

Conclusions

The existing data and methodological limitations combined with the scope limitations of the Fitness Check (a framework-wide assessment and not a full, in-depth evaluation of each and every one of the more than 40 pieces of legislation covered) meant it was not possible to estimate of the overall costs and benefits of the EU chemicals *acquis* and therefore, to determine whether or not costs are proportionate. However, from the partial evidence that was available, it appears that both the costs and the benefits generated by EU chemicals legislation are significant.

It is not possible to provide a credible estimate of the cumulative benefits or costs of the EU chemicals *acquis*. This, coupled with the partial picture on the costs and benefits at the

[198] 1st FC Annex, Annex V p.45-48, question 13, table 2-24

specific legislation level, means it was not possible to arrive at a single cost-benefit ratio and that it is impossible to draw any strong conclusions regarding the proportionality.

It appears from the analysis above that the benefits directly or indirectly generated by the EU chemicals legislation are significant while costs to companies and public authorities are also significant.[199] These views are shared by different stakeholders although the perception of the importance of the costs and therefore of whether costs are proportionate to benefits varies amongst different groups and even within the same category.

Amongst Member States, the UK is the only country to have tried to provide an estimate of the costs and benefits of chemicals legislation. The environment ministry quantified the costs and benefits of 428 of its regulations affecting UK businesses, just over half of which were derived from EU or international legislation. The most positive cost-benefits ratio amongst the different policy area clusters was for regulations on 'chemicals and genetically modified organisms' with a ratio of 1:18.9 (with 82% of the costs coming from EU legislation).[200]

6.2 Evaluation question: what aspects of the functioning of the framework are the most efficient and what are the least efficient?

This sections looks at factors that affect the efficient functioning of the EU chemicals legislation beyond the sole cost-benefit point of view.

6.2.1 Reliance on the CLP Regulation as the basis for hazard classification and labelling

A. What's the issue?

The CLP Regulation is the primary basis for identifying hazards, providing hazard classification across almost all other pieces of legislation as well as labelling and other risk and hazard communication measures. To what extent it is functioning efficiently is assessed regarding:

- its general architecture;
- resources and expertise available for putting forward harmonised classification dossiers; and
- communicating chemical hazard and risk information to consumers via labelling.

B. What are the findings?

Conclusions

The overall architecture of the CLP Regulation and many aspects of its practical implementation are operating efficiently. The CLP Regulation provides an efficient and harmonised approach to the hazard identification and classification of chemicals placed on the market in the EU. However, its full implementation and enforcement appears to be challenging. Moreover, resource and expertise constraints in a number of Member States reduce the overall efficiency, particularly with respect to harmonised classification. Whilst

[199] FC+ Study p. 138

[200] "Emerging Findings from Defra's Regulation Assessment First update covering 2012 Published February 2015", DEFRA

most of the CLP hazard pictograms are well recognised and understood by consumers, there are some inefficiencies in relation to the consumer labelling requirements under the CLP and some overlaps between the CLP, the Detergents Regulation and the Cosmetic Products Regulation.

The legal architecture of the CLP Regulation based on self-classification by duty holders and backed up by harmonised classification for substances of concern, provides a clear and consistent approach to identifying, characterising and classifying hazardous chemicals. It ensures that the science of chemical hazard assessment and classification is done separately but then fed into decision-making in the risk assessment and risk management decision steps in other, downstream pieces of legislation. Various stakeholders were of an opinion that maintaining the CLP system as purely hazard based is important[201]. It allows classification of a wide range of chemicals without creating a disproportionate burden on administration while focusing resources of public authorities to the most relevant substances for public health and the environment. Furthermore, where no harmonised classification exists, self-classifications allows for faster evaluation by companies.

Harmonised classifications rely on the initiative of either companies or Member State authorities to create and submit a proposal to ECHA for a harmonised classification which is eventually adopted by the Commission. Resource and expertise constraints in a number of Member States hinder their ability to make these proposals. The fact that the workload in developing harmonised classification dossiers is shared unequally between Member State Competent Authorities is a factor that negatively affects efficiency.[202] The pace of whole process – from proposal to final agreement - is a factor affecting the overall efficiency given that these are the cornerstone of the legislative framework (see Section 5.2.3).[203]

There are inefficiencies in relation to consumer labelling under the CLP Regulation as highlighted above in terms of proportionality of costs for companies to change some aspects of labelling and the effectiveness of the communication.[204] The CLP Regulation is amended every two years (via the Adaptation to Technical Progress (ATP)) in order to comply with the changes made at the UN Global Harmonised System (GHS) level. According to participants of one of the workshops[205], the EU approach of having an 18 month transitional period for applicability of GHS updates is generally perceived as being sufficient but the constant need to re-label is a cost. They also believed that minor changes have no real benefits but could have significant negative impacts due to re-labelling requirements. Moreover, according to these stakeholders, SMEs (downstream users) may have very little time to make labelling changes as suppliers upstream provide details late.

Regarding detergents' labelling information received from AISE and other consultees suggests that there are also legislative overlaps between the Detergents Regulation, the CLP Regulation and the Cosmetic Products Regulation with regard to the labelling of allergens which creates unnecessary regulatory burden. The CLP Regulation sets out the hazard classification criteria and requirements for respiratory and skin sensitisation and requires the

[201] See 1st FC Study workshop report p. 7, p. 18
[202] FC+ Study workshop report p. 12
[203] 1st FC Study p. 62-63
[204] 1st FC Study p. 23; see also Special Eurobarometer Survey 456
[205] 1st FC Study workshop report p. 14 and 20

inclusion of skin sensitisers in the list of ingredients when they occur above certain thresholds. The Detergents Regulation also relies on the list of allergens identified under the Cosmetic Products Regulation. The Cosmetic Products Regulation does not refer to the CLP classification criteria for skin and respiratory sensitizers.[206]

6.2.2 Use and access to data

A. What's the issue?

Data generation was identified as one of the main cost drivers. How data is developed, used, and accessed affects the speed at which risk management measures can be implemented. The current mechanisms regarding data sharing and access to data are assessed based on:

- the extent to which they are flexible and facilitate the use of data across different pieces of legislation; and
- what is the contribution of the Good Laboratory Practice (GLP) Directive in facilitating data sharing.

B. What are the findings?

Conclusions

Considerable efforts have gone into improving the sharing of hazard and risk assessment related data on chemicals generated under different pieces of legislation and/or held in several different databases. However, unnecessary duplication of effort in data generation still occurs in some instances due to a lack of data sharing as a result of various related factors including confidentiality and intellectual property rights.

The review of the priority substances list under the Water Framework Directive is an example of how taking appropriate action can be delayed even when a potential risk can be identified based on hazard data, for example. This is because adequate exposure data are often not available to allow the risk assessment to be completed. Better links with risk assessments carried out under other legislation might help in such situations, i.e. better access to full risk assessments (including relevant exposure data). The Watch List mechanism was introduced a few years ago to allow exposure data from surface waters to be generated when otherwise not available. Faster feedback of monitoring data obtained under the Water Framework Directive to that other legislation may also facilitate the prompt introduction of additional measures where necessary.

The use of the GLP Directives has played an important and useful role in standardising quality requirements for test facilities and in ensuring repeatability and consistency in data generation.

The GLP Directives are one of the most efficient elements of the EU chemicals legislation[207]. By standardising data quality requirements, they have helped to avoid double testing and thereby helped saving time and resources. In addition, the avoidance of double testing helps to avoid unnecessary animal tests. However, accepting for regulatory purposes only GLP

[206] 1st FC Study p. 85; see also Case Study 5 in Annex VI and Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) p. 77-79
[207] FC+ Study p. 139

compliant data would be counterproductive. Non–GLP data has a potential of being useful source of information (providing that the data is correctly referenced, reliable and robust) thus reducing the need to generate new data, additional costs and delays (see Section 5.2.1 Data, knowledge and information as well as Annex 5 Section 5.2.1 C) and Annex 6 Section 6.2.4).[208]

Another aspect that plays a significant role in how efficient is the EU chemicals legislation, is access to data and data sharing. Problems are still encountered with data access and sharing between regulatory areas because of the lack of a centralised access point (e.g. when useful hazard and risk assessment data is sitting in regulatory clusters linked to particular agencies, scientific committees and/or legislative risk assessment processes for individual regulations and is not readily shared or available to other users), a lack of awareness of what exists in the different databases, the lack of efforts in investigating whether data can be used, and too restrictive access rights for use and re-use of data. It leads to a certain duplication of effort where the nature of assessment made is similar between different pieces of legislation and therefore can generate extra costs, as well as longer-than-necessary timeframes and lead to duplication of testing. This issue might also have negative consequences in cases when companies are seeking a derogation, as the timeframes can be relatively short in comparison with the time it takes for new and sufficient data to be gathered to prove safe use.[209]

Difficulties encountered in updating the Water Framework Directive's list of priority substances illustrate the potential efficiency gains for better data sharing. An additional 'Watch List' mechanism was put in place in 2013[210] in order to gather data to inform decision making on candidates for potential inclusion in the list of priority substances needs to be updated.[211] This 'Watch List' was updated recently. Several substances from the first watch list are included in the updated version. This demonstrates how long it can take to gather the necessary exposure information. If adequate data is not available by the time that legislation (in this case, the priority substances list) needs to be reviewed, it can lead to delays in taking appropriate actions. Better links with risk assessments carried out under other pieces of legislation might help to avoid such situations, e.g. access to risk assessment (including exposure) data, etc.

During one of the workshops different participants believed that there are cases of duplication of effort in assessing hazards and risks because data cannot be shared, due to the above mentioned obstacles, leading to inefficiency and inconsistency. Information exchange should be improved also between the EU Agencies and scientific committees. According to these stakeholders, information gains from improved data sharing would be significant.[212]

[208] Ibidem
[209] 1st FC Study Annex IV p. 75
[210] Directive 2008/105/EC as amended by Directive 2013/39/EU
[211] FC+ Study p. 57
[212] FC+ Study workshop report p. 11, 16 and 23

6.2.3 Grouping approach vs. substance-by-substance approach

A. What's the issue?

The EU chemicals legislation is based on a substance-by-substance approach[213]. Its efficiency is assessed based on potential benefits compared to increased use of grouping approach[214].

B. What are the findings?

Conclusions

The substance-by-substance approach is efficient in identifying the hazards of a specific substance and the risk from the situation in which it is used. However, as highlighted by different stakeholders, there is a need for greater flexibility and a more integrated and holistic view in assessing substances as groups.[215] The substance-by-substance approach can limit in some cases the efficiency of the risk assessment process both in terms of protecting human health and the environment, as well as in terms of avoided costs to industry for further replacement by alternatives e.g. pre-empting industry's investment in substances that are likely to be banned subsequently. Approaches based on grouping chemicals of a similar hazard/risk nature together for risk assessment were supported by NGOs and some Member State authorities as a way of addressing this challenge.

The EU chemicals legislation is currently based on the substance-by-substance approach[216]. It is often the most pragmatic approach to conducting risk assessments.[217] Much of the hazard and exposure data needed are held by industry with assessments completed on single substances. Indeed, hazard data on chemicals are usually focussed on single substances rather than groups of chemicals and, equally, defined uses of chemical substances are also based on individual substances. Moreover, most OECD test guidelines and also alternative in-silico i.e. performed on computer or via computer simulation, approaches work on a substance-by-substance basis.

Although the substance-by-substance approach is effective in identifying the hazards of a specific substance and the risks from the situation in which it is used, stakeholders from all categories have highlighted the need for greater flexibility and a more integrated and holistic view in assessing substances as groups.[218] The efficiency of the risk assessment process is limited by this, both in terms of protecting human health and the environment, as well as in terms of avoided costs to industry for further replacement by alternatives e.g. pre-empting industry's investment in substances that are likely to be banned subsequently. NGOs and some Member State authority stakeholders supported the use of chemical grouping approaches

[213] When considering the appropriate risk management for chemicals, a substance can be assessed in an isolated context (substance-specific; risk assessments completed on given substances under given settings) or as part of a substance group, i.e. chemicals with similar properties.
[214] A short description is given in Annex 5 Section 2.11
[215] FC+ Study p. 95
[216] It can however be noted that some grouping consideration has been made in certain cases, like for the renewal of approval of anticoagulant rodenticides (PT14) as all these substances share more or less the same hazard properties. A similar approach has also been discussed concerning the approval and future renewal of approval of antifouling active substances (PT21).
[217] FC+ Study p. 90 and p. 143
[218] FC+ Study p. 95

whereby chemicals of a similar hazard/risk nature are assessed collectively. However, further grouping of chemicals, if envisaged, would need to have been designed and integrated in the current framework without leading to longer decision-making processes (and would not be suitable in all contexts).

During one of the workshops[219] views expressed by many different stakeholders were in favour of increased use of grouping approach. According to these stakeholders grouping would provide opportunities for efficiency, as it would prevent industry investing substantial resources and investments to replace a substance that would most likely be shortly banned. This is especially the case for SMEs, for which the processes can become extremely burdensome, compared to large companies. According to stakeholders, there is also potential for synergies between legislation e.g. grouping done under REACH could be used under other pieces of legislation. However, defining what the meaningful group of substances proves to be a challenge.

6.2.4 Organisational efficiency of the EU Agencies and scientific committees

A. What's the issue?

At the EU level, risk assessments are conducted by a number of different agencies and scientific committees depending on the chemicals legislation in question. The organisation efficiency is assessed in terms of the speed of different processes and the coherence of their outcomes.

B. What are the findings?

Conclusions

Currently, difference agencies and committees are involved in providing scientific advice and risk assessments within the chemicals regulatory framework. The EU organisational efficiency regarding the overall process could be improved and simplified, therefore avoiding duplication of procedures and reducing the risk of diverging opinions.

Currently, different Agencies and Committees provide scientific advice and risk assessment without prejudice to the competencies conferred to another one. In most cases, delineation of areas of competencies is clear e.g. for cosmetics ECHA is doing the environmental risk assessment while the Scientific Committee on Consumer Safety (SCCS) is in charge of assessing risks for human health. In some other, there is a potential overlap e.g. substances assessed by the Scientific Committee for Occupation Exposure Levels (SCOEL) under the Occupational Safety (OSH) legislation and ECHA (REACH)[220] or between the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and/or the SCCS and ECHA or ECHA and EFSA.

Annex 8 Section 8.2.2 provides a list of the EU Agencies and Scientific Committees involved with hazardous chemical risk assessment (see Figure 18).

[219] FC+ Study workshop report p. 19-21

[220] Please note that from 2019, the scientific evaluation of the relationship between the health effects of hazardous chemical agents and the level of occupational exposure is conducted by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). More information is available at https://echa.europa.eu/fr/-/echa-to-provide-recommendations-for-occupational-exposure-limits

The SCCS and the SCHEER have generally been capable of addressing the Commission's information needs related to the assessment of health risks on consumer products in a satisfactory manner. However, some variations between opinions, depending on the nature of the questions addressed and the availability of data and scientific literature on the subject have occurred. Since the independent risk assessment agencies have been created, the broader issue of how to ensure methodological consistence between them has appeared as prominent, as no institutional mechanism was any longer available to this aim. Therefore, while the internal coherence of their opinions and that of the opinions of the different scientific committees is fully satisfactory, the external coherence - i.e. with the opinions of other EU risk assessment bodies – presents some problematic aspects. Applicants in particular have raised concerns about the misalignment of methodological approaches of the scientific committees with those of the other EU risk assessment bodies, and expressed the need for more standardisation in this regard.[221]

The Rules of Procedure governing the functioning of the SCCS and the SCHEER explicitly recognise the need to ensure good and effective cooperation between these two Committees as well as with other scientific bodies of the EU. This means identifying and solving at their earliest stage any potential conflicts or divergence of opinions, and the obligation to seek the convergence. The good and effective cooperation between the SCCS and the SCHEER is ensured via the establishment of the Inter-committee Coordination Group (ICCG) which deals with (amongst others) matters relating to harmonisation of risk assessment and diverging scientific opinions. The SCOEL has only the obligation to seek to ensure cooperation with other scientific bodies and committees. Differences in the strength of the obligation to seek the convergence is maybe a reason explaining why there have been cases of divergence of opinions between the RAC and the SCOEL[222] while such cases have not (yet) occurred between the RAC and the SCHEER/the SCCS or between the SCHEER and the SCCS.

The majority of stakeholders consider the division of responsibilities and resources for the assessment of chemical risks to human health and the environment between ECHA's Risk Assessment Committee (RAC) for industrial chemicals (including biocides, also with ECHA's Biocidal Product Committee (BPC) involvement), EFSA for pesticides and food contact materials, and the European Medical Agency (EMA) for pharmaceutical products to be generally appropriate and efficient.

During one of the workshops[223] participants considered that merging risk assessment committees may help to avoid conflicts in responses provided. At the very least there needs to be more communication between risk assessment committees assessing the same substances/mixtures. Different results are not always wrong, but for related topics, there should be consistency in the outcomes.

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[221] Second Intermediate Evaluation of the functioning of the SANTE non-food Scientific Committees; final report April 2016; p. 79-83

[222] REACH Evaluation SWD(2018) 58 final p. 103. Please note that from 2019, the scientific evaluation of the relationship between the health effects of hazardous chemical agents and the level of occupational exposure is conducted by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). More information is available at https://echa.europa.eu/fr/-/echa-to-provide-recommendations-for-occupational-exposure-limits

[223] FC+ Study workshop report p. 13 and 16

For the sake of improved coherence and efficiency, there may be opportunities to simplify the risk assessment setup by bringing the risk assessment activities currently done by some of these scientific committees together under the remit of ECHA or EFSA. It should be however noted that in some cases, the assessment done by the committees goes beyond assessing chemical risks e.g. for toys, risks can be chemical but also mechanical and other physical risks.

7 COHERENCE

7.1 Evaluation question: to what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?

A. What's the issue?

There are some differences in approaches with respect to hazard/risk assessment and risk management processes between some of the different pieces of EU chemicals legislation. In many instances, these differences reflect variations in legal scopes and objectives and thus different needs in terms of depth of analysis and evidence required to draw conclusions and decide upon any risk management measures that may be needed. Therefore, these differences do not necessarily imply incoherence. They illustrate the legislator's intention to provide a framework that is tailored to the specific circumstances of the substances used and/or the likely hazards and exposure.[224]

The assessment looks at the consistency in the way different pieces of legislation within the scope of this Fitness Check contribute collectively to achieving the primary policy objectives. Therefore, for the purposes of this Fitness Check, any differences identified were only considered to be a coherence issue where they affected the correct functioning of hazard/risk assessment and risk management procedures.

Where coherence with REACH and other pieces of legislation which are, in principle, outside the scope of this Fitness Check[225] was considered important for a better understanding of the coherence issue, then this was also included in the analysis.

B. What are the findings?

Conclusions

Even though the objectives of different pieces of legislation within the scope of this Fitness Check are not always identical, the legal acts are generally coherent in how they attempt to reach the stated objectives, as illustrated by the use of similar underpinning legal mechanisms to do so.

The focus of the Cosmetic Products Regulation solely on human health aspects was identified as a legal gap by NGO stakeholders. While it may impact consumer ability to differentiate

[224] FC+ Study p. 106 and onwards

[225] Such as for example legislation covering medicinal products for human use (Directives 2001/83/EC) and veterinary medicinal products (Directive 2001/82/EC) regarding PBT/vPvBs assessment

between products in terms of their environmental performance (due to the lack of labelling requirements on environmental hazards) and, therefore, to make better informed purchases, in principle, any potential environmental risks arising from cosmetic ingredients are addressed under REACH, for example, via authorisations or restrictions.

While many of the pieces of the legislation within the scope of this Fitness Check are underpinned by all three core policy objectives e.g. the CLP, the Biocidal Products Regulation, the Plant Protection Products Regulation, the Detergents Regulation, a number of others are underpinned by only one or two of them, for example (see also Annex 4 Table 1):

- Human health and the environment: the Seveso III Directive;
- The internal market and human health: the Cosmetic Products Regulation;
- The internal market and the environment: the Packaging and Packing Waste Directive;
- The environment: the Urban Waste Water Directive;
- Human health: the Drinking Water Directive, the Occupation Safety and Health (OSH) legislation (the Carcinogens and Mutagens at Work, the Chemical Agents and the Asbestos Directives);
- The internal market: the Fertilizers Regulation.

Moreover, some pieces of legislation have very specific objectives e.g. establish measures for the protection of animals used for scientific or educational purposes (the Laboratory Animals Directive); provide for a harmonised system for study audit and inspection of laboratories (the GLP Directives); and establish a voluntary ecolabel award scheme intended to promote products with a reduced environmental impact (the Ecolabel Regulation).

These variations in the scope and nature of objectives do not, *per se*, point to incoherence. They simply illustrate that there is a clear delineation between different priorities depending on the scope of the legislation.

NGOs[226] and several Member States[227], however, highlighted that the Cosmetic Products Regulation focuses only on human health impacts and the internal market (while the Detergents Regulation covers all three core objectives including protection of the environment). As a result risks assessments carried out for cosmetic product ingredients do not consider the intrinsic environmental hazard properties and the environmental fate and risks of cosmetic products and their ingredients across the lifecycle of the product. For example siloxanes, triclosan, synthetic fragrances and UV filters might not constitute a significant health risk for consumers, however, the cumulated amounts of individual small dosage released into the environment when cosmetic products are washed off can be high and thus constitute a risk for the environment. The available evidence and stakeholder inputs to this Fitness Check were insufficient to identify the contributing factors and determine the significance of this gap in practice. It should, however, be noted that the environmental risks of substances used in cosmetic products should, in principle be addressed by REACH.[228] For

[226] FC+ Study p. 124

[227] 1st FC Study Annex II p. 10-11

[228] The Cosmetic Products Regulation, recital 5: "The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, which enables the assessment of environmental safety in a cross-sectoral manner".

example, as of 2020 the placing on the market of siloxane substances D4 and D5[229] will be restricted for wash-off cosmetic products.[230] REACH already restricts the use of nonylphenol, used as a surfactant, in cosmetic products.[231] To date, 9 substances used in cosmetics have been identified under REACH as endocrine disruptors with adverse effects to the environment.[232] However, the lack of labelling requirements for cosmetic products relating to environmental hazards impacts the ability of consumers to differentiate between products in terms of their environmental performance and make better informed purchases.

While the different pieces of legislation within the scope of this Fitness Check try to reach sometimes different objectives, the hazard and risk assessment and risk decision making procedures and mechanisms stipulated under the different pieces of EU chemicals legislation, are broadly consistent but do vary to some degree. Much of this variation is in line with the different scopes, focus, and objectives of the legislation in question and does not represent a framework-wide inconsistency. However, some variations pointed to a degree of incoherence.

Industry[233] holds the main responsibility for generating the data necessary for required hazard and risk assessment of chemicals. In some instances, however, data is also generated at Member State level (under the Water Framework Directive and the Marine Strategy Framework Directive for example) as well as at the EU level (under the Water Framework Directive to set a list of priority substances, under the Industrial Emissions Directive for the revision of the Best Available Technique Reference Documents (BREFs) as well as by ECHA and the existing Scientific Committees).

There are considerable variations in the data requirements (for hazard and risk assessment) specified by the different pieces of EU chemicals legislation. While the lower data requirements come at a cost of potentially missing some hazardous properties and impacting human health and environmental protection as a consequence, these differences can, for the most part, be explained and justified on the grounds of differing likelihood of exposures (risks), of costs and proportionality and of laboratory animal welfare considerations.

[229] Both substances are high tonnage substances in Europe. A risk to the environment arises from the presence of D4 and D5 in certain cosmetic products that are washed off with water after application, because of their hazard properties as a PBT and a vPvB substance in the case of D4 and a vPvB substance in the case of D5. Due to these properties, they have a potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse. The restriction should apply only to wash-off cosmetic products that, under normal condition of use, are removed with water shortly after application because in these circumstances D4 and D5 are emitted to the aquatic environment before evaporation. ECHA has recently recommended the adoption of a restriction measure on the use of D4, D5 and D6 substances for leave- on cosmetic products.

[230] Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane (‘D4’) and decamethylcyclopentasiloxane (‘D5’)

[231] point 46(a) of Annex XVII to REACH

[232] Report from the Commission to the European Parliament and the Council ‘Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products with regard to substances with endocrine-disrupting properties; COM(2018) 739 final p. 3

[233] Employers, manufacturers, importers, exporters, downstream users of a substance or of a mixture, operators of an installation or establishment, waste holders, importers or exporters, producers, manufacturers, distributors and importer of articles

Regarding information and testing requirements for CMRs, PBTs/vPvBs and EDs, differences in approaches to gathering data have been noted but they do not seem to lead to incoherence issues. In general, data requirements need to be systematically updated in order to ensure risk assessments and risk management decisions are being made based on the latest scientific knowledge and technology. This includes, for example, applying new or revised chemical test methods and guidelines. Where legislation is slow to adopt new or updated test guidelines, this can lead to a lack of systematically developed data and therefore affect the ability of risk assessment processes to reach robust conclusions.[234]

In terms of data quality requirements, consistency is supported by the Good Laboratory Practice (GLP) Directives which were introduced to ensure integrity and quality of laboratory testing and studies. However, the exact wording of the data quality requirements often deviates between regulations (referring either to GLP, to the GLP Directives, or to the OECD principles). This can cause confusion for duty holders. However, Member States and industry stakeholders indicated that it is clear what types of hazard and risk assessment data need to be provided under the different pieces of legislation and, in general, how their quality and completeness will be assessed. In addition, some outdated or inconsistent provisions in the GLP Directives have been identified.[235] This includes the undefined role of the EU chemicals agencies and a lack of clarity on how to treat GLP data from non-OECD/Mutual Acceptance of Data (MAD)[236] countries, on the exact scope of the definition of chemicals and data quality requirement for physical hazard testing under the CLP Regulation.

The following views were expressed by different groups of stakeholders:

- Industry stakeholders and Member State stated that, in general, they find the data requirements to be coherent and clear[237].
- Animal rights organisations drew attention to the ban on animal testing under the Cosmetic Products Regulation and the fact that cosmetics ingredients can be subject to different data generation requirements. While for human endpoints all new data for cosmetics ingredients has to be developed using non-animal test methods to meet the requirements of the Cosmetic Products Regulation, for the cosmetics ingredients that are also used in other products or applications, animal testing may still be required under other regulations such as the Plant Protection Products Regulation, the Biocidal Products Regulation or REACH.[238]
- All stakeholders were of the opinion that a greater harmonisation of data requirements would help ensure consistency, in particular for EDs.[239] A number of stakeholders highlighted a lack of coverage in data requirements for a number of human health endpoints (e.g. sensitisers, EDs and immunotoxic and neurotoxic) in risk assessment processes across chemicals legislation.

During the public consultation, industry associations and companies as well as civil society representatives were of the opinion that some aspects of the EU chemicals legislation

[234] FC+ Study p. 48-51
[235] 1st FC Study Annex III, pp. 69
[236] http://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm
[237] 1st FC Study p. 78
[238] 1st FC Study p. 81
[239] 1st FC Study p. 77

framework are internally inconsistent.[240] Citizens and public authorities remained neutral (neither agreed nor disagreed) while a third of public authorities respondents also considered the EU chemicals legislation to be internally inconsistent. A more in-depth analysis based on further comments and position papers received by the Commission shows, however, that although such issues were indeed identified, they most often affect specific aspects of functioning of some pieces of legislation within the scope of this FC while not necessarily being relevant to the functioning of the overall framework. Therefore, the opinion that the EU chemicals legislation is internally inconsistent needs to be nuanced and taken with caution given also that the share of opinions neither agreeing nor disagreeing was significant. Moreover, these views are also in contrast to the generally positive opinions expressed by SMEs (SME Panel) on the overall internal coherence of the EU chemicals legislation.

7.2 Evaluation question: what, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

A. What's the issue?

The coherence of hazard and risk assessment processes was assessed in terms of:

- the consistency of hazard identification via the CLP;
- whether all the relevant hazard classes are covered;
- whether legal criteria have been established for identification of all the relevant substances of potential concern;
- whether there are differences in classification criteria and approaches that could impact the hazard/risk assessment and risk management procedures;
- how the current legal provisions take into account vulnerable groups; and
- how the current legal provisions take into account risks posed by substances of specific concern.

Annex 7 provides more detailed assessment of the coherence of hazard/risk assessment and risk management procedures when dealing with specific substances such as carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bio-accumulative, toxic and very persistent and very bio-accumulative substances (PBTs/vPvBs) and endocrine disrupting chemicals (EDs).

B. What are the findings?

Conclusions

The CLP Regulation ensures the coherence of chemical hazard assessment and classification at the EU level is in line with what is done at the international level (through the UN Global Harmonised System (GHS)). It acts as a horizontal reference point for great majority of the EU chemicals and chemicals-related legislation, thus ensuring a high degree of consistency of chemical hazard identification and classification. Regarding PBTs/vPvBs and terrestrial

[240] 1st FC Study, Annex V, p. 157; public consultation Question 25.

toxicity, which are currently not defined as separate hazard classes under the CLP or the GHS, the potential additional benefits of introducing these as new hazard classes under the CLP need to be further assessed.

Regarding EDs, the recently adopted Communication on endocrine disruptors announced further actions to ensure that citizens and the environment are protected from exposure to endocrine disruptors. Inter alia, the Communication announces that the Commission will launch a cross-sectoral Fitness Check to assess whether relevant EU legislation on endocrine disruptors delivers against this overall objective.[241]

The current approach to allergens lacks coherence with respect to the provision of consumer information and to the assessment of risks to human health. It also creates overlaps in terms of labelling obligations.

There is no overarching approach to risk assessment for vulnerable groups. Reference to vulnerable groups is not systematic across the legislation and risks to these groups are not always addressed in a consistent manner across product/risk/sector specific legislation. Where such legal provisions do exist, risks are taken into consideration on a case-by-case basis with differences in definition and wording used. This could lead to different levels of protection for the same vulnerable group (e.g. children) between different pieces of legislation.

1) Hazard identification

In the EU, chemical hazard identification, assessment and classification is governed primarily by the CLP Regulation, which sets the criteria for a fairly comprehensive set of hazard classes. CLP hazard classification is the basis for chemical hazard classification in most other pieces of EU chemicals legislation. Furthermore, since the CLP is aligned to the UN Global Harmonised System (GHS), it also helps ensure coherence at international level.

During the public consultation, respondents were asked if the hazard classes in the CLP Regulation for environmental, physical and human health risks cover all relevant hazards (the views are summarized in Table 6).[242] While there was a clear 'yes' response from industry associations and companies, the most common reply from civil society representatives was 'no'. Public authorities responded mainly 'yes' regarding human health risks. Regarding environmental risks, while the predominant reply was 'yes', one third of respondents disagreed. Responses from citizens were mostly 'don't know'.

Do the hazard classes in the CLP Regulation cover all relevant hazards? Predominant replies to the public consultation (question 29)			
	Environmental risks	Physical risks	Human health risks
Citizens	'I don't know' (45%)	'Yes' (45%) 'I don't know' (45%)	'I don't know' (45%)
Industry	'Yes' (82%)	'Yes' (85%)	'Yes' (86%)
Publics authorities	'Yes' (44%) 'No' (34%)	'Yes' (71%)	'Yes' (63%)
NGOs and other civil society organizations	'No' (56%)	'Yes' (70%)	'No' (53%)

Table 6 Extent to which respondents agreed that all relevant hazards are covered: replies from the public consultation

[241] COM(2018)734 final
[242] 1st FC Study, Annex V, p. 181; public consultation Question 29.

Under some pieces of legislation and for one or two particular hazard classes, there are elements of hazard identification that are not directly linked to the hazard classes and criteria prescribed by the CLP Regulation. Examples include the hazard classes of persistent, bio-accumulative, toxic (PBT) and very persistent and very bio-accumulative substances (vPvB), terrestrial toxicity and endocrine disruptors.

a) PBTs/vPvBs

Criteria for PBT/vPvB hazard identification are stipulated in REACH Annex XIII. The Plant Protection Products Regulation adopted the criteria set out in REACH Annex XIII before its revision in 2011, whilst the Biocidal Products Regulation refers directly to REACH criteria and, therefore, remains consistent with latest updates to REACH Annex XIII. This creates a potential for inconsistent PBT/vPvB hazard determinations between the two regulations. To date, only one known case of an inconsistent PBT determination has arisen and it concerns the substance acetamiprid. This was not identified as 'Persistent' under the Plant Protection Products Regulation and therefore re-approved for 15 years. However, it was identified and classed as 'very persistent' under the Biocidal Products Regulation. Being also ‘toxic, it was identified as a candidate for substitution and only approved for 7 years.

Under REACH, the obligation to perform a chemical safety assessment applies only to substances placed on the market in quantities of 10 tonnes or more per year. This means that, for instance, some substances with PBT/vPvB properties may potentially be missed. If harmonised PBT/vPvB criteria were established under the CLP Regulation, it would result in the obligation to classify and label substances fulfilling these criteria before placing them on the market regardless the tonnage. A proposal was made by the EU in 2009 to include PBT/vPvB hazard classes and criteria in the UN GHS which would then be reflected in CLP. However, the UN GHS expert sub-committee concluded that the existing hazard classes i.e. hazardous to aquatic environment, would capture any substances with PBT or vPvB hazard properties and ensure that they are appropriately classified and labelled. There is also the option to create additional hazard classes for PBT/vPvB directly within the CLP that would apply only within the EU. However, the potential benefits of introducing this new hazard class under the CLP Regulation needs to be further assessed. The CLP Regulation (in line with the UN GHS Environmental hazards ‘building block’) covers only aquatic toxicity. As is the case for PBTs/vPvBs, in order for the CLP to include criteria for terrestrial toxicity, it would either require amending the UN GHS or the EU amending the CLP without changes made at the UN GHS level. An attempt to include a terrestrial toxicity hazard class within the UN GHS was made in 2006 by Spain but did not receive the support of the relevant UN GHS Sub-committee of experts.

The fact that the CLP does not contain harmonised criteria for terrestrial toxicity does not mean that these hazards are not identified and assessed. In principle, registrants under REACH are required to consider whether or not their substance might present a risk to the terrestrial compartment and, if so, to include this in the risk assessment done for substances which are placed on the market in quantities exceeding 10 tons per year. In practice, however, the lack of a defined hazard class under the CLP combined with the challenge for ECHA of checking the veracity of many thousands of registration entries under REACH means there is a potential for chemicals that are toxic to the terrestrial environment to be overlooked. Terrestrial toxicity is, however, explicitly and carefully addressed under the Plant Protection Products and the Biocidal Products Regulations and to some extent, by the Industrial

Emissions Directive and the Seveso III Directive. Further evidence needs to be gathered to determine the extent and significance of these potential gaps in chemical hazard identification and classification.

b) EDs

The legislative measures constituting the EU legal framework regulating chemicals have been developed at different points in time and have, in certain cases, different objectives.

- Under the Plant Protection Products Regulation and the Biocidal Products Regulation, the Commission set similar scientific criteria for the determination of endocrine-disrupting properties in 2017[243] and 2018[244], respectively. A common ECHA/EFSA guidance document drafted with support from the Joint Research Centre (JRC) has been established for the identification of endocrine disruptors in the context of these Regulations.[245]
- Several other pieces of legislation contain provisions on how to address endocrine disrupors, such as the legislation on chemicals in general (REACH), medical devices related legislation and water-related legislation. Requirements vary depending on the specific legislation.
- Food contact materials legislation, the Cosmetic Products Regulation, the Toy Safety Directive and the occupational safety and health (OSH) legislation do not contain specific provisions for endocrine disruptors. This does not, however, prevent the identification and assessment of substances with endocrine disrupting properties on case-by-case basis.

This has resulted in different approaches to endocrine disruptors and has raised questions about the level of coherence of the EU legal framework in terms of regulating endocrine disruptors.. The absence of horizontal criteria for the identification and classification of EDs has also been criticized by a number of different stakeholder groups including both NGOs and industry, as well as national authorities[246] and was identified as an area for action in the EU's 7th Environment Action Programme.[247]

The Commission considers that there should be a coherent approach to the identification of endocrine disruptors across all relevant Union legislation, based on the broadly accepted definition of the World Health Organisation. The recently established criteria for pesticides and biocides constitute a first step in that direction but EU legislation in other fields does not yet contain such criteria. However, since no single regulatory evaluation completed to date has covered all the different vertical and horizontal aspects of addressing endocrine disruptors

[243] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

[244] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36

[245] Available at https://www.efsa.europa.eu/en/efsajournal/pub/5311

[246] FC+ Study p. 118

[247] http://ec.europa.eu/environment/action-programme/

in EU chemicals legislation, the Commission has committed[248] to undertaking a cross-cutting assessment of the current situation. This will assess whether relevant EU legislation on endocrine disruptors delivers against the objectives to protect human health and the environment by minimising exposures to these substances. It will also pay particular attention to those areas where legislation does not contain specific provisions for endocrine disruptors, such as toys, cosmetics and food contact materials. In addition, attention will be paid to the consistency and intensity of actions to protect vulnerable population groups that are particularly sensitive to endocrine disruptors, such as the foetus or adolescents.[249]

2) Risk management

a) Of the known adverse effects on human health and the environment

The majority of currently known adverse effects on human health and the environment are covered. However, some inconsistencies occur regarding risk management decisions for EDs, PTBs/vPvBs and substances fulfilling the classification criteria for Specific Target Organ Toxicity (STOT[250]). Regarding neurotoxicity, immunotoxicity and allergens, further evidence needs to be gathered to determine the extent and significance of these potential gaps in chemical risk management.

i. CMRs

Approaches to the risk management of CMRs are generally coherent, as they are in principle prohibited for use in professional and consumer products based on harmonised classifications under the CLP Regulation.[251] One issue, however, is that of non-threshold CMRs i.e. where a no-effect level (a defined exposure level below which no health impact can be detected or observed) cannot be established. Since, by definition, a non-threshold CMR creates a potential risk at any level of exposure, it becomes important to define what the acceptable level of risk is. In accordance with the conclusion of the REACH Review, there is currently no consensus within the EU on defining the acceptable level of risk.

ii. EDs

Under the Biocidal and the Plant Protection Products Regulations, EDs are given the same priority as CMRs cat. 1 and are subjected to generic risk considerations, i.e. they should not be approved except if negligible risk from exposure or negligible exposure to the substance can be demonstrated or if specific derogations apply. Under the Biocidal Products Regulation EDs are also automatically banned from use in consumer products on the basis of generic risk considerations[252]. Other legislation, such as that on food contact materials, cosmetics, toys or

[248] 'Towards a comprehensive European Union framework on endocrine disruptors' COM(2018) 734 final
[249] COM(2018) 734 final
[250] STOT substances cause specific but non-lethal effects, reversible or irreversible, on organs or organ systems in the body following single exposure to a substance. Substances with STOT properties are classified according to the CLP Regulation.
[251] 1st FC Study p. 81
[252] According to article 58(2) of the Biocidal Products Regulation, "A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2) [Union list of approved active substances], for the

protecting workers at the workplace, does not contain specific provisions for EDs. However, substances with ED properties are subject to case-by-case regulatory action on the basis of the general requirements of the legislation.

NGOs and civil society representatives, as well as some Member State authorities[253] consider the regulatory action taken so far to be inadequate, and have called for stricter and broader EU measures. The issue is recognised in the Commission's recently adopted Communication on endocrine disruptors which underlines that the EU strategic approach on EDs for the years to come should be based on the application of the precautionary principle and aim (amongst others) at minimising overall exposure of humans and the environment to endocrine disruptors, paying particular attention to exposures during important periods of development of an organism, such as foetal development and puberty.[254]

iii. PBTs/vPvBs

Substances that are identified as PBTs/vPvBs can be addressed under REACH, the Plant Protection Products and the Biocidal Products Regulations, and the Water Framework Directive. However, there are some inconsistencies regarding how these pieces of legislation:

- Take into account socio-economic aspects: Under REACH and the Biocidal Products Regulation, in contrast to the Plant Protection Product Regulation, a socio-economic analysis, including an analysis of alternatives, is also required as an input to the risk management decision process (e.g. for authorisations, restrictions, etc.). The cost-effectiveness and proportionality of measures are to be taken into account under the Water Framework Directive, when taking decisions on measures against the pollution of water for the priority substances (Annex X) some of which are PBT/vPvBs.
- Apply (or do not apply) exclusion criteria:
    - Comparing the Plant Protection Product Regulation and the Biocidal Products Regulation, the main difference lies in the possibility to obtain a derogation from the automatic ban for the use of active substances identified as PBTs/vPvBs. Under the Biocidal Products Regulation, their use in products is prohibited unless conditions for derogation are met (negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered). Under the Plant Protection Product Regulation, active substances identified as PBTs/vPvBs cannot be approved and there is no possibility to obtain a derogation.
    - Substances used in cosmetics, food contact material, toys and medical devices are regulated as regards PBT/vPvB-properties under REACH. Such substances can be restricted if there is an unacceptable risk to the environment arising from their use in these product types. If a PBT/vPvB-substance is added to the authorisation list under REACH, an authorisation to use them can only be

relevant product-type and use, or in Annex I [eligible active substance for simplified authorisation process], and any conditions or restrictions specified therein are met."

[253] Council conclusions on the protection of human health and the environment through the sound management of chemicals (15046/16); 6 December 2016

[254] COM(2018) 734

granted if the socio-economic benefits outweigh their risk and if no alternatives are available.

Some inconsistencies were identified with respect to the legislation covering medicinal products for human use[255] and veterinary medicinal products.[256] An assessment of PBTs/vPvBs properties of the emissions into the environment from veterinary medicinal products, while not mandatory, can still be performed on the basis of various guidance documents.[257] If risks linked to PBTs/vPvBs properties of a substance are identified, it is not clear what impact this will have, if any, on the authorisation of the veterinary medicinal products that include the substance. For medicinal products for human use, the outcome of the environmental risk assessment (e.g. the PBTs/vPvBs assessment) is not considered in the benefit/risk analysis, and as such it does not serve as a basis for refusal of the marketing authorisation (see Annex 7 Section 7.2.5). The European Commission adopted recently an EU strategic approach to pharmaceuticals in the environment. The actions announced include considering the findings of this and recent REACH Review as regards links with the medicinal products legislation in relation to environmental protection. This could, among other things, help to clarify the PBT/vPvB requirements. Expanding environmental monitoring and knowing more about the concentrations of pharmaceuticals in the environment would allow environmental risk assessments to be improved and measures to be more focused.[258]

iv. STOTs (Single Target Organ Toxicity substances)

Under the Biocidal Products Regulation, substances classified as STOTs under the CLP Regulation are subject to risk management measures based on generic risk considerations (i.e. automatically prohibited from use by the general public). This, however, is not the case under the Plant Protection Products Regulation. There are no equivalent provisions under other product specific legislation within the scope of this Fitness Check.

Regarding the occupational safety and health (OSH) legislation, in principle, risks to the safety and health of workers arising from any chemical agent - even those not classified as hazardous under the CLP Regulation but which potentially pose an occupational health or safety risk - needs to be assessed by the employer. In the case of activities involving the potential exposure to several different hazardous chemical agents, the combined risk of these exposures should also be assessed. In both instances, hazards and risks relating to single target organ toxicity can be addressed where this is identified as a potential source of risk. These risk assessments then constitute the basis for taking preventive risk management measures at workplace.

[255] Directives 2001/83/EC (outside the scope of this Fitness Check)
[256] Directive 2001/82/EC (outside the scope of this Fitness Check)
[257] The current Committee for Medicinal Products for Veterinary Use (CVMP) guideline on 'Environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-Rev.1) specifies the need for a PBT screening of veterinary medicinal products. It refers to EU Technical Guidance Documents for industrial chemicals and biocides for cut-off values for each of PBT/vPvB criteria. The guidance also specifies how the PBT characteristics should be assessed by making cross reference to the REACH guidance documents.
[258] 'European Union Strategic approach to Pharmaceuticals in the Environment' (COM(2019) 128 final)

v. Neurotoxicity and immunotoxicity

NGOs and some Member State authorities pointed out a potential gap for some "new emerging endpoints"[259] e.g. neurotoxicity, immunotoxicity. These hazard aspects present health and environmental risks of a similar level of concern to those associated with CMRs, PBTs/vPvBs and EDs[260] but are not always explicitly addressed by the EU framework of chemicals legislation[261] e.g. these do not consitute a hazard class under the CLP Regulation.

In principle, neurotoxicity can be addressed via the STOT hazard class under CLP and via related pieces of legislation such as REACH, the Biocidal Product Regulation and the Plant Protection Products Regulation. However, in practice, expert stakeholders indicated that testing for neurotoxicity is rarely undertaken despite the availability of internationally recognised test methods.

With respect to immunotoxicity, there are currently no internationally recognised test methods to identify substances with this hazard characteristic. It requires further research and development for legislation to be able to address the potential adverse effects on human health.

vi. Allergens

There is currently no common definition of what constitutes an allergen, i.e. a substance that may cause allergic reaction. The CLP Regulation sets out the hazard classification criteria and requirements for respiratory and skin sensitisation. The Cosmetic Products Regulation does not rely on the CLP classification criteria for the identification of skin or respiratory sensitizers. Instead, it simply refers to substances that can cause allergic reaction. Such substances are identified by the Scientific Committee on Consumer Safety (SCCS). While there is no specific list of allergens under the Cosmetics Regulation, substances which can cause allergic reaction can be restricted, used only under certain specific conditions or banned. References to fragrance allergens regulated by the Cosmetics Regulation are also included in the Detergents Regulation[262] and the Toy Safety Directive[263]. There are no specific legal provisions for allergens other than fragrances under these two pieces of legislation.

There are differences in the number of allergens that are regulated under different pieces of legislation; this may be appropriate given the different scopes of the legislation, but reasons for the differences are not clear.[264]

The lack of a harmonised approach to allergens is considered by a number of stakeholders to have negative implications for the single market, competitiveness and innovation, and for ensuring a high level of protection of human health. It also impacts the communication of

[259] 1st FC Study, Annex V, p. 70; public consultation Question 29.
[260] FC+ Study p. 126
[261] They are explicitly addressed in the Plant Protection Products Data Requirements Regulation.
[262] According to Annex VI, point A of the Detergents Regulation, the allergenic fragrances that appear on the list of substances in Annex III of the Cosmetics Regulation, as a result of adaptation to technical progress, shall also be listed according to the Detergents Regulation, if added at concentrations exceeding 0,01% by weight.
[263] According to Annex II Part III point 10 of the Toy Safety Directive cosmetic toys shall comply with the compositional and labelling requirements from the Cosmetics Regulation
[264] 1st FC Study p. 29

chemical hazards to consumers and their ability to make informed purchases.[265] Regarding toys in particular, a number of stakeholders have noted that allergens are an issue too softly regulated under the Toy Safety Directive and suggested that other allergens that are not specifically fragrance allergens should also be regulated.[266]

There are legislative overlaps between the Detergents Regulation and the CLP Regulation with regard to the labelling of allergens. According to AISE[267] and other consultees, multiple regulations dealing with the labelling of detergents products (the CLP, the Cosmetic Products Regulation and the Detergents Regulation) create unnecessary regulatory burden and there is a clear opportunity for streamlining labelling requirements.[268] [269]

b) For vulnerable groups

The analysis shows that not all pieces of legislation within the scope of this FC take into account risks to vulnerable groups. Where such risks are taken into consideration, the definition of vulnerable populations covered varies as there is no horizontally applicable definition of 'vulnerable group'. This means that risks for such groups are addressed on case-by-case basis through product/risk/sector specific legislation taking into consideration circumstances, products or environments of chemical exposure that could lead to different level of protection across the legislation. The following pieces of legislation (non-exhaustive) refer to 'vulnerable groups':

- The Toy Safety Directive (children under 14 years of age);
- The Occupation Safety and Health (OSH) legislation (young workers; pregnant workers);
- The Plant Protection Products Regulation (pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term);
- The Residues of Pesticides Regulation (children and the unborn, vulnerable consumers);
- The Biocidal Products Regulation (pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to biocidal products over the long term, workers and residents);
- The Regulation on Food Additives (not mentioning 'vulnerable groups' as such but prohibiting the use of food additives in foods for infants and young children).
- The Cosmetic Products Regulation (specific assessment for cosmetic products intended for use on children under the age of three, and particular attention is to be paid to the microbiological specifications of cosmetic products intended to be used on children under three years of age, on elderly people or on persons with compromised immune responses; for derogation to CMR 1A/B ban, particular account to be taken of vulnerable population groups by the Scientific Committee on Consumer Safety (SCCS) in its evaluation).

[265] 1st FC Study p. 82
[266] 1st FC Study Annex VI Case Study 8 p. 30-33
[267] AISE is the International Association for Soaps, Detergents and Maintenance Products
[268] 1st FC Study p. 85. See also Annex VI Case Study
[269] Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) p. 71-72

NGO stakeholders indicated that clear definitions of children and vulnerable groups are missing in most pieces of the EU chemicals legislation and therefore the current approach is not consistent. They also indicated that the notion of 'vulnerable groups' should be broader and include other categories such as citizens with low income and/or socio-economic status.[270] Moreover, NGOs highlighted the fact that in some cases risk management measures taken under one piece of legislation to protect a vulnerable group are not complemented under another where the exposure could be similar. For example, certain phthalates are banned in the use of toys under REACH while they are allowed in other products such as carpets, textiles or furniture to which children can be exposed to.[271] [272]

Such differences can be partly explained by differences in legal scope. For example, workers safety legislation, by definition, will not apply to children as the child labour is prohibited[273] while the Toy Safety Directive in principle will not cover risks posed to adults. However, it is not clear:

- Why the risk assessment carried out under the Cosmetic Products Regulation take into account exposure of children under three years of age to substances classified as CMR 1A and 1B while the Toy Safety Directive also covers risks to children from CMRs of category 2.
- Why the Plant Protection Products Regulation and the Biocidal Products Regulation take into consideration pregnant and nursing women, and the unborn while the Pregnant Workers Directive only covers risks to pregnant worker herself but excludes consideration of risks to the unborn child.

The recently adopted Communication 'Towards a comprehensive European Union framework on endocrine disruptors' highlights the fact that particular attention needs to be paid to the consistency and intensity of actions to protect vulnerable population groups that are particularly sensitive to endocrine disruptors, such as the foetus or adolescents.[274] In this regard, it can be noted that the current legal provisions do not specifically identify adolescents as 'vulnerable group' (except under the Young People at Work Directive).

[270] FC+ Study p. 127-128
[271] FC+ Study p. 108
[272] The Commission adopted a Decision to amend the REACH Regulation and restrict the use of the phthalates (DEHP, BBP, DBP and DIBP) in consumer products on the EU market that will complement the existing restriction on three other phthalates (DINP, DIDP and DNOP) in toys and childcare articles (Commission Regulation (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP))
[273] The Young People at Work Directive considers children and adolescents to be specific risk groups requiring specific measures to be taken with regard to their safety and health. It prohibits child labour (minimum working or employment age is not lower than the minimum age at which compulsory schooling as imposed by national law ends or 15 years in any event). The Directive also stipulates that work by adolescents should be strictly regulated and protected. According to the Young People at Work Directive 'child' shall mean any young person of less than 15 years of age or who is still subject to compulsory full-time schooling under national law; 'adolescent' shall mean any young person of at least 15 years of age but less than 18 years of age who is no longer subject to compulsory full-time schooling under national law; 'young person' shall mean any person under 18 years of age having an employment contract or an employment relationship.
[274] COM(2018) 734 final p. 10

The main potential implications are during the risk assessment step and with potential knock on consequences for the decisions on risk management measures. However, the assessment done for the purposes of this Fitness Check did not come to a conclusion on the extent of the issue and if, in practice, risks to vulnerable populations are not sufficiently well addressed and managed because of these legislative gaps and inconsistencies.

8 RELEVANCE

8.1 Evaluation question: to what extent do the objectives of the legislative framework for chemicals meet the current needs?

In this section the relevance of the policy objectives, as well as the risk management approaches of the EU chemicals legislation is assessed. The analysis examines whether there are any mismatches between the existing chemicals policy objectives and the current situation. It revisits the underlying drivers and assumptions that were considered when designing and implementing the various components of the EU chemicals *acquis* to assess whether or not these remain valid and whether new drivers have emerged that have not yet been accommodated.

8.1.1 Do the original needs still exist or are parts of the chemicals legislative framework now redundant?

A. What's the issue?

The relevance of the legislative framework is evaluated here in terms of whether or not the issues and needs that triggered the introduction of the legislation still exist and are still relevant. In order to answer this question, it is necessary to link it to the original objectives and their alignment with the priorities that have emerged progressively since the adoption of the different pieces of EU chemicals legislation.

B. What are the findings?

Conclusions

The original needs in terms of protecting human health and the environment from the risks of hazardous chemicals, of enhancing the functioning of the internal market and of promoting innovation and competitiveness continue to exist. As such, the three core objectives of the EU chemicals legislation continue to be relevant. The basic components and approaches applied within the EU chemicals *acquis* to assess and manage the hazards and risks of chemicals also remain relevant.

1) Ensuring a high level of protection of human health and the environment

A recent assessment of the cumulative health and environmental benefits of chemicals legislation[275] identified the continued need for risk assessment and risk management measures in order to protect human health and the environment from exposures to hazardous chemicals.

[275] CuBA Study p. 335-346

Taking into account the growing volumes and complexity (number, structure/composition, form (e.g. nanomaterials), etc.) of chemicals and supply chains as well as the ever increasing number of products and uses that involve chemicals, identifying and managing the risks of hazardous chemical exposures to humans and the environment remain highly relevant. A significant share of the volume of chemicals produced are classified as hazardous to human health (+60%) and/or the environment (+40%). This share has largely remained the same over the last decade. Furthermore, the imports of consumer goods and other articles into the EU have tripled between 2000 and 2015[276] creating additional challenges for managing the risks associated with the presence of hazardous substances in articles.

There was broad consensus amongst stakeholders that the basic components and approaches of the EU chemicals *acquis* remain appropriate and relevant in reaching environmental and health objectives. It was pointed out a number of times by different stakeholders that the EU approach to identifying and managing chemical risks is considered a benchmark by other countries and regions in the world.

2) Ensuring the functioning of the Single Market and enhancing the competitiveness and innovation of EU industry

The EU chemicals *acquis* is still relevant regarding its basic goals of enhancing the functioning of the internal market and of promoting the competitiveness and innovation of the EU chemicals sector and related downstream sectors. Horizontal rules on basic information, packaging and health and environmental safety are prerequisites for a well-functioning and transparent market, including relatively equal (reciprocal) access to information, fair and equal competition and informed consumer choices.

The legislation in the scope of this Fitness Check has facilitated intra-EU trade (i.e. EU companies selling in the EU single market rather than only in their home country market) through the harmonisation of regulatory requirements as evidenced by the increase in the share of intra-EU trade of total EU chemicals sales.

In terms of international competitiveness, in 2016 the EU chemical industry represented 15.1% of the global market, behind China (39.6%) but ahead of the United States (14.2%)[277]. Although the European share of global sales has decreased (it was 32.5% in 1996), the EU chemicals industry remains internationally competitive as evidenced by the increase in exports to non-EU countries (around EUR 100 billion in 2006 and EUR 146.2 billion in 2016). Moreover, the EU is the largest chemicals exporting market in the world.[278]

The EU is frequently cited as a global leader in terms of the development and implementation of chemicals policy. Where the EU acts on restricting the use of hazardous chemicals, other countries and regions often follow.[279] Therefore, the potential for the EU chemicals legislation to act as a driver of innovation in the chemicals sector and related downstream sectors remains relevant, particularly in view of the EU commitment to achieving the UN Sustainable Development Goals (SDGs) and the United Nations Strategic Approach to Chemicals

[276] CuBA Study p. 335-346
[277] Ibidem
[278] CEFIC Facts and Figures Report, CEFIC, 2017
[279] CuBA Study p. 324

Management (SAICM) objective of shifting towards a more sustainable design and use of chemicals. Another illustration of this is in controls on the use of persistent organic pollutants (POPs), where international action has frequently followed on from EU action.[280]

8.1.2 Have new needs emerged in relation to the health and environmental risk management of chemicals? If yes, what are they?

A. What's the issue?

As science continues to evolve and new data become available regarding the links between exposures to hazardous chemicals and the impacts on human health and the environment, a number of concerns have emerged during the last 10-20 years that are still either only partially, or not at all, addressed by the existing framework of EU chemicals legislation. The most important of these are discussed below.

B. What are the findings?

Conclusions

Some gaps remain within the framework of EU chemicals legislation, namely, how to address combination effects, how to better understand and address impacts on the environment, biodiversity and eco-system resilience, and how to gather knowledge and better manage the risks related to the use of hazardous substances in articles. Concerns regarding the former have been acknowledged and steps have been taken to improve the existing methodology and risk assessment approach. Gathering knowledge about substances in articles is particularly important as the EU is in the process of shifting towards a more circular economy.

1) Combination effects

Humans and the environment may be simultaneously exposed to multiple chemicals by a single route or multiple routes, a situation referred to as 'combined exposure'. The term 'unintentional chemical mixtures' is sometimes used to refer to the combined exposure to multiple chemicals from different sources[281]. The adverse effects or toxicity of a combination of different substances might be more severe than, and/or different from, the individual substances involved. It is a cross-cutting issue relevant for a number of topics assessed under this Fitness Check (e.g. endocrine disruptors, substances in articles, etc.).

Effects from combined exposures are documented for a limited selection of substances in human biomonitoring studies[282] [283]as well as in animal studies[284]. Several such studies

[280] Ibidem

[281] Kienzler, A., Berggren, E., Bessems, J., Bopp, S., Van Der Linden, S. and Worth, A. (2014) Assessment of Mixtures - Review of Regulatory Requirements and Guidance. JRC Science and Policy Report EUR 26675 EN European Commission, Joint Research Centre, Ispra, Italy

[282] Govarts, E.et al. 'Combined Effects of Prenatal Exposures to Environmental Chemicals on Birth Weight'. Environmental Research and Public Health, vol. 13(5), 495, 2016 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4881120/

[283] Danish Environmental Protection Agency, 'Exposure of children and unborn children to selected chemical substances'. Survey of chemical substances in consumer products No. 158., 2017 https://www2.mst.dk/Udgiv/publications/2017/04/978-87-93529-84-7.pdf

indicate the occurrence of a growing number of different hazardous chemicals in human blood and body tissue, including in pregnant women and new-born infants. Chemicals identified include pesticides, biocides, pharmaceuticals, heavy metals, plasticisers and flame retardants[285] [286]. There are, however, still considerable knowledge gaps regarding human and environmental exposures to combinations of chemicals. In part, this reflects insufficient attention to combination effects in screening and human and environmental biomonitoring programs.

Risk assessment processes implemented within the framework of EU chemicals legislation are not expressly designed to identify and assess potential human health and environmental risks of different hazardous chemicals acting in combination. Intentional mixtures, i.e. products composed of a defined mixture of different chemical substances such as glue, paint and detergents are subject to hazard classification and risk assessment and classification under e.g. REACH and the CLP. By contrast, the combination effects of 'unintentional mixtures' formed e.g. during production processes, in the products themselves, in the human body or in the environment are often complex, varying and unknown and therefore currently difficult to risk assess. Moreover, the potentially high number of combinations of chemicals implies that actual physical testing of these is less feasible.

Estimation of effects of typical combined exposure to a known selection of chemicals in the working environment for a particular occupational group is generally easier to achieve and very relevant due to the high levels of exposure. However, workers are also citizens and consumers who can also be exposed to hazardous chemicals through other routes outside of the workplace e.g. food, drinking water and the external environment. While being an important reality these exposure factors are currently not easy to factor in.

The issue and risk assessment challenge of combination effects is recognised by the Commission[287]. Efforts are underway to better address this issue. An example is EFSA's development of combination effect assessment methods and guidance for pesticides, based on Cumulative Assessment Groups (CAGs)[288]. This identifies compounds that exhibit similar toxicological properties in a specific organ or system, assuming that pesticides causing the same toxic effects in tissues, organs and physiological systems can produce joint, cumulative toxicity, even if they do not have similar modes of action. EFSA published recently a Guidance document describing harmonised risk assessment methodologies for combined exposure to multiple chemicals for all relevant areas within EFSA's remit, i.e. human health, animal health and ecological areas. [289]

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[284] Hass, U. et al. (2017). Combined exposure to low doses of pesticides causes decreased birth weights in rats. Reproductive Toxicology (corrected proof under http://dx.doi.org/10.1016/j.reprotox.2017.05.004)

[285] Woodruff et. al., Environmental Chemicals in Pregnant Women in the United States: NHANES 2003–2004, Environ Health Perspect. 119:878–885 (2011).

[286] The Pollution in Newborns, A benchmark investigation of industrial chemicals, pollutants and pesticides in umbilical cord blood, Environmental Working Group, July 14, 2005 https://www.ewg.org/research/body-burden-pollution-newborns#.WuCm4f5lKUl

[287] COM/2012/0252 final

[288] https://www.efsa.europa.eu/en/press/news/130712

[289] "Guidance on harmonized methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals." (EFSA, March 2019) Available at https://www.efsa.europa.eu/en/efsajournal/pub/5634. In addition, EFSA published a "Statement on genotoxicity

2) Impacts on environment, biodiversity and eco-system resilience

Impacts of hazardous chemicals on biodiversity and eco-systems contribute, together with other stressors, to the reduction of 'eco-system resilience' i.e. the ability to resist damage and to recover. This can lead to rapid declines in animal populations (see Annex 5 Sections 5.1.1 B) and 5.1.1 C)) and, ultimately, to extinctions. Other consequences include sub-lethal effects such as reductions of fertility, impaired feeding patterns and lost ability of orientation which, over time, lead to the weakening of populations. Publications found that exposures to hazardous chemicals, in particular pesticides, in combination with other factors, are leading to significant reduction of insect populations[290] with effects in the food chain, in particular for bird populations, many of which are in decline in the EU.

Although the potential of some hazardous chemicals to cause harm is recognised and considered in the regulatory context, their role in the complex interaction with other environmental stressors and the actual contribution – compared to the other stressors – to the effects seen in the environment is less well understood. Current standard test and assessment methods typically do not focus on these long term, large scale and complex environmental effects.

3) Substances in articles and Circular Economy aspects

Hazardous substances are included in articles and may be released at any lifecycle stage, resulting in exposures and potential risks for humans and for the environment. This is true for articles newly produced or already placed on the market. Access to information on the chemical content of articles is, therefore, important for risk management across all stages of the product lifecycle, including its end-of-life and for potential recovery into secondary raw material cycles, as well as for appropriate labelling and informed consumer choices.

There is a general lack of information about the presence of hazardous substances in articles e.g. the possible presence of chemicals of concern such as flame retardants in plastics used in construction, automotive, aviation, furniture and electronics applications.[291] This lack of information renders it difficult for:

- Regulators to carry out overall risks assessment, determine the scale of risks, and to choose regulatory risk management measures.
- Economic operators and consumers to make well-informed purchasing decision about articles containing or not hazardous substances.
- Waste treatment operators to separate and treat end-of-life articles in a manner that prevents contamination of recycled materials.

Moreover, new chemicals are continuously placed on the market whilst others are forbidden or gradually phased out when it is discovered that they pose a risk. This means that products legally produced today may contain a substance that later on may be banned. When the product becomes waste and is then recovered, the banned substance may still be contained in the recovered material as so-called legacy substance. For example, certain brominated flame

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assessment of chemical mixtures." (EFSA, January 2019) available at https://www.efsa.europa.eu/en/efsajournal/pub/5519

[290] CuBA Study p. 243-274

[291] The EU Strategy for Plastics (COM(2018) 28 final)

retardants that are persistent, bio-accumulative and toxic have been reportedly found in recycled plastic products including toys and kitchen utensils.

Furthermore, an assessment conducted by ECHA across 27 Member States and reported in 2018[292] found a considerable number of non-compliance cases with existing rules on hazardous chemical restrictions or bans in articles. The non-compliance rate was higher for articles 'of unknown origin' and for articles originating from China.

An existing horizontal approach to information on chemicals content in articles is based on REACH requirements for the notification and provision of information on the content of substances of very high concern (SVHCs) to professional users and consumers (Article 7 and 33 respectively). Provisions also exist in the Biocidal Products Regulation concerning the labelling of articles treated with biocides. Communication of information to consumers (article 58(3), (4), (5) and (6) of the Biocidal Products Regulation) is done in a similar way to REACH. In parallel to these legal requirements, there are a range of voluntary business-driven initiatives to manage and make available information on chemicals in articles mainly aimed at supply chain communication. However, the coverage of article types and businesses is still limited.

Civil organisations and NGOs, as well as some Member State authorities have identified the lack of chemical safety criteria in the General Product Safety Directive (GPSD) and consider this to be a major gap within the horizontal legislative framework for consumer products. Examples of categories of articles which are not covered by any specific EU product legislation addressing chemical exposure include materials in contact with drinking water, construction materials/products, furniture, clothing and textiles[293], child care articles and sports and playground equipment and surfaces.[294]

The GPSD, however, was not designed to set out specific chemical safety criteria but to manage the risks of products in general. According to the GPSD, all articles ('consumer products') placed on the market, must be safe and comply with its provisions. In areas where no EU legislation or standards exist, the compliance with the GPSD safety requirement is determined according to other reference points such as national standards, Commission recommendations, codes of practice, etc. When measures are taken against unsafe products found on the market, national market surveillance authorities notify this to other Member States and the Commission through the Rapid Alert System for dangerous non-food products (RAPEX).

As the EU shifts towards a more circular economy, one of the commitments of the Circular Economy Action Plan[295] in 2015 was to develop a strategic approach on chemicals in the

[292] FORUM REF-4 PROJECT REPORT, Harmonised Enforcement Project on Restrictions, European Chemicals Agency, February 2018 https://echa.europa.eu/documents/10162/13577/ref_4_report_en.pdf/b53f5cd9-64a4-c120-1953-e9e176b9c282

[293] Under REACH, 33 CMR substances (and substance groups) have been restricted for use in clothing, textiles and footwear via Commission Regulation (EU) 2018/1513 of 10 October 2018 amending Annex XVII to Regulation (EC) No 1907/2006.

[294] FC+ Study p. 120-122

[295] Closing the loop - An EU action plan for the Circular Economy, Brussels, 2.12.2015; COM(2015) 614 final http://eur-lex.europa.eu/resource.html?uri=cellar:8a8ef5e8-99a0-11e5-b3b7-01aa75ed71a1.0012.02/DOC_1&format=PDF

circular economy. It covers assessing and addressing the health and environmental risk aspects associated with information about substances in articles as the recycling and re-use of products and materials in general will become increasingly relevant.

The scale of the problem is significant. The Commission has recognised the issue and proposed a number of priority areas and options for action as a part of its work on the interface between chemicals, waste and product policies. This includes accelerating work to identify possible ways to make chemicals easier to trace in recycled streams.[296] In relation to this, the recently revised Waste Framework Directive provides the legal basis for the establishment of an ECHA-managed database on the presence of SVHCs in consumer goods ('articles') with access provided to waste treatment operators as well as consumers upon request.[297]

The inclusion of circular economy considerations into chemicals risk management will require a transformation of the life cycle stages and timescales considered in risk assessment, with assessors needing to consider not only the 'first' life of a product, but also the 'second', 'third' and all potential future lives, moving to a new form of life-cycle assessment. In order to adapt hazard and exposure scenario assessments accordingly, more information and data will need to be gathered on substance uses and releases from articles, which are currently often not available. [298]

8.2 Evaluation question: to what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders?

The ability of the EU chemicals *acquis* to remain relevant and fit for purpose is dependent, among other things, on the ability of EU and Member State policy makers to take into account and address the concerns and issues raised by different stakeholders in a balanced, open and well-justified manner. A number of requirements and processes for ensuring proper stakeholder engagement are built into both the overall EU regulatory system, such as the Better Regulation programme, as well as into individual pieces of legislation. This includes active communication to citizens and other stakeholders about the hazards and risks of chemicals. This section assesses the adequacy and continuous relevance of these processes.

8.2.1 Taking into account the concerns of citizens and other stakeholders

A. What's the issue?

Public and stakeholder consultation is integral to well-informed decision-making and to improving the quality of law-making. It is also vital that citizens and other stakeholders feel they can make their concerns known and that these are heard and addressed.

[296] Interface between chemical, product and waste legislation (COM(2018) 32 final)
[297] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste; Recital 38 and Article 1 and 9(2)
[298] FC+ Study p. 129

B. What are the findings?

Conclusions

The current EU chemicals legislation includes numerous mechanisms for ensuring that concerns of citizens and other stakeholder groups are known and addressed including health, environmental, social and economic consequences. By and large, stakeholders appreciate the level of consultation that is undertaken although some stakeholders, notably NGOs but also industry, feel that their voice, whilst heard, is not always addressed.

In the design, development, implementation and update of EU chemicals legislation, there are multiple opportunities for different stakeholders to have access to the hazard/risk assessment information and considerations and to express their views. It can be done through both formal and informal processes. This includes online public consultations, workshops, targeted stakeholder interview processes, etc., during the life of a piece of legislation, starting from ex-ante impact assessment for newly proposed (or to be revised) legislation to ex-post evaluation of existing legislation as it was done for this Fitness Check (regarding the stakeholder consultation activites carried out for the purposes of this Fitness Check please see Section 4.1.2 and Annex 2). The Commission also conducts regular citizen surveys via its Eurobarometer service e.g. the two recent surveys on citizen views of chemical safety[299] and on the environment which included a focus on the impact of chemicals[300]. Many of these elements are managed as an integral part of the Commission's Better Regulation programme.

Stakeholders can also provide expert input to the policy making and implementation processes through the various expert groups created by the Commission. For example, CARACAL[301] is an expert group which advises the European Commission and ECHA on questions related to REACH and the CLP Regulations. CARACAL is composed of representatives of Member States competent authorities for REACH and the CLP, representatives from competent authorities of European Economic Area and European Free Trade Association countries as well as a number of observers from non-EU countries, international organisations and stakeholders. In a similar way, expert groups were established to ensure cooperation between Member States, stakeholders and the Commission and to ensure consistent implementation of the legislation within the EU for toys safety, detergents, cosmetics and medical devices, fertilizers and others.

These different processes help ensure that socio-economic consequences of relevance to different stakeholder groups such as impacts on businesses, especially SMEs, and consumers, increases in administrative costs, human health and environmental impacts, etc., are properly taken into account. It also helps to identify and avoid potential unintended consequences of changes in legislative requirements e.g. chemicals legislation can have an impact on recycling activities when content/concentration limits are set for a specific substance.

The following aspects were highlighted by different stakeholder groups related to their participation in the decision making process[302]:

[299] https://data.europa.eu/euodp/data/dataset/S2111_86_3_456_ENG
[300] https://data.europa.eu/euodp/data/dataset/S2156_88_1_468_ENG
[301] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2385
[302] For more details please refer to the 1st FC Study, Annex IV p. 29-33 and p. 88-89

- NGO stakeholders expressed some frustration about the lack of transparency and ability to provide input to the risk assessment processes conducted by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the Scientific Committee on Occupational Exposure Limits (SCOEL).
- Industry stakeholders reported a lack of consultation on opinions under the Scientific Committee on Consumer Safety (SCCS). They claim that the SCCS allows little to no stakeholder participation in practice while in principle the committee procedure allows to call upon stakeholders to provide further scientific information as and when required, and the potential for public consultation is available.
- The working groups under EFSA that formulate the opinions for approval of active substances have been criticised by stakeholders for their lack of stakeholder input. The main mechanisms for such input are there but they are not considered to be sufficient. It has been suggested by one stakeholder that although the procedures for scientific opinions are appropriate, because the process is not always transparent, it is not entirely clear to either industry or civil society how a decision is made.
- Member State authorities have highlighted the lack of representation of Member States in the working groups on chemicals and particularly in the SCOEL. However, the SCOEL more generally has been put forward as providing a good level of stakeholder participation in their processes even though this is not outlined in their rules of procedure in contrast to the other committees. More generally, authorities have noted that participation of stakeholders (excluding Member States) is dependent on the committee concerned.

Respondents to the public consultation were asked to identify if they thought that all relevant chemical hazard and risk assessment/management considerations are taken into account, including combined effects of chemicals, impacts on vulnerable groups, impacts on jobs and competitiveness, etc. 'No' was the most common reply from all groups of stakeholders. Based on the detailed comments received, the main topics considered to be insufficiently taken into account are combination effects (all stakeholder groups), jobs, competitiveness and cost-benefit and socio-economic analysis (industry stakeholders) and new science and data (citizens, industry and NGOs).[303]

The recent OECD Regulatory Policy Outlook 2018 report[304] ranked the Commission as one of the top performers amongst OECD countries and institutions in terms of stakeholder engagement for both primary and secondary law and for impact assessment and ex-post evaluation. The OECD used a number of parameters that included oversight and quality control, public access to information on planned consultations, comment received by stakeholders during the consultation phase or replies to consultation comments.

[303] 1st FC Study, Annex V p. 102-108; public consultation Question 15

[304] https://www.oecd-ilibrary.org/docserver/9789264303072-en.pdf?expires=1540545486&id=id&accname=oid031827&checksum=9B7DDDF0A0B3253CC5F719B9DF7C6EB3

8.3 Evaluation question: to what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

Key principles and objectives of the EU's Better Regulation programme include ensuring that decision-making is open and transparent, that citizens and stakeholders can contribute throughout the policy and law-making process and that EU actions are based on evidence and on a clear understanding of the policy/regulatory impacts.

8.3.1 Transparency of procedures

A. What's the issue?

The ability of different stakeholders, including industry, NGOs, academics, experts and citizens to gain access to the data used for, and to be part of, the decision-making process especially during key stages of hazard and risk assessment/management processes is essential for the effective chemicals risk management.

B. What are the findings?

Conclusions

The general decision making process in the chemicals policy area has been continuously improved in line with the Commission's Better Regulation principles. Overall, the different stakeholders groups are satisfied with the ability to gain access to the hazard/risk assessment/management decision-making process although both industry and NGOs expressed a degree of frustration in some particular cases e.g. access to certain steps of the harmonised classification process and to the studies and data used as a basis for certain risk assessment/management decisions by the different risk assessment agencies and scientific committees.

Respondents to the public consultation were asked to indicate their level of satisfaction regarding the transparency of procedures (the overall EU legislative framework). Public authorities together with industry stakeholders were the most satisfied while NGOs and others, and citizens assigned lower scores indicating lower level of satisfaction.[305]

During one of the workshops, participants expressed the following views[306]:

- In general, the participants agreed that transparency has increased with, for example, the publication of meeting documents, draft opinions and opinions of committees etc. Nevertheless, this transparency may be more evident to those people who regularly deal with the assessment procedures (e.g. experts) than to those who do not (SMEs, downstream users, trade unions). As regards SME participation in the processes, the issue of language (many of the hazard/risk assessment processes are conducted soley or primarily in english) being a barrier to participation was raised, as was the issue of a

[305] 1st FC Study, Annex V p. 108-112; public consultation Question 16
[306] 1st FC Study workshop report p. 10-12

lack of resources, which is also relevant to NGOs and their ability to be represented in different fora.

- Overall, expert groups were perceived as a good model for ensuring transparency, because stakeholders can participate as observers or experts. There were some concerns about the transparency of scientific committee selection processes (e.g. decisions on nominations and potential conflicts of interest).

Regarding in particular the CLP related processes:

- All stakeholder groups (industry, NGOs, government authorities, other civil society representatives, etc.) consider the Harmonised Classification and Labelling (CLH) process[307] to be well understood.
- They also stated that the process in place up to the point when ECHA's Risk Assessment Committee (RAC) opinion (pre-regulatory phase) is issued is, in principle, transparent. However, the lack of communication between the companies providing data for the CLH dossier and the Member State authorities can result in a lack of clarity as to what information was taken into account during the decision making. This is exacerbated by the fact that the raw data/full studies underlying an opinion or CLH decision are not published.
- ECHA's efforts to further improve transparency on what stage a particular substance is at within the various regulatory processes have been well received by stakeholders.
- In contrast to the pre-regulatory and RAC processes, some stakeholders, notably industry, expressed concerns about transparency and stakeholder involvement during the risk management decision making phase i.e. after the risk assessment opinion has been issued by RAC. It should be noted, however, that this lack of transparency results, in part, from industry submitting other (e.g. socio-economic) information into the process and therefore, to some extent, unnecessery duplication of efforts.
- In addition, long time periods for arriving at the final risk management decision can lead to questions over the objectivity and predictability of the process from both industry and NGOs.

Despite considerable progress, transparency of risk analysis remains an important issue under the General Food Law (GFL)[308] as recognised in its 2018 ex-post evaluation[309]. In terms of perception as regards risk assessment in the context of authorisation dossiers, EFSA is bound by strict confidentiality rules and by the legal requirement to primarily base its assessment on industry studies, laid down in the GFL Regulation and in the multiple authorisation procedures in specific EU food legislation e.g. the Plastics Food Contact Materials Regulation. These elements lead civil society to perceive a certain lack of transparency and independence of EFSA with impacts on the trust in EFSA's scientific work by the general public. Risk communication has not always been effective with consequent impacts on consumers' trust and acceptance of risk management decisions.

[307] ECHA receives as a CLH proposal from a Member State and publishes the proposal (dossier) for public consultation. Consultation responses are then taken into account by the RAC when forming their opinion on the proposal. This opinion is then sent to the commission for decision making.
[308] EU 178/2002 General Food Law
[309] SWD(2018) 37 final

Member States also expressed some concerns related to the transparency of the processes under the Plant Protection Products Regulation. In particular, they noted that there can be a lack of communication between EFSA and the Member State Rapporteur when concluding on the harmonised classification of an active substance. In this regard, in April 2018 the Commission made a proposal which aims to improve the disclosure of data contained in the dossiers submitted by industry for active ingredient approval under the Plant Protection Products Regulation and ensuring the involvement of EFSA in pre-submission meetings[310].

8.3.2 Robustness of procedures

A. What's the issue?

The robustness of chemical risk assessment and decision making is dependent on the relevance and reliability of the underlying science and data. The necessary requirements, procedures, processes and capabilities need to be enshrined and applied within the framework of EU chemicals legislation to ensure decisions are based on relevant and reliable science and data.

B. What are the findings?

Conclusions

Numerous requirements, mechanisms and safeguards have been incorporated into the framework of EU chemicals legislation to ensure that risk management decisions are based on sound science and evidence. Their application is considered to be generally effective but more can be done to ensure all relevant evidence (e.g. peer-reviewed academic studies) is available for the assessment and decision-making processes.

The EU legal framework on chemicals is generally well designed to make science and evidence based decisions. In particular[311]:

- The Cosmetic, Detergents, Biocidal Products, Plant Protection Products and Fertilizers Regulations are considered to take adequate account of scientific and technical developments. No significant issues have been identified in terms of the existence of mechanisms to adapt these pieces of legislation to new developments.
- Cosmetic, detergents, biocidal and plant protection products legislation put in place appropriate assessments based on state of the art methods. Moreover, even though there is no legally binding frequency for undertaking a review of risk assessment requirements and other procedures under these pieces of legislation, mechanisms are in place for these purposes (through updating Annexes in the case of cosmetics and detergents or through updating Annexes, Implementing Regulations, or guidance documents used for the approval of active substances for biocides and pesticides).
- The overall approach of data generation under the CLP (consideration of all available data and possibility to use alternative methods to fill data gaps) is considered to be adequate and reducing the level of uncertainty.

[310] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1523604766591&uri=COM:2018:179:FIN
[311] 1st FC Study p. 74-75

- The Fertilizers Regulation (currently under revision) lacks specific data requirements and the risk assessment process is not deemed sufficient to ensure that risk assessment is based on the latest state of the art methods.
- The responsible agency and scientific bodies take into account the latest scientific finding for classification, risk assessment and risk management decision making purposes.

The robustness of these procedures has also led to progressive improvement of the state of knowledge and to closing knowledge gaps.

As explained in Section 5. Effectiveness (as well as in Annex 5 Section 5.2.1 C)) more can be done to ensure all relevant evidence (e.g. peer-reviewed academic studies) is available for the assessment and decision-making processes and that available data in key databases held by ECHA and EFSA is made available and re-used instead of requesting new, duplicative data to be generated.

9 EU VALUE ADDED

9.1.1 Evaluation question: what is the added value of regulating the risk management of chemicals at an EU level rather than at national level?

A. What's the issue?

The principle of subsidiarity requires that legislating at the EU level should occur only when and where there is evident added-value of doing so, i.e. where necessary and more effective. This section looks at whether there is added value in regulating chemicals at the EU level as opposed to solely at the national level and, if there is one, what this added value is.

B. What are the findings?

Conclusions

The harmonisation of chemicals legislation at the EU level has proved important and largely successful in terms of the protection of human health and the environment as well as the functioning of the internal market. The sharing of knowledge and resources and the application of common rules and standards across the EU has resulted in significant positive economic, health and environmental impacts that would not have been possible to achieve on the basis of legislation at the Member State level alone. The EU chemicals legislation is also the reference point for international standards in several areas which helps to reduce potential trade frictions as well as address transboundary chemicals related issues.

In line with the subsidiarity and proportionality principles, the approach of the EU chemicals legislation guarantees that decisions are taken as closely as possible to the citizen and where necessary and more effective, at the EU level. The core pieces of chemicals legislation such as the CLP, the Plant Protection and Biocidal Products Regulations collectively provide for a harmonised framework (based on article 114 of the TFEU). Some other pieces of legislation in the chemicals legal framework, e.g. the waste legislation and other pieces of environmental legislation (based on Article 192 of the TFEU) and the occupational safety and health (OSH) legislation (Article 153 TFEU) establish a system of basic principles, rules and requirements which must be transposed into national law while leaving room for Member States to be more

stringent or go further in their implementation. These pieces of legislation typically include objectives such as the protection of human health and the environment, often with some further specifications of what aspects of environment and natural resources are of particular importance.

Risks to human health and the environment stemming from exposure to hazardous chemicals are similar across the EU. Harmonised rules, procedures, requirements, definitions, criteria etc. allow for a comprehensive risk assessment of exposure to hazardous chemicals. This approach helps ensure an equal level of protection of human health and the environment across the EU while also taking account of variations in local conditions. It also helps ensure that the same amount of information about chemical risks and hazards is made available to public authorities, citizens, consumers, chemicals industry and downstream users across the EU.

Regulating the risk management of chemicals at the EU level also increases efficiency. Hazard and risk assessment processes often require a high level of scientific expertise and therefore can imply high costs for public authorities, especially in smaller Member States. By harmonising and coordinating the hazard and risk assessment processes at the EU level (combined with the principle of reversed burden of proof and self-classification or self assessment of conformity by industry), the EU chemicals legislation helps avoid duplication of effort between Member States. This results in cost savings for public authorities as workload and expertise are shared and it reduces the administrative burden and complexity for the companies that operate in many different Member States. It also contributes to improving the state of knowledge, quality and availability of data needed for risk management decision making.

A system that guarantees the safety of products placed on the EU market and often produced via complex and global value chains is needed in order to protect consumers' interests and to secure their trust both in European companies and those who produce outside the EU. Such a system is established by the EU chemicals legislation. The Eurobarometer survey[312] showed that EU citizens consider products manufactured in the EU to contain safer chemicals than those imported from outside the EU. This indicates a higher level of confidence in the EU regulatory framework for manufactured products compared to regulatory regimes abroad. The EU chemicals legislation is, potentially, a driver of innovation although currently available evidence does not allow a clear conclusion to be drawn about whether or not the legislation is fostering innovation and substitution.

EU chemicals legislation has become a benchmark for development of chemical risk management rules, both at the international level as well as in other countries and regions. European companies also benefit from perception of quality of EU products in non-EU country markets which has brought important advantages in terms of international trade.

The EU chemicals legislation has also helped to decrease the barriers to, and costs, of intra-EU trade by limiting the application of multiple and potentially diverging national rules with limited territorial coverage and existing only in the applicable national language(s).[313]

[312] Special Eurobarometer 456

[313] Different stakeholders (industry and NGOs and consumer organisations), as well as Member States and the European Parliament have identified food contact materials non regulated at the EU level as one of the areas

Regulating the risk management of chemicals at an EU level also plays a role in preventing unfair competition between Member States e.g. based on low standards for working conditions.

Stakeholders (industry, NGOs) as well as national authorities were of an opinion that the harmonised community-wide approach in the chemicals legal framework is paramount to achievement of its core policy objectives and that there is clearly an added value in taking action at the EU level versus a situation with 28 different sets of chemicals legislation and standards at Member State level. This includes the facilitation of sharing of knowledge, data, expertise and methodology as well as pooling of resources between Member States, EU institutions and other stakeholders.

The transparency of the process and equal, reciprocal access to information and the quality of information have improved considerably through the implementation of the current legislation, as also highlighted by different stakeholders.

10 CONCLUSIONS

The different pieces of chemicals-related EU legislation adopted since late 1960s have, over time, effectively become a legal framework. All of them have been amended, updated or replaced at least once. Many of the Directives have also been repealed, codified or have become Regulations (see Annex 4 Table 2). Yet, how all these pieces work together has never been assessed. This Fitness Check is the first evaluation of most of this complex and extensive legal framework. It is important to note, however, that the REACH Regulation as well as the pharmaceutical and veterinary products legislation are outside the scope of the Fitness Check. This presented a number of challenges, particularly in terms of disentangling costs and benefits estimates where REACH is often an integral part of the policy mix that is responsible for the costs and benefits of exposure reductions.

The framework's fitness for purpose was assessed against the core policy objectives of ensuring a high level of protection of human health and the environment, ensuring a well-functioning internal market and enhancing EU business' competitiveness and innovation in an effective, efficient and coherent manner. The focus was primarily on the chemical hazard assessment, risk assessment and risk management decision processes. The Fitness Check also paid attention to the framework's relevance and capability to respond to stakeholder concerns and future challenges such as the transition towards a more circular economy.

The Fitness Check takes into consideration the findings presented in the related 'Interface' Communication.[314] Together with the findings of the REACH Evaluation[315], it helps to provide a complete picture in term of taking stock of the current EU's chemicals legislation.

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where more harmonised approach would bring additional benefits. Safety requirements for furniture is another example of area where more harmonised approach could bring additional benefits, as identified by stakeholders (environmental NGOs, industry, cancer organisations, fire fighters and labour unions).

[314] Communication on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation; COM(2018) 32 final; SWD(2018) 20 final

[315] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions; 5 March 2018; COM(2018) 116 final and SWD(2018) 58 final

Furthermore, a number of ongoing legislation-specific evaluations (see Annex 4 Table 4) will complement the findings of this Fitness Check, especially regarding the state of play, implementation and enforcement of the legislation as well as costs and benefits generated. All these different evaluations will help ensure that future improvements and refinements made in these policy areas are well-founded, coherent and well-focused.

A comprehensive and generally well-functioning framework

The Fitness Check evaluation found that, overall, the EU framework of chemicals legislation is fit for purpose in terms of meeting the core policy objectives of ensuring a high level of protection of human health and the environment, ensuring the efficient functioning of the internal market while enhancing competitiveness and innovation. These core policy objectives remain highly relevant as well as the framework's basic components and its current approach. The added value of policy action at the EU level is high.

Although a range of on-going and emerging health and environmental concerns related to the exposure to hazardous chemicals remain (see Section 5.1.1), the EU chemicals legislation has clearly led to significant benefits in terms of reduced and avoided negative health and environmental impacts for regulated hazardous substances and in terms of the efficient functioning of the internal market (see Section 6.1.2). Where these benefits can be reliably monetised, the outcomes are often significant. For example, the benefits of reduced poisoning incidents, occupational skin and respiratory diseases and occupational cancers amount to an estimated EUR 217 – 338 million per year. As another example, the better control and management of plant protection products have resulted in reduced negative impacts on ecosystem, including pollination services and have thus generated estimated benefits of EUR 15 – 50 billion per year. In addition, estimated benefits of EUR 500 million per year result from avoided costs of removing pesticides from drinking water supplies (see Section 6.1.2 Table 4 Selected monetised environmental and health benefits of reduced hazardous chemical exposures. The level of harmonisation achieved across the EU has played a significant role. In addition, the EU is considered as a frontrunner in terms of chemicals innovation. The EU remains the largest chemicals exporting market in the world and is internationally competitive.

Key benefit drivers include avoided healthcare costs, avoided productivity losses (due to avoided lost working hours as a result of illness or premature death), avoided suffering and premature deaths, avoided remediation costs (including wastewater and drinking water treatment costs) and avoided degradation of environmental/eco-system services.

The EU chemicals legislation has decreased the barriers to, and costs, of intra-EU trade by limiting the application of potentially diverging national rules with limited territorial coverage and existing only in the applicable national language(s). The EU chemicals legislation is also the reference point for international standards in several areas, which helps to reduce potential trade frictions as well as address transboundary chemicals related issues.

Generic and specific risk management approaches both have their role to play within the framework of EU chemicals legislation. Regarding the balance between the two, the preferences of different stakeholder groups vary considerably, with industry having a tendency to prefer a more extensive use of the specific approach, NGOs tending to have a higher preference for the generic approach, and many Member States expressing satisfaction

with the current balance. There is room for improvement in the application of both approaches, particularly in terms of:

- speeding up the identification and risk assessment of hazardous chemicals; and
- ensuring the concerns of, impacts on and implications for different stakeholder groups are properly identified and taken into consideration in order to avoid any disproportionate or unintended consequences.

Achieving the core objectives of the EU chemicals legislation is predicated on sound scientific knowledge and robust and comprehensive data that is reliable, comparable and reproducible. Within the EU, the quality and the availability of data needed to perform a risk assessment and to manage risks has improved considerably. The EU's knowledge base on chemical hazards and risk is now an important asset. Much of this improvement in data reflects the shift of responsibility from EU and Member State authorities to industry for generating the necessary data for hazard and risk assessment. It has, therefore, been primarily resourced and underpinned by industry assuming the responsibility of ensuring the safe use of chemicals placed on the market. The significant investment in the establishment of independent regulatory EU chemicals agencies (EFSA, ECHA, EMA) and specific scientific committees has also been instrumental in the improvement of data quality and its availability as well as to provide expertise and support to the EU decision making process.

The CLP Regulation was identified as one of the most efficient aspects of the functioning of the EU chemicals legislative framework, as it allows hazard classification of a wide range of chemicals without creating a disproportionate administrative burden for public authorities while focusing their resources on the most relevant substances for human health and environmental protection. The clear separation of hazard assessment and hazard classification from the risk assessment and risk management decision making steps is an important cornerstone of the framework's effectiveness and should be safeguarded. The CLP Regulation ensures the coherence of hazard assessment and classification at the EU level with what is done at the international level (through the UN Globally Harmonised System (GHS)).

The scope and stringency of the hazard and risk assessment processes stipulated within the EU chemicals legislation are tailored to different needs under different pieces of legislation. After more than 50 years of continuous efforts and improvements, the linkages between the different pieces of EU chemicals legislation are now generally well established and functioning reasonably well. The level of transparency and stakeholder involvement built into the various hazard and risk assessment/management processes has improved over time and is considered by the majority of stakeholders to be good.

Burden reduction and simplification

The overall regulatory costs of the EU chemicals legislation for EU industry are estimated to be approximately several billion euros per year (see Section 6.1.1).

Depending on the piece of legislation, the main cost drivers for industry are data generation (hazards, chemical uses, exposures, etc.), staff training, biomonitoring of workers and monitoring of operational conditions, and control costs. For public authorities the main costs are generated by enforcement and monitoring activities.

While it was not possible to establish an overall quantified cost-benefit ratio for the framework of EU chemicals legislation and thus conclude on their proportionality, the

evidence clearly indicates that both the costs and the benefits generated by the EU chemicals legislation are significant. The Fitness Check, however, identified a number of opportunities for burden reduction and simplification, both for companies and for Member State authorities, the most significant of these being as follows:

- Small and Medium Sized Enterprises (SMEs): SMEs are more affected than bigger companies by certain aspects of the EU chemicals legislation such as understanding and compliance with often interlinked legal obligations or opportunities to actively take part in decision making processes. Increased involvement of these stakeholders in the decision making processes can be improved and will help ensure that all interests at stake are properly taken into consideration. This will also improve their understanding of their legal obligations and thus provide for a predictable, fair and trusted environment that continues to ensure a high level of protection of human health and the environment and a well-functioning internal market.
- Data sharing: the availability and quality of data have improved and are generally good. However, some difficulties in data sharing across legal clusters are still encountered. This affects mainly industry that needs to generate data for regulatory purposes. These difficulties occur for a variety of reasons, including general data confidentiality rules and intellectual property rights but also because of the lack of a centralised access point or the lack of awareness of what exists in the different databases. It leads to a certain duplication of effort where the nature of assessment made is similar. This can generate extra costs, as well as longer-than-necessary timeframes and lead to duplication of testing. A comprehensive mapping of the existing information and an assessment of how to optimise the use of the available information are needed.
- Hazard communication to consumers: not all the opportunities to improve and simplify the communication of chemical hazards and safety information towards consumers have been seized e.g. the opportunities offered by digital technologies such as Q-R codes have not yet been assessed. The communication of hazards to consumers via pictograms and labels can also be improved e.g. labels overloaded with information and difficult to read with some duplication of certain information due to overlaps in legal requirements or because of the need to include hazard statements in all EU languages.
- Predominant substance-by-substance approach to risk assessment and management: using grouping approaches to identify and risk assess groups of chemicals with similar hazard and risk profiles as means of speeding up the risk management decision process and avoiding regrettable substitutions (that can be costly both to industry and to the society in general in terms of health and environmental impacts) warrants further attention.
- Risk of duplication of efforts by different EU agencies and scientific committees: these bodies provide the Commission with scientific advice and hazard/risk assessments. There are opportunities for simplifying their current setup and streamlining their activities thus making the functioning of the framework more efficient (i.e. avoiding duplication of efforts) and more reliable (i.e. reducing the risk of potentially diverging outcomes of hazard/risk assessments).
- Lack of clarity with respect to how to apply the CLP bridging principles method for the classification of mixtures: the clarification on how to apply these principles to

mixtures will improve the effectiveness of this method. It will also avoid discrepancies in interpretation and acceptance of hazard classification by Member States. Actions taken so far by the Commission to address this issue, including guidance on the harmonised application of the legal requirements, need to be pursued.

Needs for improvement

Even though the objectives of legislation within the scope of this Fitness Check are not always the same, the legal acts are generally coherent in how they attempt to reach the stated objectives, as illustrated by the use of similar underpinning legal mechanisms to do so. One of the mechanisms used is the reverse burden of proof by industry complemented by the use of self-assessment of conformity.[316] Where the outcome of the risk assessment is to be checked by a public authority thus determining whether, for example, a product can be used or placed on the market or an activity can be pursued, the quality of risk assessments done tends to be good. For the pieces of legislation where the underpinning mechanism relies on the presumption of compliance with the existing rules, information from enforcement activities carried out is scarce and therefore does not allow to conclude on the quality of the self-assesment of conformity carried out.

The current state of knowledge regarding exposure to hazardous chemicals needs to be further improved. Because industry and public authorities may be unaware of many uses of hazardous chemicals and there is only limited information available about the overall volumes of hazardous chemicals emitted/released into the environment, their capacity to develop realistic, acceptable and robust exposure scenarios can be hampered. Exposures to hazardous chemicals are known to or are strongly suspected of play a role in impacts on human health and the environment e.g. cancers, reproductive diseases, respiratory sensitisation, declines in insect and bird populations and water and soil pollution. In this regard, a number of on-going exposure situations to hazardous chemicals warrant further attention (e.g. endocrine disrupting chemicals and hazardous chemical exposures of the aquatic and terrestrial compartments). However, there are still uncertainties regarding the extent to which the negative trends can be attributed to exposure to hazardous chemicals rather than to other factors such as lifestyle. This hampers the legislator's capability to provide with certainty the most appropriate answers. This also renders the practical application of the precautionary principle in the area of chemicals risk assessment and management particularly challenging for the decision makers.

Although the precautionary principle is explicitly taken into account in the design of various pieces of chemicals legislation, to date, it has actually been applied in very few instances under the various pieces of EU chemicals legislation. The appropriate use of the precautionary principle is an important element in helping to ensure on the one hand the protection of human health and the environment and the avoidance of potential costly future impacts and

[316] Reverse burden of proof means that industry is responsible for ensuring the safe use of their chemicals and therefore carrying out the risk assessment and ensuring the risk management of their chemicals, including testing. Public authorities are responsible for checking if this obligation is properly implemented and, where not, to quickly and efficiently propose measures to manage risks. Self-assessment of conformity means that an economic operator declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them in which case the economic operator benefits from a presumption of conformity.

remediation, and on the other hand the avoidance of disproportionate or unnecessary risk management costs. The EU efforts in collecting human health exposure data need to be pursued. More data on hazardous chemical uses and their fate need to be collected. So far the Commission has funded the European Human Biomonitoring Initiative (HBM4EU). However, a similar initiative for animals, plants and eco-systems is currently lacking although the Commission's development of the Information Platform for Chemical Monitoring (IPCHEM)[317] can contribute to addressing this gap.

Several other important areas for future improvement or which warrant further assessment include:

- Better understanding of the impacts of hazardous chemicals on the environment, biodiversity and eco-system resilience. This includes the assessment of the benefits of introducing additional hazard classes in the CLP Regulation (e.g. persistent, bio-accumulative, toxic and very persistent and very bio-accumulative substances and terrestrial toxicity, endocrine disruptors).
- Better understanding and management of the potential human health and environmental risks associated with exposures to substances in articles (e.g. consumer products). The issue of substances in articles is particularly important as the EU is in the process of shifting towards a more circular economy. This implies the need for better traceability of substances of concern in articles (and communication of this to consumers and end-users), since such a shift will involve considerable changes in the way materials and articles are produced, used and disposed of. This warrants consideration of how to manage the health and environmental risks associated with the hazardous substances that pass through several cycles of production, use, and recycling.
- Addressing combination effects of different hazardous chemicals as well as the combined exposure via different routes.
- Improving consistency in identifying and managing the risks posed by allergens.
- Ensuring consistency and intensity of actions to protect vulnerable population groups, including those that are particularly sensitive to endocrine disruptors, such as prenatal and young infants, adolescents, etc.
- Gathering more evidence regarding neurotoxicity, immunotoxicity and respiratory sensitization to determine the extent and significance of potential weaknesses in the risk assessment of substances with these properties.
- Addressing the inconsistencies that occur regarding risk management decisions for endocrine disruptors, persistent, bio-accumulative, toxic and very persistent and very bio-accumulative substances and substances fulfilling the classification criteria for specific target organ toxicity. In some but not all pieces of legislation, they are subject to risk management measures based on generic risk considerations.
- Addressing risks posed by endocrine disruptors. The need for a coherent approach to the identification of endocrine disruptors across all relevant Union legislation

[317] https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

approach, based on the broadly accepted definition of the World Health Organisation is a key element of the recently adopted EU strategy on endocrine disruptors.[318]

- Boosting substitution of the most hazardous chemicals with less hazardous chemicals or non-chemical solutions where alternative substances or technologies are more sustainable and economically and technically viable. Efforts of supporting and encouraging research and innovation to catalyse the shift towards more sustainable chemicals need to be accelerated and pursued.
- Improving the reliability and consistency of the industry self-classifications of chemical hazards under the CLP Regulation. The current concerns need to be further investigated as these affect the value of the Classification and Labelling Inventory as a hazard communication tool.

[318] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee and the Committee of the Regions 'Towards a comprehensive European Union Framework on endocrine disruptors' COM(2018) 734 final

11 LIST OF ANNEXES

Annex 1 Procedural information

Annex 2 Synopsis report: stakeholder consultation activities

Annex 3 Methods and analytical models

Annex 4 Information regarding the legal scope of the Fitness Check, its supporting studies and other relevant sources of information

Annex 5 Effectiveness

Annex 6 Efficiency

Annex 7 Coherence of hazard/risk assessment and risk management procedures (CMRs, PBTs/vPvBs, EDs)

Annex 8 EU Approaches to Chemicals Risk Management: updated

Annex 9 Glossary

Annex 10 Evaluation questions

Annex 11 Overview of costs – benefits identified in the Fitness Check

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PART 2/3

COMMISSION STAFF WORKING DOCUMENT

FITNESS CHECK
of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses

{COM(2019) 264 final}

1 Annex 1 Procedural information

1.1 Lead DGs and internal references

The "Fitness Check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries" (FC Chemicals) was co-led by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs. The chemicals legislation covered by this exercise was identified in 2013[1] and 2014[2] as one of the policy areas, in which further efforts at the EU level can be made to facilitate the implementation of legislation and where after conducting a regulatory Fitness Check, rules can be simplified and burdens reduced. It was included as item 2015/GROW+/050 in the Agenda Planning (AP) and as Commission's REFIT Initiative in the Commission Work Programme of 2015[3] (item 52).

This initiative is linked to other actions related to chemicals legislations such as the REACH REFIT Evaluation[4] and the Circular Economy Action Plan[5] (including the EU Strategy on Plastics[6] and the work on the chemicals, waste and product Interface[7]).

1.2 Organisation and timing

An Inter-service Group to steer and provide input for the FC chemicals report was set up in March 2015 with representatives from the Directorate Generals for Environment (ENV); Internal Market, Industry, Entrepreneurship and SMEs (GROWTH); Health and Food Safety (SANTE); Employment, Social Affaires and Inclusion (EMPL), Mobility and Transports (MOVE), Justice and Consumers (JUST), TRADE, Joint Research Centre (JRC-Ispra) and the Secretariat General (SG).

The group met 14 times during the evaluation process (Table 1).

DATE	TOPICS OF DISCUSSION

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Regulatory fitness and Performance (REFIT): Results and Next Steps' COM(2013) 685 final, 2 October 2013

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Regulatory fitness and Performance (REFIT): State of Play and Outlook', COM(2014) 368,18 June 2014

[3] Annex III of COM(2014) 910 final

[4] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions; 5 March 2018; COM(2018) 116 final and SWD(2018) 58 final

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Closing the loop – An EU action plan for the Circular Economy', COM/2015/0614 final, 2 December 2015

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'A European Strategy for Plastics in a Circular Economy', COM/2018/028 final, 16 January 2018

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions, 'Options to address the interface between chemical, product and waste legislation', COM(2018)32 final, 16 January 2018

10 March 2015	Introductory meeting
15 July 2015	1st FC Study: kick-off meeting
23 October 2015	1st FC Study: Inception Report meeting
11 April 2016	1st FC Study: 1st Interim Report meeting
6 September 2016	1st FC Study: 2nd Interim Report meeting
13 October 2016	FC+ Study: kick-off meeting
28 October 2016	1st FC Study: Final report
16 November 2016	FC+ Study: Inception Report meeting
1st March 2017	FC+ Study: Interim Report meeting
28 September 2017	ISG meeting: Progress Update
31 May 2018	ISG meeting: 1st draft discussion (Sections 1-4, 5.5 EU Added Value, Annexes)
8 June 2018	ISG meeting: 1st draft discussion (Sections 5.1 Effectiveness and 5.2 Efficiency)
19 June 2018	ISG meeting: 1st draft discussion (Sections 5.3 Coherence and 5.4 Relevance)
29 June 2018	ISG meeting: Final draft discussions

Table 1 ISG meeting dates and topics of discussion

1.3 Exceptions to the better regulation guidelines

No exceptions were made to the Better Regulation Guidelines[8] during this Fitness Check.

1.4 Consultation of the Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present Fitness Check and issued its positive opinion on 14 September 2018. The Board made several recommendations to further improve the report. Those were addressed in the revised report as follows:

RSB recommendations	Modification of the report
(B) Main considerations The Board finds the fitness check to be thorough, robust and well organised. The Board gives a positive opinion, but considers that the report could be further improved with respect to the following key aspects:	
(1) The report does not sufficiently investigate stakeholder concerns.	This recommendation has been addressed by adding relevant stakeholder views, by complementing Annex 2 Synopsis Report, by including additional references to studies in Annex 4.
(2) The report does not draw evidence-based conclusions on which issues to prioritise for	'Main Conclusions' section has been revised. Cross-references to the relevant assessment

[8] https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

follow-up.	sections have been included. The conclusion boxes and 'Main Conclusions' have been aligned. Clarifications and additional elements of information (e.g. the scope of the Fitness Check and of its supporting studies, how the study findings were used, baseline and points of reference) also allow to better understand what is the evidence for the assessment and thus for drawing conclusions.
(3) The report does not sufficiently examine the potential for simplification and burden reduction.	How this recommendation has been taken into account is reflected in 'Main Conclusions' section and in the conclusion boxes where great care was taken to clearly identify areas with potential for simplification and burden reduction.
(C) Further considerations and recommendations	
The report should provide more granular and systematic reporting of the stakeholder consultations. It should dig more deeply into areas of stakeholder concern, try to corroborate with other evidence, and express a considered view on the magnitude of the problems. The synopsis report should provide a more detailed analysis of the consultations of all stakeholders, including points raised in position papers.	This recommendation has been addressed by adding relevant stakeholder views in sections 5.2.1, 5.2.3, 5.2.4, 6.1.1, 6.1.2, 6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5, 7, 8.2.1, 8.3.1. Additional information was included in the Synopsis Report (Annex 2). Annex 4 Table 3 clarifies where the findings and stakeholder opinions presented in each sub-section come from.
The report should more transparently explain how it has made use of the background studies, and built on their conclusions. It should also clarify the departures from the studies' conclusions and stakeholders' views.	This recommendation has been addressed by including additional information in section 4.1.1. A new section 4.1.3 was introduced to clarify how the studies' findings and stakeholder views were used for the purposes of this Fitness Check. In addition, Annex 4 was amended. The table 'Legislation within the scope of the Fitness Check' comprises additional columns to clarify which study cover which piece of legislation. Three tables were added (time period, legal scope and coverage by studies; where the FC findings come from; related individual evaluations).
There are some discrepancies between the final conclusions and those in the main body	The conclusion boxes and 'Main Conclusions' Section have been aligned.

of the report. It is difficult to tell what is most important. In its conclusions, the report should more systematically identify and prioritise areas for policymaker attention based on relevance and magnitude of the issues at stake, the available evidence, and on responding to stakeholders.	'Main Conclusions' section has been revised.
The fitness check is a REFIT initiative, yet the report is largely silent on the scope for simplification and burden reduction. The report should elaborate on the potential to simplify or reduce burdens, for example on SMEs. It should consider whether current outcomes could be achieved at a lower cost, e.g. by streamlining reporting requirements.	In the main document, additional clarification elements have been added. The revision of the 'Main Conclusions' section provide more clarity on these aspects.
The report should clarify what it uses as benchmarks or a baseline. The fitness check relies on different studies, each with their specific focus and timeline, and the report could better explain when comparisons draw on different sources. This would provide a more accurate picture on how the EU chemicals acquis has delivered on overarching objectives of high level of protection of human health and environment, while supporting the functioning of and competitiveness in the internal market.	This recommendation has been addressed by clarifying section 2.3 Baseline, as well as by the information and clarifications of Section 4 and in Annex 4.
The scope of the fitness check could be clearer. Given the interlinkage of chemicals legislation, the report should better clarify the rationale for excluding some legislation from its scope. On this basis, the report should avoid referring to legislation outside the scope when explaining the effectiveness and efficiency of the EU chemicals acquis.	This recommendation has been addressed by including additional elements of explanation in Section 2.1.3 Scope of the Fitness Check.

1.5 Evidence, sources and quality

The analysis underpinning this FC was undertaken via several thematic studies commissioned by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs (see Annex 3 explaining the methodology applied):

- The 1st FC Study[9] was completed in January 2017. It includes an evaluation of the CLP Regulation and the interplay between the CLP and related legislation, in particular, other legislation governing hazard identification, classification and communication ('horizontal links') and downstream legislation that establishes risk management measures directly or indirectly triggered by a CLP hazard class ('vertical links').
- In 2014, the Commission launched a study analysing cumulative costs of the most relevant EU legislation for the EU chemical industry. It was completed in July 2016.[10]
- The FC+ Study[11] was completed in November 2017. It complements the 1st FC Study by reviewing those pieces of legislation that operate independently of CLP for hazard identification and classification, and furthermore where specific risk assessment procedures form the core part of the risk management process.
- The CuBA Study[12] draws together a large body of evidence on the risks posed by chemicals and on the effects of chemicals legislation. It was completed in August 2017.

Stakeholder consultation and targeted data collection were also an important element of the FC Chemicals exercise (see Annex 2).

[9] Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation. The evaluation report is available online http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/. Annex I-V is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/. Annex VI is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/.

[10] The study is available here http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/

[11] Study supporting the Fitness Check on the most relevant chemicals legislation. The study is available here https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en.

[12] Study on the cumulative health and environmental benefits of chemical legislation. The study is available here https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

2 Annex 2 Synopsis report: stakeholder consultation activities

2.1 Consultation activities - introduction and approach

Stakeholder consultation was a key component of this Fitness Check to identify the most relevant issues, to collect data in response to the evaluation questions (outlined in the Fitness Check roadmap[13]) and to ensure a balanced and comprehensive assessment of the legislative framework. All the information thus gathered contributed helped to describing and possibly quantify the issues raised all along this document.

The objectives of the consultation activities were to:

- Identify inconsistencies, overlaps, regulatory gaps, obsolete measures and cases of excessive regulatory burdens.
- Collect information and evidence related to effectiveness, efficiency and relevance of the provisions and mechanisms of the chemicals legislation.
- Identify consequences or effects (whether socio-economic, environmental or health-related) of the legislation that were not originally planned.
- Collect relevant information on the implementation of the chemical-related provisions of the legislation.
- Collect qualitative and (wherever possible) quantitative data on costs and benefits of the implementation of chemicals legislation.
- Identify provisions and mechanisms that work well and the added value of EU regulation in this area.
- Collect information in order to support the evaluation of whether procedures are sufficiently transparent and take into account the needs of both citizens and other stakeholders.

The consultation strategy developed for the purpose of this Fitness Check[14] comprised:

- an open public consultation (from 4 March to 27 May 2016);
- an SME panel through the Enterprise Europe Network (from 30 May to 18 July 2016),
- consultation as part of case study work;
- targeted consultation of different stakeholder groups to gain some of the additional evidence needed for the evaluation (and which was not covered by a case study or was at too detailed a level for the Open Public Consultation;
- A stakeholder workshop conducted in April 2016 as a part of the 1st FC Study, a stakeholder workshop conducted in May 2017 as part of te 2nd FC Study, A stakeholder workshop conducted in January 2017 as a part of the CuBA Study, and two stakeholder validation workshops conducted during 2015 as a part of the CCA1 Study; and
- 2 Eurobarometer surveys (Special Eurobarometer 456[15] November-December 2016 and Special Eurobarometer 468[16] September-November 2017).

[13] http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf

[14] Consultation strategy for the Fitness Check on chemicals legislation (excluding REACH) http://ec.europa.eu/DocsRoom/documents/17109/attachments/1/translations

[15] https://data.europa.eu/euodp/data/dataset/S2111_86_3_456_ENG

[16] https://data.europa.eu/euodp/data/dataset/S2156_88_1_468_ENG

The open public consultation was conducted in English, German and French. The SME panel and the Eurobarometer surveys were conducted in all EU languages. Information on the results of open public consultation, SME panel and workshops were made available on both DG GROW[17] and DG ENV[18] websites.

Further details regarding the targeted data collection, including the SME Panel consultation and the Eurobarometer surveys, is provided under Section 5 below and in Annex V of the 1st FC Study report. Findings from the targeted data collection are reported on in Annexes II to IV, as part of the evaluations carried out for these tasks. It should also be noted that the findings from these consultations form an important part of the evidence base used in developing the conclusions presented in the main evaluation report of the 1st FC Study.

2.2 Stakeholder groups covered by the consultation activities

In line with the consultation strategy, input from a wide range of stakeholders was collected:

- Public authorities, notably competent authorities responsible for the implementation and enforcement activities
- Industry associations covering both the chemicals industry and downstream sectors (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators)
- Companies in both the chemicals industry and downstream sectors, focusing in particular on Small and Medium-sized Enterprises (SMEs) (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators)
- Civil society organisations – NGOs (e.g. environmental, health, animal welfare)
- Consumer associations
- Trade unions
- Other interested groups such as academics / research institutes
- Consumers / workers /citizens.

Table 2 demonstrates how each of the tools mentioned above was used to collect information from different categories of stakeholders.

	Public authorities	Industry associations	Companies / SMEs	NGOs	Consumer associations	Trade unions	Academia / research institutes	Consumers / workers / citizens
Public consultation	√	√	√	√	√	√	√	√
SME panel			√					
Targeted interviews	√	√	√	√	√	√	√	
Stakeholder workshop	√	√		√	√	√	√	
Expert group	√							
Eurobarometer								√

[17] http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm

[18] http://ec.europa.eu/environment/chemicals/better_regulation/index_en.htm

Table 2 Different stakeholder groups consulted

These different consultation activities and tools allowed receiving feedback from all stakeholder groups. A summary of these views is provided below.

2.3 Outcome of the consultation activities

2.3.1 Summary of Stakeholder views on the five evaluation criteria

A. Effectiveness

The EU chemicals legislation is considered to be moderately effective in reaching its goal of protecting human health (all stakeholder groups). Regarding its goal of protection environment, citizens and industry associations and companies considered it to be mostly effective while public authorities considered it to be moderately effective. Civil society considered it to be slightly effective.

The EU chemicals legislation was considered by citizens, industry and companies and public authorities as mostly effective in ensuring a well-functioning internal market while civil society considered it to be moderately effective. Regarding this particular aspect, SME Panel Results showed that the EU chemicals legislation is considered to be sufficiently harmonised across Member States for the proper functioning of the European single market while there were some negative opinions on the extent to which EU chemicals legislation is consistently enforced by Member States.

While citizens, industry and companies and civil society considered the legislation moderately effective in stimulating competitiveness and innovation, public authorities were of an opinion that it is mostly effective in reaching this objective.

The main reason for lower effectiveness was that legislation is not adapted at issues at stake (human health and environment (citizens, industry and companies, public authorities), internal market (civil society), competitiveness and innovation (citizens, industry and companies) and/or that legislation is not effectively implemented (human health and environment (public authorities and civil society), competitiveness and innovation (civil society).

B. Efficiency

All stakeholder groups identified costs due to the EU chemicals legislation as the most significant for SMEs while industry association and companies pointed out that bigger companies also face significant costs. Public authorities and civil society recognised the significance of costs for public authorities at both national and EU level. The main benefits generated by the EU chemicals legislation are reducing the damage to the environment and to eco-systems (citizens) and reducing the exposure to toxic chemicals of consumers, citizens and workers (industry and companies, public authorities and civil society).

C. Coherence

Industry association and companies as well as civil society representatives during the open public consultation were of an opinion that the EU chemicals legislation framework is internally inconsistent. Citizens and public authorities remained neutral (neither agreed nor disagreed) while 1/3 of public authorities also considered the EU chemicals legislation to be internally inconsistent. All stakeholders also agreed that the EU chemicals legislation contains gaps, missing links and has overlaps (except civil society on the latter). A more in-depth

analysis based on further comments and position papers received shows however that although such issues were indeed identified, they most often affect specific aspects of functioning of some pieces of legislation within the scope of this Fitness Check while not necessarily being relevant to the functioning of the whole framework. Therefore, the opinion that the EU chemicals legislation is internally inconsistent needs to be nuanced and used with caution given also that the share of opinions neither agreeing nor disagreeing was significant. Moreover, these views are also contrasted by generally positive opinion of SMEs (SME Panel) on the overall internal coherence of the EU chemicals legislation.

D. Relevance

Stakeholders from all groups considered that not all relevant considerations are taken into account in regulatory decision-making on risk management. Regarding the way the EU legislative framework addresses emerging areas of concern, opinions varied: slightly (civil society), moderately (citizens and public authorities) and mostly (industry associations and companies) sufficiently.

E. EU Added value

Industry and companies, public authorities and civil society considered the EU chemicals legislation to have a high level of added value while citizens considered the added value to be moderate.

2.4 Open public consultation

The objective of the 12 weeks open public consultation[19] was to obtain stakeholder views on the functioning of the legislative framework for chemicals[20]. The questionnaire available in English, German and French, had five parts (35 questions). Respondents also had the opportunity to submit any additional comments and upload position papers[21].

[19] from 4 March to 27 May 2016

[20] Its results were analysed by the contractors as part of the 1st FC Study commissioned by the European Commission (DG Internal Market, Industry, Entrepreneurship and SMEs) and led by Risk & Policy Analysts Ltd. (RPA).

[21] Analysis of responses to the closed questions has been undertaken using Excel. The number and percentage of responses is broken down by group, allowing a comparison of the views of the four groups. Analysis of the open-text responses involved reviewing each comment, identifying the key points that are being made, recording these key points as 'themes' and then comparing other comments to see if they make the same point. Due to the number of open-text responses received, it was necessary to start by taking a sample of the responses when applying this approach. . In addition, the manual analysis of the open text responses to the OPC for each group was supported by automated analysis using NVivo software to ensure that all comments have been taken into account. In addition to these formal analyses for the purposes of reporting on the OPC, the study team searched responses using a series of different key words to pull out responses to feed into the Task 1 to 3 evaluation work.

2.4.1 Participants to the public consultation

The Commission received 356 valid responses. This included 57 responses (16%) from citizens, 93 responses (27%) from companies, 103 responses (29%) from industry associations, 46 responses (13%) from public authorities, 37 responses (10%) from NGOs, consumer associations, trade unions and academia and 17 responses (5%) from others. The input is to be considered balanced. In addition, 21 position papers were submitted.

The majority of respondents (56%) belonged to Industry and business, top four fields of interest or activities being manufacture of other chemical products (65 responses or 31%), manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (50 responses or 24%), manufacture of paints, varnishes and similar coatings, printing ink and mastics (35 responses or 17%), manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (34 responses or 16%). Table 3 below presents respondents from Industry and business group by size.

Group	Type	Number	Percentage
Group 2 - Industry, business	Large company (250 employees or more)	64	48%
	Medium-sized enterprise (under 250 employees)	22	17%
	Small enterprise (under 50 employees)	23	17%
	Micro-enterprise (under 10 employees)	17	13%
	Self-employed	6	5%

Table 3 Number and percentage of industry/business responses by size

The majority of businesses who replied to the open public consultation operate at the EU (34% or 71) or global (37% or 77) levels with 22% (47) of responses operating at the regional level. Government or public authority, and intergovernmental organisations responses were mainly from those operating at a regional level (51% or 25), with just 8% at the national level (4) and 14% at the local level (7). The highest number of responses from NGOs, consumer associations, trade unions, academia and other was from those who operate at the EU level (36% or 20), followed by the regional level (29% or 16).

A. Main outcomes of the public consultation[22]

1) Citizens

Citizens said to be the most affected by the CLP Regulation (45%), Biocidal Products Regulation (30%) and REACH Annex XIII (25%).

They considered the EU chemicals legislation:

- Important in protecting human health and stimulating innovation and competition and very important in protecting the environment and ensuring a well-functioning internal market.
- Mostly effective in protecting the environment and ensuring a well-functioning internal market and moderately effective in protecting human health and stimulating

[22] Annex V of the 1st FC study available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/ provides a detailed report of the answers received

innovation and competition. Main reason for lower effectiveness: legislation is not adapted to issues at stake.
- Having a moderate level of added value.

To these stakeholders, the EU legislative framework has had a moderate contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with the stability of the legal framework ('Moderately satisfied') and the least satisfied with international collaboration and harmonisation ('Slightly satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard and risk communication to workers ('Moderately satisfied') and the least satisfied with risk assessment and characterisation ('Slightly satisfied'). Citizens also thought that the quality requirements for safety data for chemicals were appropriate (41%).

Stakeholders from this group considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (45%) and that the EU legislative framework addresses emerging areas of concern moderately sufficiently. No answer to the question whether chemicals legislation framework overall should be more oriented towards generic risk considerations or specific risk assessment was provided by 49 % of this stakeholder group (while 11% provided 'I don't know' answer).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the damage to the environment and to eco-systems (58%), reducing the exposure to toxic chemicals of consumers, citizens and workers (54%).

31 % of respondents from this group thought that there were significant costs for small and medium enterprises due to EU chemical legislation. Regarding such costs, respondents ranked classification requirements for substances and mixtures and chemical labelling and packaging requirements as the main cost drivers (25%).

The current elements relating to CLP classification criteria[23] were considered overall moderately satisfactory while responses from these stakeholders to the question whether the CLP Regulation cover all relevant hazards were mostly 'I don't know'. The current elements of the procedures for harmonised classification and labelling (CLH)[24] were considered slightly satisfactory with exception to quality of scientific data and related information which was considered moderately satisfactory. The effectiveness of the CLP labels in communicating hazards to workers and consumers was considered moderately effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (59%) answered 'I don't know'.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, citizens considered it overall moderately effective.

46% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links (compared to 33% neither agreeing nor disagreeing and 21% disagreeing) and

[23] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

[24] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

has overlaps (52%). Regarding the internal consistency, this stakeholder group mostly neither agreed nor disagreed.

2) Industry associations and companies, including SMEs

Industry and companies said to be the most affected by the CLP Regulation (92%), REACH Annex XIII (78%) and Waste Framework Directive (73%).

They considered the EU chemicals legislation:

- Important in protecting human health and stimulating innovation and competition and very important in protecting the environment and ensuring a well-functioning internal market.
- Mostly effective in protecting the environment and ensuring a well-functioning internal market and moderately effective in protecting human health and stimulating innovation and competition. Main reason for lower effectiveness: legislation is not adapted to issues at stake (human health, environment, innovation and competition) or legislation is not effectively implemented (internal market and competition).
- Having a high level of added value.

To these stakeholders, the EU legislative framework has had a moderate contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with the speed with which hazards/risks are assessed and with which identified risks are addressed ('Moderately satisfied') and the least satisfied with predictability of the outcomes assigning ('Slightly satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard and risk communication to workers and risk managements measures regulating the safe use of chemicals ('Mostly satisfied') and the least satisfied with risk management measures restricting or banning the use of chemicals (Moderately satisfied'). This group also thought that the quality requirements for safety data for chemicals were appropriate (63%).

This group also considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (72%). Respondents gave consideration that "impact assessment should be systematic and better address employment and competitiveness issues across the industry chain". According to these stakeholders, the EU legislative framework addresses emerging areas of concern mostly sufficiently. These stakeholders were also strongly in favour of specific risk assessment (72%).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the exposure of workers to toxic chemicals (85%), reducing the damage to the environment and to eco-systems (84%) and reducing the exposure of consumers and citizens in general to toxic chemicals (79%).

This group also thought that there were significant costs for small and medium enterprises due to EU chemical legislation (89%) as well as for large enterprises (89%). Regarding costs for companies, respondents ranked understanding and keeping up-to-date with changes in legal requirements as the main cost driver (84%).

The current elements relating to CLP classification criteria[25] were considered moderately satisfactory except the appropriateness of classification criteria and methods for substances which was considered mostly satisfactory. Responses from these stakeholders to the question whether the hazard classes in the CLP Regulation cover all relevant hazards were 'yes' for environmental (82%), physical (85%) and human health risks (86%). The current elements of the procedures for harmonised classification and labelling (CLH)[26] were considered moderately satisfactory. The effectiveness on the CLP labels in communicating hazards to workers was considered mostly effective while to consumers moderately effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (40%) answered that enforcement is not harmonised across Member States.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, industry and companies considered it moderately effective. Industry association guidance and materials were considered more effective.

45% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links (compared to 27% neither agreeing nor disagreeing and 29% disagreeing) and has overlaps (75%). 60% of respondents agreed that the EU chemicals legislation framework is internally inconsistent.

3) Public authorities (Member State, national and regional authorities)

Public authorities said to be the equally the most affected by the CLP Regulation and the Plant Protection Products Regulation (64%) and Biocidal Products Regulation (56%).

They considered the EU chemicals legislation:

- Important in protecting human health and very important in protecting the environment, ensuring a well-functioning internal market and stimulating innovation and competition.
- Moderately effective in protecting human health stimulating innovation and competition and mostly effective in protecting the environment and ensuring a well-functioning internal market. Main reason for lower effectiveness: legislation is not adapted to issues at stake and legislation is not effectively implemented (human health, environment internal market).
- Having a moderate level of added value.

To these stakeholders, the EU legislative framework has had a significant contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with time to allow duty holders to adapt to legal changes ('Mostly satisfied') and the least satisfied with speed with which identified risks are addressed ('Moderately satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard identification criteria ('Mostly satisfied') and the least satisfied with hazard and risk communication to consumers as well as risk management measures restricting or banning the use of chemicals ('Mostly satisfied'). Public authorities

[25] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

[26] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

also thought that the quality requirements for safety data for chemicals were appropriate (51%).

This group also considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (71%). Respondents gave consideration that "the combined effects and vulnerable groups are mentioned in occupational safety and health legislation but it is not very clear how to enforce them". According to these stakeholders, the EU legislative framework addresses emerging areas of concern moderately sufficiently. This group of stakeholders was in favour of staying with the current approach i.e. both generic risk considerations and specific risk assessment (37%).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the exposure of consumers and citizens (95%) and workers (92%) to toxic chemicals and reducing the damage to the environment and to eco-systems (89%).

This group also thought that there were significant costs for small and medium enterprises due to EU chemical legislation (64%). 33% of responses from this group mentioned significant costs for national authorities and 25% who indicated significant costs for authorities at EU level. Regarding costs for companies, respondents ranked risk management measures under different legislation as the main cost driver (42%).

The current elements relating to CLP classification criteria[27] were considered moderately satisfactory except for the appropriateness of classification criteria and methods for substances and for international harmonisation through the GHS which was considered mostly satisfactory. Responses from these stakeholders to the question whether the hazard classes in the CLP Regulation cover all relevant hazards were ‘yes' for environmental (44%), physical (71%) and human health risks (63%). The current elements of the procedures for harmonised classification and labelling (CLH)[28] were considered mostly satisfactory. The effectiveness on the CLP labels in communicating hazards to and to consumers mostly effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (58%) answered 'I don't know'.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, public considered it mostly effective.

57% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links and has overlaps (50% against 44% neither agreeing nor disagreeing). Regarding the internal inconsistency, this stakeholder group mostly neither agreed nor disagreed (47% compared to 32% agreeing that the EU chemicals legislation framework is internally inconsistent).

4) Civil society (non-governmental organisations (NGOs), consumer organisations, trade unions, academia and others)

NGOs and others said to be the most affected by the CLP Regulation (76%), the Chemical Agents Directive (73%) and the Waste Framework Directive (57%).

[27] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

[28] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

Civil society considered the EU chemicals legislation:

- Moderately important in protecting human health and the environment and important in ensuring a well-functioning internal market and stimulating innovation and competition.
- Moderately effective in protecting human health, ensuring a well-functioning internal market and stimulating innovation and competition while slightly effective in protecting the environment. Main reason for lower effectiveness: legislation is not adapted to issues at stake.
- Having a high level of added value.

To these stakeholders, the EU legislative framework has had a moderate contribution to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Respondents said to be the most satisfied with stability of the legal framework ('Mostly satisfied') and the least satisfied with speed with which identified risks are addressed, as well as public awareness and outreach ('Moderately satisfied'). Regarding more in particular risk management measures, they were the most satisfied with hazard and risk communication to workers ('Moderately satisfied') and the least satisfied with risk assessment and characterisation, risk management measures restricting or banning the use of chemicals as well as risk management measures regulating the safe use of chemicals ('Slightly satisfied'). This group thought that the quality requirements for safety data for chemicals were not appropriate (41%).

This group also considered that not all relevant considerations are taken into account in regulatory decision-making on risk management (85%). Respondents gave consideration that "risk assessments… do not take into account the specific risk that chemical substances… pose to women and children". According to these stakeholders, the EU legislative framework addresses emerging areas of concern slightly sufficiently. This group of stakeholders was in favour of generic risk considerations approach (41%) with still a strong preference for specific risk assessment (25%).

According to this stakeholder group, the main benefits generated by the EU chemicals legislation are reducing the exposure of workers (91%), consumers and citizens (80%) to toxic chemicals and reducing the damage to the environment and to eco-systems and encouraging research and innovation, generating jobs and improving competitiveness (70%).

This group also thought that there were significant costs for small and medium enterprises due to EU chemical legislation (70%). These stakeholders were the most likely to indicate that there were significant costs for national authorities (42%) and authorities at EU level (40%). Regarding costs for companies, respondents ranked risk management measures under different legislation as the main cost driver and understanding and keeping up-to-date with changes in legal requirements (42%).

The current elements relating to CLP classification criteria[29] were considered overall moderately satisfactory. Responses from these stakeholders to the question whether the hazard classes in the CLP Regulation cover all relevant hazards were ‘yes' physical risks (70%) and 'no' for human health (53%) and environment risks (56%). Transparency of the

[29] Ease of implementation for duty holders, classification criteria and methods for substances and mixtures, international harmonisation through the GHS

procedure for harmonised classification and labelling (CLH)[30] was considered mostly satisfactory, involvement of stakeholders moderately satisfactory, and quality of scientific data and related information and speed of procedures both slightly satisfactory. The effectiveness on the CLP labels in communicating hazards to workers was considered mostly effective while to consumers moderately effective. Regarding the enforcement of the CLP across Member States, most respondents from this group (63%) answered 'I don't know'.

Regarding the effectiveness of support provided to companies through guidance and helpdesks, citizens considered it overall moderately effective.

79% of respondents agreed that the EU chemicals legislation framework contains gaps and missing links but disagreed that it has overlaps (45% against 20% neither agreeing nor disagreeing and 35% agreeing). 60% of respondents agreed that the EU chemicals legislation framework is internally inconsistent.

2.5 Other consultation activities

2.5.1 Eurobarometer surveys

Two Eurobarometer surveys (Special Eurobarometer 456 November-December 2016 and Special Eurobarometer 468 September-November 2017) were carried out by TNS Political & Social network in the 28 Member States of the European Union. Around 28 000 EU citizens from different social and demographic categories were interviewed for each. The methodology used is that of Eurobarometer surveys as carried out by the Directorate-General for Communication ("Strategic Communication" Unit)[31]. A technical note concerning the interviews conducted by the member institutes of the TNS Opinion & Social network can be found in the full version of the reports[32]. It also specifies the interview methods and the confidence intervals.

The key findings of the Special Eurobarometer 456 survey of relevance for this Fitness Check can be summarsied as follows:

- Less than half of respondents say they feel well informed about the potential dangers of the chemicals contained in consumer products, although there is considerable variation by Member State.
- Almost half think that chemical products are safe for human health and the environment, although perceptions of safety vary considerably between Member States. At the same time half of respondents say that the current level of regulation and standards in the EU is not high enough and should be increased.
- Awareness and comprehension of four (out of nine) CLP[33] hazard pictograms was tested. Awareness and comprehension vary across pictograms. Overall, the findings on

[30] Transparency of procedures, involvement of stakeholders, quality of scientific data and related information, speed of procedures

[31] http://ec.europa.eu/commfrontoffice/publicopinion

[32] Special Eurobarometer 456 https://data.europa.eu/euodp/data/dataset/S2111_86_3_456_ENG and Special Eurobarometer 468 https://data.europa.eu/euodp/data/dataset/S2156_88_1_468_ENG

[33] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the 'CLP Regulation')

the varied comprehension of CLP hazard pictograms suggest that there is scope for improving the effectiveness of consumer communication and labelling.

The key findings of the Special Eurobarometer 468 survey of relevance for this Fitness Check can be summarsied as follows:

- More than four in five respondents (84%) are worried about the impact on their health of chemicals present in everyday products.
- When asked to identify the most effective ways of tackling environmental problems, more than a third (35%) favour investment in research and development to find technological solutions. There is also relatively high support for tighter legislative control, specifically introducing heavier fines for breaches of environmental legislation (34%), ensuring better enforcement of legislation (31%) and introducing stricter environmental legislation (30%).

2.5.2 SME panel[34]

Consultation was undertaken through the SME panel among the members of the Enterprise Europe Network (EEN) to ensure that the impacts and opinions of small and medium-sized enterprises are represented within the analysis. There was a total of 209 responses from companies with fewer than 250 employees[35]. The survey was very similar to that of the OPC to provide consistency. .

Opinions of SMEs on the EU chemicals legislation overall are generally positive. There are some negative opinions on the extent to which EU chemicals legislation is consistently enforced by Member States. Respondents also considered the EU chemicals legislation to be sufficiently harmonised across Member States for the proper functioning of the European single market[36].

Regarding costs, some 60% of all SME respondents identified that they incurred significant costs on an annual basis in complying with the CLP Regulation or other chemicals legislation. The main cost drivers identified were training likely linked to the need for staff to understand the new pictograms and hazard and precautionary statements (89%) and costs associated with understanding and keeping up-to-date with changes in legal requirements (45%). In addition, 50% of all respondents reported a short-term increase in costs due to implementation of CLP. However, a significant proportion of respondents (31%) reported that they had not incurred any short-term costs (they had also not seen any benefits from implementation of CLP).

The EU chemicals legislation framework was also considered coherent[37].

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[34] Annex V of the 1st FC study provides a detailed report and is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/. The European Commission commissioned a team led by Risk & Policy Analysts Ltd. (RPA) to conduct this study.

[35] 1-9 employees (21%), 10-49 employees (42%), 50-249 employees (37%)

[36] 98 agree or strongly agree compared with 32 neutral and 31 who disagree/strongly disagree and 41 'I don't know' responses

[37] 93 agree or strongly agree compared with 47 neutral and 27 who disagree/strongly disagree and 37 'I don't know' responses

2.5.3 Targeted data collection

Targeted data collection has been conducted in support of the three main tasks of the 1st Fitness Check study[38] regarding different aspects of the CLP implementation. When sending out the surveys, recipients were encouraged to also send the links to national associations (e.g. national consumer associations, national trade unions) to gather a broader range of information than just that of the EU-level organisation. Targeted questionnaires were developed for the following stakeholders:

- Industry (manufacturers and importers of chemicals, distributors of substances and mixtures, formulators (industrial chemicals, plant protection products, detergents and cosmetics). 250 companies in total provided responses[39].
- Non-industry stakeholders including trade union/worker representative organisations, consumer associations, environmental NGOs and health-related NGOs. Seven replies in total were received.
- Authorities and expert groups. Responses were submitted by 14 authorities from 11 different Member States.

In addition, a separate questionnaire was developed and submitted to the Expert Group on Toy Safety. In total there were 10 responses to the questionnaire sent to the Expert Group on Toy Safety, and a further two additional consultation responses. These included responses from EU authorities, a market surveillance authority, a health and environmental NGO, national and EU industry representatives and a consumer organisation.

2.6 Stakeholder Workshops

2.6.1 Workshop of 19 April 2016[40]

Conducted as a task under the 1st FC Study, the objectives of the workshop discussions were to identify what works well within the chemicals legislative framework and why and the associated impacts, as well as what does not work well, why not and the associated impacts. Registration for the Workshop was open to all. The number of registrants exceeded the capacity of the venue (90 people) and a selection of registrants was invited to attend, ensuring a balanced representation of relevant stakeholder groups. The workshop provided an early check on preliminary study findings, identify potential gaps and opportunities for further investigation and to collect ideas and information from stakeholders.[41]

[38] reported in Annexes II, III and IV of the study

[39] 12% micro enterprises, 13% small, 21% medium, 54% large

[40] The workshop was organised by the Commission assisted by Risk & Policy Analysts Ltd. (RPA) in charge of the 1st Fitness Check study. The workshop report can be found here: http://ec.europa.eu/DocsRoom/documents/17110/attachments/1/translations

[41] Full report of discussions held during the breakout sessions can be found http://ec.europa.eu/DocsRoom/documents/17110/attachments/1/translations

2.6.2 Workshop of 4 May 2017[42]

Conducted as a task under the 2nd FC Study, the objective of the workshop was to gather expert stakeholder inputs on how the current EU chemicals regulatory framework is functioning with a particular focus on specific risk assessment processes applied under EU chemicals legislation. The workshop brought together senior representatives from the European Commission, Member State officials, industry and civil society. The workshop was attended by a total of 76 people. Four morning presentations were followed by an exchange of views and several breakout sessions.[43]

2.6.3 Workshop of 17-18 January 2017[44]

The workshop brought together experts from Member State authorities, industry, non-governmental organisations (NGOs), international organisations, trade unions and academia. The two-day interactive workshop was an opportunity to discuss and validate the preliminary study findings, to engage with stakeholders and to communicate to a wide audience the substantial benefits that the body of EU chemical legislation has achieved to date. It also addressed the health and environmental costs still incurred within the EU as a result of on-going exposures to hazardous chemicals. In advance of the workshop, a summary report on the provisional findings of the study was provided to participants. The workshop was attended by a total of 47 people and a list of the workshop participants is included in Appendix B of the Workshop Report.

2.6.4 Workshops conducted in 2015

Two workshops were organised as part of the CCA1 Study, to validate the estimated costs as a percentage of both the value added and the revenue of the reporting companies, before the grossing up of costs for the EU level and the estimation of absolute values. The first validation workshop targeted companies and industrial associations. The second workshop, organised by the European Commission, was open to a wider audience of stakeholders such as industry, trade unions, NGOs and Commission services.

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[42] A second workshop was organised within the FC+ Study and conducted by Amec Foster Wheeler Environment & Infrastructure UK Limited. The workshop report can be found here: https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF

[43] Appendix B of the FC+ Study (https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en/format-PDF) describes key points of discussions held during the breakout sessions

[44] A two-day workshop was organised as a part of the Study on the Cumulative Health and Environmental Benefits of Chemicals Legislation conducted by Amec Foster Wheeler Environment & Infrastructure UK Limited. The workshop report can be found in annex/attachment to the main study report here: https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

3 Annex 3 Methods and analytical models

The purpose of this Annex is to summarise the main methodologies applied and the information sources used for the "Fitness Check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries" (FC Chemicals). As described in the Section 4. Methodology, a number of thematic studies have been carried out by external consultants for the Commission services. In addition, other sources of information were used (see Annex 2 Synopsis report).

3.1 The key supporting studies of the Fitness Check on chemicals legislation

3.1.1 Study on the regulatory fitness of chemicals legislation (excluding REACH), in particular the CLP Regulation and related legislation (1st FC Study)

A. Methods and analytical models

The first Fitness Check study ('1st FC study')[45] was conducted between July 2015 and December 2016 and published in January 2017. The study evaluated the CLP Regulation ((EC) No 1272/2008) and its interface with other related chemicals legislation in terms of effectiveness, efficiency, coherence, relevance and EU added value. Mapping was undertaken to establish the scope of relevant legislation followed by desk research and a suite of stakeholder consultation activities, which assisted in answering a range of evaluation questions. The evaluation considered the rules and processes for classifying the hazards of substances and mixtures, the methods of communication of the associated hazard information and the properties of concern that require consideration. It also considered linkages between the CLP Regulation and downstream legislation, with a focus on assessing risk management based on generic risk considerations (triggered automatically by a CLP classification).

As the different pieces of legislation within the scope of the Fitness Check only have high-level general objectives in common (see Table 1 in Annex 4), for which few quantifiable indicators exist, and as there is no single baseline for a framework of +40 pieces of legislation implemented at different times with different scopes, it was clearly going to be challenging to try and assess the effectiveness and efficiency at the framework-wide level. Therefore, the study focused on the CLP Regulation and on specific issues at the interface between the CLP Regulation and downstream legislation. As a result, a number of different reference points and timeframes were used (see Annex 4 for more detail). For example, the reference point for assessing the costs of transition to the CLP Regulations was the previous Dangerous Substances and Dangerous Preparations Directives (67/548/EEC and 1999/45/EC) over a time period of 2008-2015 whilst the assessment of on-going costs of meeting the requirements of the CLP Regulation were assessed in present time (2016) using a zero-counterfactual (i.e. a scenario of no regulation in place at the Member State level in the absence of EU legislation) as the point of reference. The (partial) assessment of human health and environmental benefits of the CLP Regulation also used a zero counterfactual and considered benefits generated under the previous DSD/DPD regime together with those generated after the implementation of the CLP Regulation thus covering a timeframe of 2000-2016.

[45] The evaluation report is available online http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/. Annex I-V is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/. Annex VI is available here http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/.

The assessment of on-going cost reflects the cost implications of a situation where there are no other regulatory requirements on manufacturers and importers of hazardous substances and mixtures (i.e. a 'zero counterfactual'). The reality is that, had the DSD, DPD and subsequently the CLP Regulation not been introduced to provide overarching requirements, some/all Member States are likely to have introduced their own requirements under national legislation. Some or all might have been similar in emphasis and requirements to the CLP Regulation, while others might have varied significantly. Clearly there is no definitive way of knowing either way; hence, there is no means of identifying whether costs would have been higher or lower than those presented in the study assessment. Thus, when considering the individual cost components presented below from the perspective of the burden on industry, it should be borne in mind that similar costs might have been incurred under an alternative non-EU regulatory reality, with this also being the case for health and environmental benefits.

The study was organised into four tasks:

1. Evaluating the implementation of the CLP Regulation,
2. Evaluating the horizontal links between EU legislation on hazard identification and communication,
3. Evaluating the vertical links between the CLP Regulation and relevant EU and national downstream legislation identifying risk management measures based on hazard classification, and
4. Supporting the Commission in organising an open public consultation, SME panel and workshop. A number of industry sector and stakeholder specific surveys and workshops were also organised (see Annex 2). In line with the Fitness Check roadmap, when analysing risk management measures under Task 3, the study distinguished risk management based on generic risk considerations (i.e. risk management measures automatically triggered by a hazard classification under CLP, without further assessment of the risk) and risk management based on specific risk assessment (i.e. risk management measures following an assessment of both the hazards and specific exposure).

The evaluation methodology was developed around the needs of these four tasks. The work included a literature review to obtain key information from impact assessments, position papers, academic and scientific research etc.; legal mapping to identify relevant legislation and specific provisions within this; consultation activities including the Open Public Consultation, a Stakeholder Workshop, an SME Panel, consultation as part of case study work as well as targeted consultation (including surveys) of key stakeholder groups; and case study research involving a more in-depth examination of some of the more pertinent issues identified as part of initial research (see Table 1). Importantly, the aim of the case studies was not to re-consider specific decisions that have already been taken; instead, it was to examine the mechanisms and procedures of the CLP Regulation and to assess whether the current linkages are appropriate (which may necessitate examining some of the impacts of past decisions). The study assessed the costs of transition to the CLP Regulation from the two Directives that it replaced (the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD)) in 2008 as well as the on-going regulatory costs faced by industry and by EU and Member State authorities. This included consideration of the cost impacts ('transition costs') of moving from a Directive based system to a Regulation, any national differences in implementation of the CLP Regulation, and the costs (and benefits) of the harmonisation of information requirements across the national Poison Centres. It also examined the impacts from different provisions, for example, CLP packaging requirements

(in particular child resistant closures and tactile warning devices), labelling requirements, obligations placed on regulators and authorities, etc. The work drew on the Fitness Check cumulative costs (CCA1) and the cumulative benefits (CuBA) studies, as well as the 2006 Impact Assessment for the implementation of CLP.

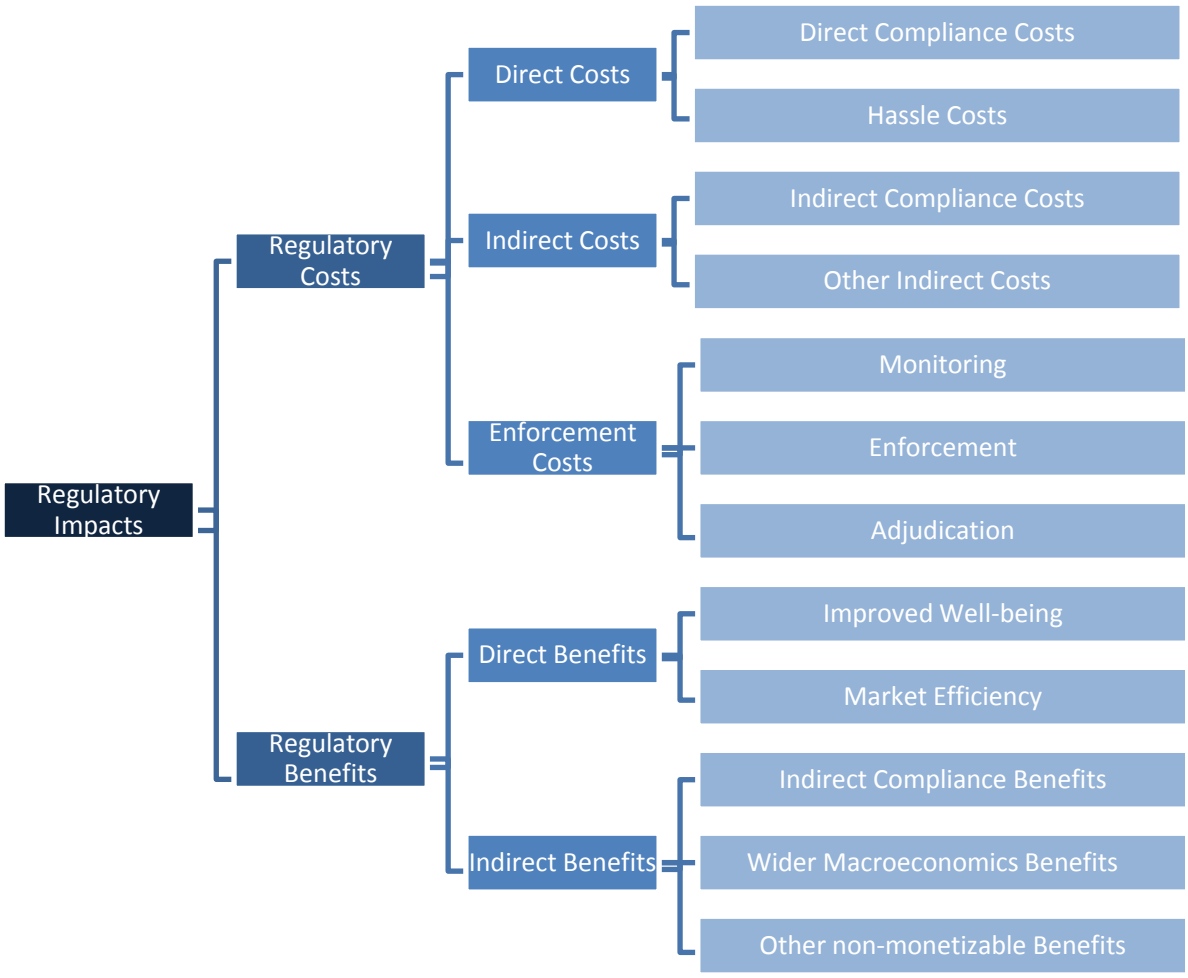
With respect to calculating the costs of transition to CLP, the approach followed the cost assessment model set out in the Better Regulations Toolbox, as illustrated in Table 4 below. The cost types outlined in this diagram are described in further detail as follows:

- Direct Costs: Within this category are two sub-categories of costs: direct compliance costs and hassle costs. The first of these consists of regulatory charges which include fees, levies and taxes; substantive compliance costs which entail the costs of investing in human and physical capital, as well as other expenses incurred in complying with legal requirements introduced by new legislation; and, administrative burdens which encompass the costs borne in performing administrative activities for complying with the information obligations set out under the legislation. Hassle costs include the costs associated with corruption, annoyance and waiting times. Note that direct compliance costs can be further categorised as CAPEX where they relate to capital expenditure, OPEX where they are annual operating costs and administrative costs where they relate to reporting obligations. This study also categorised regulatory charges under the monetary obligations category.
- Indirect Costs: Indirect costs are those incurred in the sector targeted by the legislative measures, which are not directly related to the measure, or by other sectors or stakeholders which are not directly targeted by the legislative measure (i.e. downstream sectors). These indirect costs can be transmitted through price increases or changes in the supply of certain goods and services to the market. In some cases, this can have a multiplier effect (for example if a substance is withdrawn when the impact downstream was actually higher than the cost of keeping it on the market). For the purposes of this study, our attention will be focused on the indirect costs relating to re-formulating products or removing certain product lines from the market due to the changes induced by the CLP Regulation.
- Enforcement Costs: Enforcement costs are those incurred by Member States, public bodies and the European Commission through activities relating to the implementation of legislative measures. Costs can be categorised under the following: monitoring; enforcement; adjudication.

Case study #	Case study title	Case study description
1	Impacts of differences in the uptake of UN GHS **building blocks** for costs, competitiveness health and the environment	Different countries have adopted different building blocks both in terms of hazards covered and sectors covered. Consideration will be given to differences in the potential costs and benefits for chemical suppliers, as well as for consumers (public health) and the environment. The focus is on building blocks within the GHS which have (not) been implemented in the EU and North American countries and any differences in costs and benefits arising as a result.
2	Suitability of the CLP Regulation **classification criteria for metals**	It may be the case that there is a gap in the legislation as the CLP contains no criteria for the classification of metal alloys, with this potentially impacting on their treatment under other horizontal legislation, e.g. REACH, waste legislation, etc. The case study would

Case study	Case study title	Case study description
		identify problems arising from this gap. It could also consider the extent to which default classification rules under the CLP regulation may trigger under/over classification of metals more generally.
3	Lack of consistency in **parallel hazard assessments** under different legislation	Different bodies are responsible for the hazard assessment and classification of a substance/mixture under the CLP, Biocides and PPP. This case study would focus on the coherence of the parallel procedures under these three Regulations and, time permitting, also take into account other legislation such as the CAD (depending on the scope of other case studies and hence resources available).
4	Relevance and coherence as regards the introduction of **new test methods** and GLP within chemicals legislation	The classification criteria under the CLP for some hazards are linked to the outputs from existing animal test methods, with these used to fulfil REACH information requirements. This case study would examine the relevance of the CLP classification criteria in terms of their ability to respond to changes in scientific methods, and the horizontal coherence of these also taking into account prohibitions on animal testing under the Cosmetics Regulation.
5	Coherence of classifications, definitions and the **labelling requirements for detergents**	This case study will explore whether there are any negative impacts on industry and on the single market as a result of a lack of coherence in the definitions of 'placing on the market' and 'manufacturer' between the CLP Regulation and Detergents legislation. It will also examine requirements under the Cosmetics and the Biocidal Products Regulation.
6	Inconsistencies in assessment procedures for **PBT and vPvB** as properties of concern	The CLP Regulation does not include classification and labelling requirements based on PBT and vPvB properties. This case study looks at whether there are inconsistencies or overlaps in the identification or risk management of PBTs, what types of risk management measures are triggered by PBTs, what issues arise in relation to the coherence of risk management, whether the current processes are effective and views on integration of PBT/vPvB into CLP.
7	**SME awareness** of ATPs and changes in classification and of labelling and packaging requirements	This case study focus on the awareness of SMEs of the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur every two years. It will also look at issues regarding SME understanding of packaging requirements under CLP and international transport legislation.
8	Awareness of Chemical Safety Assessment and labelling requirements for **Toys**	The TSD lays down toy safety rules which include requirements for Chemical Safety Assessments, compliance with specific chemical requirements laid down in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.), and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. This case study would examine SMEs awareness of this range of obligations. The case study will examine the awareness of SMEs in of labelling requirements, including traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for use, precautions and warnings.

Case study	Case study title	Case study description
9	**Consumers comprehension** of and relevance of safety information on product **labels**	The focus of this case study will be on the hazard pictograms that the CLP introduced when implementing the GHS. Research suggests that comprehension of the various pictograms amongst EU citizens is variable; findings indicate that a low percentage of citizens may understand all of the hazard pictograms or equally understand only a few of the pictograms. Some EU legislation uses different safety phrases and does not rely on the pictograms. Similarly, where the GHS building block for consumer products has not been implemented (e.g. North America) different communication tools may be used
10	Linkages with **Occupational Health and Safety Legislation**	The case study is looking at whether there are overlaps and inconsistencies between CLP and OSH legislation: • If there are inconsistencies or overlaps what causes these? • What are the implications of these? • Do the inconsistencies give rise to incoherence? • Are there measures that could be taken to address them? Formaldehyde will be used as a case study substance to illustrate some of the issues.
11	**Risk management procedures triggered by harmonised classifications** under the CLP Regulation	This is an overarching case study involving a comparative assessment of the procedures triggered by a CMR or other health classification (e.g. sensitiser). It will cover REACH, PPPR, BPR, cosmetics, toys, food contact materials and CMD. This case study will also consider selected substances, such as lead, TCEP, gallium arsenide, etc. This case study will also include a comparison between RMM based on generic risk considerations and specific risk assessment.
12	Use of CLP classifications for **waste management**	There appears to be national, regional and local authorities using CLP classification criteria and packaging requirements as the basis for the sorting and recycling of domestic wastes. These are unintended uses of the packaging and labelling aspects of the CLP Regulation and may be leading to a lack of coherence and impact on achievement of other EU objectives related to recycling and the circular economy. In addition, consistencies have been identified with regard to the linkages between CLP and the Waste Directive, in particular in relation classification for toxic to the aquatic environment and bioavailability. This case study will examine the consequences of both of national implementation of waste legislation, as well as what the constraints are to recycling if a waste is classed as hazardous and whether a logic can be developed with regard to bioavailability considerations.
13	**Linkages between the CLP and Seveso III** Directive, including risk management under Seveso III	Seveso III aligns, amongst others, requirements for establishments using or storing hazardous chemicals with the CLP Regulation. Due to the alignment some establishments may change tier or fall out of scope all together because for some hazard classifications the criteria in DSD are CLP are not identical. The case study will review the procedures for risk management under Seveso as a potential example of best practice, and the procedures for excluding substances from the scope of the Directive and whether the linkages between CLP and Seveso III are efficient and effective.



In line with the approach to calculating the transition costs of CLP, the study employed the methodology set out in the Better Regulations Toolbox which categorises costs under the types listed in Table 5. The cost elements which make up our model for ongoing costs are listed under each relevant cost type.

Type of Cost	Cost elements for which estimates have been generated
Direct Costs	
Regulatory Charges	Fees or penalties paid in complying with regulation
Substantive Compliance Charges	Costs of updating IT systems Costs of training staff to understand updates in requirements of CLP Costs of employing FTEs for compliance activities Costs of Child Resistant Closures and Tactile Warning Devices
Administrative Burdens	See Chapter 8
Hassle Costs	Costs of checking CLI
Indirect Costs	
Indirect compliance Cost	Opportunity cost of removing a product line from the market

Table 5 Data collected for each cost type for ongoing costs

The Standard Administrative Costs Model acted as the basis for estimating administrative costs to industry, and complementary approaches were adopted for the estimation of compliance costs. Where appropriate, separate consideration was given to SMEs compared to larger companies. In this respect, efforts were made to ensure SME views were represented, for example, through use of the Commission's SME Panel, discussions with national associations, and separate analysis of cost information provided by SMEs where relevant.

All assumptions in this respect are made clear in the more detailed study Task reports (see the 1st FC study, Annex II: Evaluating the implementation of the CLP regulation pp55-125). In addition to developing its own estimations, the study used figures from other sources, in particular in relation to costs and benefits of measures under downstream legislation with vertical linkages to CLP for risk management purposes.

The final report[46], its annexes[47] and case studies[48] are available online.

B. Evidence base and limitations

As with any study of this scale, numerous challenges were encountered in gathering the data needed to provide a robust evidence base, as well as in providing quantitative estimates of impacts. Although extensive efforts were made to overcome the challenges and to ensure that accurate and reliable information acted as the basis for the evaluation, many remained and some could not be overcome. There are therefore limitations that ultimately impact on the study conclusions. These include limitations stemming from the following (with further details provided in Annex I of the 1st Study Report):

- The broad scope of the study and the number of pieces of legislation to be considered.

[46] http://ec.europa.eu/DocsRoom/documents/22063/attachments/1/translations/

[47] http://ec.europa.eu/DocsRoom/documents/22063/attachments/2/translations/

[48] http://ec.europa.eu/DocsRoom/documents/22063/attachments/3/translations/

- The lack of available information on the scale of some of issues identified (both positive and negative) and the subsequent need to rely on information provided by stakeholders.
- The limited response received from civil society stakeholders. However, further desk-based research of published information from NGOs was undertaken to inform the study.
- The limited data available to assist in determining the effectiveness and efficiency of the legislative framework (particularly in quantitative terms).
- The inability or unwillingness of companies to provide certain data creating difficulties in quantifying some aspects of the impacts (e.g. costs and benefits) of the CLP Regulation and other legislation.
- The lack of up-to-date information regarding the effect of the CLP Regulation on consumer behaviour.

3.1.2 'Study supporting the Fitness Check on the most relevant chemicals legislation' (FC+ Study)

A. Methods and analytical models

The FC+ Study[49] was completed in November 2017. It complemented the 1st FC Study by reviewing those pieces of legislation within the scope of the Fitness Check that operate independently of the CLP Regulation for hazard identification and classification, and furthermore where specific risk assessment procedures form the core part of the risk management process. Following the completion of an initial mapping stage it was possible to identify which legislation either relied solely on CLP for hazard identification and characterisation, or had been significantly covered by the work in the 1st FC Study. Such legislation was then marked as 'out of scope' for the FC+ study. The remaining 27 pieces of legislation either had hazard identification and characterisation completely independent of CLP or had elements which were partially independent and thus had not been fully covered in the 1st FC Study, or included specific risk assessment approaches that were not wholly linked to hazard identification under CLP. The legislative scope of the study is summarised in Table 6 below.

	(Partially) In Scope	**Out of Scope**
Independent of CLP	**Utilises both CLP and other approaches for specific components.**	**Legislation which is either:** **a) fully dependent on CLP and/or;** **b) fully covered by the First Study**
Detergents regulation	Safety of Toys Directive	REACH Annex XIII[b]
Explosives Directive	Cosmetic products regulation	Regulation on Classification, labelling and packaging of substances and mixtures

[49] The study is available here https://publications.europa.eu/en/publication-detail/-/publication/07ad8b92-dbca-11e7-a506-01aa75ed71a1/language-en.

(Partially) In Scope		Out of Scope
		(CLP)[a,b]
Pyrotechnic articles Directive*	Medical devices (regarding medical devices; regarding active implantable medical devices; regarding in vitro diagnostic medical devices.	Test methods regulation[a,b]
Asbestos Directive (human health only)	Pressure equipment directive	Aerosol dispensers directive[b]
Water Framework Directive	Industrial emissions (integrated pollution prevention and control) Directive	Carcinogens and mutagens at work Directive[a,b]
Urban Waste Water Directive	Waste shipments Regulation	Fertilisers regulation[b]
Marine Strategy Framework Directive	Export and import of hazardous chemicals Regulation (PIC)	Young people at work Directive[a,b]
Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive	EU Ecolabel Regulation	Pregnant workers Directive[a,b]
Batteries Directive	Biocidal products Regulation	Chemical Agents Directive[a,b]
Packaging and Packaging Waste Directive	Plant protection products Regulation	Waste framework Directive and List of Waste[a,b]
Persistent organic pollutants Regulation	Food contact materials Regulations**	End of life vehicles Directive[a,b]
Drinking Water Directive	General Product Safety Directive	Tobacco Directive*[b]
Protection of animals used for scientific purposes Directive		Active and Intelligent Materials Regulation (food contact)**[b]
Contaminants in food and feed Regulation and Directive		Landfill of Waste Directive*[b]
Residues of pesticides Regulation		Environmental Liability Directive*
		Major-accident hazards involving dangerous substances (Seveso) Directive*[b]
		Signs at work Directive*[b]

(Partially) In Scope	Out of Scope
	Good laboratory practice*[b]
	Inland transport of dangerous goods Directive*[b]

Table 6 Overview of legislation within the scope of the FC+ Study

* Additional to the 41 pieces of legislation included within the 1st FC Study. Further legislation was discussed at the inception meeting based on those covered by the 1st FC Study. As these pieces of legislation were fully reviewed as part of the 1st FC Study they were treated as out of scope (with the exception of the Pyrotechnic Articles Directive) of the FC+ Study, but have been included in Table A3.4 for completeness.

** The Fitness Check Roadmap identifies 'Food contact materials' as relating to 2011/10/EC on the use of plastics materials and articles intended for food contact and 2009/450/EC active and intelligent materials intended for food contact. Following completion of Task 1, 2009/450/EC on active and intelligent materials is out of scope of the FC+ Study. 2011/10/EC on plastic materials and articles is partially witnin scope. This included discussion of overlaps with EC/1935/2004, which is the Framework Directive for Food Contact Materials and which covers non-plastic materials.

The FC+ Study was completed through a combination of desk-based research including literature review, policy review and taking into account the findings of the First Study. It has also included a significant amount of stakeholder engagement including interviews with Commission Services, Member State Competent Authorities, industry, NGO groups and academics. As part of the study, a one-day workshop was held in Brussels for approximately 70 delegates that spanned these different stakeholder groups to discuss the functioning of EU chemicals legislation.

The main focus of this study was on the use of specific risk assessment approaches within EU chemicals legislation, particularly in cases where the hazard identification and characterisation stages are either fully independent or partially independent of hazard classification through the CLP regulation. More particularly, the following aspects were covered:

1. Science, data and knowledge;
2. Risk management based on specific risk assessment (SRA);
3. The role and use of generic and specific risk management approaches within EU chemicals legislation;
4. Coherence of data, science, and risk management procedures and measures;
5. Gaps in the EU chemicals acquis as regards achieving high level protection of human health and the environment, as well as for the functioning of the internal market and competitiveness.

The report briefly sets out the history of and rationale for chemicals legislation, and in particular the approach to risk assessment and risk management. It includes a review of:

- The use of specific risk assessment approaches, and their use as compared to the identification of risk management measures based on generic risk considerations.
- The different types of risk management measures and the circumstances under which different measures are selected.

The approach developed for the study included five tasks, detailed within Table 7. Additionally, a 'Task 0' was used as a cross-cutting task to manage all of the data gathering aspects needed to support the later tasks.

Task number	Title of the task	Aims of the task
0	Data and information collection and management	This was a cross-cutting task to manage the data gathering and compilation. It included the development of evaluation questions under the fitness check and the identification of the project's data needs. This included a mechanism to fulfil these data needs through a combination of policy review, literature search, a workshop and targeted stakeholder engagement. This included the use of targeted interviews across a range of stakeholder groups (industry, member state authorities, European Commission, EU agencies, and organisations representing civil society).
1	Mapping out of legislation and legislative links	The objective of Task 1 was to identify and map the EU legislative framework for hazard identification, risk assessment (both generic and specific) and linked risk management measures. This task also included reference to the First Study to understand work already completed and avoid duplication. Sub tasks included: 1A: Map links between hazard identification other than CLP and risk management measures (RMMs) taken as a consequence (in view of generic risk considerations or after specific risk assessment (SRA) 1B: List and map out all other provisions that provide for SRA, identify/describe the SRA procedures and describe links with RMMs taken as a consequence. 1C: Compile an overview table on whether approach is based on (i) generic risk consideration (GRC), (ii) SRA, or (iii) combination of both. 1D: Design an overall intervention logic.
2	Evaluation of risk assessment procedures	The objective of Task 2 was to provide an analysis of specific risk assessment procedures and to evaluate these based on the criteria from the better regulation toolbox for evaluations. This included a comparative analysis of approaches based on specific risk assessments, generic risk considerations and how these approaches contrast and compare to work effectively. Sub tasks included: 2A: Describe the SRA procedures not directly triggered by CLP classification, identify their similarities and differences 2B: Analyse SRA based on the five evaluation criteria 2C: Compare procedures based on GRC (mainly from FS[50]) and those based on SRA against criteria (looking for positives and negatives)
3	Evaluation of risk management measures and risk management approaches	The objective of Task 3 was to assess risk management measures. This included a review of the relationship between risk management measures and generic and specific risk assessments, the selection and grouping of risk management measures and further analysis for the coherence and consistency in how such measures practically meet policy goals. Sub tasks included: 3A: Identify, analyse and categorise the various types of RMMs based on SRA (not directly triggered by a CLP hazard classification) 3B: Identify, analyse and categorise the various types of RMMs based on GRC (other than the ones resulting from CLP hazard classification).

[50] First Study (European Commission, 2017a)

Task number	Title of the task	Aims of the task
		3C: Comparative assessment of the categories of RMM adopted following SRA with those adopted following GRC, as identified in the first study (FS) (based on evaluation criteria) 3D: Analyse and assess the RM approaches on their own, and in comparison, with one another. 3E: Analyse whether there are cases where the link between an identified hazard and RMM should be adopted based on GRC instead of the existing SRA approach. 3F: Analyse whether there are any ineffective, inefficient or irrelevant links between chemicals management and identified hazard classes i.e. cases in which a SRA approach should be adopted instead of the existing link between identified hazard and a risk management measure based on GRC.
4	Analysis of the coherence of the legal framework	The objective of Task 4 was to analyse the coherence of the legislative approach and procedures regarding hazard identification, generic risk considerations, specific risk assessment or risk management measures. Sub tasks included: 4A: Based on Task 1 mapping and FS, compare the various ways the links between legislation are formulated and implemented at the level of SRA, RA procedures, and related RMM and analyse the links in order to identify gaps, overlaps, contradictions, inconsistencies, synergies and virtuous interactions. 4B: Analyse to what extent a given chemical or category of chemicals is treated consistently by the legislative framework (cases where different pieces of legislation involve different kinds of RMM applied to the same or similar substances).
5	Validation and discussion workshop	The objective of Task 5 was to engage with relevant stakeholders to explore the outputs from the preceding tasks and further enrich the outputs to draw conclusions for the evaluation. Sub tasks included: 5A: Preparation for the workshop; 5B workshop; and 5C post workshop collation of information.

Table 7 Overview of the methodology used for the current study

A series of assessment themes were developed to look at the function of risk assessment approaches under the EU legislation within the context of specific topics and included:

- Data requirements and limitations;
- Exposure scenarios – data, theory and reality;
- Hazards with equivalent risk of concern to CMRs;
- Regrettable substitutions – single substance by single substance review vs group assessment;
- Effectiveness and efficiency of specific risk assessment approaches; and
- Lessons learnt from 30 years of managing CMRs.

The assessment themes were used alongside the evaluation questions to provide common topics as a means of further comparison and review of the risk assessment approaches under

different legislation. Appendix B of the FC+ Study provides a copy of the workshop report, including further details on how the focus themes were explored.

B. Evidence base and limitations

This sub-section provides further details of the types of information that have been gathered and used for the FC+ Study. It also provides further details on the limitations of the study, including details of what information sets were not used/available and the possible limitations as to what can and cannot be concluded from the results.

As part of the approach to data gathering and analysis for the FC+ Study the following types of information have been used:

- A range of different types of literature, which included:
  - The legislation itself.
  - Policy and technical guidance documents: This is literature developed by the European Commission, EU agencies and industry to provide further details on how the obligations of legislation should be met. This includes details on how specific risk assessment processes should work, and further guidance on any problematic issues or areas where the legislation may have required further elaboration.
  - Peer-reviewed scientific literature: This includes a range of journal papers reviewing particular scientific or technical issues that relate to EU chemicals policy. It also includes journal papers assessing the role of policy and science and how academic research can inform policy.
  - Non-peer reviewed scientific literature: This includes a number of research studies published through non-governmental organisation (NGOs), industry and others relating to both scientific topics (such as chemical effects on human health) but also the functioning and effectiveness of EU policy to protect human health.
  - Government reports: This includes a number of member state level reports on scientific and technical issues (such as endocrine disrupting chemicals) but also national level actions related to EU policy, particularly EU directives and regulations.
- Targeted stakeholder engagement 1. As part of Task 0 and the development of evaluation questions, interview guidelines were developed. These were then used as part of a broad interview campaign with 68 stakeholders from a range of different backgrounds, including Commission services (18 stakeholders), EU agencies (3 stakeholders), member state authorities (16 stakeholders), industry representatives (21 stakeholders), NGOs and academics (10 stakeholders)[51].
- Targeted stakeholder engagement 2. In addition to the first stakeholder engagement process, a second set of questions were developed looking at efficiency and in particular the economic costs of compliance with the different pieces of EU legislation. This second survey was aimed at consultancies and laboratories and was used to generate data and complete processes needed for

[51] The original proposal for this study included a questionnaire (which was potentially to have been run online). Based on the emerging study findings, it was confirmed that such a questionnaire was unlikely to yield useful results and so more emphasis was placed upon targeted interviews and other forms of engagement and data collection

applications to EU agencies for a sub-set of the legislation in scope. The data gathered from five laboratory consultancies was intended to provide an indication of possible costs of the existing processes as a means of informing the evaluation of their efficiency.

- Workshop engagement. As part of the FC+ Study a workshop for approximately 80 delegates was organised. Ahead of the workshop a 'thought starter' paper was developed based on the focus themes and issued to the delegates. The workshop included a number of presentations detailing the initial findings of the study, followed by break-out sessions with groups of approximately 15 each to openly discuss each of the themes and obtain feedback and suggestions for use in the study.
- Final report of the First Study, which along with the key headline findings also included:
    - A series of case studies which explored in detail different aspects of the risk assessment approaches and risk management measures used across the European Union.
    - Results of a public consultation. As part of the work from the First Study a public consultation was undertaken to seek the opinions of a wide range of stakeholders. While the current study did not include such a public consultation, it has been possible to review the results from the consultation completed under the First Study to support the findings of the current work.
    - Outcome of the Fitness check SME Panel. The present study considered implications for SMEs in various cases, and the SME panel from the First Study was taken into account.

The following limitations should be considered when assessing the results and findings of the FC+ Study:

- The data gathered for use in the analysis under the FC+study included a mixture of peer-reviewed literature and referenced materials alongside opinion gathered from targeted consultation. Wherever possible the study tried to make use of published references to help support the analysis supplemented by the opinions of the stakeholders contacted, and to select stakeholders likely to have the best insights into how well legislation is working. All interviewees were asked to point to evidence supporting the information and opinions that they provided. However, the diversity of the topic and data scarcity for some aspects has meant that the opinions provided by stakeholders remain an important source of information, particularly where this relates to the opinion of experts, who have worked in the field for many years. Where the analysis has relied on the opinions of stakeholders, the study aimed to gather a measured and balanced set of opinions from different groups. However, the following key limitations should be kept in mind:
- Stakeholders were identified based on their active engagement with specific pieces of legislation. However, involvement in the study was on a voluntary basis. Therefore, it could be perceived that those who felt strongly about particular processes or pieces of legislation were more likely to take part. To offset this possible limitation stakeholders included regulators, industry and NGOs, as well as officers of the European Commission and EU agencies responsible for chemicals legislation.

- In a limited number of cases particular stakeholder groups (e.g. industry, regulators, NGOs) dominated the responses for certain aspects of legislation. The FC+ Study report states where this is the case.
- The stakeholder engagement, while broadly diverse, could still be argued to be a relatively small sub-set compared to the size and scale of the EU chemicals industry. While a full public consultation was not used for the FC+ Study, it could be argued that there are limitations in how strongly the conclusions can be argued. To offset this limitation the work completed under the study included a review of the findings of the 1st FC Study to enable a more complete analysis, and evidence was sought wherever possible to back up opinions. Findings from the 1st FC Study (including its public consultation and SME panel) have been used to help corroborate findings in the FC+Study where appropriate.
- The available economic data on costs and efficiency reported in a quantitative fashion was very limited. Literature data, and two stakeholder engagements were used to gather quantitative and qualitative information on the functioning and efficiency aspects of the risk assessment and risk management processes used under the EU legislation. However, it was not possible to provide extensive costed examples related to efficiency within the scope of the FC+ Study.
- The available information on specific pieces of legislation varied, with some legislation and risk assessment processes well covered by multiple different stakeholder groups and literature/data sources. Other pieces of legislation were not as well covered and the analysis relied more on policy guidance documents and review of the legislation to ascertain how the processes function and what potential issues may exist. Table 8 provides an overview of which legislation was (relatively) data rich and which was data scarce.

Legislation	Data availability
Detergents regulation	Moderate levels of data
Explosives Directive	Data scarce
Pyrotechnic Articles Directive*	Data scarce
Asbestos Directive (human health only)	Data scarce
Water Framework Directive	Moderate levels of data
Urban Waste Water Directive	Moderate levels of data
Marine Strategy Framework Directive	Moderate levels of data
Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive	Moderate levels of data

Legislation	Data availability
Batteries Directive	Moderate levels of data
Packaging and Packaging Waste Directive	Moderate levels of data
Persistent organic pollutants Regulation	Data Rich
Drinking Water Directive	Moderate levels of data
Protection of animals used for scientific purposes Directive	Data Scarce
Contaminants in food and feed Regulation and Directive	Moderate levels of data
Residues of pesticides Regulation	Data rich
Safety of Toys directive	Moderate levels of data
Cosmetic products regulation	Moderate levels of data
Medical devices (regarding medical devices; regarding active implantable medical devices; regarding in vitro diagnostic medical devices)	Data Scarce
Pressure equipment directive	Data Scarce
Industrial emissions (integrated pollution prevention and control) Directive	Moderate levels of data
Waste shipments Regulation	Moderate levels of data
Export and import of hazardous chemicals Regulation (PIC)	Moderate levels of data
EU Ecolabel Regulation	Moderate levels of data
Biocidal products Regulation	Data Rich
Plant protection products Regulation	Data Rich
Food contact materials Regulations	Data Rich

Legislation	Data availability
General Product Safety Directive	Moderate levels of data

Table 8 Overview of available data by legislation (data rich – data scarce)

3.2 The complementary studies

3.2.1 Cumulative Cost Assessment for the EU Chemical Industry (the CCA1 Study)

A. Methods and analytical models

In 2014, the Commission launched a study analysing cumulative costs of the most relevant EU legislation for the EU chemical industry during the period 2004-2014. The EU legislation subject to analysis includes chemicals legislation, energy, emissions and industrial processes, workers' safety and health and product-specific legislation. The study objectives were to:

- provide for quantification of the cumulative costs related to those packages of EU legislation with the highest cost impact, and quantify the cumulative costs in the subsectors of the chemical industry;
- demonstrate how the costs have changed over time; and
- compare the costs with relevant financial indicators for the chemical industry.

The study was completed in July 2016. The CCA1 study conclusions are available online[52].

The study covered the whole chemical sector, although cost is assessed only for the subsectors for which the available data are sufficient to produce reliable estimations. These are, according to the statistical classification of economic activities in the European Community (NACE): 20.13 — inorganic basic chemicals; 20.14 — organic basic chemicals; 20.16 — plastics in primary forms; 20.20 — pesticides and agrochemical products; 20.41 — soaps and detergents, and cleaning and polishing preparations; 20.30 — paints, varnishes and similar coatings and 20.59 — other chemicals products.

Among the pieces of legislation affecting the EU chemical industry, only those incurring high cost directly to chemical companies were included. Legislation that affects upstream non-chemical companies, which then pass on costs to the chemical industry through the prices of inputs, was not within the scope of the study. Similarly, indirect costs — such as opportunity cost due to forgone business or transaction cost and costs related to national legislation exceeding EU requirements — were not taken into account.

As opposed to other methods assessing the costs of policies, the CCA1 Study provides a quantitative assessment of all costs (monetary obligations, capital expenditure, operating expenses and administrative burden) incurred by EU chemical companies with regards to the EU legislation most relevant to them. The study did not assess the benefits of EU legislation and did not aim to provide insights related to the proportionality of costs and benefits of legislation, nor its efficiency or effectiveness. The main steps for implementing the cumulative cost assessment and the methodology for estimating legislation costs are summarised in Figure 2 and Figure 3 respectively.

Furthermore, a cumulative approach is to be distinguished from a non-cumulative approach as traditionally used in a cost-benefit analysis (CBA). The standard cost-benefit approach

[52] http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/

examines the incremental costs and benefits related to policy proposals against a baseline. This implies that a CBA focuses on the net change in costs and benefits, relevant to a specific policy decision, not the aggregate (or cumulative) level of regulatory costs and benefits (European Commission, 2015). On the other hand, the cumulative cost assessment (CCA) focuses on the whole sector, rather than on a particular policy proposal or legislation, and aggregates the costs generated by all relevant existing EU legislation. Hence, this cumulative cost assessment did not focus on a policy field and did not aim at assessing whether the regulatory framework is fit for purpose in a policy field, which is an approach used when conducting fitness checks.

While there is no recognised standard methodology for the assessment of cumulative impacts, the methodology of this study drew on previous similar cumulative cost assessment exercises performed by Member States and the European Commission. For the overall CCA approach the previous studies on the aluminium and steel industries have been consulted. In particular, for the estimation of the various types of costs, CCA studies are based on established methodologies that have been used for several years by Member States and the European Commission, including the Standard Cost Model, or the Cost-driven Approach to Regulatory burden (CAR) developed for the Dutch Government. The Standard Cost Model methodology (SCM) is used by several Member States (Network Standard Cost Model, 2005), as well as the European Commission, as part of its REFIT programme and the "Better Regulation Toolbox" (European Commission, 2015). The CAR methodology, used by the Dutch government (SIRA, 2015), is similar to the SCM, yet its scope is broader regarding the types of cost covered and gives more emphasis to linking legislation cost with the cost structure of companies.

Methodologies to measure legislation burden follow the principle, summarised by the European Commission in its presentation of the SCM: "the purpose of the SCM methodology is to produce estimates that allow an order of magnitude of the burdens in different regulatory areas to be identified. Considering the level of detail and the number of parameters, it is not cost-efficient to seek statistically valid results rather than more general estimates" (European Commission, n.d.)

To facilitate the collection of data and the estimation of costs, the pieces of legislation were grouped into seven packages on the basis of their overarching and specific policy objectives as follows: chemicals, energy, emissions and industrial processes, workers' safety, product-specific, customs and trade, and transport legislation.

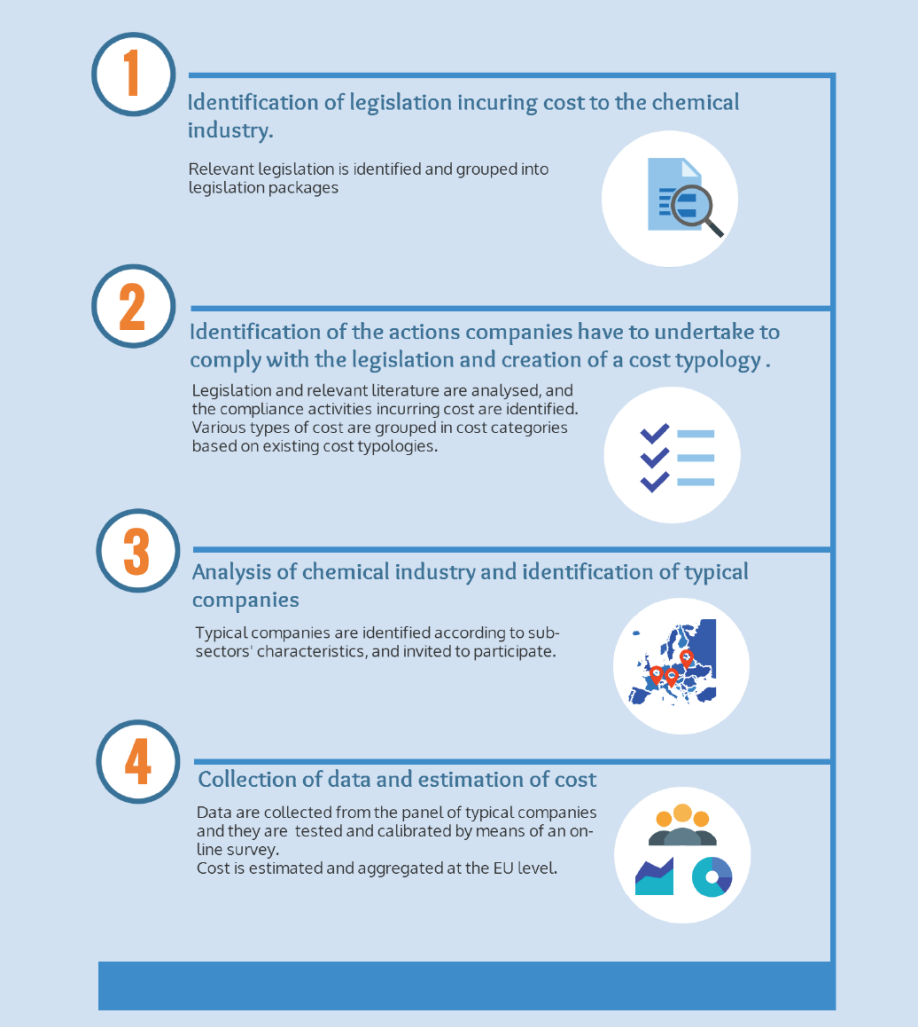


Figure 2 Steps for implementing the cumulated cost assessment

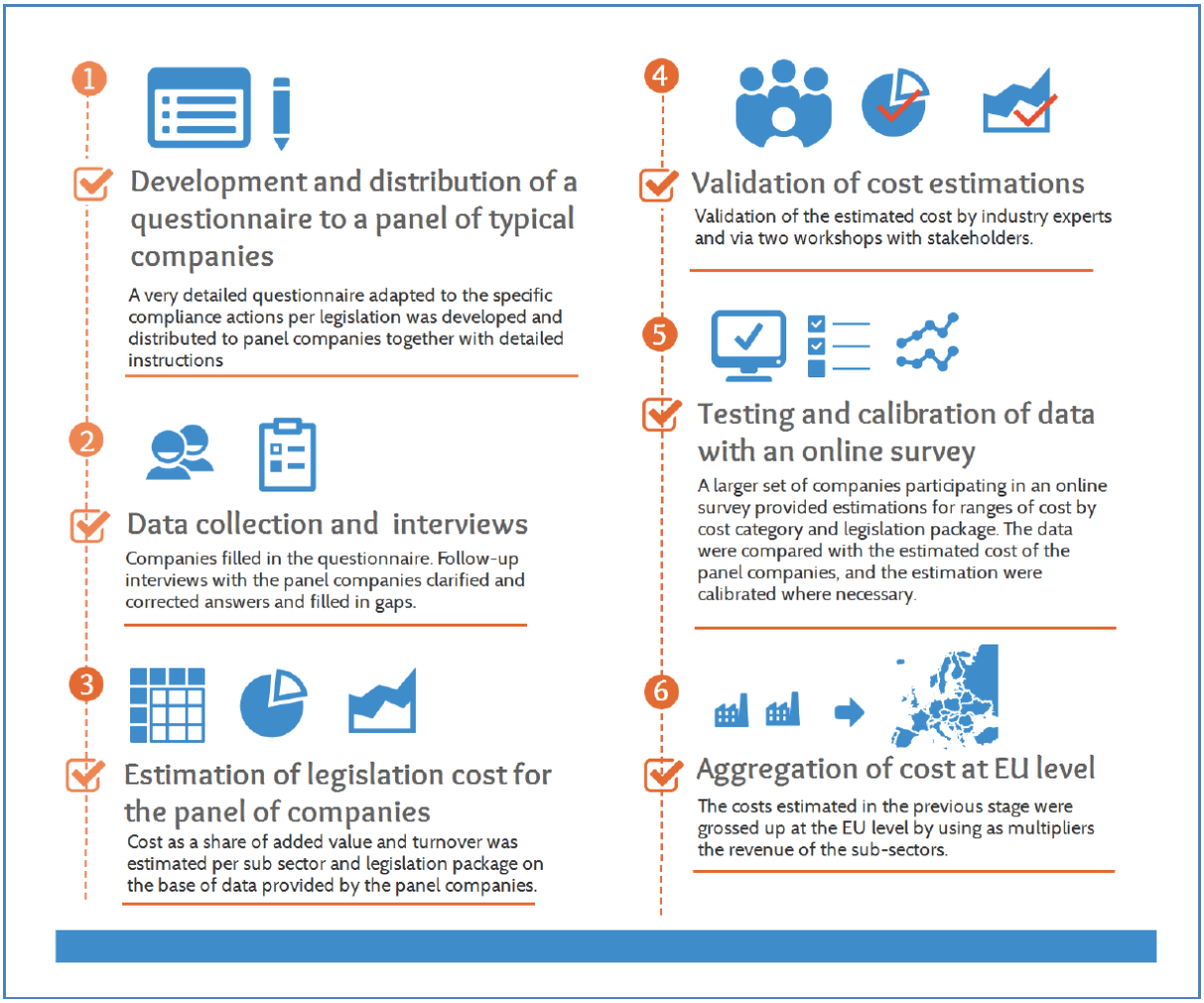


Figure 3 Methodology for estimating legislation cost

To facilitate the collection of data and the estimation of cost, the pieces of legislation have been grouped into seven packages based on their overarching and specific policy objectives. In some packages, pieces of legislation were further grouped into sub-categories based on the similarity of their cost generation mechanism. Framework legislation (e.g. the Waste or Air Quality Framework Directive) and their "daughter" legislation are presented together, as the former sets the general principles while the latter sets the implementation measures and therefore costs. The results of this grouping, indicating the relevance of packages to specific subsectors, are shown in Table 9 below.

National legislation that is not related to EU legislation is excluded from the study. Companies participating in the panel and the online survey were therefore asked to report only the costs associated with the requirements set out in the EU legislation. However, in the case of energy taxes a distinction between the costs generated by the EU policy and those by the national legislation was not possible. Therefore, the estimated cost in this case includes also the effects of national legislation.

In addition, to the selected subsectors, a rough picture of legislation's effects on the wholesale costs of chemical products (NACE 46.75) is presented, based on information collected during the study.

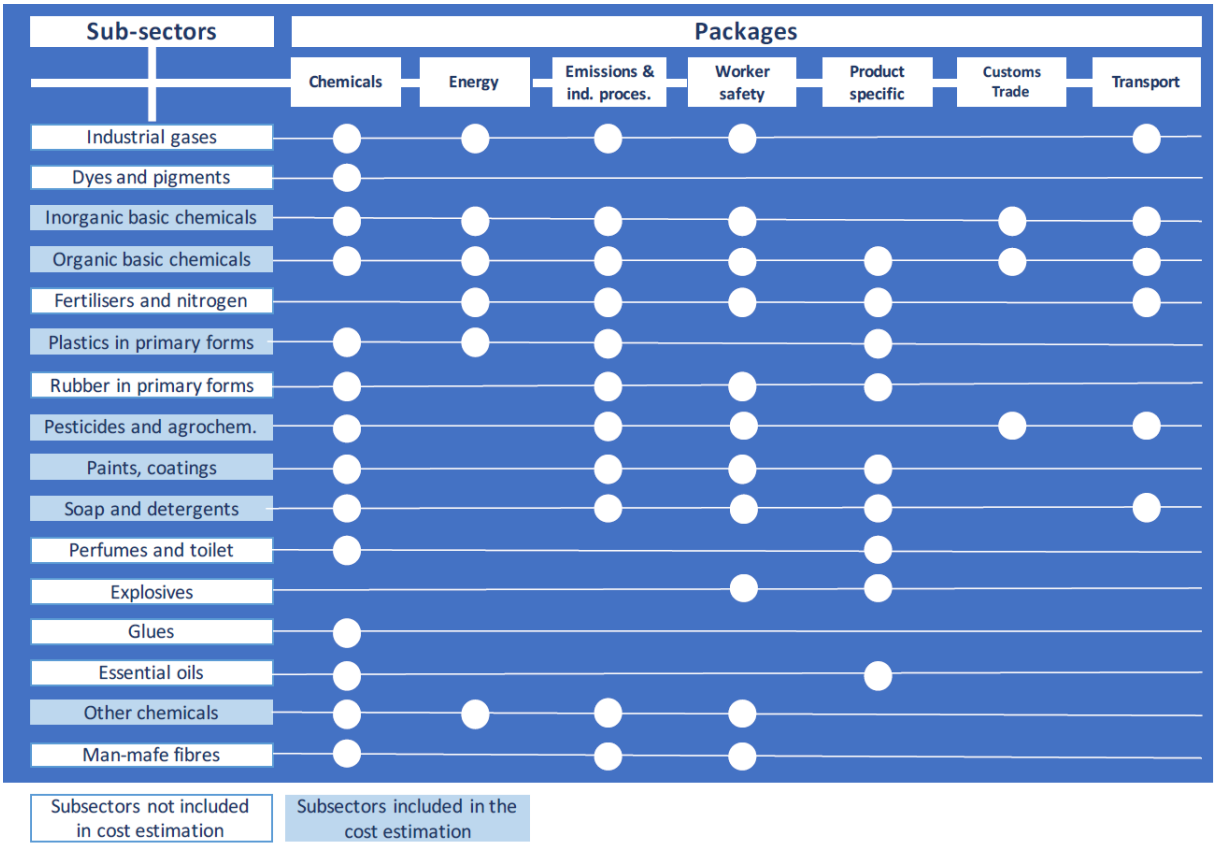


Table 9 Legislation packages per subsector

B. Evidence base and limitations

Data collection in the CCA1 study did not rely on statistical methods. Detailed data were collected from a panel of 31 typical companies[2], which were selected according to a set of criteria. The estimated costs for this panel of companies were validated in two workshops with industry experts and stakeholders. Then the data were adjusted based on the results from an online survey that addressed a larger sample of 90 companies. The results from the online survey appeared to be in line with the cost figures provided by the panel companies, supporting the premise that the initial panel consisted of typical firms. Finally, the data were grossed up to represent the whole population of each subsector by multiplying the turnover of each subsector by the adjusted cost per turnover of the typical companies of the sub sector. The grossing up by using multipliers that represent the whole population of a particular group relies on the hypothesis of full compliance, which however is not always the case. Therefore, in certain cases, it could lead to an overestimation of absolute values by assuming that all companies fully comply with the legislation.

Despite its significant advantages regarding feasibility, the method is less accurate when compared to statistical methods, and it can only provide an estimate of the order of magnitude of cost borne by companies due to EU legislation. Furthermore, the cost estimates derived in the CCA1 study cannot be considered as an entirely accurate estimate of the cost of the EU chemicals *acquis* due differences of scope between the study and Fitness Check and certain limitations with the methodology applied:

- The period covered (2004-2014) corresponds only partly to the one covered by this Fitness Check.

- Costs correspond to only six subsectors (organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) and not all the industry and companies.
- Costs presented above also include regulatory costs for several pieces of legislation that are not in the scope of this Fitness Check (REACH, Sustainable Use of Pesticides Directive, Large Combustion Plant Directive, EU Emissions Trading System (ETS) Directive, National Emissions Ceilings (NEC) Directive, Air Quality framework Directive and related, OSH Framework Directive, Directive on Personal Protective Equipment, Construction Products Regulation, Paints Directive, Tyre Labelling Regulation, Drug Precursors Regulation). In addition, several other pieces of legislation although within the scope of this Fitness Check, were not covered by the abovementioned cumulative cost assessment attempt.
- While the OSH Framework Directive, *per se*, is not in the scope of this Fitness Check, it can be reasonably assumed that the costs related to occupational health and safety legislation in the chemicals sector derive primarily from the daughter regulations (the Chemical Agents Directive, the Carcinogens and Mutagens Directive, etc.) which are within the scope of the Fitness Check. That said, it should also be noted that the estimated occupational health and safety costs probably include costs of worker safety protection beyond specific risks posed by exposure to hazardous chemicals(e.g. falls from heights, electrocution, burns, etc.) which are substantive but are not within the scope of the Fitness Check.
- Regarding the emissions and industrial processes legislative package, it should be noted that the ETS related legislation is not in the scope of this Fitness Check. In this legislative package, most of the monetary obligations are due to ETS. Therefore, the regulatory costs of emissions and industrial processes legislative package as assessed for the purposes of this Fitness Check can be estimated to represent EUR 2.6 billion (instead of EUR 3.1 billion).

3.2.2 Study on the cumulative health and environmental benefits of chemical legislation (CuBA Study)

A. Methods and analytical models

The CuBA Study pulled together a large body of evidence on the risks posed by chemicals and on the effects of chemicals legislation. It was completed in August 201753.

The study aimed at answering the following questions:

1. In terms of avoided damage to human health and to the environment, what has been achieved through chemicals legislation adopted by the European Union since 1967.
2. Recognising substantial progress has been made, what is the nature and scale of contemporary damage to human health and the environment that can be attributed to chemicals exposure today, under current legislation?
3. Given the current situation, what are the key emerging and evolving risks to European economy and society caused by chemical exposure and what are the major gaps in our current understanding of the risk and effects of legislation that now need to be addressed?

53 https://publications.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

The overall approach and model used to arrive at the estimates – both physical and monetary – of the environmental and human health benefits of EU chemicals legislation are outlined in Figure 4, Figure 5 and Figure 6 below.

First, the study identified the receptor (i.e. specific health or environmental effect of concern). Background information is also presented. Second, it examined chemical substances that are known or suspected to cause this damage and the strength of that relationship. Third, it evaluated the end impacts (i.e. what does the evidence show that chemicals substances actually cause; this may include cancer, mild mental retardation, imposex, infertility or egg shell thinning). Fourth, what is the exposure route and what legislative action has been taken to address this damage?

Fifth, sixth and seventh, as far as available evidence permits, what has been the result. This may include changes in emissions/exposure or evidence of changes in biological concentration of chemicals in human blood, breast milk, urine, or water, for example. It includes physical improvements, such as improvements in water quality, fish populations, biodiversity, for example and in some cases includes monetary estimates of the benefits.

Finally, for each health and environmental impact end point, information on the current health burden is summarised, alongside an evaluation of knowledge and data gaps, which may continue to inform future policy action. Each chapter in the main study report is supplemented by a technical annex, with further detail on specific legislation is provided (the same individual piece of legislation may be referred to more than once), technical analysis is explained and references are provided. This is provided as a separate document with separate chapters for each chapter in the main report. This is referred to as the 'technical appendix'[54].

[54] Study on the cumulative health and environmental benefits of chemical legislation, Final Report – Technical Appendix

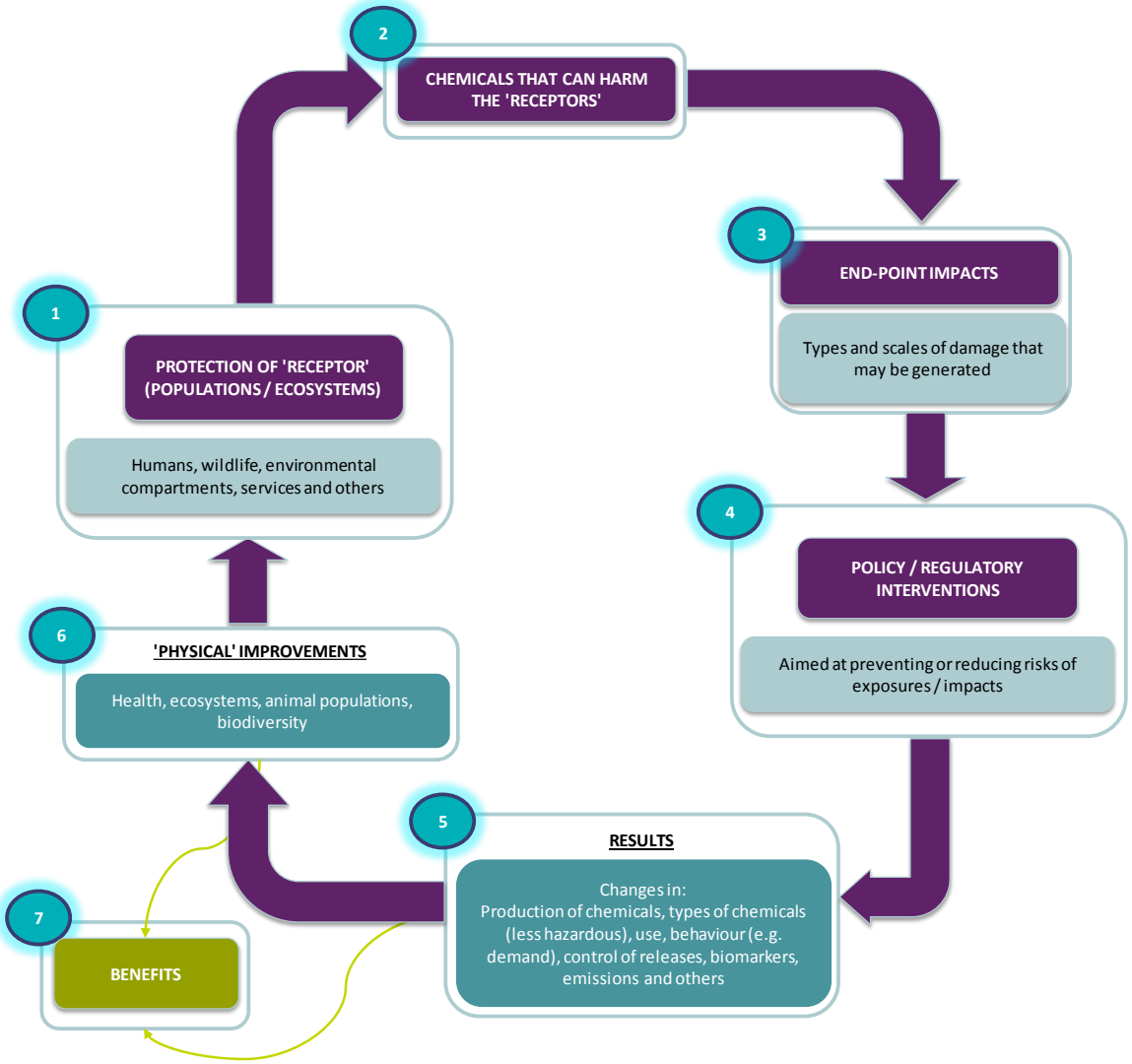


Figure 4 Overall structure of the analysis

Legislative scope*:* The CuBA Study covered "chemicals and related legislation". This included the chemicals legislation covered by Annex I to the study entitled "Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps". This list was published in the context of the 2013 Review of REACH. It covered relevant legislation between 1967 and September 2011. A review undertaken at the start of the project also identified legislation implemented between September 2011 and August 2015 that was also of relevance. In total over 200 individual pieces of legislation were identified – including many amendments and revisions. This included, for example, legislation on biocides, occupational exposure to chemicals and pesticides (i.e. where legislation has been introduced with the primary aim of to addressing the harmful effects of chemicals). The scope also included some key pieces of legislation such as the Water Framework Directive (WFD) and Industrial Emissions Directive (IED) that, although not specifically or solely aimed at chemicals risk management, contain specific articles which address emission control of some specific chemicals and hence have contributed to the outcomes. Whilst volatile organic compounds VOCs were considered in the context of paints and solvents, combustion by-

products such as NO_x, SO_2 or PM are not, as these are addressed by air quality and industrial emissions legislation, amongst others. The overlap between the broader legislative scope of the CuBA Study and the Fitness Check evaluation is summarised in Annex 4 of this Staff Working Document.

Geographical scope: The focus of the CuBA study was the European Union. Clearly, the number of Member States continues to evolve[55]. This is referred to where relevant on a case-by-case basis.

Approach to assessment of benefits: Assessing the effects of chemicals legislation of the scope attempted by the CuBA Study was challenging. It required various data, on uses, emissions and exposure, on legislative provisions and the effects of these, on health and environmental indicators and the associated changes in specific effects. Moreover, some assumptions had to be made, in particular in the selection of dose-response functions, willingness to pay (WTP) values, disability adjusted life year (DALY) losses and values, amongst others. These are set out in the main study report with further detail in the technical appendix. This is complicated by the multiple causal factors involved, the time period in question and the number of individual pieces of legislation that have been considered alongside the latency of the diseases. As such there has been no single approach taken; the study pieced together the available evidence, but in general did not attempt to generate new primary data. Whilst new primary data was not generated, new analysis and, therefore, information was generated where practicable. Broadly, there are three routes to identifying the impacts, which combine a "top down" and "bottom up" approach (see figure 3).

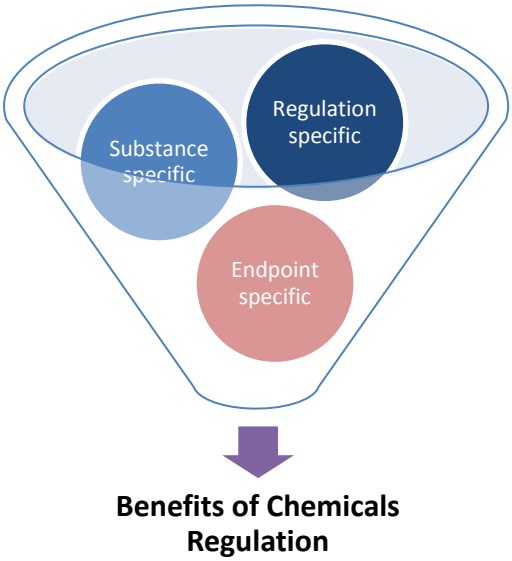


Figure 5 Assessing benefits - three windows

- Evidence which relates to a chemical substance. This includes data on production of carcinogens, on emission of heavy metals or data on chemical concentration in human

[55] 1967 founding Members: Belgium, Germany, France, Italy, Luxembourg and the Netherlands. 1973 Denmark, Ireland and the UK; 1981 Greece, 1986 Spain and Portugal; 1995 Austria, Sweden and Finland. In 2004 Cyprus, the Czech Republic, Estonia, Hungary and Lithuania, Latvia, Malta and Poland, Slovenia and Slovakia. Bulgaria and Romania joined in 2008, Croatia in 2013. https://europa.eu/european-union/about-eu/countries_en

samples (biomarkers), for example. In combination with an understanding of the human or environmental damage caused by these substances this provides a picture of likely changes in the ultimate effects and on the role of legislative action – alongside other factors – in any change.

- Evidence which relates to a specific (or group of) chemical regulation. This includes evidence where the benefits from specific action, such as restrictions on use of chemicals (e.g. under the REACH regulation) have been considered. This provides a relatively straightforward answer as to the effects, but examples of ex-post, rather than ex-ante evidence are comparatively few.
- Evidence which relates to an health or environmental impact endpoint, for instance cancers, reproductive health disorders or water quality, drawing out – as far as practicable – the role of chemical exposure. This is rather more straightforward for the human health effects given the high level data published by bodies such as the WHO, than for the environmental effects.

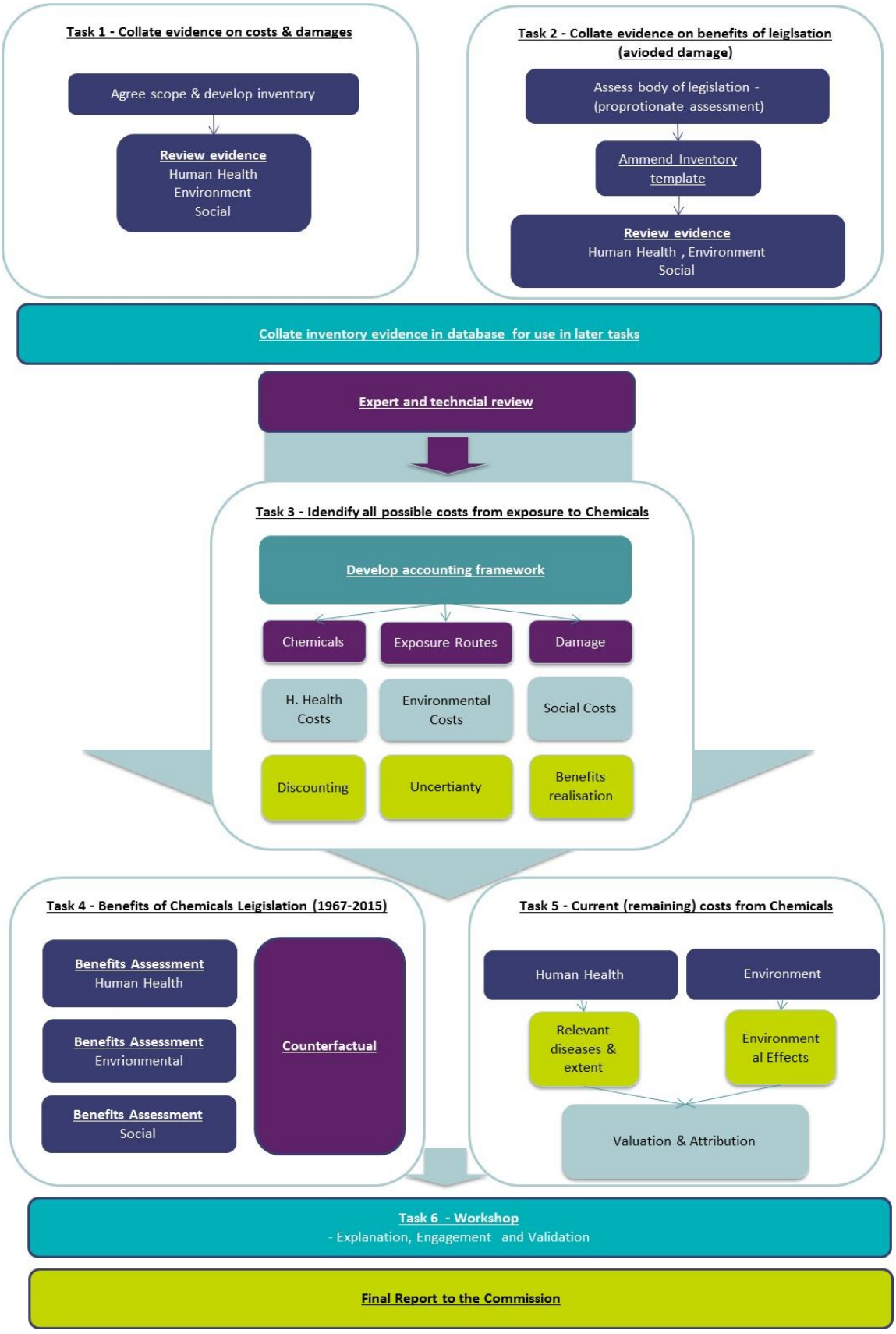


Figure 6 Method overview

There are several *potential* drivers in changes in the manufacture/use of dangerous chemicals in Europe, of which regulation is arguably the most important. These include efficiency gains, initiatives by industry carried out on a voluntary basis, alongside wider changes in economic structure. Given the legislative, geographical and temporal scope of the CuBA Study, it was not practicable to evaluate each casual factor in detail. However, the study drew extensively on a wide literature which has sought to evaluate the role that regulation has played specifically, evaluated the casual factors qualitatively in several case study examples, which suggest the role of regulation in driving the benefits observed has been significant.

"Any report on the "economic cost" of impacts on human health, be it from air pollution or any other source, involving as it does a "valuation" of life and of health, needs to explain as clearly as possible what precisely is meant by the terms "value" and "cost". This is a non-trivial task. For the use of these terms is frequently misunderstood.

The world is not yet free of the illusion that the wealth of the world subsists in gold (or some other form of money): the "chrysohedonistic illusion". Even though an explicit rejection of this view characterises the founding works of economic science in the mid-eighteenth century following through to today, long after gold has given way to paper money, it is all too frequently supposed that what economists really mean by "value", or by "cost", is a given sum of money.

It is therefore as well to begin by stating that this is not so: money is not the thing being measured but the instrument with which we measure it. Of course, money plays several roles wherever it is present rival schools of economic thought hold rival views on the roles that it plays. In the context of the present analysis, however, and irrespective of these otherwise rival views, all economists can agree that money serves here merely as a common unit of account, an imperfect instrument with which to measure certain non- monetary phenomena: namely, the several various items that all of us as individuals "value" in the ordinary sense of the word.

So, what is it that we as individuals' value and that economists as observers seek to measure? They include:

consumption – and, with it, the sacrifice of some items of consumption in order to secure others, including the sacrifice of current consumption in the act of investment in order to secure greater future consumption;

- leisure – and the sacrifice of some leisure in the act of labour in order to secure consumption;
- health – and the sacrifice of some part of consumption in order to secure health;
- life – and the sacrifice of some part of consumption in order to preserve it.

"Value" as used here – also called "utility" – is simply a measure of these items that we all value in the ordinary sense of the word "cost" is a measure of their loss, absolutely or as a means of securing other valuable items. The task of the economist then becomes one of aggregating at a social level these millions of individual valuations at their marginal rates of substitution"[56]

[56] OECD (2014), The Cost of Air Pollution: Health Impacts of Road Transport, OECD Publishing. http://dx.doi.org/10.1787/9789264210448-en

Quantification and monetisation of benefits: Where a quantitative or monetised estimate of benefits of chemicals legislation was derived, this took into account both 'direct financial' benefits (including the avoided cost of diagnosis and treatment and productivity savings from avoided loss of working days or reduced cognitive potential) and wider 'personal valuation' or intrinsic benefits (including willingness to pay (WTP) to avoid a health condition and the associated loss of function/quality of life or environmental outcome). Monetary benefit estimates in this study used a wide range of available unit values including WTP data, values of statistical life (VOSL) and life-year lost (VOLY) as well as average treatment and environmental abatement measure costs. The approach to valuation was an important aspect in the study and in the field of policy assessment more generally. These issues were considered - based on first principles - in 2014 by the OECD, quoted in full below, and provide a useful reflection on what it is that policy analysts aim to assess and value.

Case studies and discounting: Case studies form part of the CuBA Study analysis of cancers, neurodevelopment, cardiovascular and respiratory diseases and reproductive health. The case studies provided quantitative estimates of human health benefits based on specific chemical, effect relationships (e.g. lead and its effects on IQ). These, in turn, drew on dose-response relationships and other data drawn from secondary evidence. The case studies evaluated and compared effects over time. Because they were drawn from different secondary data sources, the time periods were not always consistent. The results were presented in two ways.

- First, the study provided a "snapshot" by comparing the difference in the health damage at the beginning of the case study period to that at the end. This enabled the study to draw conclusions regarding how much damage has reduced for individuals/groups of people.
- Second, the study provides a "cumulative" benefit estimate, whereby all the benefits for each and every year within the case study period were estimated. Average annual benefits were then presented, based on this cumulative figure.

Both the cumulative and snapshot benefit estimates presented in the CuBA Study are undiscounted values. Discounted values of these benefits were noted where applicable in the footnotes. The discount rate used in the case studies followed that used in the underlying source analysis. The values presented in the study are undiscounted due to different time periods of the case studies used, ranging from 1982-2015 up to 2000-2014 and the fact that the periods covered by the case studies was in the past.

Interpretation of "cumulative": The study did not seek to attribute specific impacts to each and every individual piece of legislation. This was considered impracticable and would not permit an overview of what has been achieved. However as far as the evidence allowed, the assessment attributed benefits to groups of legislation. The focus is on "cumulative" benefits (avoided health and environmental damage) delivered through the cumulative effect (accumulation) of various different pieces of legislation, each addressing a risk or group of risks. The study did not arrive at a single number to represent the cumulative benefit accrued to the EU as a result of avoided health and environmental damages due to chemical exposure as a result of legislation between 1967 and 2015. Rather, various analyses were undertaken – using a range of quantitative, qualitative and case study evidence.

Counterfactual and the role of Member State legislation: The history and evolution of EU environmental (and chemical) legislation is inextricably linked to Member State action. That

was fully recognised here[57]. The scope of the CuBA Study was not to assess implementation at Member State level, nor to narrowly examine the added value of EU chemicals and chemicals related legislation above and beyond what Member States might have done in the absence of EU action (i.e. the marginal benefit of EU action). This was considered impracticable on this scale. The study considered benefits from chemicals and chemicals-related legislation in the EU, compared to a reference point of no legislation (either EU or Member State). Where meaningful and possible, benefits that could be attributed specifically to EU chemicals and chemicals-related legislation were identified. This includes for example, cases where there was no Member State legislation prior to the promulgation of the EU legislation. That was not to ignore or downgrade the role of Member States in the development of policy, rather it was an acknowledgement that they cannot meaningfully be separated. In terms of the counterfactual, this was quantified in a small number of cases, but was more often descriptive (i.e. evaluating the problem and nature of harm before implementation and how was this ultimately addressed). Again this reflects the myriad factors at play and the different time periods over which benefits were assessed.

B. Evidence base and limitations

The CuBA Study aimed to assimilate a very large body of information, this was collated in an "inventory" of information conducted as part of Task 1 and Task 2 of the study. Whilst secondary data was applied in novel ways – for instance in case study analysis - the purpose of the study was not to generate new primary evidence; however, elements of new analysis were undertaken, based on existing data sources. Equal focus was placed on both qualitative and quantitative information and on health and environmental issues; the available studies, data and other evidence varies significantly in terms of its robustness, and this was taken into account in the work.

Similarly, the analysis did not focus solely on monetary/economic data, but sought to draw out physical improvements where possible. This approach was important not only in the context of practicability, but also in terms of presenting the study outputs and key messages in a range of different ways. Where a quantitative estimate of monetary benefits of chemicals legislation was derived, this took into account both 'direct' benefits (including the avoided cost of diagnosis and treatment and productivity savings from avoided loss of working days) and 'full' benefits (including willingness to pay to avoid the condition and the increased consumer surplus). The CuBA Study excluded an analysis of the administrative and compliance costs of legislation that had been considered elsewhere. Similarly, issues typically referred to as "social" benefits, such as effects on innovation and employment were excluded.

A 'three tiered' approach was adopted to categorise data and information in terms of its robustness for the purposes of the CuBA assessment:

- Tier 1 evidence: a relationship (between a chemical substance and a particular health and environmental impact) where the science, methodologies and data are reasonably robust and will allow for a high level of certainty and could be used as the basis for good, defensible benefit estimates.
- Tier 2 evidence: relationships where the science, methodologies and data are less robust but there is sufficient evidence to suggest probable health or environmental

[57] A good overview is provided in Haigh (2016) EU Environmental Policy: Its journey to centre stage. Routledge.

impacts. This evidence will be presented with acknowledgement of the significant uncertainties and error margins.

- Tier 3 evidence: these would be areas where significant health and environmental impacts are suspected but the science, data, or monetisation methodologies are too limited to even attempt determining broad estimate ranges. It would, essentially, be a qualitative discussion of science/data/evaluation gaps on suspected impacts.

The CuBA Study focussed on complex issues with very many contributing factors, with incomplete evidence and, in some instances, with large margins of uncertainty. Notwithstanding this, an attempt was made to draw out the evidence, and to present this in different ways, according to what is available. The assumptions are clearly stated in the CuBA Study report. The key uncertainties in the benefits estimates approach used are:

- The modelling to derive the physical effects (avoided damage to human health arising from reduced exposure to chemical substances).
- The approach to monetising some of the key benefits identified. The approach and associated uncertainties are explained in in the report, with more detail in the technical appendix).

The type of analysis possible is largely driven by scientific knowledge and data available on the impacts that chemicals have on the environment. The analysis is however further complicated by the fact that other pressures (e.g. changes in population, technology, consumer preferences and economic activity) will also have impacts (both positive and negative) on the natural environment. This is reflected in another "scorecard" indicator in the summary findings section of each chapter of the study report as 'regulatory attribution'.

In this study, a wide range of evidence was reviewed literature (much of this qualitative, rather than quantitative) in an attempt to establish the impacts of chemicals on the environment (and through the environment on human health). The CuBA study sought to identify and use studies that already assessed aggregate 'top-down' figures (at EU-28 level where possible) of the benefits from chemicals regulations or in general or at the level of individual chemical regulations. Studies that cover all regulations at the EU level were not identified. Equally studies that look at individual pieces of legislation are often only available focusing on particular substances and at Member State level (i.e. the impact of a particular substance for one Member State). It was rare that a study looked at the impact on an environmental end-point (e.g. water quality or specific species) from multiple substances.

As a consequence, estimates derived in the CuBA study are often 'bottom up', building an EU level aggregate estimate from individual chemicals, often based on site-specific or Member State level data. To extrapolate to generate an EU-28 level estimate requires there to be a significant number of similar studies so that there is at least more certainty that such site/country specific estimates are 'representative'. However such studies are rare, making it only possible in many instances to derive indicative EU level estimates to give a feel of the scale of likely impacts (e.g. benefit is likely to be in several billions euros per year rather than several millions euros per year).

The "chrysohedonistic illusion": finally, and critically relevant for the CuBA study, in those instances where it has been possible to understand what the identified "risks" mean in terms of actual physical impacts, these are only a minority, a small sub-set of environmental end-points. A consequence is that, when attempting to value (monetise) a sub-set of impacts, the resulting analysis can inadvertently create the (misleading) perception that actual benefits are modest, because it has only been possible to assign a quantitative or monetary value to some

of those benefits. This is particularly evident in the water quality chapter where it has only been possible to present estimates for a subset of impacts (and not at EU level) and the 'market' benefits presented are not the main benefits. The main benefits here are 'non-market' benefits, which could not practically be assessed in quantitative and monetary terms within the scope of the CuBA study.

It is important to note that this is the first time a study on this scale and scope has been attempted. The work is based on drawing together existing information, though a number of calculations/interpretations have been necessary to derive some of the quantitative figures in the report. In some cases the estimates provided are associated with significant uncertainties. These are discussed at length, but are provided as a starting point for additional research and discussion. Where benefits relate to productivity and/or healthcare treatment ("direct financial") costs, these are compared to GDP in national accounts to provide context on their significance; others reflect "personal valuation" (willingness to pay to avoid certain medical ailments or for ecosystem services, for example). These costs are no less real than those that are linked to GDP: society places a high value on having a long, healthy and fulfilled life. Where appropriate, they are expressed in monetary terms.

4 Annex 4 Information regarding the legal scope of the Fitness Check, its supporting studies and other relevant sources of information

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
1. Classification, labelling and packaging (Regulation No (EC) 1272/2008, 'CLP')	• High level of protection of human health and the environment • Free movement of substances, mixtures and articles	-	-	X		X	X
2. REACH, Annex XIII (Regulation (EC) No 1907/2006, 'PBT/vPvB criteria')	• High level of protection of human health and the environment • Promotion of alternative methods for assessment of hazards of substances • Free circulation of substances on the internal market • Enhancing competitiveness and innovation	No	Both	X		X (*covers entire REACH)*	X (*covers entire REACH*)

[58] Please note that the CCA1 Study also covers pieces of legislation that are not in the scope of this Fitness Check while also not covers entirely the scope of this Fitness Check

[59] Please note that the CuBA Study covers pieces of legislation that are not in the scope of this Fitness Check while also not covers entirely the scope of this Fitness Check. Moreover, it only provides examples of quantified benefits and does not provide an overall benefit estimate of the EU chemicals legislation.

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
3. Inland transport of dangerous goods (Directive 2008/68/EC)	• Ensure the uniform application of harmonised safety rules throughout the Community and a high level of safety in national and international transport operations	Indirectly	Both	X		X	X
4. Carcinogens and mutagens at work (Directive 2004/37/EC)	• Protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work.	Yes	Both	X		X	X
5. Young people at work (Directive 1994/33/EC)	• Prohibit work by children • Ensure that work by adolescents is strictly regulated and protected • Ensure in general that employers guarantee that young people have working conditions which suit their age • Ensure that young people are protected against economic exploitation and	Yes	Both	X		X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	against any work likely to harm their safety, health or physical, mental, moral or social development or to jeopardize their education						
6. Pregnant workers (Directive 1992/85/EEC)	• Encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or who are breastfeeding	Yes	Both	X		X	X
7. Signs at work (Directive 92/58/EEC)	• Encourage improvements in the safety and health of workers at work	No	Both	X		X	
8. Chemical Agents (Directive 98/24/EC)	• Protect workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents	Yes	Both	X		X	X
9. Asbestos (Directive 2009/148/EC)	• Protect workers against risks to their health, including the prevention of such	No	Both		X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	risks, arising or likely to arise from exposure to asbestos at work						
10. Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)	• Prevent and control pollution arising from industrial activities • Prevent or, where that is not practicable, to reduce emissions into air, water and land and to prevent the generation of waste, in order to achieve a high level of protection of the environment taken as a whole	Yes	Both	X	X	X	X
11. Waste Framework (Directive 2008/98/EC) and List of Waste **(Commission Decision 2000/532/EC)**	• Protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use	Indirectly	Both	X		X	X
12. Waste shipments (Regulation (EC) No 1013/2006)	• Protect the environment • Establish procedures and control regimes	Indirectly	GRC	X	X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	for the shipment of waste						
13. Major-accident hazards involving dangerous substances ('Seveso') (Directive 2012/18/EU)	• Prevent major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to ensuring a high level of protection	Yes	Both	X		X	X
14. Water Framework (Directive 2000/60/EC)	• Protect and prevent further deterioration of inland surface waters, transitional waters, coastal waters and groundwater and reduce pollution; achieve good surface water status • Promote sustainable, balanced and equitable water use including the provision of the sufficient supply of good quality	No	Both	X	X	X	X
15. Urban Waste Water Treatment (Directive 91/271/EEC)	• Protect the environment from the adverse effects of discharge of waste water from households and certain industrial sectors	No	GRC		X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
16. Marine Strategy Framework (Directive 2008/56/EC)	• Achieve or maintain good environmental status in the marine environment by the year 2020 at the latest	No	GRC		X		X
17. Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)	• Protect human health and the environment, including the environmentally sound recovery and disposal of electrical and electronic equipment waste	Indirectly	GRC		X	X	X
18. End of life vehicles (Directive 2000/53/EC)	• Prevent waste from vehicles and, in addition, at the reuse, recycling and other forms of recovery of end-of life vehicles and their components so as to reduce the disposal of waste, as well as at the improvement in the environmental performance of all of the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-	Yes	GRC	X		X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	of life vehicles						
19. Batteries (Directive 2006/66/EC)	• Improve the environmental performance of batteries and accumulators and of the activities of all economic operators involved in the life cycle of batteries and accumulators	No	GRC		X	X	X
20. Packaging and Packaging Waste (Directive 94/62/EC)	• Harmonize national measures concerning the management of packaging and packaging waste in order, on the one hand, to prevent any impact thereof on the environment of all Member States as well as of third countries or to reduce such impact, thus providing a high level of environmental protection, and, on the other hand, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community	Indirectly	GRC		X	X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
21. Biocidal products (Regulation (EU) No 528/2012)	• Improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment	Yes	Both	X	X	X	X
22. Plant protection products (Regulation (EC) No 1107/2009)	• Ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production	Yes	Both	X	X	X	X
23. Residues of pesticides (Regulation (EC) No 396/2005)	• Ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of	Indirectly	Both		X		

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	pesticide residues in or on food and feed of plant and animal origin						
24. Export and import of hazardous chemicals (Regulation No 649/2012)	• Implement the Rotterdam Convention Promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals in order to protect human health and the environment from potential harm • Contribute to the environmentally sound use of hazardous chemicals	Yes	GRC		X	X	X
25. Persistent organic pollutants (Regulation (EC) 850/2004)	• Protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants and and by	Yes	GRC		X	X	X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of these substances						
26. Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)	• Ensure agricultural productivity and sustainability and to make it possible to ensure public and animal health, animal welfare and the environment • Ensure the free movement of goods, persons, services and capital	No	Both		X		X
27. EU Ecolabel (Regulation (EC) 66/2010)	• Establish a voluntary ecolabel award scheme intended to promote products with a reduced environmental impact during their entire life cycle and to provide consumers with accurate, non-deceptive, science-based information on	Yes	Both	X	X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	the environmental impact of products						
28. Toy Safety (Directive 2009/48/EC)	• Lay down rules to ensure the safety of toys and their free movement in the Community	Yes	Both	X	X	X	X
29. Cosmetic products (Regulation (EC) No 1223/2009)	• Establish rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health	Yes	Both	X	X	X	X
30. Detergents (Regulation (EC) No 648/2004)	• Achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health	Yes	Both	X	X	X	X
31. Drinking Water (Directive 98/83/EC)	• Protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean	No	Both		X		X

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
32. Fertilisers (Regulation (EC) No 2003/2003)[60]	• Ensure the internal market in fertilisers	No	GRC	X		X	X
33. Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, which have undergone a revision)[61]	• Harmonise the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices in order to guarantee the free movement of such devices within the internal market	Yes	Both		X		X
34. Aerosol dispensers (Directive 75/324/EEC)	• Remove barriers to the establishment and functioning of the common market	Yes	GRC	X			

[60] Currently undergoing a revision

[61] To be repealed (subject to exceptions) on 26 May 2020 and 26 May 2022 respectively by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 which entered into force on 25 May 2017

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
35. Explosives (Directive 93/15/EEC)[62]	• Ensure the protection of end-users and the safety of the public	No	Both		X	X	X
36. Pressure equipment (Directive 2014/68/EU)	• Harmonise national provisions on risks due to pressure • Remove obstacles to free movement of pressure equipment within the Union	Yes	Both	X	X		X
37. Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)	• Ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of	Yes	Both	X	X	X	X

[62] Repealed by Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	human health and the interests of consumers						
38. General Product Safety (Directive 2001/95/EC)	• Improve the functioning of the internal market • Ensure a high level of consumer protection and safety by introducing a general product safety requirement, and containing provisions on the general obligations of producers and distributors, on the enforcement of Community product safety requirements and on rapid exchange of information and action at Community level in certain cases	Both	GRC		X	X	X
39. Test methods (Regulation (EC) No 440/2008)	• Set out the test methods to be applied for the purposes of Regulation 1907/2006/EC • Review, where appropriate, the test methods contained in this Regulation	Yes	Not triggering RMMs	X			

Title	Objectives	Refers to the CLP for hazard identification, classification or labelling?	Risk management measures (RMMs) triggered by Generic Risk Considerations (GRC), Specific Risk Assessment (SRA) or both?	Covered by			
				1st FC Study	FC+ Study	CCA1 Study[58]	CuBA Study[59]
	with a view to replacing, reducing or refining testing on vertebrate animals						
40. Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)	• Provide for a harmonised system for study audit and inspection of laboratories to ensure that that they are working under GLP conditions and that test data generated by laboratories in one Member State are also recognised by other Member States	No	Not triggering RMMs	X			
41. Protection of animals used for scientific purposes (Directive 2010/63/EU)	• Establish measures for the protection of animals used for scientific or educational purposes	No	Not triggering RMMs		X		

TABLE 2 Evolution of the EU chemicals legislation

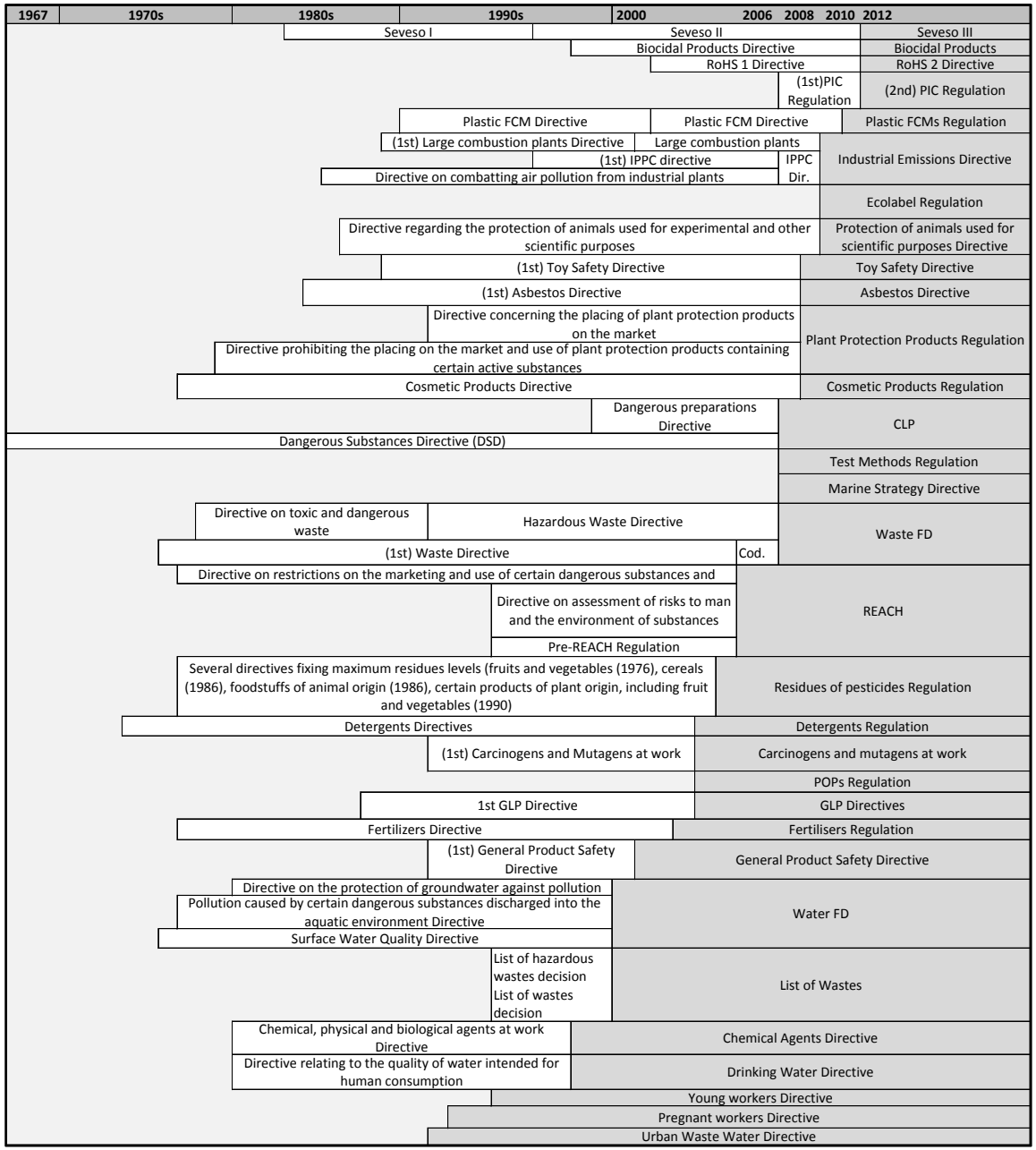

1967
1970s
1980s
1990s
2000
2006
2008
2010
2012
Seveso I
Seveso II
Seveso III
Biocidal Products Directive
Biocidal Products
RoHS 1 Directive
RoHS 2 Directive
(1st)PIC Regulation
(2nd) PIC Regulation
Plastic FCM Directive
Plastic FCM Directive
Plastic FCMs Regulation
(1st) Large combustion plants Directive
Large combustion plants
(1st) IPPC directive
IPPC Dir.
Industrial Emissions Directive
Directive on combatting air pollution from industrial plants
Ecolabel Regulation
Directive regarding the protection of animals used for experimental and other scientific purposes
Protection of animals used for scientific purposes Directive
(1st) Toy Safety Directive
Toy Safety Directive
(1st) Asbestos Directive
Asbestos Directive
Directive concerning the placing of plant protection products on the market
Directive prohibiting the placing on the market and use of plant protection products containing certain active substances
Plant Protection Products Regulation
Cosmetic Products Directive
Cosmetic Products Regulation
Dangerous preparations Directive
CLP
Dangerous Substances Directive (DSD)
Test Methods Regulation
Marine Strategy Directive
Directive on toxic and dangerous waste
Hazardous Waste Directive
Waste FD
(1st) Waste Directive
Cod.
Directive on restrictions on the marketing and use of certain dangerous substances and
Directive on assessment of risks to man and the environment of substances
REACH
Pre-REACH Regulation
Several directives fixing maximum residues levels (fruits and vegetables (1976), cereals (1986), foodstuffs of animal origin (1986), certain products of plant origin, including fruit and vegetables (1990)
Residues of pesticides Regulation
Detergents Directives
Detergents Regulation
(1st) Carcinogens and Mutagens at work
Carcinogens and mutagens at work
POPs Regulation
1st GLP Directive
GLP Directives
Fertilizers Directive
Fertilisers Regulation
(1st) General Product Safety Directive
General Product Safety Directive
Directive on the protection of groundwater against pollution
Pollution caused by certain dangerous substances discharged into the aquatic environment Directive
Water FD
Surface Water Quality Directive
List of hazardous wastes decision
List of wastes decision
List of Wastes
Chemical, physical and biological agents at work Directive
Chemical Agents Directive
Directive relating to the quality of water intended for human consumption
Drinking Water Directive
Young workers Directive
Pregnant workers Directive
Urban Waste Water Directive

TABLE 3 Evidence and source of Fitness Check Chemicals findings

EFFECTIVENESS **1st evaluation question: to what extent does the EU legislative framework for the risk management of chemicals meet its objectives?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Substitution of hazardous substances by less hazardous substances has not yet occurred to any notable extent	**Main source**: Eurostat Chemical product and consumption statistics (December 2017)	Open public consultation (question 23)
Human and environmental exposures to hazardous chemicals: meaningful and successful reductions, concerns about ongoing exposures	**Main source**: CuBA Study **Additional sources**: reports from EU-OSHA, EEA and EFSA	Open public consultation (question 24)
Human health and environmental impact evidence and indicators	**Main source**: CuBA Study	
Internal market, competitiveness and innovation	**Main sources**: 1st FC Study; CCA1 Study; CEFIC reports (facts and figures) **Additional sources**: REACH REFIT (SWD(2018) 58 final)	Open public consultation (question 10) SME Panel
EFFECTIVENESS **2nd evaluation question: what factors affect (either positively or negatively) the correct functioning of the EU legislative framework for the hazard identification and risk management of chemicals? What are the consequences or effects that were not originally planned for?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Data, knowledge and information	**Main source**: FC+ Study **Additional sources**: KEMI Market survey report; DG GROWTH and DG ENV websites; EMA; 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final)	1st FC Study workshop
Hazard and risk assessment	**Main source**: FC+ Study **Additional source**: ECHA	Open public consultation (question 17)
Hazard classification	**Main source**: 1st FC Study **Additional source**: ECHA	Open public consultation (question 34)

Communication of hazards and risks	**Main source**: 1st FC Study **Additional source**: FC+ Study; the Commission's proposal with the 'Goods Package' ((COM(2017)795); RAPEX and RASFF annual reports	Eurobarometer Surveys (456 and 468) SME Panel 1st FC Study workshop
Precautionary principle	**Main source**: FC+ Study **Additional sources**: 1st Fc Study; the Commission's communication (COM/2000/0001 final); DG ENV Study 'The precautionary principle in EU environmental policies' (2017);	Open public consultation (questions 14, 15 and 30) FC+ Study workshop Position papers and targeted interviews (FC+ Study)
Balance between GRC and SRA	**Main sources**: 1st FC Study; FC+ Study	Open public consultation (question 14) 1st FC Study and FC+ Study workshop
EFFICENCY **1st evaluation question: what are the costs and benefits associated with the implementation of the legislative framework for chemicals? What are the key drivers for those costs and benefits? To what extent are the costs proportionate to the benefits**?		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Costs and cost drivers	**Main sources**: 1st FC Study; CCA1 Study **Additional sources**: FC+ Study; Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (interim report; June 2018); Fitness Check of Reporting and Monitoring of EU Environment Policy (SWD(2017)230); EFSA and ECHA websites; Better Regulation Guidelines, Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation)	Open public consultation (question 20) SME Panel 1st FC Study workshop
Benefits	**Main source**: CuBA Study **Additional sources**: EFSA; the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); UN Sustainable Development Goals website	Open public consultation (question 19) SME Panel
Proportionality of costs and benefits	**Main source**: 1st FC Study; FC+ Study **Additional sources**: DEFRA (2015)	
EFFICENCY **2nd evaluation question: Evaluation question: what aspects of the functioning of the framework are the most efficient and what are the least efficient?**		

TOPIC	EVIDENCE/SOURCE	STAKEHOLDER VIEWS
Reliance on the CLP Regulation	**Main source**: 1st FC Study	1st FC Study workshop FC+ Study workshop Eurobarometer Survey (456)
Use and access to data	**Main source**: FC+ Study **Additional source**: 1st FC Study	FC+ Study workshop
Grouping approach vs. substance-by-substance approach	**Main source**: FC+ Study **Additional sources**: 1st FC study; OECD website and guidelines	FC+ Study workshop
Organisational efficiency of the EU Agencies	**Main sources**: 1st FC Study; FC+ Study; ECHA, EFSA, SCHEER, SCOEL and SCCS websites (legal documents, rules of procedure; opinions; Second Intermediate Evaluation of the functioning of the SANTE non-food Scientific Committees report) **Additional sources**: REACH REFIT (SWD(2018) 58 final)	FC+ Study workshop

COHERENCE
Evaluation questions: to what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified? What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

TOPIC	EVIDENCE/SOURCE	STAKEHOLDER VIEWS
Coherence of data and testing requirements	**Main source**: 1st FC Study; FC+ Study **Addition sources**: OECD website and guidance documents	
Coherence of hazard assessment and classification	**Main sources**: 1st FC Study; FC+ Study **Additional sources**: Regulations setting out scientific criteria for the determination of endocrine disrupting properties (plant protection and biocidal products; 2018); DG ENV website; the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final)	Open public consultation (question 29)
Coherence of risk assessment	**Main source**: 1st FC Study; FC+ Study **Additional sources**: EMA guidance documents; Report from the Commission to the European Parliament and the Council 'Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on	

	cosmetic products with regard to substances with endocrine-disrupting properties (COM(2018) 739 final)	
Coherence of risk management measures	**Main source**: 1st FC Study; FC+ Study **Additional sources**: Council conclusions on the protection of human health and the environment through the sound management of chemicals (15046/16); 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final); 'European Union Strategic approach to Pharmaceuticals in the Environment' (COM(2019) 128 final)	
RELEVANCE **1st evaluation question: to what extent do the objectives of the legislative framework for chemicals meet the current needs?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
Ensuring a high level of protection of human health and the environment	**Main source**: CuBA Study **Additional sources**: Eurostat	Open public consultation (question 15)
Internal market, competitiveness and innovation	**Main sources**: 1st FC Study; CCA1 Study; CEFIC reports (facts and figures) **Additional sources**: CuBA Study	Open public consultation (question 10) SME Panel
Combination effects	**Main sources**: FC+ Study **Additional sources**: 1st FC study; publications in scientific journals; Commission's communication (COM/2012/0252 final); EFSA website	Open public consultation (question 15)
Impacts on environment, biodiversity and eco-system resilience	**Main source**: CuBA Study	
Substances in articles and circular economy aspects	**Main source**: FC+ Study **Addition sources**: 1st FC Study; Circular Economy Action Plant (2015) and its deliverables (the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); the EU Plastics Strategy (COM(2018) 28 final)); ECHA report on enforcement and market surveillance (2018)	FC+ Study workshop
RELEVANCE **2nd evaluation question: to what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**

Taking into account the concerns of citizens and other stakeholders	**Main source**: 1st FC Study **Additional sources**: the Commission's website (e.g. expert groups, Better Regulation Guidelines), the OECD Regulatory Policy Outlook 2018 report	Open public consultation (question 15)
Transparency of procedures	**Main source**: 1st FC Study **Additional sources**: the General Food Law REFIT (SWD(2018) 37 final); the Commission's proposal on the transparency and sustainability of the EU risk assessment in the food chain	Open public consultation (question 16) 1st FC Study Workshop
Robustness of procedures	**Main source**: 1st FC Study	
EU ADDED VALUE **Evaluation question: what is the added value of regulating the risk management of chemicals at an EU level rather than at national level?**		
TOPIC	**EVIDENCE/SOURCE**	**STAKEHOLDER VIEWS**
EU added value	**Main sources**: 1st FC Study; FC+ Study	Open public consultation (question 9) Eurobarometer Survey (456)

TABLE 4 Related and targeted evaluations of individual pieces of legislation with the scope of this Fitness Check

LEGISLATION	EVALUATION .	PROVIDES INFORMATION ON
Plant protection products (Regulation (EC) No 1107/2009) **Residues of pesticides (Regulation (EC) No 396/2005)**	***ONGOING***	Costs and cost drivers (industry, public authorities, the Commission, EFSA)
REACH (Regulation (EC) No 1907/2006)	***FINISHED***	Coherence SCOEL/ECHA Testing and alternatives to animal testing Coherence (hazard/risk assessment and risk management measures; derogation mechanisms)
Occupational Safety and Hygiene (OSH) Legislation[63]	***FINISHED***	State of play and implementation Cost drivers
Waste legislation (Five Waste Stream Directives: sludge, PPWD, PCB/PCT, ELV, Batteries)	***FINISHED***	State of play and implementation
Waste shipments (Regulation (EC) No 1013/2006)	***ONGOING***	-
Urban Waste Water (Directive 91/271/EEC)	***ONGOING***	-
EU Ecolabel (Regulation (EC) 66/2010) (EMAS and Ecolabel)	***FINISHED***	-
Safety of toys (Directive 2009/48/EC)	***ONGOING***	State of play and implementation
Detergents (Regulation (EC) No 648/2004)	***ONGOING***	State of play and implementation Costs and cost drivers Coherence

[63] Including Carcinogens and mutagens at work, Safety signs at work, Pregnant workers, Chemical agents at work, Young people at work, Asbestos at work Directives but also covers many pieces of OSH legislation, including the OSH framework Directive that are not in the scope of this Fitness Check

Drinking Water (Directive 98/83/EC)	***FINISHED***	-
Fertilisers (Regulation (EC) No 2003/2003)	***FINISHED*** *external*	-
Aerosol dispensers (Directive 75/324/EEC)	***FINISHED*** *external*	-
Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)	***ONGOING***	-
EU Water Legislation (Water Framework Directive (2000/60/EC), Groundwater Directive (2006/118/EC), Environmental Quality Standards Directive (2008/105/EC), Floods Directive (2007/60/EC))	***ONGOING***	-

4.1.1 Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation (1st FC Study)

A. Objectives

The 1st FC Study's objective is to evaluate the CLP Regulation and the interface with other related chemicals legislation, including other legislation governing hazard identification and communication and legislation establishing risk management measures linked to CLP. The evaluation carried out by the study is based on the criteria of effectiveness, efficiency, coherence, relevance and EU added value in accordance with the Commission's Better Regulation guidelines.

B. Scope

The 1st FC Study covers the legislation that has horizontal linkages with the CLP Regulation in terms of hazard identification, classification and communication and/or that has vertical linkages in terms of risk management measures and risk assessment procedures triggered by the CLP classification.

<table>
<tr><th>Legislation with horizontal linkages with the CLP Regulation</th><th>Legislation with vertical linkages with the CLP Regulation</th></tr>
<tr><td>The REACH Regulation (Regulation (EC) No 1907/2006) (limited to Annex XIII on PBTs and vPvBs)</td><td></td></tr>
<tr><td colspan="2">Plant Protection Products Regulation (Regulation (EC) No 1107/2009)
Biocidal Products Regulation (Regulation (EU) No 528/2012)
Cosmetic Products Regulation (Regulation (EC) No 1223/2009)</td></tr>
<tr><td>Detergents Regulation (Regulation (EC) No 648/2004)</td><td></td></tr>
<tr><td colspan="2">Toy Safety Directive (Directive 2009/48/EC)</td></tr>
<tr><td>The Water Framework Directive (Directive 2000/60/EC)</td><td></td></tr>
<tr><td>Fertilisers Regulation (Regulation (EC) No 2003/2003)</td><td></td></tr>
<tr><td colspan="2">OSH legislation (Directive 92/85/EEC pregnant workers; Directive 94/33/EC young people at work; Directive 98/24/EC chemical agents at work; Directive 2004/37/EC carcinogens or mutagens at work)</td></tr>
<tr><td rowspan="7"></td><td>Directive 2014/40/EU on manufacture, presentation and sale of tobacco</td></tr>
<tr><td>Regulation (EC) No 66/2010 on the EU Ecolabel</td></tr>
<tr><td>Regulation (EC) No 450/2009 on active and intelligent materials</td></tr>
<tr><td>Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food</td></tr>
<tr><td>Directive 2014/68/EU pressure equipment</td></tr>
<tr><td>Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals</td></tr>
<tr><td>Directive 2012/18/EU on the control of major-</td></tr>
</table>

	accident hazards involving dangerous substances (Seveso III)
	Directive 2010/75/EU on industrial emissions
	Directive 2008/98/EC on waste
	Directive 1999/31/EC on the landfill of waste
	Directive 2000/53/EC on end-of life vehicles
	Regulation (EC) No 1013/2006 shipments of waste
	Directive 2004/35/CE on environmental liability

In addition, the 1st FC Study also covered:

- The Test methods Regulation (Regulation (EC) No 440/2008))
- The Aerosol dispensers Directive (Directive 75/324/EEC)
- The Inland Transport of dangerous goods Directive (Directive 2008/68/EC
- The GLP Directives (Directives 2004/9/EC and 2004/10/EC)
- The Signs at work Directive (Directive 92/58/EEC)

C. Time period covered

As the 1st FC Study covers legislation that has links with the CLP Regulation, the reference in time is aligned to the adoption of the CLP (2008) and goes until 2016 approximately (the 1st FC Study was competed an published in January 2017). Cost-benefit assessment covers:

- Transition costs: comparison to cost estimated done in 2006 (impact assessment for the implementation of the UN GHS via the adoption of the CLP Regulation).
- Ongoing costs: comparison to no legislation in place (2008-2016).
- Benefits: annual benefits of the DSD and the DPD (2000-2008) and of the CLP (since 2008).

D. Deliverables

The work required for the 1st FC Study was organised into a series of main tasks and sub-tasks. The Evaluation report provides evidence on the following aspects:

- An analysis of the different pieces and provisions of legislation, which make up the framework of chemicals regulation;
- The identification of areas where the cost of implementation is high compared to the benefits for health and the environment, as well as positive examples where the implementation is particularly efficient;
- The identification of gaps in health and environmental protection as well as gaps, overlaps, inconsistencies and other issues affecting the performance of the legislation;
- The identification of areas where potential for improvement, modernisation and simplification have not yet been harnessed; and
- The identification of existing mechanisms and procedures that work well and that could be considered as best practice.

The Evaluation report is organised as follows:

- The main document sets out the higher level conclusions of the evaluation for each of the main evaluation criteria (Section 3 to 7).

- Annexes II to V provide more detailed analysis that supports the higher-level conclusions presented in the main document. Annex VI provides separate reports on individual case studies.

E. Engagement with stakeholders

The work required for the 1st FC Study included supporting the Commission in organising an online open public consultation, SME Panel Survey and a stakeholder workshop.

In addition to the formal consultation activities, targeted data collection from key stakeholder groups took place. This targeted consultation covered: Member State authorities, civil society (as represented by various non-governmental organisations), workers representatives, consumer representatives and industry (via the main EU industry associations).

F. Main conclusions

Effectiveness:

- CLP and its links to other legislation are an important contributor to health / environmental protection by providing a coherent system for the identification and communication of hazards and forming the basis for risk management under other legislation.
- Issues negatively affecting effectiveness include specific differences in implementation between Member States, inappropriateness of classification rules for certain mixtures and information overload on labels.
- Legal gaps include the lack of consideration of combination effects of different chemicals and multiple routes of exposure for a single chemical, as well as the lack of certain classification criteria under CLP and the delayed completion of criteria for endocrine disruptors.

Efficiency:

- It is not possible to provide full quantification of all the costs and benefits of the chemicals framework. The study does provide detailed cost estimates of the implementation of CLP, amounting to 1.3 billion euros in annual costs for industry. This is in the same price range as the recent estimate in the Cumulative Cost Assessment (CCA) for the chemicals industry.64 This is complemented by costs related to poison centre notifications (around €1.7 billion).
- In terms of benefits, classification, labelling and related risk management have generated significant health and environmental benefits, in particular due to reductions in poisoning incidents and occupational diseases.
- Costs for the transition to the CLP Regulation from the EU's system are estimated at 1.2 billion euros, which is significantly higher than the original estimate in the impact assessment in 2007.65 Anticipated benefits with respect to international trade have

64 The CCA study estimated 1.47 billion euros of annual costs for capital and operational expenditures (CAPEX/OPEX) generated by chemicals legislation and incurred by the chemicals industry. The estimate in the fitness check study only covers the CLP Regulation, yet comprises all sectors of industry.

65 The impact assessment (SEC(2007) 854) provided an estimate of 526 million euros transition costs (albeit based on a slightly different transitional period). Annual costs for CLP may decrease in the future, in particular after the REACH 2018 deadline.

been realised by only a small percentage of companies, as significant differences in GHS implementation around the world continue to exist.
- Revisions in harmonised classifications can generate significant costs, either due to the impacts of labelling on consumer perception or due to legal requirements (automatically triggered) in downstream legislation.

Coherence:
- The central position of CLP in the chemicals framework ensures a coherent approach to hazard classification.
- Incoherent scientific opinions can occur between ECHA and EFSA with regard to the hazardousness of active substances in plant protection products.
- There are inconsistencies within the framework, e.g. inconsistent legal definitions, overlaps and inconsistent requirements (e.g. GLP)
- There are inconsistent approaches to labelling, in particular between cosmetics and other chemicals (including detergents), e.g. for environmental hazards.

Relevance:
- There is agreement among stakeholders that the objectives of the legislative framework remain relevant.
- Some needs are not adequately addressed by the legislative framework, notably the minimisation of hazardous substances in consumer products.
- There is scope for the use of more innovative approaches, notably to convey safety information to consumers, in particular given the increasing interest of consumers in the ingredients of the products that they purchase (e.g. allergens).
- Development of opinions on harmonised classifications by ECHA's Committee for Risk Assessment is considered to be very transparent.

EU added value:

There is consensus that risk management of chemicals at an EU level is needed to ensure a high level of health / environmental protection while avoiding barriers to trade.

4.1.2 Study supporting the Fitness Check on the most relevant chemicals legislation (FC+ Study)

A. Objectives

The FC+ Study's objective is to gather, compile and analyse evidence to inform the Fitness Check and to complement the 1st FC Study that covers a substantial part of the FC scope (identified in the Roadmap) but not all aspects e.g. specific risk assessment procedures were not investigated in detail, particularly those that are not linked to the CLP. Similarly, a comparison of the various risk management approaches in the EU chemicals and chemicals related legislation needed to be performed.

B. Scope

The FC+ Study reviews those pieces of legislation that operate independently from the CLP for hazard identification and classification, and furthermore where specific risk assessment procedures form the core part of the risk management process.

Independent of CLP	Utilises both CLP and other approaches for

	specific components.
Detergents Regulation (Regulation (EC) No 648/2004)	Safety of Toys directive (Directive 2009/48/EC)
Explosives Directive (Directive 93/15/EEC)66	Cosmetic products regulation (Regulation (EC) No 1223/2009)
Pyrotechnic articles Directive (not in the scope of the FC)	Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, which have undergone a revision)[67]
Asbestos Directive (Directive 2009/148/EC)	Pressure equipment directive (Directive 2014/68/EU)
Water Framework Directive (Directive 2000/60/EC)	Industrial emissions (integrated pollution prevention and control) Directive (Directive 2010/75/EU)
Urban Waste Water Directive (Directive 91/271/EEC)	Waste shipments Regulation (Regulation (EC) No 1013/2006)
Marine Strategy Framework Directive (Directive 2008/56/EC)	Export and import of hazardous chemicals (PIC) Regulation (Regulation No 649/2012)
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive (Directive 2011/65/EU)	EU Ecolabel Regulation (Regulation (EC) 66/2010)
Batteries Directive (Directive 2006/66/EC)	Biocidal products Regulation (Regulation (EU) No 528/2012)
Packaging and Packaging Waste (PPWD) Directive (Directive 94/62/EC)	Plant protection products Regulation (Regulation (EC) No 1107/2009)
Persistent organic pollutants (POPs) Regulation (Regulation (EC) 850/2004)	Food contact materials Regulations (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
Drinking Water Directive (Directive 98/83/EC)	General Product Safety Directive (Directive 2001/95/EC)
Protection of animals used for scientific purposes Directive (Directive 2010/63/EU)	
Contaminants in food and feed Regulation and Directive (Regulation (EEC) No 315/93 and Directive 2002/32/EC)	
Residues of pesticides Regulation (Regulation (EC) No 396/2005)	

The FC+ Study also looked at cross-cutting themes and asked the question ‘what works well?’ and ‘what works less well?’ covering:

- Science, data and knowledge,
- Risk management based on specific risk assessment,

66 Repealed by Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses

67 To be repealed (subject to exceptions) on 26 May 2020 and 26 May 2022 respectively by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 which entered into force on 25 May 2017

- The role and use of generic and specific risk management approaches within EU chemicals legislation,
- Coherence of data, science and risk management procedures are measures,
- Gaps in the EU chemicals acquis as regards achieving high level protection of human health and the environment, as well as for the functioning of the internal market and competitiveness.

C. Time period covered

The FC+ Study was launched in October 2015 and completed in November 2017. The focus of the Study was therefore on the state of play of the EU chemicals legislation by that time.

D. Deliverables

The report briefly sets out the history of and rationale for chemicals legislation, and in particular the approach to risk assessment and associated risk management. It includes a review of the use of specific risk assessment approaches, and their use as compared to the identification of risk management measures based on generic risk considerations. It also includes a review of the different types of risk management measures and the circumstances under which different measures are selected.

The FC+ Study Evaluation report provides evidence on the following aspects:

- Science, data and knowledge:
  - Uptake and treatment of different scientific inputs;
  - Test methods for hazard determination;
  - Availability and suitability of occurrence and exposure data;
  - Data sharing and access.
- Risk Management Based on Specific Risk Assessment (SRA):
  - Risk assessment triggers;
  - Health and environmental end-point coverage;
  - Exposure assessment and reduction;
  - Transparency, access and stakeholder inputs;
  - Efficiency of specific risk assessment procedures;
  - Socio-economic assessment;
  - Uncertainty and the precautionary principle.
- The role and use of generic and specific risk management approaches within EU chemicals legislation:
  - Effectiveness, efficiency and balance: the application of the generic and specific risk management approaches under the EU chemicals acquis;
  - The use of specific risk assessment derogations within generic risk management approaches;
  - Consistency of application of each approach.
- Coherence of data, science, and risk management procedures and measures:
  - Coherence of use of science, data and knowledge across legislation;
  - Coherence of decisions to trigger a risk assessment / regulatory action;
  - Coherence of risk assessment procedures (hazard identification, exposure assessment, risk assessment);
  - Coherence of risk management measures.
- Gaps in the EU chemicals acquis:

- Combination effects of chemicals;
- Endocrine disruptors;
- Nanomaterials;
- Chemicals in products;
- Pharmaceuticals and the environment;
- Missing hazard classes;
- Vulnerable groups;
- Circular economy considerations.

E. Engagement with stakeholders

The FC+ Study included a significant amount of stakeholder engagement including interviews with Commission Services, Member State Competent Authorities, industry, NGO groups and academics. The study has also included a one day workshop.

F. Main conclusions

Effectiveness:

- Overall, the EU's chemicals legislation, including its risk assessment and associated risk management approaches, have been effective in meeting their objectives of protecting health and the environment, while improving the free movement of substances, mixtures and articles on the market and enhancing the EU's competitiveness and innovation.
- There are specific areas where the legislation could work better e.g. ongoing exposure to substances present in (imported) articles, how chemicals are managed in recycled materials in the context of the circular economy.
- There are some cases where the highest-hazard chemicals are given particular regulatory attention, but also cases where chemicals with arguably equally significant hazards are not managed in a comparable way (e.g. neurotixicity).
- The high resource requirements for specific risk assessments (and submissions for approval/authorisation) that are triggered by industry mean that, under some legislation, the submissions are dominated by larger companies, with SMEs finding the resource needs a barrier to applying.
- The fact that assessments of a chemical under one piece of legislation do not always trigger (re)assessment under other legislation has also been highlighted as an area where risks are not being adequately assessed/managed and hence benefits not being fully realised.
- There are also examples of unnecessary regulatory burden being placed on industry and authorities through the difficulties in sharing information on chemicals between different pieces of legislation, largely due to intellectual property issues.
- Overall the balance between the use of risk management based on specific risk assessment and that based on generic risk considerations seems to work well.
    - There are a few instances where it has been questioned whether the right balance between the two approaches is being struck, most notably in the case of whether the generic approach should be applied to a wider range of hazard classes (e.g. neurotoxicity, sensitisers, and environmental effects where currently only health impacts are covered), or should be applied to a more consistent list of hazard classes across legislation.

    - Likewise, however, there are cases where adverse socio-economic impacts are occurring through e.g. automatic bans under the generic approach, and these could perhaps have been mitigated if there was more potential for specific risk assessment (and socio-economic considerations) to be taken into account, allowing for derogations from automatic restrictions on substances.
    - Furthermore, there are cases where the resource burden of undertaking specific risk assessments means that insufficient progress is being made (e.g. for risk assessment of substances in food contact materials).
- Implementation and enforcement at Member State level is still a challenge.

Efficiency:

- Costs of the legislation, and in particular the specific risk assessment processes, vary significantly amongst the pieces of legislation.
- In general, specific risk assessments under legislation covering the most hazardous chemicals and most widespread uses are more costly and time-consuming (e.g. on biocides and plant protection products). Conversely assessments in clearly defined uses (e.g. cosmetics, toys) are generally less resource intensive.
- The requirement for approval of active substances and subsequent authorisation of the products (in two stages) and the need to apply for authorisation of products in multiple member states have been highlighted as areas where there are opportunities to streamline and reduce costs.
- While differences in approaches of the various scientific committees have been highlighted (sometimes with seemingly contradictory conclusions on the same substances), some actions are already being taken to improve consistency in approaches and decision making. One of the least efficient elements highlighted was the speed at which substances used in food contact materials are being assessed.

Coherence:

- In general, chemicals legislation is coherent in terms of the use of science, data and knowledge across legislation and their use in assessing and managing risks.
- There are different information requirements, different approaches and different levels of stringency in identifying/applying RMMs; however the different approaches are largely tailored to the specific circumstances of the legislation in question.

Relevance:

- Overall, the chemicals legislation in scope continues to meet current needs in terms of the risk assessment and associated risk management approaches. Changes in scientific knowledge are taken into account; product authorisations are largely reviewed regularly; and the legislation covers new substances and products as they are introduced to the market.
- A number of gaps in relation to relevance to current needs have been identified e.g. omission of environmental risks from consideration under some legislation; a number of emerging health/environmental endpoints that are seemingly not taken into account such as neurotoxins, immunotoxins, sensitisers and endocrine disrupting chemicals.
- A number of gaps in the current chemicals acquis are identified, including how legislation deals with the effects of chemicals in combination (or from multiple sources); endocrine disrupters; nanomaterials; chemicals present in products; pharmaceuticals in the environment; vulnerable groups; circular economy

considerations (hazardous chemicals in closed material loops); and the missing hazard classes identified above.

EU added value:

- The current approach to regulating the majority of chemicals through assessment and management of risks at EU level in general works well. It leads to good sharing of data and pooling of resources; it enables consistency of approach and predictability in terms of risk management; and helps to facilitate the internal market.
- Collectively, EU-level action on chemicals has helped to create a unified approach which in some cases has set the standard for managing health and environmental risks at a global level.

4.1.3 Cumulative cost assessment (CCA1 Study)

A. Objectives

The aim of the CCA1is to provide for quantification of the cumulative costs of the most relevant EU legislation with a bearing on the chemicals industry in the 28 EU Member States during the period 2004-2014 and quantify the cumulative costs in the subsectors of the chemical industry. The objective is also to demonstrate how the costs have changed over time and to compare the costs with relevant financial indicators for the chemical industry.

This study does not assess the benefits of EU legislation and does not aim to provide insights related to the proportionality of costs and benefits of legislation, nor its efficiency or effectiveness

B. Scope

The CCA1 Study analyses cumulative costs of EU legislation with a bearing on six subsectors of the chemicals industry during the period 2004-2014. The six subsectors concerned are inorganic basic chemicals, organic basic chemicals, plastics in primary forms, pesticides and other agrochemicals, specialty chemicals, soaps and detergents. The choice of the subsectors is based on the availability of reliable data (and therefore not on the volumes produced and placed on the market, market shares, etc.).

The different pieces of legislation within its scope are divided in seven legislative packages:

Legislative package	Legislation covered by CCA1 Study
Emissions and industrial processes package	Emission Trading Scheme (ETS) legislation Industrial Emissions Directive (repealing IPPC and Large Combustion Plants Directives) National Emission Ceilings (NEC) Directive Waste Framework Directive and related (WEE, Landfill, ELV, Batteries, PPWD) Seveso Directives Water Framework Directive Air quality legislation
Energy package	Energy Taxation Directive Renewable Energy Directive Energy Efficiency Directive Promotion of COGENERATION Directive
Chemicals package	CLP (including the repealed anterior legislation) Plant Protection Products Regulation and related

	(including the repealed anterior legislation) Sustainable Use of Pesticides Directive Biocidal Products Regulation (including the repealed anterior legislation) REACH (including repealed pre-REACH legislation) POPs Regulation
Workers safety package	Occupational Safety and Health (OSH) framework Directive Carcinogens and mutagens at work Directive Young people at work Directive Pregnant workers Directive Signs at work Directive Chemical Agents Directive Directive on Personal Protective Equipment
Product specific, customs and trade and transport package	Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive Food Contact Materials (FCMs) Regulation General Product Safety Directive PIC Regulation RoHS Directive Inland transport of dangerous goods Directive Tyre Labelling Regulation Ethanol Denaturation Regulation and Directive Deco-Paints Directive Explosives Legislation

The CCA1 therefore covers several pieces of legislation that are not in the scope of this Fitness Check but also does not cover the full scope of the Fitness Check.

COVERED ONLY BY CCA1	COVERED BY CCA1 AND FC CHEMICALS	COVERED ONLY BY FC CHEMICALS
REACH Sustainable Use of Pesticides Directive ETS Directive Air Quality legislation OSH Framework Directive Directive on Personal Protective Equipment Construction Products Regulation and Directive Deco Paints Directive Ethanol Denaturation Regulation and Directive Tyre Labelling Regulation Drug Precursors Regulation National Emission Ceilings (NEC) Directive	CLP Plant Protection Products Regulation Biocidal Products Regulation REACH Annex XIII Inland Transport of Dangerous Goods Carcinogens and Mutagens at Work Directive Young People at Work Directive Pregnant Workers Directive Signs at Work Directive Chemical Agents Directive Industrial Emissions Directive (repealing IPPC and Large Combustion Plants Directives) Waste Framework Directive and related (ELV, Batteries and PPWD) Seveso Directive Water Framework Directive RoHS directive PIC (Import and Export of Dangerous Chemicals) Regulation POPs Regulation Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive Food Contact Materials Regulation General Product Safety Directive	Test Methods Regulation Good Laboratory Practice Directives Protection of Animals Used for Scientific Purposes Directive Pressure Equipment Directive Medical Devices Directives Aerosol Dispensers Directive Drinking Water Directive EU Ecolabel Regulation Contaminants in Food and Feed Regulation and Directive Residues of Pesticides Regulation Urban Waste Water Directive Marine Strategy Framework Directive Waste Shipments Regulation Asbestos Directive

Figure 7 Comparison of pieces of legislation covered by the Fitness Check and by the CCA1 Study

C. Time period covered

The CCA1 study covers legislation active during the period 2004-2014 even if repealed or amended within this period.

D. Deliverables

The final report briefly provides:

- a broad overview of the chemical sector;
- a short overview of each legislation package and focuses more on the types of cost incurred by legislation to the industry;

- a presentation of different types of costs per legislative package;
- an overall picture of the cost (as a total and for each legislation package and subsector); and
- estimates of the evolution of the costs over the period 2004-2014.

E. Engagement with stakeholders

The CCA1 Study engagement with stakeholders was done through its different preparation phases e.g. discussion of the legal scope with industry and during the data collection phase e.g. sending to a list of pre-identified companies a detailed questionnaire, interviews. While only an online survey was carried out was used to test and adjust the estimated legislation costs, a validation workshop with targeted companies and industrial associations took place. A second workshop was organised by the European Commission and gather a wider audience of stakeholders (industry, trade unions, NGOs and Commission services).

F. Main conclusions

When all legislation relevant to chemical companies is cumulated, the estimated average annual total direct cost borne by the subsectors covered by the study during the period 2004-2014 approaches €9.5 billion, representing around 2% of their turnover and 12% of the value added. In addition to the estimated cumulative cost, companies also bear indirect legislation costs, passed on to them through feedstock and other inputs (e.g. electricity or machinery). The opportunity costs due to the withdrawal of substances or the loss of markets may also be important. Although companies raised the issue of indirect cost during the interviews, no robust assumptions could be made for estimating the relevant costs based on the provided qualitative information.

Among the legislation packages, the emissions and industrial processes package represents approximately 33% of the regulatory cost (4% of the subsectors' value added), the chemicals package 29% (3.5% of value added) and workers' safety 24% (2.9% of value added). The contribution of the other legislation packages to the overall regulatory cost is much smaller. The share of the energy package is around 9% (1.1% of the value added), transport 3% (0.3% of value added), product-specific 1% (0.2% of value added) and customs and trade only 0.4% (0.05% of value added). Although the other reported figures do not include costs associated with national legislation, the estimation of the energy taxes cost, which represents 69% of the energy package, does contain the contribution of national legislation.

The variability of costs across the different subsectors is significant and reflects not only differences in product groups and their production chains but mainly differences in the anticipated impact of each subsector on health and safety (of both consumers and employees), and the environment. Thus, the higher cost as a percentage of value added is observed in pesticides and other agrochemicals, amounting to 23.2%, and the lowest in plastics, at 2.7%. The cost for specialty chemicals represents 16.7% of the subsectors' value added, for inorganic basic chemicals the cost amounts to 12.1%, for organic basic chemicals it is 11.3%, and for soaps and detergents 11.4%.

Within subsectors, variability reflects the size of companies and their organisational structure, efficiency, level of integration and product portfolio. SMEs in general incur higher costs compared to large organisations because the costs to comply with legislation are not linear and cannot be amortised on a large volume of chemicals.

Administrative burden is mainly related to the cost of the preparation and submission of information for registrations and the issue of permits, as well as for the information of product users (e.g. labelling), while it does not include the associated monetary obligations (e.g. fees for registration, permits or certification). Overall, it amounts to 10% of the total regulatory cost. Although administrative burden is the smallest cost category, it affects all subsectors. The highest administrative burden is observed in soaps and detergents, where it represents almost 28% of the legislation cost and 3.2% of the subsector's value added. Pesticides also bear a relatively high administrative burden, representing 14% of their regulatory costs and 3.2% of their value added. It is less significant, but with a share higher than average, for specialty chemicals, amounting to 12% of the regulatory cost, equivalent to 2% of the value added. This cost is mainly driven by the chemicals legislation package, which is responsible for 75% of the administrative burden, and more specifically by the legislation related to REACH, Plant Protection Products (PPPs), Biocides and Classification, Labelling and Packaging (CLP). However, a noticeable reduction of administrative burden is expected in the future, due to the final registration deadline for REACH in 2018.

Monetary obligations amount approximately to 20% of the regulatory cost. They include mainly taxes, levies, charges and registration fees. The latter contributes to the financial viability of the monitoring and enforcement system by covering part or all of their costs (for example, REACH registration fees cover the cost of maintaining the REACH registration and monitoring system). Out of all monetary obligations, those stemming from the chemicals legislation package, representing 7% of the total cost, are related to the sustainability of the enforcement and monitoring system. The remaining monetary obligations (representing 13% of this type of costs) are linked directly to energy and environmental policy objectives (taxes and allowances related to the Emission Trading System).

When restricting the focus to the chemicals package, the highest monetary obligations cost is observed in pesticides and other agrochemicals (25% of the cost), specialty chemicals (8% of cost) and inorganic basic chemicals (7% of cost). The pieces of legislation generating the highest monetary obligations are REACH, PPPs and biocides. Again, as in the case of administrative burden and monetary obligations, a reduction is expected after 2018 in the costs due to REACH.

Capital Expenditures (CAPEX) and Operating Expenditures (OPEX), representing the highest portion of the legislation cost (approximately 71%), affect all subsectors and are mainly driven by the emissions, chemicals and workers' safety legislation packages. CAPEX and OPEX generated by the emissions and industrial processes package aim at reducing emissions and at complying with the best available technique principle. They represent 3.2% of the value added and 27% of the total legislation cost. CAPEX and OPEX driven by the workers' safety and health package aim at increasing the safety conditions and protection of workers. They represent 2.9% of the value added and 24% of total cost. The CAPEX and OPEX generated by the chemicals legislation are mainly driven by CLP and represent 1.7% of the value added and 14% of the total legislation cost. However, similar to REACH registrations, a significant reduction in the costs related to CLP can be expected after the final deadline in 2017.

Changes in the classification of substances published in Adaptations to Technical Progress (ATP) affect the compliance of companies with several legislation packages, requiring additional investments or generating administrative burden. When frequent changes in classification affect the same family of products or the same subsector, the economic impact

on the value added can be significant. Classification changes are difficult to predict and, therefore, ex-ante impact assessments fail to consider them in their estimation of cost. CAPEX and OPEX are also often overlooked by impact assessments that mainly focus on administrative burden and monetary obligations that are easier to estimate.

An attempt, presented in the following graph, was made to interpret the evolution of legislation burden by estimating the changes of cost as a percentage of turnover. However, this estimate has to be interpreted with caution, as this is an estimate of the trend based on the extrapolation of data from a limited number of typical companies and their recollections of past costs. Therefore, information about the most recent years is more accurate than about the earliest years of the examined period, as it is demonstrated by comparing collected data with Eurostat data for CAPEX and OPEX for environmental protection. However, direct comparison is difficult due to different definitions and assumptions about the costs. Comparing the data series of Eurostat with the evolution of cost of the emissions and industrial processes package, which is the most relevant to Eurostat data, there are clear differences in the period 2004-2007, where Eurostat data presents a declining of cost. However, for the period after 2008 both data sets demonstrate a similar trend, namely an increase during the period 2008-2010 followed by a period of stability.

The major milestones of the evolution of cost is the introduction of REACH and CLP in 2007 and 2008 respectively (affecting the cost of chemical legislation) and investment by companies after 2009, in anticipation of the enforcement of Seveso III in 2012 and ETS Phase 3 in 2013. Energy legislation also contributes to costs, especially after 2012. One can expect that CLP and REACH costs will decrease after 2017 and 2018 respectively, while cost of compliance with Biocides and PPPs will continue to expand. Costs of compliance with workers' safety and transport legislation should remain stable.

4.1.4 Cumulative health and environmental benefits of chemicals legislation (CuBA Study)

A. Objectives

The objective of the CuBA study is twofold:

- Evaluate the benefits – in terms of avoided damage to human health and to the environment from exposure to chemicals – of chemicals legislation that have been achieved since 1967.
- Evaluate the costs of on-going damage to human health and the environment that is caused by chemicals exposure today.

The assessment of benefits does not include the consideration of wider socio-economic benefits or impacts of chemicals legislation (in terms of accelerated or foregone innovation, loss of consumer surplus, for example). Similarly, health/environmental benefits of certain chemicals in facilitating efficiencies or technologies for example and potential negative impacts of removing these from the market due to EU chemicals legislation have not been taken into account.

B. Scope

The CuBA Study covers "chemicals and related legislation" ("chemicals" as defined in REACH):

- The chemicals legislation covered by Annex I to the study entitled "Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps", published in the context of the 2013 Review of REACH (1967-September 2011).
- Relevant legislation implemented between September 2011 and August 2015 (the vast majority of these are amendments to the existing body of legislation rather than 'new' legislation).

The CuBA covers several pieces of legislation that are not in the scope of this Fitness Check but also does not cover the full scope of the Fitness Check. The legal scope can be presented as follows:

COVERED ONLY BY CuBA	COVERED BY CuBA AND FC CHEMICALS	COVERED ONLY BY FC CHEMICALS
REACH	CLP	Signs at Work Directive
Directive on the assessment of the effects of certain public and private projects on the environment	REACH Annex XIII	Residues of pesticides Regulations
Sewage Sludge Directive	Inland Transport of Dangerous Goods Directive	Aerosol Dispensers Directive
Dangerous Products Resembling Foodstuffs Directive	Carcinogens and Mutagens at Work Directive	Test Methods Regulation
Food Additives Legislation	Young People at Work Directive	Good Laboratory Practice Directives
Occupational Safety and Health Framework Directive and related	Pregnant Workers Directive	
Nitrates Directive	Chemical Agents Directive	
Regulation on Community Customs Code	Asbestos Directive	
Recovery of Petrol Vapors during Storage Directive	Industrial Emissions Directive	
PCB/PCT Directive	Waste Framework Directive and related (ELV, Batteries and PPWD)	
Directive on Certain Methods for the Quantitative Analysis of Binary Textile Fibre Mixtures	Waste Shipments Regulation	
Internal Combustion Engines for Non-road Mobile Machinery Directive	Seveso Directive	
Novel Foods legislation	Water Framework Directive	
Information Procedures legislation	Urban Waste Water Directive	
Fuels legislation	Marine Strategy Framework Directive	
Landfill Directive	RoHS directive	
GMOs legislation	Biocidal Products Regulation	
Tobacco Directive	Plant Protection Products Regulation	
Air Quality legislation	PIC (Import and Export of Dangerous Chemicals) Regulation	
WEEE Directive	POPs Regulation	
General Food Law	Contaminants in food and feed Regulation and Directive	
Recreational Craft Directive	Ecolabel Regulation	
ETS legislation	Toy Safety Directive	
Measuring Instruments Directive	Cosmetic Products Regulation	
Drug Precursors Regulation	Detergents Regulation	
Medicinal Products legislation	Drinking Water Directive	
Bathing Water Quality directive	Fertilisers Regulation	
Directive on Machinery	Medical Devices Directives	
Pyrotechnics directive	Explosives Directive	
Textiles Name Directive	Pressure Equipment Directive	
Market Surveillance legislation	Food Contact Materials Regulation	
Simple Pressure Vessels Directive	General Product Safety Directive	
EMAS Regulation	Protection of Animals used for Scientific Purposes Directive	

Figure 8 Comparison of pieces of legislation covered by the Fitness Check and by the CuBA Study

C. Time period covered

The CuBA Study covers pieces of legislation adopted and amended from 1967 to 2015.

D. Deliverables

The CuBA Study draws together a large body of evidence on the risks posed by chemicals and on the effects of chemicals legislation on human health and on the environment, including in a cross-cutting manner.

E. Engagement with stakeholders

A two-day workshop took place in January 2018. The purpose of the workshop was to present the study findings and to gather stakeholder views on these.

F. Main conclusions

Since the late 1960s the body of chemicals legislation has delivered significant benefits in terms of avoided damage to human health and the environment. These benefits have included:

- Avoided health care costs; avoided lost productivity (from illness/disease and care); avoided damage to cognitive development, reflected in greater long term earnings potential and avoided suffering (assessed through willingness to pay methods).
- Reducing the risk of widespread release of hazardous substances – especially those that are persistent, bio-accumulative and/or toxic - and the associated health, environmental and clean-up costs. These can be most readily observed where action to restrict or ban the use of substances was taken some time after the risks became known, but there has more recently been a general shift toward more proactive risk-based management of chemicals in Europe.
- Avoided environmental damage (such as various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs) are harder to quantify and monetise. However, the available evidence suggests they are likely to be significant and in the order of tens of billions of Euros per year for the European Union.
- When individuals' personal valuations (based on "willingness to pay" to avoid environmental or health damage) are taken into account the values are greater still. For example, long term action taken to protect the ozone layer is cumulatively valued at several hundred billion Euro. The environmental benefits on nutrient recycling arising from tributyltin (TBT) regulations are estimated at upwards of tens of millions of Euro, whilst more general valuations of improved water quality are valued at several billion Euro per year.

Whilst there are many uncertainties, the overall conclusion is that the monetary value of all of these benefits over the last 50 years are likely in the high tens of billion Euro per year, perhaps more. It has only been possible to quantify and monetise a subset of benefits, largely due a lack of data available to quantify the physical impacts of chemical releases (especially on the environment). As methods to aggregate monetary values, particularly for some environmental end points, are improved and as more data becomes available, the balance of evidence indicates the known value of these benefits are likely to increase, perhaps significantly.

Whilst much lower than they otherwise would have been, significant health and environmental impacts from chemicals remain to be tackled. Nor is the situation static, new risks are emerging. Moreover, there is still much we do not know about the health and environmental hazards and risks of many existing chemicals in the EU.

Despite regulatory intervention (and other factors like consumer preferences) there remains an ongoing cost to the environment, from (i) continued use of substances that may be harmful to the environment, (ii) continued use of substances for certain applications that have been exempted from regulation to date, and (iii) residual concentrations of harmful chemicals in the natural environment.

There are several challenges associated with estimating the benefits of chemicals legislation on human health and the environment.

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SWD(2019) 199 final

PART 3/3

COMMISSION STAFF WORKING DOCUMENT

FITNESS CHECK
of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries

Accompanying the document

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses

{COM(2019) 264 final}

5 Annex 5 Effectiveness

Section 5 on Effectiveness in the main document analyses the progress made towards achieving the three core objectives of the EU chemicals *acquis*. It looks for evidence of why, whether or how the progress identified is linked (or not) to the EU chemicals policy intervention as well as identifying any unexpected or unintended effects and consequences. Where progress has fallen short of the desired objectives and targets, the factors influencing this are identified and assessed including the feasibility of the objectives and timescales.

Many of the factors that affect the effectiveness of the EU framework of chemicals legislation are also closely linked to the efficiency, coherence, relevance and implementation of the EU chemicals *acquis*. Issues identified in the Effectiveness section are, therefore, sometimes referred to in other sections where they are analysed in more detail.

This Annex provides a more detailed description of the Fitness Check findings regarding effectiveness.

5.1 Evaluation question: to what extent does the EU legislative framework for the risk management of chemicals meet its objectives?

The performance of the EU chemicals legislation is assessed against its three core policy objectives that are shared by nearly all individual pieces of legislation within the scope of this Fitness Check:

- Ensuring a high level of protection of human health from the adverse effects of hazardous chemicals.
- Ensuring a high level of protection of the environment from the adverse effects of hazardous chemicals.
- Supporting the efficient functioning of the internal market for chemicals and enhancing the competitiveness and innovation of EU industry and business.

As the first two objectives are rather different in their nature from the third objective and, therefore, have different sets of performance indicators, they are assessed separately.

5.1.1 The objective of high level of protection of human health and environment

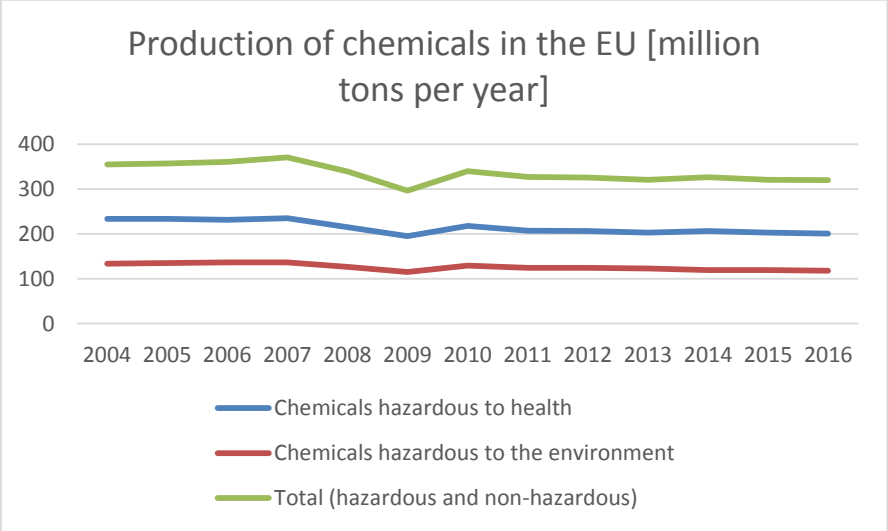
The EU chemicals legislation aims to achieve a high level of protection of human health and the environment by stimulating substitution of hazardous substances by less hazardous chemicals (or alternative non-chemical solutions) and/or by minimising the exposure to hazardous chemicals. The effectiveness of the EU chemicals *acquis* can therefore be measured by analysing the trends in:

- the production and consumption of hazardous substances;
- the human and environmental exposures to hazardous chemicals; and ultimately
- the impacts in the form of the main health and environmental impact parameters associated with exposures to hazardous chemicals, such as trends in the EU incidence rates of certain human diseases, trends in animal population levels, trends in eco-system health/resilience.

A. Production and consumption of hazardous substances

Trends in the production and consumption of hazardous substances, either expressed in absolute terms or relative to overall chemicals production and consumption, are one potential indicator of the substitution of hazardous substances by less hazardous substances. While not shared by all the pieces of legislation within the scope of this Fitness Check, it remains one of the specific goals of the EU chemicals legislation e.g. the Plant Protection Products Regulation and the Biocidal Products Regulation. Eurostat has been producing relevant data sets on this since 2004 for industrial chemicals. The findings of the latest analysis[1] for EU-28 published in December 2017 are:

- The trend in the production of chemicals hazardous to health and environment followed the trend for the overall chemicals production, reaching a peak in 2007, after which there was a significant decline in production during the financial and economic crisis, followed by a strong rebound between 2009 and 2010 and a subsequent more stable phase.
- The share of chemicals hazardous to health and the environment was relatively unchanged over the period 2004–2016. The share of chemicals hazardous to the environment fluctuated between 37% and 39%, while the share of chemicals hazardous to health fell from about 66% in 2004 to 62% in 2016.



[1] http://ec.europa.eu/eurostat/statistics-explained/index.php/Chemicals_production_and_consumption_statistics

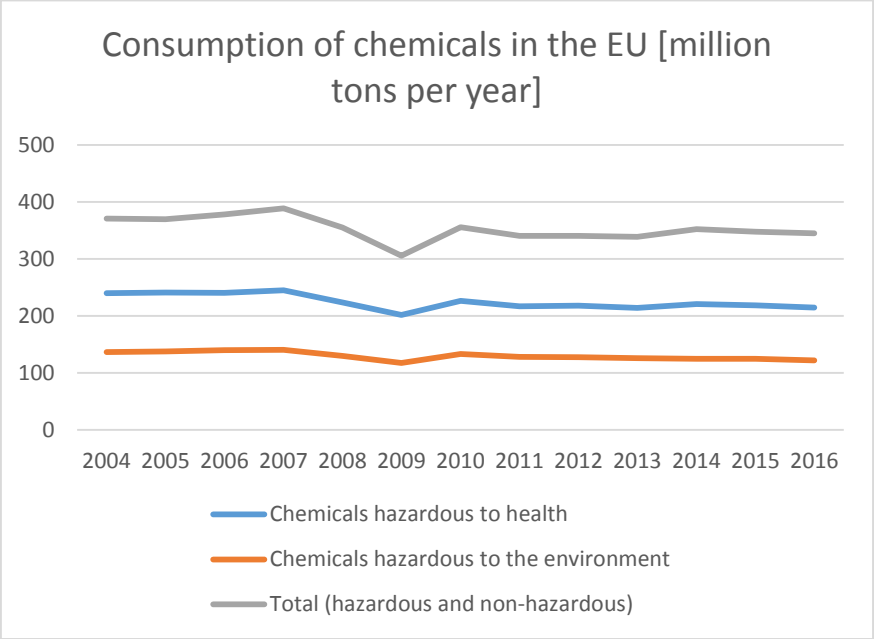


Figure 1 Production and consumption of chemicals, EU-28, 2004-2016. Source: Eurostat (online data codes: env_chmhaz) Note: some chemicals are hazardous to both the environment and human health therefore adding these total together and subtracting the result from the total production or consumption volume to determine the volume of non-hazardous chemicals cannot be done.

Whilst production of chemicals hazardous to the environment fell broadly in line with chemicals production overall, there was variation amongst the five different classes[2] of chemicals.

- The largest overall decrease of 18% in EU-28 production between 2004 and 2016 was recorded for chemicals with the highest level of hazard for the environment (i.e. for chemicals with 'severe chronic environmental hazard and with significant acute environmental hazard').
- The lowest decrease of 4% was for chemicals with moderate chronic environmental hazard (for the period under consideration).

[2] Hazardous to the environment chemicals covers the following 5 classes: (1) Significant acute environmental hazard, (2) Chronic environmental hazard, (3) Moderate chronic environmental hazard, (4) Significant chronic environmental hazard, (5) Severe chronic environmental hazard

Figure 2 Production (1st diagram) and consumption (2nd diagram) of chemicals hazardous to the environment, EU-28, 2004-2016 (million tonnes). The different classes of chemicals are ranked according to their environmental impact from the most harmful (bottom class) up to the least harmful (top class). Source: Eurostat (online data code: env_chmhaz)

- Production of chemicals[3] that are most hazardous for health (i.e. carcinogenic, mutagenic and toxic for reproduction (CMRs)) fluctuated between 39 million tonnes and 41 million tonnes over the period from 2004 to 2007. Production fell between 2007 and 2008 to stand at 35 million tonnes. This rebounded in 2009 and 2010 back to a level that was similar to that recorded prior to the financial and economic crisis. In part, however, this reflects changes in the underlying categorisations of chemicals used by Eurostat when the CLP Regulation was introduced, although the exact impact of this is not known. From 2010, the level of production of CMRs declined once more to around 33 million tonnes in 2016, the lowest level over the whole period from 2004 to 2016. The relative share of CMRs in total EU-28 chemical production fluctuated between 10% and 12% over the period under consideration.

[3] Hazardous to health covers the following 5 classes: (1) Harmful to health hazard, (2) Toxic health hazard, (3) Very toxic to health hazard, (4) Chronic toxic health hazard, (5) Carcinogenic, mutagenic and reprotixic (CMR) health hazard

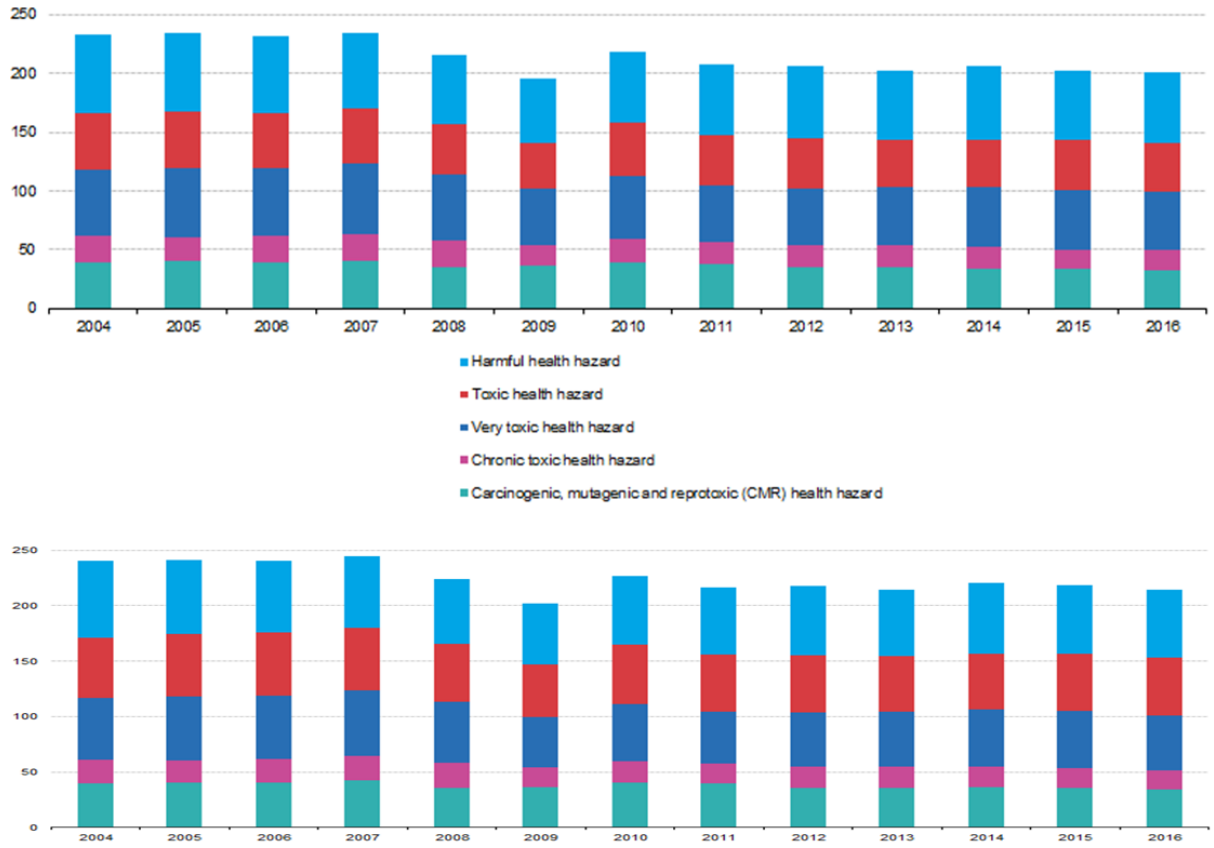


Figure 3 Production (1st diagram) and consumption (2nd diagram) of chemicals hazardous to health, EU-28, 2004-2016 (million tonnes). The different classes of chemicals are ranked according to their human health impact from the most harmful (bottom class) up to the least harmful (top class). Source: Eurostat (online data code: env_chmhaz)

- In general, differences between the consumption and the production of chemicals are small. The consumption is always slightly higher than the production reflecting a net import surplus.

The analysis suggests that substitution of hazardous substances by less hazardous substances has not yet occurred to any notable extent. Essentially, the share of industrial chemicals hazardous to health and the environment in the total chemicals production has remained relatively unchanged over the last decade. This may, in part, reflect the effectiveness of risk management measures in reducing exposures and risks, therefore reducing the incentive to substitute to less hazardous substances.

However, there are also hints of what might be the beginning of a positive substitution trend. The largest overall decrease in EU-28 production between 2004 and 2016 was recorded for chemicals with severe chronic environmental hazard and for chemicals with significant acute environmental hazard (as the production volume was reduced by about 18 % for both classes over the period under consideration). This may indicate that the substitution for these groups to less hazardous chemicals has started to happen (while it does not seem to be the case yet for chemicals hazardous to health). It should be noted, however, that where substitution is referenced in existing pieces of the EU chemicals legislation, it does not provide any qualitative or quantitative basis against which to assess the pace of substitution per se. Also, the currently available statistics do not allow to link changes in the share of chemicals

hazardous to health and the environment to the EU intervention. In order to do so, more in-depth analysis would be required.

When drawing conclusions from this analysis, one should be aware of its limitations. The results are developed on the basis of the Classification and Labelling Inventory (CLI), covering harmonised classification under the CLP Regulation but also self-classifications. New harmonised classifications and re-classifications are on-going. Furthermore, the 'consumption' of chemicals that are contained in articles imported into the EU is not captured in the data presented above.

Respondents to the open public consultation[4] were asked to assign a score of between 1 (no contribution) to 5 (large contribution) to the role of the EU legislative framework in reducing the use of hazardous chemicals and/or substitution with safer alternatives. Scores assigned show considerable variation among the four groups. The weighted scores show that it is Group 2 Industry association/business and 3 Public authority (with weighted scores of 3.4 and 3.5, respectively) that consider the EU chemicals framework to have made the largest contribution to a reduction in number or use of hazardous chemicals and/or an increase in substitution to safer alternatives. Citizens (Group 1) and NGOs and others (Group 5) were less positive with weighted scores of 2.9 and 3.0 respectively.

B. Human and environmental exposures to hazardous chemicals

There is clear evidence that, where targeted EU policy and regulatory actions have been taken, human and environmental exposures to a number of well-known hazardous chemicals have been successfully reduced and, in many cases, minimised. As one example, consumer exposure to lead e.g. in petrol, paints, toys, drinking water, etc., has been reduced by an estimated 89% in the EU between 1990 and 2011, following a variety of risk management measures implemented by Member States, at least in part due to EU legislation.[5] This has resulted in a sustained and significant reduction, on average, in measured levels of lead in blood[6] (see Figure 4 below).

[4] Question 23

[5] CuBA Study p. 373

[6] Ibidem p. 78

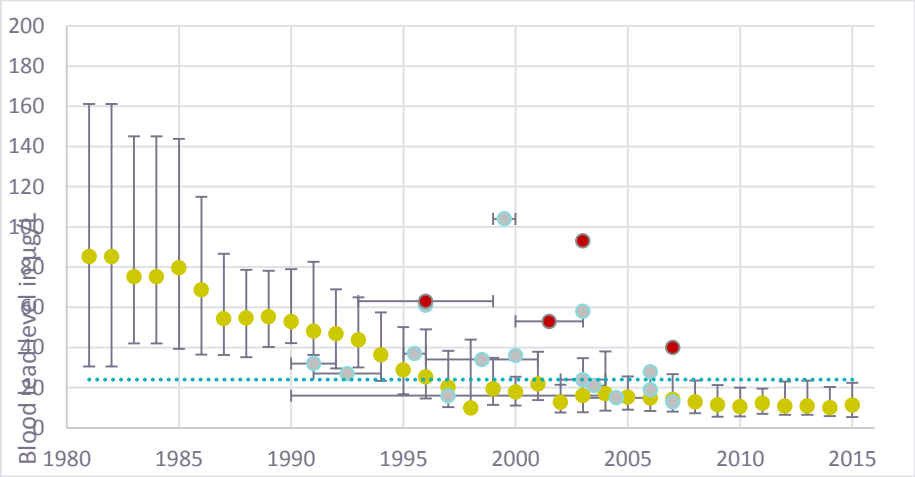


Figure 4 Medians (green dots) and 5th to 95th interval of the distribution of lead levels in the blood of German students from 1981 to 2015, along with levels of lead in blood of children from various European cohorts included in the WHO ENHIS database in grey (no known large lead pollution sources) and red (in the vicinity of known lead pollution sources). Dotted line represents the threshold implied by the WHO IQ loss model.[7]

Another example is emissions of volatile organic compounds (VOCs), which contribute to a host of adverse health effects, including hypertension and chronic obstructive pulmonary diseases (COPD). Following EU and Member States policy interventions, emissions fell by approximately 37% in the EU between 2000 and 2012.[8]

From the environmental perspective, similar outcomes have been achieved in the EU between 1990 and 2011 for a number of heavy metals such as mercury (66% emissions reduction), cadmium (64% emission reduction) and arsenic (78% emissions reduction) over similar timeframes[9] (see Figure 5). Reductions in the concentration of a number of other hazardous chemicals in the environment such as tributyltin, polychlorinated biphenyls (PCBs), dioxins, dichlorodiphenyltrichloroethane (DDT), have also been achieved following EU policy intervention.

[7] Ibidem p. 75

[8] Ibidem p. 90

[9] Ibidem p. 89

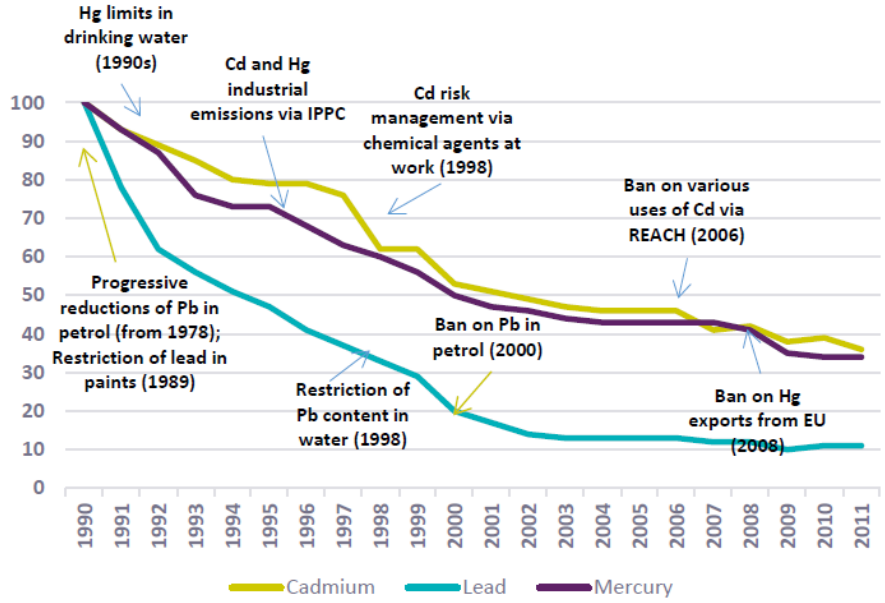


Figure 5 Mercury, Cadmium and Lead emissions (indexed, 1990-2011) alongside selected regulatory action

There are, however, a number of on-going exposure situations that give cause for concern and which point to some shortcomings in meeting the objectives of protecting human health and the environment. These reflect both new, emerging issues, as well as existing ones that require further attention in terms of exposure reduction and control.

Based on current evidence[10], some of the most notable human health related on-going exposure issues in the EU are:

- **Exposures to carcinogenic substances at the workplace:** the European Agency for Safety and Health at Work (EU-OSHA) estimated in 2017 that cancer is the main cause of work-related deaths with 106,307 fatal cases per year in the EU-28[11]. There are many cases of occupational cancers due to past exposures. Setting EU-wide occupational exposure limits (OELs) for a number of substances has helped reduce these exposures. However, regarding substances for which OELs have not been set there are on-going exposure issues. For example, it is estimated that the recent proposal to introduce EU-wide OELs for beryllium, cadmium, arsenic, formaldehyde and 4,4'-Methylenebis(2-chloroaniline) (MOCA) when adopted, in the longer term would prevent over 22 000 cases of work-related ill-health (cancers and non-cancers).[12]
- **Exposures to neurotoxic substances:** whilst the estimates are uncertain, in the EU, some 30 000 disability adjusted life years (DALYs)[13] related to neurodevelopmental

[10] Ibidem, Part A: Protecting Human Health

[11] EU OSH (2017): What are the main work-related illnesses and injuries resulting in death and in DALY: https://visualisation.osha.europa.eu/osh-costs

[12] COM(2018) 171 final

[13] A Disability Adjusted Life Year (DALY) is a method of quantifying the burden of disease. One DALY can be equated to one lost year of "healthy" life. The sum of DALYs across the population - the burden of disease – measures the gap between current health status and an ideal health situation.

disease may be the result of chemicals exposure (and irrespective of a person's genetic predisposition/sensitivity), with some 250 000 DALYs for both chemicals exposure combined with underlying genetic predisposition. This is based on a 'top down' assessment of impacts of pervasive neurodevelopmental disorders from the World Health Organisation (WHO) and an estimate that 3% is due to environmental exposure to chemicals such as lead and other environmental pollutants.

- **Exposures to chemicals linked to cardiovascular and respiratory (CVR) disease:** despite the successful reduction of exposures to lead by some 89% over the last two decades, on-going exposures of EU citizens still account for an estimated 45 000 premature deaths per annum and just over 1 million DALYs related to heart attacks and strokes. Respiratory diseases (primarily obstructive chronic pulmonary disease (COPD) and asthma) account for just over 50 000 deaths per year and some 2.3 million DALYs. Of this, asthma accounts for 10 000 deaths and approximately 1 million DALYs.
- **Exposures to endocrine disruptors (EDs):** the costs of on-going exposures to EDs in the EU-28 have been estimated in a few studies[14] [15] [16] [17] [18] to amount to hundreds of billion euros per year with an estimated median annual cost of EUR 163 billion per year[19] - a significant proportion of which relates to lost productivity and earning potential, being a cost for both society and industry. EDs are considered in these studies as probably responsible for IQ loss and associated intellectual disability, autism, attention deficit hyperactivity disorder, genital malformation, fibroids, childhood obesity, adult obesity, adult diabetes, male infertility and mortality associated with reduced testosterone levels[20]. The above mentioned studies and their conclusions have received some criticism in the past[21] [22] [23] because of the hypothesis

[14] Olsson, I-M., et al. 2014. The cost of inaction - A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Copenhagen: Nordisk Ministerråd. Retrieved from http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf

[15] Legler, J., et al.2015. Obesity, diabetes, and associated costs of exposure to endocrine-disrupting chemicals in the European Union. The Journal of Clinical Endocrinology & Metabolism. 100(4):1278-1288. DOI http://dx.doi.org/10.1210/jc.2014-4326

[16] Bellanger, M., Demeneix, B., Grandjean, P., Zoeller, R. T., & Trasande, L. 2015. Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union. The Journal of Clinical Endocrinology & Metabolism. 100(4):1256-1266. DOI http://dx.doi.org/10.1210/jc.2014-4324

[17] Trasande, L., et al. 2015. Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union, Journal of Clinical Endocrinology and Metabolism. 100(4):1245-1255. DOI http://dx.doi.org/10.1210/jc.2014-4324

[18] Hauser, R., et al. 2015. Male reproductive disorders, diseases, and costs of exposure to endocrine-disrupting chemicals in the European Union. The Journal of Clinical Endocrinology & Metabolism.100(4):1267-1277. DOI http://dx.doi.org/10.1210/jc.2014-4325

[19] Study on the cumulative health and environmental benefits of chemicals legislation

[20] CuBA Study p. 16 and p. 134 and onwards

[21] Gregory G Bond, Daniel R Dietrich, Journal of Epidemiology and Community Health, 2017, Further thoughts on limitations, uncertainties and competing interpretations regarding chemical exposures and diabeteshttp://jech.bmj.com/content/71/9/943

on which they were based and the attribution challenge (e.g. that EDs are responsible to cause several diseases for a certain minimal percent factor of probability).

Some of the more notable environment related on-going exposure issues[24] in the EU are:

- **Presence of hazardous substances in land:** EU regulatory action has contributed to the remediation of known contaminated sites as well as to prevention of creating new contaminated sites through stringent industrial and major accident policies as well as substance-specific actions. Hazardous substances in land have the potential to cause harm to people, species and/or significant pollution of surface waters or groundwater. The most common contaminants affecting soils in Europe include heavy metals and mineral oils (contributing around 60% of contaminated sites), polyaromatic hydrocarbons (PAHs), PCBs, dioxins, phenols, asbestos and pesticides. Many Member States however still lack comprehensive inventories on contaminated sites and details on the pollutants present which renders challenging the identification of all contaminated sites requiring an action and estimating the full extent of local soil and groundwater contamination.
- **Hazardous chemical exposures affecting the quality of surface and groundwater[25]:**

  – for surface waters, good chemical status is defined by limits (environmental quality standards (EQS)) on the concentration of certain pollutants (i.e. priority substances) found across the EU. 38 % of surface water bodies are in good chemical status, while 46 % have not achieved good chemical status and for 16 % their status is unknown. In many Member States, relatively few substances are responsible for failure to achieve good chemical status. Mercury causes failure in a large number of water bodies. If the widespread pollution by ubiquitous priority substances (pBDEs, PAHs, mercury) is omitted, the proportion of water bodies in good chemical status increases to 81 %, with 3 % that have not achieved good status and 16 % whose status is unknown. The main reasons for failure to achieve good status are atmospheric deposition and discharges from urban waste water treatment plants.
  – Since the publication of the first river basin management plans (RBMPs), Member States have made progress in tackling priority substances, leading to a reduction in the number of water bodies failing to meet standards for substances such as priority metals (cadmium, lead and nickel) and pesticides.
  – More recent concerns, for example newly identified harmful substances such as polybrominated diphenyl ethers or fluoranthener, or issues such as toxicity of mixtures of chemicals, are not reflected in the current list of priority substances

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[22] Hermann M. Bolt, Archives of Toxicology, 2017, The current debate on cost burden by human exposure to endocrine disrupting chemicals, https://link.springer.com/article/10.1007/s00204-017-2014-x

[23] European Commission Impact Assessment Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation: https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

[24] CuBA Study, Part B Environmental Protection

[25] EEA Report 'European Waters- Assessment of status and pressures 2018 (July 2018) p. 47

(the list was established in 2008) and therefore not yet reported by Member States. While these standards are to be met only by 2021, some Member States e.g. Sweden, Luxembourg and Netherlands, have started already to implement these. Experience thus gathered seems to indicate the new standards will be difficult to achieve.[26]

- **Hazardous chemical exposures with implications for eco-system health/resilience:**

  - Much has been done in the EU to ensure that particularly problematic pesticides are identified and banned or restricted. For example, EFSA recently confirmed that most uses of neonicotinoid pesticides such as clothianidin, imidacloprid and thiamethoxam represent a risk to wild bees and honeybees[27]. As a result, the EU Commission has restricted the use of these three pesticides to permanent greenhouses only[28].
  - Total sales of pesticides across the EU as a whole stayed constant between 2011 and 2015 (there was an insignificant increase of 0.2 %). After a small decline from 2011 to 2013, sales increased again in 2014 to just under 400 000 tonnes and came back to the 2011 level in 2015. The EU demand for pesticides has therefore remained nearly stable. While exposure to pesticides cannot be directly equated with pesticide sales, which is why the indicator tells us little about the absolute magnitude of the specific risks, these figures could however indicate that the risks of pesticides to humans and the environment have remained constant.[29]
  - Chemical pollution coupled and sometimes exacerbated by habitat degradation, lack of feed sources, etc., impacts terrestrial organisms.

Respondents to the open public consultation[30] from industry and companies as well as those representing public authorities were overall the most positive about the extent to which the EU legislative framework sufficiently addresses emerging areas of concern while civil society representatives and citizens assigned the lowest scores.

C. Human health and environmental impact evidence and indicators

The trends in the main health and environmental impact parameters that are known, or strongly suspected, to be associated with exposures to hazardous chemicals (e.g. trends in the incidence rates of certain cancers, reproductive diseases, sperm count and quality and trends in animal populations and eco-system health/resilience) are important to consider when examining the effectiveness of EU chemicals policy. However, using human health and environmental adverse effects as direct and reliable indicators of chemicals policy performance needs to be treated with caution because of the attribution challenge: many of the

[26] EEA Report 'European Waters- Assessment of status and pressures 2018 (July 2018) p. 47

[27] https://www.efsa.europa.eu/en/press/news/180228

[28] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

[29] Environmental indicator report 2017 – In support to the monitoring of the 7th Environment Action Programme, EEA report No21/2017, European Environment Agency

[30] Question 24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern?

observed health and environmental adverse effects may derive from multiple causes (life-style, genetics, habitat destruction/degradation, etc.) and it is difficult to determine to what extent exposure to hazardous chemicals contributes to the observed adverse effects. Complicating things further is the fact that observable adverse effects in human health and the environment often do not materialise immediately after exposure. For example, the latency between exposure to carcinogens and the development of cancer can often be as much as 20 years or more.

The available evidence regarding the trends in the main health and environmental impact parameters points to a mixed picture. Some clear improvements have been achieved, for example, in the reduction of cancers related to workplace exposure to a number of targeted carcinogens which has resulted in the estimated prevention of 1 million new cancer cases in the EU over the last 20 years partly through the implementation of the occupation safety and health (OSH) legislation[31]. However, a number of other trends suggest there is still cause for concern, for example:

- The health burdens resulting from most cancers continue to rise in the EU (except for lung cancer) (see Figure 6 for trends for breast cancer). For many cancers, the contributing role of chemical exposures is not yet well understood and defined while at the same time suspected to be a contributing factor. As a result, it is often unclear which specific chemical exposures should be targeted by regulation, in an attempt to eliminate preventable disease causes.

[31] Carcinogens and Mutagens at Work Directive (2004/37/EC).

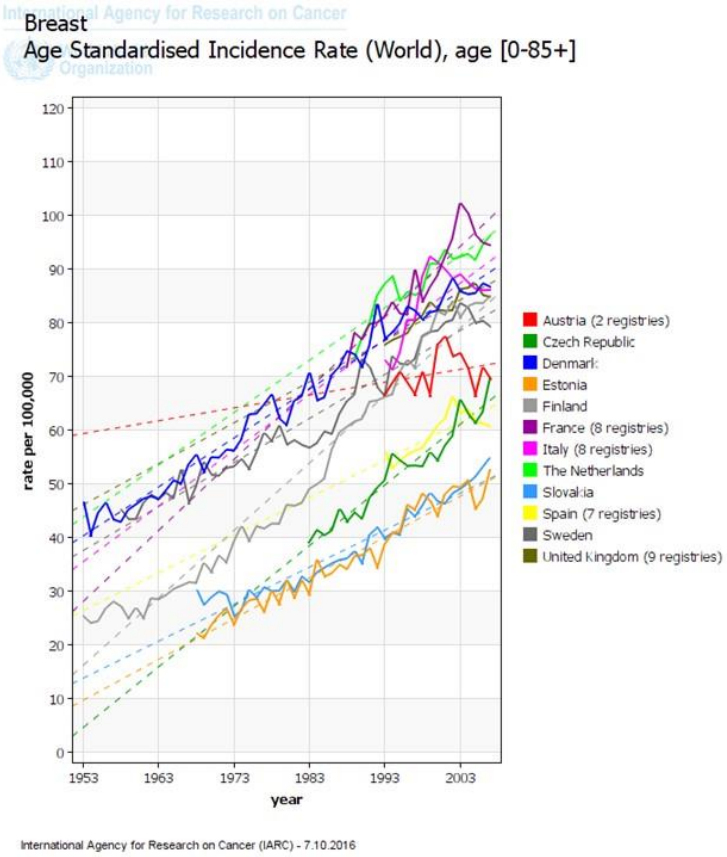

Figure 6 Age-standardised incidence rate trends for breast cancer in several European countries[32]

- The same is true for neurodevelopment and reproductive health. While both male and female fertility rates are decreasing in Europe[33] [34] and while some neurodevelopmental disorders (e.g. autism) increase[35] there is no data on how many of these cases are attributable to exposure to hazardous chemicals. However, it is likely that hazardous chemicals play a role in these adverse health outcomes.[36] Substance categories of concern include certain phthalates, dioxins, perfluorinated chemicals, analgesics, etc. These issues are more generally linked to the need to obtain better information about the spectrum of chemicals with relevance to human exposures and diseases. Achieving this includes improvments regarding data requirements, toxicological testing and screening methods, human biomonitoring as well as better predictive and prioritisation approaches.

[32] CuBA Study, p. 47 Figure 4.2

[33] Temporal trends in sperm count: a systematic review and meta-regression analysis, Hagai Levine et al, Human Reproduction Update, pp1-14, 2017.

[34] Male reproductive disorders and fertility trends: influences of environment and genetic susceptibility Skakkebaek NE, Rajpert-De Meyts E, Buck Louis GM, Toppari J, Andersson AM, Eisenberg ML, Jensen TK, Jorgensen N, Swan SH, Sapra KJ et al. Physiol Rev 2016;96:55–97.

[35] CuBA Study, p. 60

[36] CuBA Study p. 326-328

In the area of environment, the trends also point to a mixed picture:

- Improvements in water quality[37] in some areas may have contributed to some recovery of aquatic ecosystems[38] and the restriction on the use of tributyltin (TBT) as an antifoulant in marine paints has resulted in the recovery of mollusc populations in many ports and coastal areas in Europe[39] (see Figure 7).

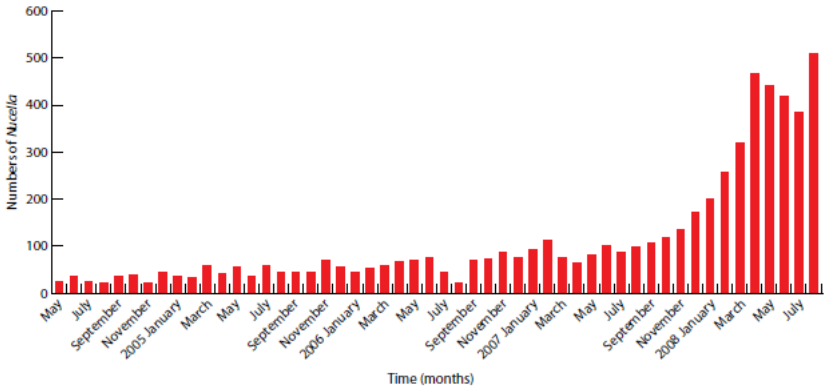

Figure 2.29. The numbers of dog whelks (*N. lapillus*) recorded from a single location (Mewsbrook Groyne at Littlehampton on the southeastern coast of England) every month from May 2004 to August 2008 coinciding with the period immediately after TBT was banned globally as a ship anti-foulant (Morton, 2009). During the study period, the size of the population of *N. lapillus* grew from ~25 individuals to >500, i.e., a 20-fold increase. (Figure redrawn from Morton, (2009); Used with publisher's permission)

Figure 7 Recovery of mollusc populations after the restriction on use of tributyltin (TBT) in marine paints

- Major declines (as high as 50-75%) in the populations of a number of animal species in the EU have been observed over the past 3-4 decades including pollinators, other flying insects[40] (see Figure 8), amphibians, and birds. Europe's wild bee population is in decline with nearly one in ten species facing the threat of extinction and more than a quarter of bumblebee species being currently at risk of dying out[41]. The populations of over 20% of bird species in the EU are in significant decline[42] [43], with the largest declines (46% between 1990 and 2014) for common farmland birds. The causes of these declines requires further research but are likely to be multifaceted including exposure to hazardous chemicals, changes in agricultural practices, habitat degradation, climate change, etc.

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[37] CuBA Study, p185

[38] https://www.eea.europa.eu/publications/state-of-water, p32

[39] CuBA Study, p204

[40] Hallmann CA, Sorg M, Jongejans E, Siepel H, Hofland N, Schwan H, et al. (2017) More than 75 percent decline over 27 years in total flying insect biomass in protected areas. PLoS ONE 12 (10): e0185809

[41] CuBA Study, p. 387

[42] Inger, R., Gregory, R., Duffy, J. P., *et al.* (2014). Common European birds are declining rapidly while less abundant species' numbers are rising *Ecology Letters*, DOI:10.1111/ele.12387

[43] The State of Nature in the EU, Reporting under the EU Habitats and Birds Directives 2007–2012 European Union, 2015

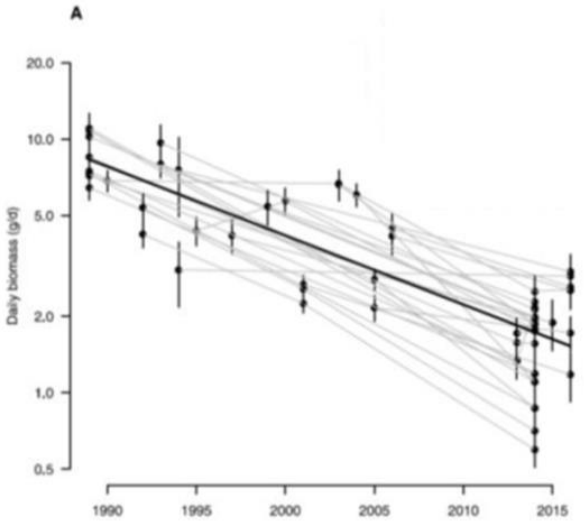

Figure 8 Temporal distribution of insect biomass at selected locations in Germany. Daily biomass across 26 locations in multiple years

The current approach and indicators used in monitoring and assessing human health and environmental impacts could benefit from being more holistic. For instance, such more holistic impact assessments could feed into exposure indicators (e.g. passive sampling, representative mixtures, human biomonitoring) as well as impact indicators (e.g. (eco)epidemiology, effect based methods as proposed in the Water Framework Directive).

5.1.2 Internal market, competitiveness and innovation

The EU chemicals legislation aims to ensure the efficient functioning of the internal market and to enhance competitiveness and innovation. The effectiveness of the EU chemicals legislation in achieving these objectives can therefore be measured by analysing:

- trends in the development of intra-EU sales of chemicals compared to domestic sales;
- trends in the EU export of chemicals and global market share;
- the role that the legislation plays in boosting the competitiveness of the EU chemicals industry and innovation

A. Internal market

The free circulation of chemicals within the internal market through harmonisation and reduction of the barriers for intra-EU trade is one of the main objectives of most of the pieces of the EU chemicals legislation within the scope of this Fitness Check.

The EU chemicals legislation has been instrumental in creating harmonised standards and requirements e.g. product labelling, communication of chemical hazard and risk information, concentration/migration/emission limits, authorisations, restrictions, bans, etc. Over the years, many pieces of chemicals legislation that were previously Directives have been turned into Regulations because of Member State and industry demands for improved harmonisation at the EU level. For example, the CLP Regulation (repealing the Dangerous Substances Directive and the Dangerous Preparations Directive) provides the basis for consistently identifying properties of concern, with this information then used in hazard communication to workers, downstream users and consumers of chemicals. The CLP is broadly considered by industry, Member State authorities and civil society stakeholders to be a more easily applied

system than the previous Directives, with this contributing towards the efficient functioning of the single market. Similar stories can be told for cosmetics, detergents, fertilisers, etc., where EU product specific chemicals legislation has been enacted.

Europe has a large and integrated market of over 500 million consumers and with chemicals sales (within the EU and worldwide) worth EUR 507 billion in 2016[44]. A first finding is that the internal market seems to have been strengthened for chemicals, as shown by the shift from domestic production to intra-EU trade[45]:

- More than 50% of all EU chemical sales in 2016 were intra-EU 'exports' (EU companies selling in the EU single market rather than only in their home country market[46].
- There has been a continuous increase of the share of the intra-EU trade of chemicals in the total sold production of chemicals from 43% in 2006 to 55% in 2016. Removal of trade and non-trade barriers within the EU and the enlargements of the European Union in 2004 and 2007 have strengthened this development. Intra-EU sales increased from EUR 219 billion in 2006 to EUR 280 billion in 2016 – a 28 % increase during the last 10 years.
- At the same time, domestic (home country market) sales have dropped from EUR 184 billion in 2006 to EUR 81 billion in 2016. This is an indication that, as a result of a functioning internal market, domestic sales have been replaced by intra-EU sales.

As most rules affecting the safe management of chemicals in the EU have been harmonised over the past decades, it is difficult to speculate about the dimension of the internal market benefits compared to a hypothetical scenario of 28 different sets of chemicals legislation at the national level that would likely have arisen in the absence of harmonised EU rules. An indication of the dimension of those benefits, however, can be drawn from the conclusions of a recent study on the harmonisation of information requirements for poison centres[47]. Those requirements are currently still set at national level. Harmonising those requirements to one single set of requirements alone is assessed to result in an estimated EUR 890 million of annual cost savings for industry in the EU.

Nevertheless, there are areas where divergences persist at Member States level, in particular on emerging and controversial issues where national rules are set ahead of EU legislation (e.g. on restrictions of Bisphenol A in France) or where EU rules are implemented and interpreted in a different way. Although such divergences are in principle undesirable in terms of further development of internal market and harmonisation, they may be necessary to accommodate

[44] CEFIC Facts and Figures Report, CEFIC, 2016, viewed 10 March 2017

[45] The intra-EU sales increased from EUR 219 billion in 2006 to EUR 280 billion in 2016 (+28%). Domestic sales (sales in the home country) dropped from EUR 184 billion in 2006 to EUR 81 billion in 2016 (-56%). Extra-EU exports increased from EUR 102 billion in 2006 to EUR 146.2 billion in 2016 (+43%). Source: CEFIC Facts and Figures Report, CEFIC, 2017

[46] Ibidem

[47] Study on the harmonisation of the information to be submitted to Poison Centres, according to article 45 (4) of the regulation (EC) No. 1272/2008 (CLP Regulation); http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations

strongly diverging national preferences or simply occur shortly after the entry into force of new legal rules for an adaptation period.

An example of such divergences in interpretation is the application of calculation rules and bridging principles for the classification of chemical mixtures. In addition to potentially inaccurate estimates of the hazardousness of mixtures, this may also result in differences in classification and labelling between Member States, the need to relabel products and different legal consequences of classification. Rules based on specific risk assessments may be interpreted and applied differently from Member State to Member State and may even diverge within one Member State, depending on companies and regional enforcement authorities. Moreover, there are significant variations in approaches to, and levels of, enforcement, which works against the achievement of the single market and the establishment of a level playing field for companies[48].

With regards to downstream users, chemicals legislation is helping to ensure that they have better and more comparable information e.g. through the harmonisation of chemical hazard labels and risk communication which allows for the improved management and use of chemicals.

Under a number of pieces of the EU chemicals legislation Member States are not required to report information on enforcement or information provided is of poor quality. This will be reviewed, for example, in line with the commitments in "Actions to streamline Environmental Reporting[49]" as follow up to the Fitness Check of monitoring and reporting of environmental policy.

The majority of stakeholders are clearly in favour of EU-level harmonisation of chemicals legislation. The open public consultation found that this was ranked as very important by citizens and industry. Industry and national authorities considered chemicals legislation to be generally effective in meeting the internal market objective, while citizens considered it to be moderately effective[50]. Citizens, authorities and NGOs generally considered that the weakness in delivery came from legislation not being adapted to issues at stake; whilst industry felt that lack of consistent enforcement was an issue.

B. Innovation

The beginnings of a possible positive trend can be observed concerning substitution to less hazardous or non-chemical solutions[51] for substances hazardous to the environment. In many cases, hazard classification under the CLP alone, for example, is an incentive for substitution as it triggers a number of legal obligations, including labelling and communication to downstream users as well as consumers. Indeed, increasing consumer awareness of the health risks associated with certain hazard classifications (most notably carcinogens) is a powerful

[48] More information on implementation, monitoring and enforcement is available in the 1st FC Study, Annex II, chapter 12 and Annex IV chapter 8, p. 156 ff. However, presentation of quantified information remains problematic, as clearly divergent terminology is applied, e.g. in tables 12-4 and 12-5 of Annex II, p. 198-199.

[49] COM (2017) 312

[50] 1st FC Study, Annex II table 7-13, p. 103, and Annex IV table 3-4, p. 64.

[51] The 1st FC Study Annex IV p. 55

trigger for substitution in the supply chain.[52] In other cases, risk management measures (such as bans and restrictions) triggered by a certain hazard classification provide such incentives[53].

Innovation and substitution are encouraged by many pieces of legislation acting in concert and supported by drivers, such as consumer demands, market circumstances and initiatives e.g. the Substitution Support Portal (SUBSPORT) under the European Union's Life programme[54]. Overall impacts of chemicals legislation on innovation are, however, more complex, as described in the REACH Evaluation[55]. As no specific indicators exist for assessing these and many other factors play a role e.g. intention to develop new applications in order to conquer new markets, it is currently not possible to know whether the EU chemicals legislation has been a major trigger of, or a barrier to, innovation.

The innovation objective may be undermined if alternatives result in similar or even worse risks than the hazardous substance replaced ('regrettable substitution')[56]. The risk of regrettable substitution is one of the disadvantages of risk management measures based on specific risk considerations, because producers do not get any guidance on what properties to avoid in newly developed chemicals.[57] One way to avoid regrettable substitution is to promote grouping approach of substances[58], when they are assessed, or when risk management measures are defined, and to promote the use of generic risk assessment approaches[59].

The effect of chemicals legislation on innovation is viewed very differently among stakeholders. While only 10% of industry respondents identified innovation as a benefit of chemicals legislation, 27% of citizens, 41% of authorities and 70% of NGOs saw innovation as a benefit. Citizens, industry and NGOs consider chemicals legislation to be moderately effective in stimulating competitiveness and innovation, while authorities consider chemicals legislation to be mostly effective in meeting this objective.

In general, stakeholders consider that chemicals legislation is important in triggering innovation towards less hazardous substances and other, non-chemical solutions. For example, 8 out of 14 of the Member States who responded to the targeted consultation carried as a part of this Fitness Check believed that the chemicals legislative framework has had a positive impact on the promotion of access to and use of substances/products with a more favourable hazard or risk profile.

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[52] 1st FC Study, Annex IV, p. 56

[53] Ibidem

[54] https://www.subsport.eu/

[55] REACH Evaluation SWD, chapter 6.1.1.3.3, p. 51 ff.

[56] 1st FC Study, Annex III, p. 45

[57] 1st FC Study, Annex IV, p. 111.

[58] When considering the appropriate risk management for chemicals, a substance can be assessed in an isolated context (substance-specific; risk assessments completed on given substances under given settings) or as part of a substance group, i.e. chemicals with similar properties.

[59] 1st FC Study, Annex IV, section 4.3, p. 76 ff.

C. Competitiveness

The EU chemicals legislation can improve competitiveness by strengthening the internal market (see above) and by promoting innovation (see above). On the other hand, it can reduce competitiveness compared to other regions of the world by increasing costs for the sector in such a way that competition inside or outside the EU is on an uneven basis i.e. if imports are treated differently to domestic production.

The use of chemicals continues to increase. From 1950 until 2000, chemicals production globally expanded 60-fold by tonnage. Global chemicals sales increased from EUR 1 029 billion in 1996 to EUR 3 360 billion in 2016).

The chemical manufacturing industry is the fifth largest in the EU, accounting for 7% of the EU's industrial production. With annual EU chemicals sales of EUR 507 billion[60], the sector compromises over 28 000 companies and it directly employs around 1.2 million people as well as generating estimated additional 3.6 million indirect jobs. SMEs account for around 96% of the companies in the sector, approximately one third of the direct employment and one third of the sector's value-added.[61] The EU chemicals sector generated a value-added of approximately EUR 115 billion[62] in 2014 representing about 0.8% of EU GDP. In 2016, extra-EU chemicals exports amounted to EUR 146.2 billion and extra-EU imports reached EUR 99 billion (the EU chemicals trade surplus outside the EU being valued at EUR 47.2).[63] In 2017, there was an increase in both exports and imports compared to 2016 (+ 6.5% and + 8.3%).[64]

In terms of international competitiveness, the EU chemical industry in 2016 represented 15.1% of the global market, behind China (39.6%) but ahead of the United States (14.2%)[65]. Although the European share of global sales has decreased (32.5% in 1996) the EU chemicals industry remains internationally competitive as evidenced by the trade surplus of 2016. The decrease in the share of global sales is mainly due to relative growth in other parts of the world, such as China and India, served by their own domestic production. Other potential reasons given for this are high energy prices, currency appreciation, high labour costs, regulatory and tax burdens. Yet the EU remains the largest chemicals exporting region in the world. The main competitive advantage of the EU chemical industry is the high level of technological development, skilled workforce and strong research base.

Over 100 000 chemical substances are present on the EU market today, with some 35 000 chemicals marketed in volumes above 1 tonne per year. Moreover, the number of known

[60] CEFIC Facts and Figures Report, CEFIC, 2017, p. 5

[61] The intra-EU sales increased from EUR 219 billion in 2006 to EUR 280 billion in 2016 (+28%). Domestic sales (sales in the home country) dropped from EUR 184 billion in 2006 to EUR 81 billion in 2016 (-56%). Extra-EU exports increased from EUR 102 billion in 2006 to EUR 146.2 billion in 2016 (+43%). Source: CEFIC Facts and Figures Report, CEFIC, 2017

[62] Eurostat 2014 figure for NACE 20

[63] CEFIC Facts and Figures Report, CEFIC, 2017, p.15

[64] Monthly summary of the Chemicals Trends Report; Cefic; 20 April 2018

[65] Ibidem

chemicals continues to grow. The CAS Registry[66], which already lists over 129 million unique organic and inorganic chemical substances, is reportedly updated with 15 000 new substances every day[67].

It is also interesting to note that several countries in competitor regions (e.g. China, South Korea, and India) consider the EU framework of chemicals legislation to be an important benchmark and are in the process of introducing or aligning their existing legislation to the EU model and standards for chemicals risk assessment and management (mainly REACH).

Citizens, industry and NGOs consider chemicals legislation to be moderately effective in stimulating competitiveness and innovation, while authorities consider chemicals legislation to be mostly effective in meeting this objective[68]. Despite differences in implementation of the UN Global Harmonised System (GHS) building blocks worldwide, numerous industry stakeholders believe that the GHS (implemented via the CLP Regulation) has helped to reduce technical barriers to international trade within the EU and externally[69]. Nevertheless, industry remains concerned that stricter measures in the EU vis-à-vis the main competitor regions of North America and Asia affect the competitiveness of the EU chemicals industry. Industry stakeholders worry that differences in approaches to risk management on a global scale could make the EU export market less competitive.

It should be noted that, in principle, any competitiveness impact is mitigated by the fact that companies, whether they export from the EU or import in the EU, face the reciprocal legal rules e.g. a non-EU company willing to place its products on the EU market need to ensure that these are compliant with the EU rules and vice versa when an EU company wants to export its products. Enforcement of EU rules vis-à-vis imported products remains however an issue.

5.2 Evaluation question: what factors affect (either positively or negatively) the correct functioning of the EU legislative framework for the hazard identification and risk management of chemicals? What are the consequences or effects that were not originally planned for?

An effective framework of chemicals legislation ensures the timely and sound identification of chemical hazards and risks, the appropriate control of human and environmental exposures to hazardous chemicals and, for hazardous chemicals where the exposures cannot be reliably controlled, a progressive shift towards the use of less hazardous chemicals (substitution) including non-chemical solutions.

The basic steps of the risk management procedures and processes applied to chemicals within the EU framework of chemicals legislation are:

- hazard identification (based on toxicity tests and other relevant information);
- dose (concentration) – response (effect) assessment;

[66] CAS Registry Numbers (often referred to as CAS RN® or CAS Numbers) are universally used to provide a unique, unmistakable identifier for chemical substances.

[67] https://www.cas.org/content/chemical-substances#how (accessed 30.03.2017)

[68] 1st FC Study, Annex II, Table 7-13, p. 103

[69] 1st FC Study, Annex II, p. 186.

- exposure assessment – exposure scenarios for relevant uses of the chemical (based on models and measurements of the occurrence of the chemical);
- risk characterisation; and
- risk estimation.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

The correct functioning of each of these risk management steps can be affected by one or more key performance factors, including:

- Whether the necessary scientific knowledge (including recognised and accepted test methodologies for hazard identification) and data/information (e.g. on chemical uses and exposure scenarios) are available, are used appropriately and can be shared between different risk assessment regimes to ensure the coherence of findings and to avoid duplication of effort.
- Whether and how the hazard identification and risk assessment process is triggered.
- Whether the overall 'speed' of the hazard identification and classification and risk assessment processes can handle the quantity of existing and newly designed hazardous chemicals placed on the market. This is not simply a question of efficiency but, fundamentally, of effectiveness. If the framework fails to identify and address the hazards and risks of chemicals in a timely manner, its effectiveness is reduced. This also requires further discussion on how to better prioritise and in which areas and/or for which substances such prioritisation would be necessary.
- Whether the necessary competences and resources are available at EU and Member State level to ensure robust and timely hazard identification/assessment/classification, risk assessment and risk management decision-making.
- Whether the use of generic risk considerations (GRC) and specific risk assessment (SRA) based approaches is appropriate and balanced.
- Whether the desired transition to non-animal test methods is happening and is effective.
- These different factors can affect the performance of one or more of the risk management steps outlined above. For example, poor quality or missing data affects the ability to correctly identify and classify hazards, to determine reliable exposure scenarios, and, therefore, to arrive at a robust risk assessment. The assessment of the effectiveness of the framework of EU chemicals legislation has, therefore, been structured and presented according to these factors.

5.2.1 Data, knowledge and information

Scientific understanding and the availability of good-quality, reliable data underpin the effective functioning of the EU chemicals legislation. It includes, among other things, knowledge and information on chemical properties, data on eco-toxicity of chemicals and on chemical uses and exposures to chemicals (including occurrence in, and release from, articles (consumer products)).

A. State of science / state of scientific understanding

The scientific understanding of how chemicals interact with living organisms including the adverse effects that can be caused, the dose response relationships, and the real exposures levels has improved considerably over the last two decades in the EU. Support via the Commission's research framework programmes and the Life Plus initiatives has contributed significantly to the recent progress.

Although knowledge gaps are progressively being closed, the understanding of mechanisms and pathways of how chemicals interact with organisms (i.e. the Adverse Outcome Pathways (AOP)[70] of chemicals) is still far from complete. An understanding of AOPs improves the ability to predict chemical toxicity, avoid animal testing, and make better informed regulatory decisions.

As regards exposure data, there continue to be significant gaps in our knowledge of which chemicals and their combinations, and at what concentrations, human and the environment are being exposed to. To address the issue for humans, the EU Commission has funded the European Human Biomonitoring Initiative (HBM4EU[71]). However, a similar holistic initiative for animals, plants and eco-systems is currently lacking[72] [73]. Further, the screening of 'unknowns' (i.e. sampling and testing designed to detect unsuspected hazardous chemicals) in humans and the environment is missing. Chemical monitoring, whether in humans or the environmental species, is a powerful tool to assess aggregated exposure to hazardous chemicals and their mixtures from various sources. It helps assess the effectiveness of regulatory risk control and measures and compliance activities as well as identify as yet undetected risks. However, chemical monitoring is not a suitable tool for predictive (ex-ante) risk assessment, as the monitoring detects exposures that have already happened. Therefore, to complete the knowledge base on exposure additional information would be needed regarding the use, presence of hazardous chemicals as well as the frequency with which people and workers come into contact with these in their daily lives.

B. Data quality

Much has been done under the EU chemicals *acquis* to improve the quality, reliability and reproducibility of hazard and risk assessment studies and data. Quality standards are prescribed for how hazard and risk analysis is to be conducted, including the testing methodologies. Toxicity studies submitted by producers or importers need to be performed

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[70] http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[71] https://www.hbm4eu.eu/

[72] However the monitoring of emerging pollutants is carried out since 2011 by the Network of reference laboratories for monitoring emerging environmental pollutants (NORMAN Association) together with the Commission to support the Common Implementation Strategy of the Water Framework Directive. More information is available at https://ec.europa.eu/jrc/en/publication/norman-interlaboratory-study-ils-passive-sampling-emerging-pollutants

[73] SOLUTIONS is a project funded by the EU aiming at searching for new and improved tools, models, and methods to support decisions in environmental and water policies. The overall goal of the project is to produce consistent solutions for the large number of legacy, present and future emerging chemicals posing a risk to European water bodies with respect to ecosystems and human health. More information available at https://www.solutions-project.eu/project/#article-24

according to validated test guidelines (as far as such guidelines exist for specific endpoints), such as those adopted by the Organization for Economic Co-operation and Development (OECD), the US Environmental Protection Agency (US EPA), and the European and Mediterranean Plant Protection Organization (EPPO). In addition, the laboratories where chemical hazard and risk assessment studies are performed must comply with the requirements stipulated within the system for Good Laboratory Practices (GLP), which was introduced to ensure integrity and quality of the laboratory studies. The existence of these requirements has helped make data more reproducible, reliable and trustworthy. In addition, it has helped to achieve the mutual acceptance of data across jurisdictions and thus reduce costs for industry as well as the number of animals used in testing.

Beyond the reproducibility of data, there are only certain pieces of chemicals legislation where the quality and completeness are being systematically checked by public authorities; primarily where approval/authorisation is needed before the substance/product can be placed on the market (e.g. plant protection products, biocidal products).

The majority of respondents to the open public consultation[74] from Group 2 Industry association/business (63% or 111) and from Group 3 Public authority (51% (18)) replied that they did think the quality requirements were appropriate. The most common response from Group 1 Citizens was 'don't know' at 48% (13), followed by 'yes' at 41% (11). For Group 4 NGOs and others, though, the most common response was 'no' at 44% (21) with 31% (15) saying 'yes' and 25% saying 'don't know'. Views on the extent to which GLP is considered to be important for ensuring reliability of information were, however, diverging and somewhat contradictory.

C. Data/information use

The EU chemicals legislation allows, and in some cases requires, both industry and regulatory authorities to consider 'all available information' (including peer-reviewed studies published by academic researchers) when performing and reporting on hazard or risk assessments.

A number of stakeholders, however, expressed concern that potentially relevant and useful peer-reviewed scientific studies and data were being ignored or overlooked during regulatory hazard and risk assessments because they are not GLP-compliant. Examples of highly debated cases, where the reliability (i.e. inherent quality) and relevance of peer-reviewed studies have been contentious include assessments of the brominated flame retardant decaBDE, bisphenol A, and the herbicides atrazine and glyphosate. In addition, industry and NGO stakeholders raised concerns that different EU agencies (e.g. ECHA and EFSA) have different expectations and quality acceptance criteria for data used under different legislation, with some more conservative than others in their approach to the uptake of potentially relevant non-GLP data or data not produced according to internationally accepted standardised protocol.

There are two issues with the uptake of peer-reviewed scientific studies in the regulatory hazard and risk assessments.[75] First, scientific peer-reviewed studies are often not adequately documented which results in difficulty assessing their reliability. In part, this arises from a lack of awareness by scientists (and scientific journal publishers) of the EU regulatory

[74] Question 18: Do you consider the quality requirements aimed at ensuring the reliability and reproducibility of safety data for chemical to be appropriate?

[75] FC+ Study p. 45-47

assessment and data quality criteria when publishing their results. Several recommendations have been made by academic researchers, consultancies and governmental representatives to ensure sufficient reliability and reporting of peer-reviewed studies[76]. However, progress has been slow so far. The second issue is that the current weight-of-evidence[77] practice tends to give a higher weight to a study performed according to standardised protocols and GLP as opposed to a scientific peer-reviewed study that has not been performed according to standardised protocol and GLP, even if the peer-reviewed study is very well documented. This warrants some attention and action because the peer-reviewed studies may use test designs, test species and test endpoints that are more sensitive and relevant than those used in standardised studies and can, therefore, be an important complement to the standardised studies.

It remains a challenge for EU and Member State authorities to check whether 'all available data' has been used in the development and submission of industry performed risk assessments. However, the recent Commission proposal to improve transparency and public trust in scientific studies on food safety takes steps forward to address this in the area of food-related legislation by creating a common European register of industry-commissioned studies[78].

D. Data access and sharing

Data sharing between different legal clusters and, therefore, between Member States competent authorities, the Commission services and EU agencies is an important factor that influences the effectiveness of the EU chemicals legislation.

As the information used in risk assessments is held in a variety of databases across the EU with no centralised access point, part of this issue relates to awareness of what data is available where. For chemical occurrence data generated as a result of chemical monitoring activities, this has recently started to be addressed by the Information Platform for Chemical Monitoring data (IPCHEM[79]). IPCHEM provides a single access point to chemical occurrence data held by all Commission services and EU Agencies and also by Member States and scientists and could become an important information source provided that IPCHEM continues to be populated with the data. For hazard data, the problem continues to exist.

Another part of the issue is having full access to data which, in some cases, has not been possible due to intellectual property rights, legal concerns or existing agreements between the

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[76] Ågerstrand, M., Sobek, A., Lilja, K. *et al.* (2017). An academic researcher's guide to increased impact on regulatory assessment of chemicals. *Environmental Science: Processes & Impacts*. 19: 644-655. DOI: 10.1039/C7EM00075H.

[77] The weight of evidence approach involves the use of a combination of information from several independent sources to give sufficient evidence to fulfil an information requirement. This approach is beneficial when (i) the information from a single piece of evidence alone is not sufficient to fulfil an information requirement and/or (ii) individual studies provide different or conflicting conclusions. The weight given to the available evidence depends on factors such as the quality of the data, consistency of results, nature and severity of effects, and relevance of the information. The weight of evidence approach requires use of scientific judgment and, therefore, it is essential that it's use is underpinned by adequate and reliable documentation

[78] http://europa.eu/rapid/press-release_IP-18-2941_en.htm

[79] https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html#intro

EU agencies and Member States.[80] For example, the chemical occurrence data being collected by EFSA under the EU food legislation or by European Environmental Agency (EEA) for its 'State of the Environment' reporting cannot be re-used for other purposes or by another entity, at least not without specific agreement from the individual sources. Issues with access to REACH registration data have created obstacles for the hazardous chemical prioritisation exercise under the Water Framework Directive, but the situation is improving. A wide range of stakeholders expressed a need for further action to improve access to and sharing of data between regulatory frameworks.

Awareness of, and readily available access to knowledge and to scientific peer-reviewed data is another important aspect. Searching for, and getting access to, peer-reviewed studies is resource demanding and therefore, they are not used to the extent that they could be in regulatory assessments[81] [82]. A proposal was made to develop a tool that provides a single point of reference to identify, to access and to retrieve relevant scientific studies in order to enhance accessibility of peer-reviewed data to policy makers and to industry stakeholders.

E. Hazard data/information requirements

Data/information requirements are legal obligations placed on manufacturers or importers to generate and make available relevant hazard/exposure/risk assessment information to the authorities (and, in some cases, to other parties along the supply chain). Setting the data/information requirements requires a carefully balanced trade-off between protection of human health and the environment on one side and burden on economic operators on the other side.

Information requirements vary considerably between the different pieces of the EU chemicals legislation ranging from extensive hazard data requirements to only partial or no hazard data requirements. Such differences in hazard data requirements are in general justified by differences of intended use of products and substances and likely exposures to the hazardous chemicals concerned. Data requirements are the most demanding for substances that are designed purposely to be very biologically active and/or to which there are high exposures for humans or the environment, such as pesticides, biocides and food additives. Less hazard data is required for chemicals that are not designed purposely to be biologically active and to which exposures are expected to be lower (compared to pesticides or biocides) such as food contact materials or cosmetics.

The legislation with less stringent requirements (toys, textiles, environmental legislation) are entirely dependent on the generation of data under other legislations (primarily the CLP and REACH), on the data from academic literature or on data supplied voluntarily at the own-initiative of the industry parties concerned.

Hazard data requirements underlying the legislative framework are considered in principle by most stakeholders to be adequate, but there are some gaps that affect the achievement of the

[80] FC+ Study p. 79-84

[81] E. Ingre-Khans, M. Agerstrand, A. Beronius and C. Ruden, Transparency of Chemical Risk Assessment Data under REACH, Environ. Sci.: Processes Impacts, 2016, 18, 1508-1518.

[82] M. Agerstrand, M Brenig, M. Fuhr and J. Schenten, Environ. Sci.: Processes Impacts, 2017, 19, 1466.

objectives of the EU chemicals policy. These are linked to the availability and regulatory uptake of test methods and guidelines. These are:

- Lack of information requirements for certain environmental adverse effects e.g. soil biota, reptiles, and other terrestrial animal species. Current data requirements rarely extend beyond toxicity to the aquatic environment.
- Lack of information requirements for certain human health adverse effects e.g. neurotoxicity, immunotoxicity and epigenetics[83]. The two elements contained within the Extended One Generation Reprotoxicity Study test guideline that have been developed specifically to detect neurotoxic and immunotoxic effects are optional and are rarely performed.[84]
- A lack of information requirements as regards identification of endocrine disruptors. While existing data requirements in some cases allows to detect some of the adverse effects caused by chemicals having endocrine disrupting properties, the existing data requirements do not allow to identify endocrine modes of action, which is required to identify endocrine disruptors.

F. Exposure data requirements and assessment

Exposure to hazardous chemicals can occur during each of the four key phases of a product life cycle: production, use, end-of-life, and reuse/recovery. Hence exposure scenarios developed under the different pieces of the EU chemicals legislation need to adequately capture these four aspects.

Whilst the importance of developing robust and realistic exposure scenarios is generally well recognised and incorporated in the EU chemicals legislation, detailed examination of the exposure assessment step under the different pieces of legislation has revealed a number of issues and weaknesses.

Exposure scenarios used in setting 'safe' exposure limits, are established based on intended and foreseeable use of the product (e.g. cosmetic, plant protection, biocidal, detergent products) or foreseeable/predictable situation (e.g. occupation or industrial settings). Exposure data requirements will therefore vary accordingly. The main difficulty is in determining realistic, acceptable and robust exposure scenarios for several reasons:

- Exposure assessments typically make use of a combination of models, laboratory data and monitoring to calculate the potential exposure within a given scenario. In order to successfully conduct exposure assessments, the models in use have to be underpinned by data, and likewise real world analysis is needed to validate results. Additional

[83] Study of heritable changes in gene expression that does not involve changes to the underlying DNA sequence. Epigenetics literally means "above" or "on top of" genetics. It refers to external modifications to DNA that turn genes "on" or "off." These modifications do not change the DNA sequence, but instead, they affect how cells "read" genes. Epigenetic changes alter the physical structure of DNA. Epigenetic changes can be heritable to the next cell generations (mitotic) but also to the next generation of an organism (meiotic).

[84] The Test Guideline is designed to provide an evaluation of reproductive and developmental effects that may occur as a result of pre- and postnatal chemical exposure as well as an evaluation of systemic toxicity in pregnant and lactating females and young and adult offspring. For more detailed description please consult https://www.oecd-ilibrary.org/environment/test-no-443-extended-one-generation-reproductive-toxicity-study_9789264185371-en

monitoring to validate models is often a step that is overlooked in EU risk assessment processes and this undermines the quality of the results.[85]

- There is also evidence that for hazardous chemicals with a broad range of applications in a myriad of different consumer products, industry and public authorities may be unaware of many uses. As an example, a recent Swedish KEMI market survey report[86] on articles treated with biocides revealed a significant lack of knowledge and awareness by industry about just how widespread the uses are of biocidal products in consumer products placed on the market in Sweden.
- In addition, exposure scenarios and the underlying models make assumptions about the volumes of chemicals used and, therefore, about the volumes emitted to the environment (of a potential concern for both the environment and human health (consumers/general public). There are, however, no requirements on producers to make available substance-specific information on actual amounts marketed. This makes it difficult for authorities to make ex-post assessments of the overall load of chemicals to the environment. As an initial step, the Commission recently began to tackle this issue for veterinary antibiotics where reporting obligations on volumes used have been introduced. As an initial step, the Commission recently began to tackle this issue for veterinary antibiotics where reporting obligations on volumes used have been introduced.[87]
- Yet, even when all uses and amounts are known, determining realistic exposure scenarios can still be problematic where consumer behaviour is difficult to predict. Determining and characterising exposure in an occupational setting by way of comparison is relatively more straightforward, as the exposure scenario is more controlled and predictable.[88]

Each exposure scenario/model that is developed as a part of the risk assessment decision-making process assumes certain worker/consumer behaviours happen and certain risk management controls are implemented e.g. the application of pesticides by farmers. It is important that these assumptions are actually tested and checked in reality in order to validate and calibrate them. Real life monitoring to validate exposure models is often a step that is overlooked in EU risk assessment processes.

Another factor to consider is the capacity of SMEs to perform the risk assessment at the workplace based on the exposure scenarios provided in the safety data sheets (SDS) due to the limited resources and expertise. ECHA together with industry organisations developed a set of tools to simplify and harmonise the elaboration of exposure scenarios for the chemical safety report and their incorporation in the SDSs.[89]

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[85] FC+ Study p. 51

[86] Market survey on articles treated with biocides, KEMI PM 6/16

[87] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000302.jp

[88] FC+ Study p. 68

[89] Many guideline documents are available on https://echa.europa.eu/safety-data-sheets

G. Test methods/guidelines

The EU chemicals *acquis* relies on the availability of recognised and standardised test methods to identify the different hazard properties of a substance or a mixture. Validated test methods and guidelines help to ensure comparability and reproducibility of data produced and thus increase the reliability and quality of data. International agreement on the validated test guidelines (under OECD) ensures the mutual acceptance of the data among countries and regions, which lowers the technical barriers to trade and reduces also the number of animals used for testing. For these reasons, the EU and its Member States always develop test guidelines under the OECD programme for chemical testing.

The existing test guidelines cover the majority of known adverse effects on human health. However, recent reviews[90] and consultation with Member States authorities pointed to some gaps in existing OECD guidelines, which means that certain hazards might not be identified and addressed. The main gaps concern:

- Standardised test methods and guidelines are lacking for investigating certain environmental adverse effects, for example: soil, biota, reptiles, and other terrestrial animal species.
- Inadequate coverage and identification in existing test methods and guidelines of certain hazards, such as neurotoxicity, immunotoxicity and epigenetics[91].
- As regards endocrine disruption, there are no suitable models for some endocrine-related diseases such as breast and hormonal cancers, endometriosis, metabolic syndrome, insulin resistance or IQ drop. Furthermore, methods for detection of endocrine pathways other than oestrogenic, androgenic, thyroidal and steroidogenic in mammals and fish are missing.
- Current chemical safety tests may need to be adapted or newly developed to capture different peculiarities of nanomaterials.

5.2.2 Policy on protection of animals used for scientific purposes

Identifying the hazardous properties of chemicals in terms of potential effects on human health and the environment has traditionally relied on the use of animals in laboratory testing. The efforts to avoid or reduce the use of animals for testing purposes by using information from alternative (non-animal) test methods has become in the recent years a stated objective under several pieces of the EU chemicals legislation e.g. the Biocidal Products Regulation, the Plant Protection Products Regulation and the Cosmetic Products Regulation, complemented by the Directive on animals used for scientific purposes[92]. The Cosmetic Products Regulation is the most stringent legislation as it prohibits testing finished cosmetic

[90] CuBA study p. 368.

[90] EU OSH (2017): What are the main work-related illnesses and injuries resulting in death and in DALY: HYPERLINK "https://visualisation" https://visual isation. osha.europa.eu/osh-costs

[91] Epigenetics literally means "above" or "on top of" genetics. It refers to external modifications to DNA that turn genes "on" or "off." These modifications do not change the DNA sequence, but instead, they affect how cells "read" genes. Epigenetic changes alter the physical structure of DNA. Epigenetic changes can be heritable to the next cell generations (mitotic) but also to the next generation of an organism (meiotic).

[92] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

products and cosmetic ingredients on animals and marketing finished cosmetic products and ingredients in the EU which were tested on animals. Some testing strategies have been developed, also leading to an overall reduction of the use of animals.[93]

Significant amounts of resources have been directed to the development and promotion of alternative (non-animal) tests. Over the last decade, EU funding in the field of research into alternatives has remained stable with, on average, more than EUR 35 million per year awarded to new research projects. In addition, the Commission is also operating the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) with an annual budget since 2012 of approximately EUR 6.5 millions[94].

Several alternative chemical hazard assessment methods are available for topical toxicity, genotoxicity and skin sensitisation, including OECD test guideline methods[95], and have become part of the standard data requirements in the regulatory context. In addition to these *in vitro*[96] methods, grouping and read across approaches[97] are frequently used in the regulatory context. However, not all of them are used to the same degree. In general, the use of read-across and grouping is predominant, according to ECHA's evaluation reports. Under REACH (which is outside the scope of the Fitness Check), they are used mainly to wave the obligation on registrants to generate animal data but less for regulatory decisions.

Although a lot has been invested in the development of the non-animal test methods, their uptake and use in regulatory hazard/risk assessment remains relatively limited due to the following reasons:

- Complete replacement is not currently possible because alternative methods are not available for all endpoints, in particular in view of systemic/chronic toxicity. Although classification and labelling is possible with validated in vitro tests for the endpoints mentioned above i.e. skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation, sub-categorisation for classification categories is not yet possible in all cases[98].

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[93] See for example the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) Strategy to replace, reduce and refine the use of fish in aquatic toxicity and bioaccumulation testing available at https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eurl-ecvam-strategy-replace-reduce-and-refine-use-fish-aquatic-toxicity-and-bioaccumulation

[94] REACH REFIT, Annex IV

[95] Skin corrosion/irritation, serious eye damage/eye irritation and skin sensitisation

[96] The term *in vitro* ("in the glass") refers to the technique of performing a given experiment in a test tube, or, generally, in a controlled environment outside a living organism. For a more detailed description of different alternative methods please refer to EURL ECVAM FAQs https://eurl-ecvam.jrc.ec.europa.eu/faqs_animal_testing_2013

[97] Read-across involves the use of relevant information from analogous substance(s) (the 'source' information) to predict properties for the 'target' substance(s) under consideration. If the grouping and read-across approach is applied correctly, experimental testing can be reduced as there is no need to test every target substance. For more information please refer to ECHA's guidance and other publications available here https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

[98] Regulatory fitness check of CLP and related legislation - Case study 4, p. 9-12

- Industry as well as public authorities are reluctant to accept the available new testing methods as their interpretation requires a different type of expertise. There is also some uncertainty on the industry side about the regulatory acceptance of data generated via these new test methods. As the acceptance of alternative methods is lower in other countries, it might also mean that industry will have to conduct additional tests for different approval procedures[99].

While a lot has been done to improve and develop alternative methods, the EU funding allocated to development and refinement of animal test methods (e.g. for neurotoxicity) has been minimal and is currently mainly part of the basic research. In addition, the activity on the improvement of animal models under OECD, in particular for mammalian endpoints, is low.

However, it should be noted that because there are still some gaps for particular human health effects which are not covered by the existing test guidelines, new methods for the assessment of these hazards are needed, i.e. the development of both animal and non-animal tests. The aim is to use the best science available to identify hazards relevant for human health and the environment. Data gathering can be based on use of animal data, alternative methods, or a combination of both, what counts is that it is fully accepted for the regulatory decision making. This implies allocation of adequate resources for both testing approaches, animal and non-animal. This also implies removing barriers for acceptance of available non-animal methods e.g. improving cooperation and exchange of information between 'non-animal' and 'animal' communities and to make comparisons of available information from non-animal data and animal data. In addition, introduction of more alternative test methods into the standard data requirement, where necessary and possible, would further increase the acceptability of non-animal data for regulatory decision making.

5.2.3 Triggering Hazard/Risk (Re-)Assessment

A. Triggering of hazard/risk assessments

Triggering the hazard and risk identification/assessment is the first step to be taken for an effective hazard and risk assessment to occur. Without a trigger (mandatory or not), potential risks would not be identified and managed. The obligation to perform hazard and risk assessments sits primarily with the industry in line with the principle of reverse burden of proof[100]. It is only in the event of suspicion about a potential hazard or risk that Member State and/or EU regulatory authorities take the initiative to carry out risk/hazard assessment.

Industry performed hazard/risk assessments are triggered by the legal obligation to ensure the safety of the products placed on the market or safe use of chemicals. The effectiveness of the triggering, i.e. whether they are done and to what quality, is influenced by the following aspects:

- The obligation to gain authorisation to place a substance or product on the market. This works well as the producer/applicant has a commercial interest to gain

[99] Regulatory fitness check of CLP and related legislation - Case study 4, p. 19-20

[100] Reverse burden of proof means that industry is responsible for ensuring the safe use of their chemicals and therefore carrying out the risk assessment and ensuring the risk management of their chemicals, including testing. Public authorities are responsible for checking if this obligation is properly implemented and, where not, to quickly and efficiently propose measures to manage potential risks appropriately.

approval/authorisation e.g. the Plant Protection Products Regulation, the Biocidal Products Regulation.

- CE marking requirements. When a CE marking is required in order to place a product on the market, it can have a similar effect to what is described above for authorisation.
- Existence of a prescription for how the hazard and/or risk assessment should be performed and documented. Where there is no obligation to document the hazard and/or risk assessment it is often difficult to know and verify whether the hazard and risk assessment has been performed. For example, the Cosmetic Products Regulation requires the responsible party to ensure that the product has undergone a safety assessment and that a cosmetic product safety report is developed for that product (see Annex I of the Regulation). On the other hand, the General Product Safety Directive (GPSD) is an example where the form of risk assessment and its documentation is not specifically prescribed.
- Existence of an obligation to communicate the outcome of the assessment to public authorities and/or downstream users. The existence of such an obligation makes the control and enforcement of performance of assessment by public authorities easier. For example, some legislation requires industry to communicate the performed hazard /risk assessment along the supply chain (REACH chemical safety data sheets) or submit it to the regulatory agency (CLP self-classifications) and some legislation does not require communicating the outcome to anybody (e.g. the GPSD).

Where there is only a general obligation for industry to ensure the safety of the products placed on the market, i.e. no legal requirement to perform a risk/hazard assessment, ensuring that this obligation is respected relies on Member States and in particular on market surveillance activities carried out at national level. The recent ECHA report[101] has shown that the compliance with the general safety obligation is challenging.

Authority-initiated hazard and/or risk assessment occurs in two situations:

1. Where the industry is submitting an application to require the approval or authorisation. This is a well prescribed and effective process with legal deadlines on authorities to finalise the assessment and decide on the approval/authorisation. It is the best incentive for industry to make studies on their substances/products, submit data to authorities, build collective knowledge and demonstrate their safety.
2. In case of specific suspicion of a potential risk to human health or the environment. The triggering is thus dependent on the knowledge or suspicion of potential risks or hazard and on the resources and priorities of the competent authorities.

The authorities' decision to investigate suspected chemical hazards and/or risks is based on the information from hazard and risk assessments performed by industry, from the academic research and in some cases from the hazard and exposure data generated by the authorities themselves. The introduction of REACH registration obligations and the CLP self-classification requirements has led to a significant improvement in the knowledge and identification of most hazardous substances. The experience shows that the availability of, and access to, chemicals data help to evaluate the hazard profile of a chemical and triggers the risk assessment process relatively quickly. However, as explained above, some difficulties

[101] https://echa.europa.eu/-/inspectors-find-phthalates-in-toys-and-asbestos-in-second-hand-products

have been identified regarding the access and availability of these data to public authorities and other experts involved.

The triggering of authority-performed hazard/risk assessments e.g. by the Commission under the Water Framework Directive and the Industrial Emissions Directive or by a Member State under the Cosmetic Products Regulation through a safeguard clause,[102] is in general rather slow. Experience shows that it usually takes several years[103] between when the first concerns and evidence were published in the academic journals and when the regulatory hazard and risk assessments are triggered. This is mainly because it is time consuming to continuously monitor scientific papers and publications and there is no mechanism for identifying early warnings. Furthermore, in some cases, reference to only one scientific article or review can be considered as an insufficient basis for triggering an authority-initiated risk assessment as it may be challenged by evidence reported in other articles. Last but not least, availability of and limited resources at Member State level following the financial crisis can lead to streamlining resources for risk/hazard assessment where suspicion is considered to be stronger and more evidence is available.

Respondents to the open public consultation were asked to indicate their satisfaction with risk assessment and characterisation[104]. These elements of the EU chemicals legislations received the lowest weighted score from Group 1 citizens (2.5 (28)) and Group 4 NGOs and others (2.6 (45)). This compares with scores of 3.2 from Group 2 Industry association/business (177) and 3.7 from Group 3 Public authority (33).

B. Triggering of hazard/risk re-assessments

Triggers for risk/hazard re-assessment vary between different pieces of legislation depending on their specific aims and provisions. Legislation governing for example toys, explosives, medical devices, and pressurised equipment requires existing hazard and/or risk assessments already performed by industry to be continually updated. The legislation itself does not give a specific frequency or conditions that would trigger a reassessment. However there is a requirement to take account of the "generally acknowledged state of the art" meaning when new scientific knowledge and/or evidence appear. While there could be a degree of ambiguity as to what this term means, guidance documents and harmonised standards are available e.g. the Toy Safety Directive.[105]

Other industry-driven legislation typically states specific occurrences and conditions that will trigger a new assessment or review. For example, reassessment can be required:

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[102] FC+ Study p. 59

[103] Polychlorinated Biphenyls (PCBs) are among a group of man-made chemicals that are known as Persistent Organic Pollutants (POPs). PCBs were commercially produced world-wide on a large scale between the 1930s and 1980s. In the 1970s, owing to severe concerns pertaining to their human toxicity, suspected carcinogenicity, and environmental persistence, several countries limited the use of PCBs. Finally in 1985, the use and marketing of PCBs in the European Community were very heavily restricted. Measures regarding the disposal of PCBs and PCTs and equipment containing PCBs were taken in 1996. In 2001, the Commission adopted a Community Strategy on Dioxins, Furans and PCBs aimed at reducing as far as possible the release of these substances in the environment and their introduction in the food chains.

[104] Question 17

[105] FC+ Study p. 64

- if there are changes in the design or formulation of a product or working conditions (e.g. asbestos).
- after specified time limits for product or active substance approval (e.g. the Biocidal Products Regulation, the Plant Protection Products Regulation, the Ecolabel Regulation). For biocidal products for example, evidence suggests that this is rarely done during the life of the approved/authorised substance/product, and rather done at the time of the renewal of the approval/authorisation.[106]
- in cases where new scientific or technical data become available (e.g. food contact materials, detergents).[107]

It is noted that a key factor in the triggering of a review of re-assessment of chemical substances and products across the chemicals legislation framework is the surveillance and monitoring of products at Member State level. The ability and capacity to monitor compliance is likely to vary considerably between Member States.

For the Commission-driven risk assessment (i.e. under the Industrial Emissions Directive and the Water Framework Directive), there are specified time periods for review and re-assessments to be made.

All the factors identified above for triggering of the initial authority performed assessment are also valid for re-assessments. The effective triggering of re-assessments tends only to happen when there is an automatic trigger in the legislation such as expiration of the approval of active substances for plant protection products (usually 10-15 years). Earlier re-assessments for plant protection products are possible based on new evidence (was done for neonicotinoid pesticides) but rare. The few examples of where re-assessments have been triggered as a result of new evidence coming to light include harmonised classifications under the CLP Regulation and in the Cosmetic Products Regulation which led to revision of Annex II. There are also examples of re-assessments of acceptable levels of exposure, such as amendments of the Environmental Quality Standards (EQS)[108] under the Water Framework Directive or in food law including the food contact materials legislation. The EQS Directive includes a requirement for the results of monitoring of priority substances under the Water Framework Directive to trigger reviews under certain other pieces of legislation if additional measures appear necessary to meet the relevant standards.

Overall, however, re-assessments are rarely triggered when new evidence emerges unless it is linked to the legally required re-approval/authorisation of product in order to keep it on the market.

5.2.4 Hazard classification

The communication of chemical hazard properties to downstream users is an important risk management measure that helps ensure the safe handling of chemicals and mixtures. It needs to be underpinned by reliable, robust hazard classification. Hazard classification is also crucial for other risk management processes within the framework of EU chemicals legislation, such as restrictions or authorisations.

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[106] FC+ study p. 64

[107] FC+ Study p. 64

[108] Directive 2008/105/EC as amended by Directive 2013/39/EU – Article 7a

A. CLP classification

For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMRs) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH). Harmonised classifications are listed in Annex VI to the CLP Regulation. Provisions linked to the harmonised hazard classification of chemicals serve as the basis for risk assessment and risk management measures under several pieces of downstream chemicals legislation.

Under the CLP, a substance must be self-classified by manufacturers, importers or downstream users when it has no harmonised classification in Annex VI to the CLP and it presents hazardous properties. All relevant hazard classes must be assessed by the manufacturer or importer and the self-classification must be applied to all hazard classes for which the classification criteria are fulfilled. This classification and labelling information for the substances to be placed on the market is then notified by manufacturers and importers to the Classification and Labelling Inventory (CLI) held by ECHA.

Mixtures must always be self-classified before being placed on the market, as they are not subject to CLH. Classifying mixtures follows a similar process. They can be classified based on data on the mixture itself, data on similar tested mixtures, or data on the individual components in the mixture.

1) Harmonised classification

The CLH process is considered by public authorities and industry stakeholders to be more effective than it was under the Dangerous Substances Directive (DSD) mainly due to its globally harmonised approach via the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Indeed, before the adoption of the GHS in 2003 and still under the previous Directive led system, different systems for the classification and labelling of substances and preparations/mixtures existed in different jurisdictions around the world. Whilst many of the requirements of the different legal jurisdictions were similar, their differences were significant enough to result in multiple labelling requirements for the varying health and safety information that had to be provided for the same product in different countries and/or markets. As a result of these multiple systems of classification, there was recognition that companies involved in the international trade in chemicals had to closely follow the laws and regulations in each of the destination countries, prepare different labels and Safety Data Sheets (SDS) for the different jurisdictions, and keep themselves up to date with any changes to the regulations operating in multiple countries/jurisdictions.[109]

There are currently 4573 harmonised classifications (September 2017), most of which originate from harmonised classifications decided under the DSD that were incorporated into the new CLP regime. By January 2017, 323 CLH proposals have been submitted to the Risk Assessment Committee (RAC) since the CLP Regulation came into force in January 2009. As a point of reference, there are total of about 142 000 substances (July 2018) in the CLP inventory, most of which are self-classified by industry. Many of these may not require a harmonised classification. However, ECHA considers the number of harmonised

[109] 1st FC Study, Annex II p. 4

classifications low compared to the likely number of chemicals which merit a harmonised classification.[110]

In addition, most of the new CLH proposals relate to active substances under the Plant Protection Products and Biocidal Products Regulations. The need for harmonised classifications under these Regulations is constraining the degree to which Member States are able to focus on other industrial chemicals. ECHA suggests that for industrial chemicals (i.e. those falling under REACH) between 10 and 20 substances per year go through the CLH process[111]. One of the reasons for this is the fact that the preparation of CLH proposals places a high burden on Member States. Another reason is that the workload is unevenly shared amongst Member States due to lack of resources allocated to this work and/or experience and expertise in some Member States. The Registry of Intentions available on ECHA's website[112] and the survey carried out for the purposes of this Fitness Check both show that a small number of Member States are considerably more active than others in bringing forward and developing proposals.[113]

Under the CLP, both companies and Member States are able to submit proposals to ECHA for the harmonised classification of a substance. Only Member States may propose a revision of an existing harmonised entry, for any substance that is under the scope of the CLP Regulation or when a substance is an active substance in biocidal or plant protection products. The fact that the Commission currently lacks the legal basis to initiate a CLH proposal or to ask ECHA to develop dossiers hinders the effectiveness of the harmonised classification process.

2) Self-classification

The CLP Regulation requires industry to 'self-classify' all substances placed on the market irrespective of tonnage. It also introduced a new obligation for industry to notify the outcome of the self-classifications to the Classification and Labelling Inventory (CLI), managed by ECHA, to promote harmonisation. However, in many instances there are multiple classifications for the same substance because different notifiers fail to arrive at an agreed entry despite the legal obligation 'to make every effort to do so'. Furthermore, there are concerns about the reliability of some of the self-classifications. Possible reasons for this situation are the following:

- ECHA is not allowed to share the names of notifiers so that they cannot contact each other in order to agree on a classification.
- Errors of notifiers or use of an inadequate set of data when notification was done. There are no legal provisions allowing ECHA to correct or delete obvious mistakes in the CLI.
- Lack of engagement of notifiers to find an agreement.
- Objective reasons such as differences in impurities or physical states.

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[110] ECHA Report on the Operation of REACH and CLP 2016 p. 117

[111] Report on the Operation of REACH and CLP 2016, ECHA 2016 https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf/4c958d7a-3158-447b-9e81-d8bae9a7e7f9

[112] https://echa.europa.eu/registry-of-intentions

[113] 1st FC Study Annex II, pp. 47-48

- Classification done by 3rd country exporters according to their national requirements, etc.

These variations in self-classification affect the value of the CLI as a hazard communication tool and are leading to confusion or even misinformation on chemical hazards. In this regard, two pilot projects were launched in 2015 and 2016 by ECHA to invite notifiers to come to an agreed classification for the same substance. Despite these efforts, the aim of agreeing on a single classification for each of the selected substances was not achieved.

The lack of a legal basis for ECHA or Member State authorities to perform quality checks of self-classifications can also lead to internal market issues when industry competitors deliberately notify particular chemicals used only by their competitor(s) as more being hazardous than they are in reality.

3) Mixtures classification under the CLP

For mixtures, the CLP Regulation provides for an elaborate classification system and allows the use of test data for mixtures to be included in the hazard evaluation even though these data may be difficult to interpret. This classification system follows the hierarchy:

- using available test data;
- using data on similar mixtures or ingredients on the basis of bridging principles; or
- using the calculation method (based on the ingredients of the mixture).

As data on mixtures is often not available and the generation of new animal test data is discouraged, duty holders, in particular smaller companies, often rely on the other two approaches i.e. bridging principles or calculation methods.

The lowering of generic concentration limits for some hazard classifications under the CLP Regulation compared to the levels prescribed under the previous regime (i.e. the Dangerous Substances and the Dangerous Preparations Directives repealed by the CLP Regulation), in particular for skin and eye irritation or corrosion, has resulted in more stringent classification when applying calculation methods. Stakeholders representing the detergent sector stated that it leads to over-classifications. Similarly, because SMEs are more likely to depend on the calculation methods to classify mixtures (due to cost considerations), they are also more likely to place more conservative hazard classifications on their products than companies that can do the necessary testing.

In principle, the bridging principle method[114] (bridging principles are basic principles used to classify un-tested mixtures under the CLP Regulation and the UN Global Harmonised System (GHS)) could address this issue. However, there is a lack of clarity with respect to how to apply these principles which hampers the effectiveness of this method. It also leads to discrepancies in interpretation and acceptance of classification by Member States. The Commission is now taking steps to address this issue, including guidance on the harmonised application of the legal requirements.

Issues with mixture classification have also been raised by metal industry stakeholders in relation to metals and metal alloys e.g. the alloy used in Euro coins and the stainless steel-nickel-cobalt alloys used as medical implants. While the metal alloys are to be classified

[114] ECHA Guidance on the Application of the CLP Criteria Version 5.0 – July 2017, p. 68-72

following the CLP chemical mixtures classification rules, this stakeholder group believes that it leads to metallic alloys receiving classifications that do not match their real hazard properties. They also believe that this situation could have negative consequences on metals recycling and thus on the realisation of circular economy with some unintended consequences in downstream legislation (e.g. the Toy Safety Directive, the Transport of Dangerous Goods Directive, the Industrial Emissions Directive).

It should be noted that the Commission has already been made aware of these concerns and acknowledged the issue. A more in-depth assessment is provided in one of the Fitness Check supporting studies[115]. As part of this more detailed analysis, a specific case study was carried out.[116] More recently (end of June 2018) the issue was discussed at the REFIT Platform (brought up by the Federation of Finnish Technology Industries).[117] The Commission has started to address it, in particular through the bio-elution project [118] [119] (involving industry stakeholders) which is reviewing possible test methods for assessing the bioavailability/exposure to metals in alloys[120]. The issue of biological availability[121] has been discussed by the Commission, at CARACAL meetings and at industry workshops[122], also involving ECHA. While the issue is also acknowledged and understood by national authorities, views are mixed as to how to address it as some of them fear that it might have a negative impact on the application of the CLP classification criteria and their fitness for

[115] 1st FC Study Annex II p. 27 and onwards.

[116] 1st FC Study Annex VI Case study 2

[117] This stakeholder group called upon the Commission to review the current classification rules for metallic alloys and issue a guidance on the interpretation of article 1.3.4 of the CLP in the context of the circular economy, as well as to support to support the efforts of the metal industry in developing a new test method in order to improve the classification of metallic alloys to be based on their intrinsic properties. A joint opinion is expected to be adopted in October 2018.

[118] Biological availability in the context of Art. 12(B) CLP, 19th Meeting of Competent Authorities for REACH and CLP (CARACAL), 12 – 13 November 2015, Brussels, 03/11/2015, Doc. CA/90/2015

[119] Bioaccessibility testing (Bioelution) of metals, inorganic metals compounds and metals-containing materials: simulated gastric fluid, Joint Research Centre, European Commission 2016 https://tsar.jrc.ec.europa.eu/test-method/tm2016-02

[120] The bioelution test is a test whereby the bioaccessibility of metals/alloys is tested in synthetic gastric fluid and other fluids (simulating other body fluids such as saliva).

[121] Bioavailability (or biological availability) is defined in the CLP Annex I as being the extent to which a substance is taken up by an organism, and distributed to an area within the organism. Bioavailability is dependent upon physico‐chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. The bioavailability of metals is influenced by physical factors such as temperature, phase association, adsorption and sequestration (Tchounwou, PB, Yedjou, CG, Patlolla, AK, Sutton, DJ, (2012): Heavy metal toxicity and the environment). It is also affected by chemical factors that influence speciation at thermodynamic equilibrium, complexation kinetics, lipid solubility and octanol/water partition coefficients (Hamelink, JL, Landrum, PF, Bergman, HL, Benson, WH, (1994): Bioavailability: Physical, Chemical and Biological Interactions).Based on the properties of a metal in its pure form, the classification may also apply to the alloy, although, the metal, as part of an alloy, may be held more strongly within a matrix. In other cases, some metals may be more biologically available in an alloy form and may therefore be under classified.

[122] See, for example, workshop summary available at: http://www.reach‐metals.eu/force‐download.php?file=/images/BioelutionWorkshop/report%20em%20bioelution%20workshop%2022052014.pdf

purpose, taking also into account that they are closely linked to development at UN level (via the GHS).

B. Other hazard classification

Other regulations such as the Plant Protection Products and Biocidal Products Regulations and REACH identify other additional hazard classes not covered by the CLP Regulation. These are:

1. Persistence, Bioaccumulation and Toxicity – PBT;
2. very Persistent, very Bioaccumulative – vPvB;
3. Endocrine Disruption – ED; and
4. Neurotoxicity.

PBT/vPvB criteria are included in Annex XIII to REACH, as well as in the Plant Protection Products Regulation and the Biocidal Products Regulation referring to or drawing from the criteria in REACH. The current legal provisions are effective in identifying these substances.[123] ECHA carried out an analysis of the work done by authorities on carcinogenic, mutagenic or toxic to reproduction substances (CMRs), PBT/vPvB and ED properties.[124] Regarding PBTs/vPvBs, the analysis considered all known or potential substances having these properties before the SVHC Roadmap implementation. A total of 1699 substances have been looked at. Among these, 250 were pre-listed as (potential) PBTs/vPvBs out of which 13 were identified as requiring further work.[125] The outcome of the PBT/vPvBs assessment done under the Plant Protection Products Regulation and Biocidal Products Regulation is mentioned in the assessment report of the approval of the substance. A list of the status of each approved active substance is also publicly available on CIRCABC, and regularly updated.[126]

Few EDs have been identified so far under the Plant Protection Products and Biocidal Products Regulations. This due to the fact that the most toxic pesticidal substances (many of which would also have been identified as EDs according to the WHO-UNEP Report 2012) have been already withdrawn from the market since 1993 based on Directive 91/414/EEC, Directive 79/117/EC, or the Plant Protection Products Regulation because they had unacceptable risks to the human health and the environment.

5.2.5 Communication of hazards and risks to consumers, professional users and public authorities

The communication of hazard, risk and safety information about chemical substances and mixtures to users, consumers and workers as well as public authorities is a key measure to promote the safe use of chemicals, to mitigate risks and to help users make informed

[123] ECHA "Authorities to focus on substances of potential concern – Roadmap for SVHC identification and implementation of REACH management measures – Annual report' (2018)

[124] https://echa.europa.eu/svhc-roadmap-to-2020-implementation

[125] ECHA "Authorities to focus on substances of potential concern – Roadmap for SVHC identification and implementation of REACH management measures – Annual report' (2018) p. 13

[126] https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en ; https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

product/substance related choices. Various communication measures exist across the legislative framework.

A. Communication to consumers and workers through labelling

The CLP Regulation is the key piece of chemicals legislation governing the labelling of hazardous chemicals and mixtures. Some product-specific legislation provides for supplemental labelling information in addition to the CLP label (e.g. detergents, biocidal products), while labelling of certain product groups (cosmetic products, medicinal products) is fully exempted from the CLP and is regulated solely by product-specific legislation. Treated articles with biocides have also to comply with some labelling rules, and consumers can request some information.

A recent Eurobarometer survey[127] indicated that 70% of EU citizens find information on the hazards of chemicals on the label useful. It also showed that, for the 4 out of the total of 9 pictograms that were addressed by the survey, there are varying levels of awareness and comprehension. While 'flammability' is well recognised and understood (92% of respondents have seen it before and 96% could correctly state its meaning), it is less the case for the 'environmental' hazard pictograms (47% of respondents have seen it before and 83% could correctly state its meaning), 'serious health hazard' pictograms (20% of respondents have seen it before and 69% could correctly state its meaning), and 'exclamation mark' pictograms (63% of respondents have seen it before and 17% could correctly state its meaning). Nevertheless, when they see one of the chemical hazard pictogram on an unfamiliar product, most respondents (76%) read the safety instructions (57% read the safety instructions on the product label, while 19% say they go further by reading the safety instructions on the product label and then trying to find further information from other sources). The Eurobarometer Survey also found that even in Member States where understanding of the issues surrounding chemical products is high, the comprehension of some of the hazard pictograms is relatively low. In part, this is an issue of citizen education and awareness raising by Member States. Opportunities to use digital tools have not yet been explored and used to their full. Hazard communication to workers and professional users is considered to be more effective with a higher level of awareness, recognition and understanding of the pictograms than consumers; in part due to employee training.[128] [129].

At a more general level, another recent Eurobarometer survey[130] found that less than half of the respondents (45%) feel well informed about the potential dangers of the chemicals

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[127] Special Eurobarometer 456

[128] 1st FC Study p. 70

[129] Open public consultation Question 17: To what extent are the following elements of risk management satisfactory? Industry stakeholders attributed the highest score to hazard and risk communication measures to workers (4/5; 177 respondents). The highest score from Group 1 Citizens is 3.1 for hazard and risk communication measures to workers (28) while Group 4 NGOs and others assigned the score of 3.2 (45 respondents). Similarly, respondents to the question 28 "Indicate the extent to which communication of hazards to workers and consumers is effective" considered the CLP labels in communicating risks to consumers being less effective than to workers.

[130] Special Eurobarometer 468, Attitudes of European citizens towards the environment

European Commission, October 2017

contained in consumer products. However, again, this proportion varies considerably between Member States.

Furthermore, industry stakeholders expressed concern about labels becoming overloaded with information, making it difficult for consumers to focus on the essential hazard information.[131]

B. Hazard/risk communication to downstream users of chemicals

Complementary to the CLP labelling requirements are the requirements under REACH to communicate hazard and risk information to downstream users in the value chain via safety data sheets. This requirement ensures the passing on of information on hazards of substances, risks associated with their use and/or the necessary risk management measures down the supply chain to ensure safe use. In addition, downstream users need to pass information on how they use chemicals up the supply chain. These requirements are applicable to all chemicals and mixtures that are hazardous according to the criteria in the CLP Regulation, that are persistent, bioaccumulative and toxic/very persistent and very bioaccumlative substances (PBT/vPvB) substances according to criteria specified in REACH and all other substances of very high concern (SVHCs) identified under REACH. However, the requirements do not apply to the mixtures in the finished state, intended for the final user as medical products for human health or veterinary use, as cosmetic products and as additives and flavourings in food- and feed-stuffs.

These provisions were evaluated as part of the REACH evaluation. It showed that there has been a continued increase in the information passed through the supply chain, though it needs to be made more efficient (e.g. reduce costs of producing and supplying Safety Data Sheets), especially for SMEs. Improvement is also needed in the ability of companies to develop specific exposure scenarios, in particular for mixtures, and in helping with implementing the obligation to notify substances of very high concern in articles.

This Fitness Check showed that the interface between these provisions and the CLP Regulation functions well. The CLP criteria are used to trigger the obligation to develop a safety data sheet and the safety data sheet must provide information on all hazards covered by the CLP Regulation. The safety data sheets also have to contain information on whether the substance or mixture meets the criteria for PBT or vPvB. However, safety data sheets are not required to contain information on whether a substance is an endocrine disruptor or whether a substance is in the nano form (except labels on biocidal products and, under certain circumstances, also treated articles with biocides which need to include this information). This lack might constitute a gap and impact the ability of companies along the supply chain to protect workers from exposures to substances with these properties.

C. Alert and rapid response systems

The EU has established two alert systems to enable rapid exchange of information between Member States and the EU authorities in emergency situations when products, food or feed pose an immediate risk to health and safety of consumers:

1. The Rapid Alert System for non-food dangerous products (RAPEX) covers such as toys, textiles, cosmetics, etc. Third countries like China[132] and international

[131] 1st FC Study p. 24; see also Annex III, Section 7.3; Case Study 5

[132] Notifications included in the Rapid Alert System concern dangerous products produced all over the world. China remains the number one country of origin but figures have gradually been going down since 2013. In

institutions are also involved. The presence of harmful chemicals is one of the most notified risks in RAPEX. Even though the major increase in RAPEX notifications over the last four years is a clear indication that market surveillance under the General Product Safety Directive has been successful, in an increasingly global market with more and more products coming to the EU from third countries, there is a need for further co-ordination of market surveillance activities between the Member States, including cooperation with customs authorities. This aspect is being addressed by the Commission as a part of its new 'Goods Package' via the proposed Regulation on Compliance and Enforcement[133].

2. The Rapid Alert System for Food and Feed (RASFF) was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. It also covers the cases where undesirable chemicals in food cause food poisoning e.g. not labelled allergens Most issues are related to food contact materials regarding the migration of chemicals from the food contact material into food e.g. formaldehyde, plasticizers, volatile organic compounds etc. The majority of notifications concerned in 2016 the presence of heavy metals[134]. In 2016, 50 notifications were identified as triggered by a food poisoning event. In 6 cases consumers suffered from allergic reactions due to the presence of an allergen that was not indicated on the label.

Therefore these two systems are effective tools for allowing public authorities to rapidly take appropriate risk mitigation measures.

D. Information tools

The Classification and Labelling Inventory (CLI), maintained by ECHA and containing classification and labelling information about more than 129 000 substances, is one of the main information tools to communicate hazard information on substances and is used by industry as well as public authorities. Relevant information from the CLI and other sources is provided in Infocards and Brief Profiles on ECHA's website, thereby increasing accessibility for citizens. The issues mentioned above resulting in variations in self-classification prevent it from reaching its full potential as an information tool and reduce its effectiveness in terms of health/environmental protection and single market.

2016, the percentage of notifications for which China (including Hong Kong) was indicated as country of origin went down to 53%, a drop of 9% compared to 2015. Since 2006, the Commission works in close collaboration with China in order to reduce the presence of unsafe products on our markets. A specific module of the Rapid Alert System was created to allow for swift flagging of notifications concerning unsafe products from China. The Chinese authorities investigate these cases in order to trace back the manufacturers, exporters and businesses concerned with the aim of making them aware of product safety rules in Europe. Where necessary, they take further measures to ensure that those products are no longer produced and shipped to Europe.

[133] The draft Regulation on Compliance and Enforcement will help create a fairer internal market for goods, through fostering more cooperation among national market surveillance authorities. This will include sharing information about illegal products and ongoing investigations so that authorities can take effective action against non-compliant products. The Regulation will also help national authorities to improve checks on products entering the EU market. Since 30% of goods in the EU are imported, the Commission further proposes to reinforce inspections of ports and external borders.

[134] https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2016.pdf

A multitude of tools and systems to trace substances in articles and handle the information flow along supply chains have been developed by companies, industry sector associations, authorities and international bodies in order to comply with the various requirements under different EU and international legislation[135], but the systematic use of these tools is still limited to pro-active actors and not widespread across different supply chains.

5.2.6 Legislative gaps affecting the effectiveness

The Fitness Check found a number of gaps in legislative provisions that affect the effectiveness of the chemicals legislation. These are briefly described below and additional assessment can be found for some of them also in the assessment of coherence (Section 7 in the main document and Annex 7) or relevance (Section 8 in the main document) of the EU chemicals legislation.

Combination effects of chemicals are required to be assessed under two pieces of legislation, i.e. the Plant Protection Product Regulation and the Maximum Residue Levels (MRL) Regulation when the methodology becomes available. Although EFSA has made significant progress in developing such a methodology, the legislative provisions have not yet been applied because the methodology is not yet considered finalised and ready for use.[136] However, under other pieces of chemicals legislation, there are no specific requirements to assess the combination effects systematically nor to take it into account in the risk assessment, which can be seen as a gap of the framework.

Exposures to substances in articles cannot be sufficiently addressed by the existing legislation due to information gap on their presence and possibly missing legislative specific provisions. In relation to this however, the recently revised Waste Framework Directive provides the legal basis for the establishment of an ECHA-managed database on the presence of SVHCs in consumer goods ('articles') with access provided to waste treatment operators as well as consumers upon request.[137]

In addition, as the REACH evaluation has shown, it creates an unequal level playing field between imported articles and those produced in the EU. For example, EU companies are at a competitive disadvantage in relation to imported articles containing CMR substances because they are generally not used in the EU in consumer articles.[138]

Protection of vulnerable groups is covered by specific legislation targeting identified exposure scenarios of these groups, such as the Toy Safety Directive, the Pregnant and the Young

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[135] Scientific and technical support for collecting information on and reviewing available tools to track hazardous substances in articles with a view to improve the implementation and enforcement of Article 33 of REACH. Published: 11/08/2017. https://publications.europa.eu/en/publication-detail/-/publication/58f951af-809b-11e7-b5c6-01aa75ed71a1/language-en/format-PDF

[136] Please note that while this document was in its finalisation process, in June 2018, EFSA published a "Draft guidance on harmonized methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals." In addition, EFSA published a "Statement on genotoxicity assessment of chemical mixtures." Public consultations on both documents are open until September 15 and September 9, 2018, respectively. Source: https://www.efsa.europa.eu/en/press/news/180626

[137] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste; Recital 38 and Article 1

[138] REACH REFIT SWD SWD(2018) 58 final p. 35

Workers Directives. However, the same groups can be exposed to hazardous substances via other routes of exposure, which fall under the scope of other legislation with no specific provisions regarding the protection of vulnerable groups. This is a gap in protection of vulnerable groups. For example, toys for children under 3 shall not contain carcinogenic, mutagenic and toxic for reproduction substances (CMRs) according to the Toy Safety Directive, while these substances can be used for example in carpets/pats/textiles which have similar exposure potential.[139] [140]

Endocrine disruptors are specifically addressed in several pieces of legislation in a similar way to CMRs and persistent, biocaccumlative, toxic (PBT) and very persistent, very bioaccumulative (vPvB) substances (i.e. REACH, the Plant Protection Products and the Biocidal Products Regulations) and their identification is progressing. However, the data/information requirements are insufficient to identify endocrine disrupting properties. Also, some other pieces of legislation are lacking specific provisions in order to ensure a coherent approach (see Section 7 Coherence and Annex 7).

5.2.7 Application of the Precautionary Principle

The precautionary principle enables a rapid response to be given in the face of a possible danger to human, animal or plant health, or to protect the environment. In particular, where scientific data do not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous.

It is laid down in article 191(2) of the TFEU. It is explicitly taken into account in the design of various pieces of chemicals legislation (e.g. those requiring safety assessments such as the Biocidal Products Regulation and the Plant Protection Products Regulation, the Water Framework Directive, the POPs Regulation and the RoHS Directive, as well as REACH (many persistent, biocaccumlative, toxic (PBT) and very persistent, very bioaccumulative (vPvB) substances are regulated on a precautionary basis)).

While the principle has not been legally defined, its implementation/application is elaborated in the Commission's Communication[141]. The evaluation of the scientific uncertainties in the chemical risk assessment by policy makers leads to the decision whether to apply the precautionary principle or not. In other terms, it is a question of how effectively the EU's chemical risk assessment and management processes are working in terms of detecting and acting upon early warnings and avoiding late lessons versus taking over precautious, unnecessarily restricting measures and unwarranted recourse to the precautionary principle, as a disguised form of protectionism for example.

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[139] FC+ Study p. 108

[140] The Commission adopted a Decision to amend the REACH Regulation and restrict the use of the phthalates (DEHP, BBP, DBP and DIBP) in consumer products on the EU market that will complement the existing restriction on three other phthalates (DINP, DIDP and DNOP) in toys and childcare articles (Commission Regulation (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP))

[141] COM/2000/0001 final

The precautionary principle should not be confused with the element of caution that scientists apply in their assessment of scientific data e.g. generic risk management approach based measures and application of safety factors are examples of preventative action and not the application of precautionary principle. Whereas both the precautionary and prevention principles can be strictly divided conceptually, it is not always straightforward to separate them as clearly in their application. Some legal instruments based on a general preventive approach nonetheless integrate a precautionary approach for specific substances where risks to health and the environment or the thresholds needed to limit hazards are not identifiable (e.g. the Seveso III Directive aims at prevention, preparedness and response to accidents involving dangerous substances in industry in the EU, the Industrial Emissions Directive takes into account the whole environmental performance of a plant through granting a permit).[142]

Where a scientific uncertainty is encountered, the challenge is therefore in finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken. An examination of the benefits and costs of action and lack of action is another general principle of application for measures adopted on the basis of the precautionary principle. Whatever is the measure decided, it remains subject to review, in the light of new scientific data, and should allow assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

The following examples show cases where the precautionary principle was applied (non exhaustive):

- The "Community strategy for endocrine disruptors" adopted in 1999 and updated in 2001, 2004 and 2007.
- Ban of Bisphenol A (BPA) in polycarbonate infant feeding bottles in 2011.
- Setting lower specific migration limits for Bisphenol A for varnishes or coatings applied to materials and articles intended to come into contact with food in 2018. Similarly, BPA should not migrate from varnishes and coatings applied to materials or articles specifically intended to come into contact with food intended for infants and young children[143].

A number of stakeholder groups including NGOs, trade unions, and some Member State Competent Authorities have raised concerns that in the assessment of chemicals, authorities often hesitate to introduce risk management measures in situations where the precautionary principle applies and prefer to wait and request additional data to reduce the level of uncertainty.[144] The BPA case shows however that this not always the case. Indeed, while still

[142] The precautionary principle in EU environmental policies; Final Report, November 2017; Milieu Ltd; p. 93

[143] Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials; applicable as of 6 September 2018

[144] This situation is illustrated by the outcome of risk assessment carried out in 2001 and 2003 for penta-brominated diphenyl ether (PBDE) and octa-brominated diphenyil ether (OBDE) which led to a ban in 2004 (under the legislation preceding REACH though). At the same time, for deca-BDE it was decided to proceed with the scientific research required to resolve the uncertainty, rather than take a precautionary approach. However, on the basis of the evidence gathered after the additional testing, it was decided to ban deca-BDE in 2008. Source: The precautionary principle in EU environmental policies; Final Report, November 2017; Milieu Ltd; p. 50

facing uncertainties including about the potential replacement substances and their safety and effectiveness, the Commission has mandated EFSA to undertake a full re-evaluation of BPA on the basis of the results of anticipated new studies and scientific data. Following the principles established in the 2000 Communication mentioned above, the Commission will then decide what and if any further action is necessary to protect consumers the precautionary principle.

5.2.8 Balance and Mix Between the Risk Management Measures based on 'Generic' and 'Specific' Risk Considerations

Risk management measures in the EU chemicals legislation are taken considering the risks to human health or the environment associated with exposure to hazardous chemicals. As described in more depth in Annex 8, there are two basic approaches to risk management used, often in combination, in the EU chemicals *acquis*: one based on specific risk approach (SRA) and one based on generic risk consideration (GRC). Under the GRC approach, hazards are assessed generically and without considering specific exposure scenarios based on the hazard of a substance or mixture. Under the SRA both the hazards and the potential specific exposure scenarios (levels, specific situations or uses) of humans and the environment to the substance or mixture in question are assessed at the same time. One could also note that even when the GRC approach is applied, a specific risk assessment in some cases will still be carried out including when considering a possible derogation from an automatically triggered measure.

Respondents to the open public consultation were invited to indicate to what extent they find that the chemicals legislation framework overall should be more oriented towards SRA, GRC or should remain as it is. The preferences of the different groups varied quite considerably. Industry and in particular bigger companies tended to prefer a more extensive use of SRA approaches[145] while NGOs tended to have a higher preference for more GRC approaches[146]. The most common response among Member State competent authorities was that the current application of GRC and SRA approaches within the framework of EU chemicals legislation is well balanced and should remain as it is[147]. Responses from citizens were mixed[148], providing equal support for more SRA and for more GRC approaches, but a majority of citizens (ca. 60%) did not know how to answer or did not provide an answer to the question.

Respondents were also asked to provide comments on their preference. The main comments received are summarised below.

Category of respondents	GRC approach	SRA approach
Business and industry	• More convenient to maintain innovation and competitiveness for a sustainable	• In general more appropriate to define the most effective risk management

[145] 72% (151) from Group 2 (business/industry) was in favour of SRA

[146] the most common response from Group 4 (NGOs and others) was for generic risk considerations (41% or 23), but there were also 25% (14) who agreed that there should be more orientation towards specific risk assessment and 16% (9) who thought the legislation should remain as it is

[147] (37% or 18) but 29% (14) provided no answer

[148] with almost half stating (49% or 31) 'I don't know'; the next most common response is 17% (11) for both specific risk assessment and generic risk considerations

	risk management if the approach taken is proportionate and does not 'overuse' the precautionary principle or overestimate exposure. • Has greater regulatory predictability and clarity. • Can result in absurd situations e.g. the prohibition of the use of ethanol in cosmetic products, whilst alcohol-containing food and beverages and perfumes would not be affected.	measure whilst preserving societal benefits.
NGOs and other civil society organisations	• Areas for extension include, but are not limited to, food contact materials, toys, furniture and certain construction materials and certain human health and environmental impact endpoints that give rise to concerns equivalent to that of CMRs, PBT, and EDs; this includes neurotoxicity, immunotoxicity, terrestrial toxicity and persistent, mobile and toxic (PMT) substances.	• Too slow.
Citizens	• Especially important with regard to substances that are not controlled, cannot be easily traced and where it is not possible to calculate "safe" levels (EDs, PBTs) or where there is uncertainty due to poor and little scientific information, such as for nanomaterials?	• Too slow.
Government and public authorities	• GRC approach provide greater predictability and provide clear indication which properties of substances should be avoided	• SRA approach is less predictable and more costly for the economic operators.

Table 1 Main comments received from stakeholders

Overall, findings of this Fitness Check show that both the GRC and SRA have their role to play in the EU chemicals legislative framework and that the current balance between the use of generic and specific risk management approaches works well, each under particular circumstances (see Table 2):

	Advantages	**Drawbacks**
Generic Risk Considerations (GRC)	Provide a clear signal to all the actors involved (enforcement authorities, industry and downstream users) on the types of hazardous substances which should be avoided	Automatically triggered risk management measures may lead to disproportionate outcomes and unintended (legal and/or socio-economic) consequences if a mechanism for derogation is absent or not appropriate
	The outcome of the risk management decision making process is more predictable (compared to SRA)	Potential consequences of automatically triggered measures in downstream legislation might influence the upstream

		scientific debate leading to the classification
	Might be more appropriate for substances of higher concern and where vulnerable populations are at risk and/or cannot be protected through e.g. training or protection equipment (e.g. children under the Toy Safety Directive)	Less appropriate where exposures are minimal or would not occur through the route of exposure of concern and therefore can lead to over-regulation for non-relevant routes of exposure
Specific Risk Assessments (SRA)	Allow more targeted and differentiated consideration of exposures and thus risks and therefore more appropriate identification of actual risks and of risk management measures	The process might be slower compared to GRC and often more costly
	Allow more targeted consideration of costs and benefits of various risk management options	Predictability of risk management decisions can be more difficult

Table 2 Main comments received from stakeholders regarding the GRC and SRA application

Where a derogation mechanism is connected to the GRC approach (i.e. a derogation from e.g. an automatic restriction or ban if certain conditions are fulfilled, such as demonstration of negligible exposure), industry stakeholders stated that it helps to ensure that the risk management measure stipulated will not lead to disproportionate costs or unintended effects e.g. regrettable substitutions.

5.2.9 Member States and EU Authority/Agency resourcing and capacity

One of the biggest challenges of chemicals risk management has always been to conduct robust risk and hazard assessments for a large number of chemicals present on the market in a timely manner given the resources of public authorities. In order to cope with these constraints, the EU legislation has progressively put the burden of proof on industry. This has helped to improve the knowledge on chemical hazards, to progress in assessing hazards and risks, and to take appropriate risk management measures to protect human health and the environment while enhancing the internal market.

Despite the reversal of the burden of proof, the effectiveness of the EU chemicals legislation continues to depend on the capacities and expertise of Member States and EU authorities (Agencies and the Commission). These entities are essential for almost every step of the risk management process, from triggering the assessment to enforcement of risk management measures.

The Fitness Check showed that workload distribution between Member States authorities is unequal.[149] Moreover, stakeholders has expressed concern about the current pace and the capacity of Member States and EU risk assessment bodies to conduct the needed hazard and risk assessments of chemicals at a pace sufficient to achieve the EU chemicals legislation objectives, in particular regarding assessments of biocidal active substances, recycled plastic food contact materials and harmonised classification dossiers. Stakeholders also highlighted

[149] 1st FC STUDY Annex II, pp. 47-48

the importance of enforcement of the legislation by Member States. According to these stakeholders more efforts should be put in ensuring the compliance.

5.2.10 Regulatory design aspects: regulatory 'silos' and missing links among legislation

The different pieces of the EU chemicals legislation share, in principle, the same objectives. The exact focus and coverage differ depending on the scope and intentions of the legislator. Whereas some are focused on protection of human health and the environment, others focus only on one of these. Some pieces of legislation, when assessing the risk for human health and the environment, consider a specific route of exposure (dermal, oral, inhalation) while others consider all possible routes. Some legislations cover the risk from specific uses or products (e.g. toys, cosmetics, plant protection products, food contact materials, etc.) while others are cross-cutting and apply to chemicals in general (e.g. the CLP). Same substances are used in different areas covered by individual legislation and overarching legislation and thus in some case subject to different rules.

The delineation between the different pieces of legislation is clear and the existing linkages function well. The attribution of tasks and responsibilities is clear and appropriate.

However, this clearly delineated legal framework sometimes leads to the situation that the focus of a risk assessment is too narrow and does not take into account overall exposure to a hazardous substance from various sources (so called aggregate exposure) or via various routes of exposure (inhalation, dermal, oral). In other words, one piece of legislation will not take into consideration for example the outcome of the risk assessment carried out under another piece of legislation unless required to do so. This also applies to sharing information and data as described above. Thus, the risk assessment even though corresponding to the legal scope, in practice, can be only partial, i.e. not covering all exposure routes or uses. An example of such a case is Bisphenol A (BPA) assessment, which was evaluated several times by EFSA between 2006 and 2015 first to assess the dietary exposure and then to assess non-dietary sources, such as exposure through the skin due to contact with thermal paper (used in receipts) and cosmetics. It concluded that there is no health concern for BPA at the estimated levels of dietary exposure. However, also taking into account other possible sources of exposure, a new temporary Tolerable Daily Intake was established. In June 2017, BPA was identified as a substance of very high concern (SVHC) due to its endocrine-disrupting properties. The entry was updated in January 2018 in order to reflect an additional reason for inclusion in the SVHC list but this time due to its endocrine disrupting properties causing adverse effects to the environment.

In addition, because of the missing interlinkages between different pieces of legislation, a concern identified under one may not trigger assessment or risk management measures under another. One example is the missing link between the Water Framework Directive and REACH and the Plant Protection Products Regulation. Once a substance is identified as priority substance under the Water Framework Directive, Member States shall ensure that its concentration in surface waters is below the specified environmental quality standard level. However, often, in order to achieve this, a restriction under REACH or the Plant Protection Products Regulation is needed. However, the process of identifying a substance as priority substance does not trigger any risk management or assessment process beyond the Water

Framework Directive. Regarding biocides, a note was made in 2014 to clarify the interaction between the Biocidal Products Regulation and the Water Framework Directive.[150]

5.2.11 Substance-by-substance approach vs. grouping approach to avoid regrettable substitutions

One unintended consequence of the existing approach of assessing substances on a 'substance-by-substance' basis relates to regrettable substitution i.e. a banned or restricted hazardous substance substituted by another one just as hazardous, or may be less toxic but carrying a greater potential for release. In these cases, similar risk management measures are taken once more data and information becomes available about the substitute. The use of TCEP as a flame retardant in children's toys is an example of regrettable substitution. [151] It replaced other brominated flame retardant subject to risk management measures in the EU, even though it is itself a carcinogen category 2 and a toxic for reproduction category 1B and was recommended by ECHA for inclusion in REACH Annex XIV (Authorisation List).[152]

When regrettable substitution takes place, it impacts the correct functioning of the EU chemicals legislation both in terms of its effectiveness to provide high level of protection of the environment and human health, and its efficiency due to industry's investment in substances that are shortly to be banned.

An alternative to substance-by-substance approach is to assess substances as part of a group or category[153]. In the grouping approach not every chemical needs to be tested for every endpoint. Endpoint information for one chemical (part of the group) is used to predict the same endpoint for another chemical (also part of the group), considered to be "similar" in aspects relevant for assessing the hazard.[154] The similarities may be based on the following:

- a common functional group (e.g. aldehyde, epoxide, ester, specific metal ion);
- common constituents or chemical classes, similar carbon range numbers;
- an incremental and constant change across the category (e.g. a chain-length category);
- the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g. the metabolic pathway approach of examining related chemicals such as acid/ester/salt).

An advantage of a chemical category assessment approach is that identification of consistent patterns of effects within a category in itself increases confidence in the reliability of the results for all the individual chemicals in the category, compared to evaluation of data purely

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[150] CA-Sept14-Doc.4.2 - Final - Links between BPR and WFD on approvals of AS.doc

[151] 1st FC Study p. 61 and 104; see also case study 11 in Annex VI

[152] https://echa.europa.eu/documents/10162/13640/axiv-bd_tcep_20101217_en.pdf/f448e657-47e5-43ee-9358-4e2a2c7817cb

[153] There are two approaches to chemical grouping: the category approach and the analogue approach. The category approach to the grouping of chemicals reduces the need for *in vivo* testing, as not every chemical in the group will need to be tested. Data for the chemicals and endpoints that have been tested for can be used to estimate the corresponding properties for the untested chemicals and endpoints. The analogue approach can be used when the target and source chemicals share a common mode of action. All groups of chemicals are not based on the same properties, and each group can be defined by different criteria, depending on the regulatory purpose and/or risk management measures.

[154] OECD Guidance on grouping of chemicals; 2nd edition; 2014

on a chemical-by-chemical basis. The grouping approach can help gaining efficiencies, reducing costs and improving animal welfare through reducing the number of in vivo testing.[155]

[155] OECD Guidelines ibidem

6 Annex 6 Efficiency

This Annex 6 corresponds to Section 6 Efficiency in the main document. The evaluation of efficiency looks at the costs and benefits of the EU chemicals *acquis* and then at whether there are excessive cost burdens and opportunities to reduce these whilst either maintaining effectiveness or improving it. In doing so, the efficiency assessment answers the following evaluation questions:

- What are the costs associated with the implementation of the legislative framework for chemicals? What are the key drivers for these costs?
- What are the benefits associated with the implementation of the legislative framework for chemicals? What are the key drivers for these benefits?
- To what extent are the costs proportionate to the benefits?
- What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

The three first of these evaluation questions are dealt with together and the fourth separately.

6.1 What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?

The wide scope of this Fitness Check, involving a large number of Directives and Regulations and a variety of chemical risk assessment and management processes that have evolved over more than 50 years, resulted in the use of a simple counterfactual of no EU or Member State chemicals legislation as the main point of reference for the analysis. In reality, each Member State would have had its own national legislation in the absence of any EU legislation but to agree on what the situation might have been would be too hypothetical, and would be subject to multiple interpretations.

For reasons outlined in more detail below it was not possible to quantify the overall cumulative costs and benefits of the EU chemicals legislation. However, where it was possible to derive robust estimates of individual cost/benefits elements this was done. Please see Section 4 Methodology in the main document and Annex 3 for more details about which baselines and points of reference where used and how costs and benefits were calculated, including the application of alternative valuation techniques, such a willingness-to-pay.

The inability to arrive at overall estimates for the cumulative benefits and costs of the EU chemicals *acquis*, coupled with the partial picture on the costs and benefits at the specific legislation level, means it is also not possible to arrive at a single cost-benefit ratio. This meant it was not possible to assess the proportionality of the overall costs and the benefits. However, there is growing evidence[156] that, in many instances, the health and environmental benefits of reduced hazardous chemical exposures outweigh regulatory costs.

[156] Emerging Findings from Defra's Regulation Assessment, Published February 2015 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/406225/defra-regulation-assessment-2015.pdf)

Annex 11 gives an overview of the individual costs and benefits identified in the Fitness Check.

6.1.1 Costs and cost drivers: overview

The 'costs' follow from the drivers, and relate primarily to the direct regulatory costs and to the enforcement costs, which are incurred primarily by industry and by EU and Member State authorities. Indirect costs and the costs of risk management measures triggered under downstream legislation are not assessed here, but the Fitness Check does consider those processes and whether they themselves are working properly.

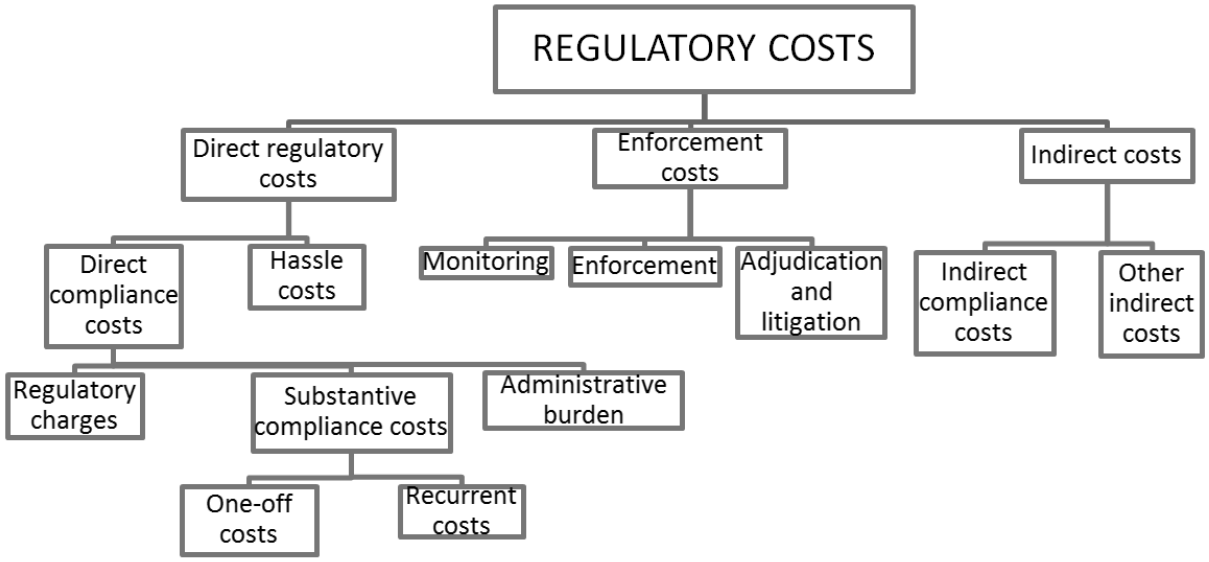

Figure 9 Categories of regulatory costs

All stakeholders recognise that the costs of the chemicals legislation can be significant, especially for SMEs[157]. This perception, however, varies between stakeholder groups. Industry, for example, considers costs of understanding and keeping up to date with changes in legal requirements as particularly significant, whereas other stakeholder groups consider this to be a less significant part of overall costs. Similarly, training, inspections and administrative requirements are perceived as more significant by industry compared to other stakeholder groups. Risk management measures, and to a slightly lower degree labelling and packaging requirements are considered of high cost significance by all actors. Classification requirements are perceived to be relatively significant by industry and public authorities but to a lesser degree by NGOs/others.

The following sections explore the main cost drivers. As the other major horizontal piece of EU chemicals legislation that acts as a basis and complement to the REACH Regulation, particular attention was given to the examination of both the transition and on-going costs of the CLP Regulation.

[157] Question 20 of the Open Public Consultation; 89% (159) of Group 2 Industry association/business, 70% (30) of Group 4 NGOs and others, 64% (23) of Group 3 Public authorities and 31% or 8 of Group 1 Citizens respondents thought costs for small and medium sized enterprises were the most significant.

Given the differences in the organisation of public administrations across the EU, enforcement costs imposed on public authorities at national level are analysed from a cost drivers' perspective. [158]

6.1.2 Direct regulatory costs

When the costs of the most relevant EU legislation with a bearing on the chemical industry were cumulated, the estimated average annual total direct cost borne by the six subsectors (i.e. organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) during the period 2004-2014 was around EUR 8 billion. This represented around 1.7% of their turnover and 9% of the value added (including REACH and for the chemical sector only; it does not include costs borne by downstream industries e.g. CLP labelling costs).[159] Table 3 below presents the list of pieces of legislation by legislative package covered by the CCA1 Study.

Legislative package	Legislation covered by CCA1 Study
Emissions and industrial processes package	IED Waste Framework Directive and related (ELV, Batteries, PPWD) Seveso Directives Water Framework Directive
Chemicals package	CLP Plant Protection Products Regulation Biocidal Products Regulation REACH Annex XIII POPs Regulation
Workers safety package	Carcinogens and mutagens at work Directive Young people at work Directive Pregnant workers Directive Signs at work Directive Chemical Agents Directive
Product specific, customs and trade and transport package	Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive FCMs Regulation General Product Safety Directive PIC Regulation RoHS Directive Inland transport of dangerous goods Directive

Table 3 Pieces of legislation by legislative package covered by the cumulative cost assessment

Among the legislation packages, the emissions and industrial processes package represents approximately 33% of the regulatory cost (4% of the subsectors' value added), the chemicals

[158] Quantification of costs incurred in the EU was carried out only in respect to the CLP Regulation. See 1st FC Study Annex II p. 211

[159] Ibidem

package 29% (3.5% of value added) and workers' safety 24% (2.9% of value added). The evidence suggests that the costs have remained relatively stable over the last decade[160].

However, the figure of EUR 8 billion cannot be considered as an entirely accurate estimate of the cost of the chemicals *acquis* due to differences of scope and in the methodology applied:

- The period covered corresponds only partly to the one covered by this Fitness Check.
- Costs correspond to only six subsectors (organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products) and not all the industry and companies.
- While the OSH Framework Directive, *per se*, is not in the scope of this Fitness Check, it can be reasonably assumed that the costs related to occupational health and safety legislation in the chemicals sector derive primarily from the daughter regulations (the Chemical Agents Directive, the Carcinogens and Mutagens Directive, etc.) which are within the scope of the Fitness Check. That said, it should also be noted that the estimated occupational health and safety costs probably include costs of worker safety protection beyond specific risks posed by exposure to hazardous chemicals(e.g. falls from heights, electrocution, burns, etc.) which are substantive but are not within the scope of the Fitness Check.
- Regarding the emissions and industrial processes legislative package, it should be noted that the EU Emissions Trading System (ETS) related legislation is not in the scope of this Fitness Check. In this legislative package, most of the monetary obligations are due to ETS. Therefore, the regulatory costs of emissions and industrial processes legislative package as assessed for the purposes of this Fitness Check can be estimated to represent EUR 2.6 billion (instead of EUR 3.1 billion).
- Costs presented above also include regulatory costs for several pieces of legislation that are not in the scope of this Fitness Check (REACH, Sustainable Use of Pesticides Directive, Large Combustion Plant Directive, EU Emissions Trading System (ETS) Directive, National Emissions Ceilings (NEC) Directive, Air Quality framework Directive and related, OSH Framework Directive, Directive on Personal Protective Equipment, Construction Products Regulation, Paints Directive, Tyre Labelling Regulation, Drug Precursors Regulation). In addition, several other pieces of legislation although within the scope of this Fitness Check, were not covered by the abovementioned cumulative cost assessment attempt (see Figure 10).

[160] CCA1 Study p. 114

COVERED ONLY BY CCA1	COVERED BY CCA1 AND FC CHEMICALS	COVERED ONLY BY FC CHEMICALS
REACH Sustainable Use of Pesticides Directive ETS Directive Air Quality legislation OSH Framework Directive Directive on Personal Protective Equipment Construction Products Regulation and Directive Deco Paints Directive Ethanol Denaturation Regulation and Directive Tyre Labelling Regulation Drug Precursors Regulation National Emission Ceilings (NEC) Directive	CLP Plant Protection Products Regulation Biocidal Products Regulation REACH Annex XIII Inland Transport of Dangerous Goods Carcinogens and Mutagens at Work Directive Young People at Work Directive Pregnant Workers Directive Signs at Work Directive Chemical Agents Directive Industrial Emissions Directive (repealing IPPC and Large Combustion Plants Directives) Waste Framework Directive and related (ELV, Batteries and PPWD) Seveso Directive Water Framework Directive RoHS directive PIC (Import and Export of Dangerous Chemicals) Regulation POPs Regulation Toy Safety Directive Cosmetic Products Regulation Detergents Regulation Fertilisers Regulation Explosives Directive Food Contact Materials Regulation General Product Safety Directive	Test Methods Regulation Good Laboratory Practice Directives Protection of Animals Used for Scientific Purposes Directive Pressure Equipment Directive Medical Devices Directives Aerosol Dispensers Directive Drinking Water Directive EU Ecolabel Regulation Contaminants in Food and Feed Regulation and Directive Residues of Pesticides Regulation Urban Waste Water Directive Marine Strategy Framework Directive Waste Shipments Regulation Asbestos Directive

Figure 10 Comparison of pieces of legislation covered by the Fitness Check and by the CCA1 Study

Therefore, additional cost elements were gathered where possible and qualitative assessment is presented where quantitative assessment couldn't be done.

It was not possible within the scope of this Fitness Check to determine to what extent these costs have had an effect on the trade and the competitiveness of the EU chemical sector[161].

[161] Commission study on the impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries/regions on international competitiveness of EU industry (CCA2 Study) is on-going.

A. Regulatory charges

Regulation charges correspond to fees, levies or taxes imposed by the legislation on stakeholders. For the pieces of legislation in the scope of this Fitness Check, these charges are imposed on industry and, ultimately, on consumers. In principle, fees and charges should reflect the cost recovery principle. Table 4 provides a list by piece of legislation.

Legislation		Description charges and fees to be paid
Covering hazard identification, classification and risk assessments	CLP[162]	ECHA shall levy a fee for a request to use an alternative chemical name for a substance in mixtures and for submission of proposals for harmonisation of classification and labelling. Where the applicant, i.e. a manufacturer, importer or downstream user, is an SME, the Agency shall levy a reduced fee.
	Plant protection products[163]	Member States may recover the costs associated with any work they carry out within the scope of the Plant Protection Products Regulation, by means of fees or charges. They shall ensure that these fees or charges are established in a transparent manner and correspond to the actual total cost of the work involved except if it is in the public interest to lower the fees or charges. Most countries charge a fee for the evaluation of new active substances. EFSA does not charge a fee for its scientific evaluations of active substances used in plant protection products in the EU.
	Biocidal products[164]	ECHA levies a fee for: work in relation to active substances; work in relation to Union authorisation of biocidal products; work to be carried out in relation to establishment of technical equivalence; applications for mutual recognition; requests for inclusion in the list of relevant persons; and requests for confidential treatment of information submitted to the Agency. ECHA also levies an annual fee for every biocidal product or biocidal product family authorised by the Union. Reductions of fees to SMEs established in the Union. Member States directly charge applicants fees for services under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority. Member States may levy annual fees with respect to biocidal products made available on their markets. Member States set and publish the amount of fees payable to their competent authorities. Fees are set to ensure that the revenue derived is, in principle, sufficient to cover the cost of the services delivered and no more.
Covering risk management measures	Waste legislation[165]	In line with the extended producer responsibility (EPR) principle, the producer of the product to become waste might be subject to payment of modulated fees reflecting their life-cycle including their repair, re-use, disassembly and recycling. Such fees do not necessarily take into account chemical components such as additives

[162] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32010R0440

[163] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009R1107

[164] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528

[165] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008L0098

		potentially hampering the recyclability of waste. But, this aspect might be further developed in order to support the shift towards more circular economy starting already at the design and production of goods phase.
	Export and import of hazardous chemicals[166]	Member States are permitted to charge administrative fees, in order to cover their costs in carrying out export notification procedure.
	Residues of pesticides[167]	Member States may recover the costs of work associated with setting, modifying or deleting maximum residue levels (MRLs), or with any other work arising from obligations under the Residues of pesticides Regulation, by means of a fee or charge. The fee should cover the cost of the work involved.
	Detergents[168]	If a manufacturer of a detergent containing surfactants, for which the level of ultimate aerobic biodegradation is lower than that stipulated in Annex III, asks for derogation, the request can be made dependent upon the payment to the Member State's competent authority of a fee. Such fees, if any, should not exceed the cost of processing the application.
	Fertilisers (Regulation (EC) No 2003/2003)[169]	Member States may subject fertilisers marked 'EC fertiliser' to official control measures for the purpose of verifying that they comply with the Fertilizers Regulation. Member States may charge fees not exceeding the cost of tests needed for such control measures, but this shall not oblige manufacturers to repeat tests or to pay for repeated tests where the first test was made by a laboratory which fulfilled the conditions of Article 30 and where the test showed compliance of the fertiliser in question.

Table 4 Regulatory charges imposed by the EU chemicals legislation

While creating business opportunities for innovative and specialised SMEs, chemicals legislation also remains a key challenge for them. Therefore, mitigating measures such as reduced fees have been introduced under some pieces of legislation (the CLP Regulation, the Biocidal Products Regulation). Such support measures are useful to assist SMEs in complying with their legal obligations.

However, the SMEs fee reduction mechanism does not exist under all pieces of legislation (e.g. the Plant Protection Product Regulation, the Waste legislation, the Residues of pesticides Regulation, the Export and import of hazardous chemicals Regulation, the Detergents Regulation and the Fertilizers Regulation). Where the mechanism exists, the level of fees reduction can vary, as it is up to Member States to define it which can lead to uneven application even though Member States usually have to ensure that the fee or charge corresponds to the actual cost of the work involved, and covers the cost of the services delivered.

[166] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:en:PDF

[167] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R0396

[168] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0648

[169] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:304:0001:0194:en:PDF

B. Substantive compliance costs

Substantive compliance costs are the investments and expenses incurred to comply with legal obligations or requirements, defined as "individual provisions inducing direct changes in costs, time expenditure or both for its addressees", which "oblige addressees to comply with certain objectives or orders, or to refrain from certain actions". It also covers "cooperation with third parties or to monitor and control conditions, actions, figures or types of behaviour". Compliance costs include capital costs[170], financial costs[171] and operating and maintenance costs[172], and can be broken down into: one-off/transition costs and recurrent (on-going) costs.

1) One-off and transition costs

One-off costs are often the result of a regulated group e.g. manufacturers, having to adjust and adapt to the changes in legal rules. For example, if new equipment needs to be purchased or if one-off changes in production processes need to be made. So one-off costs exclude costs that need to be borne on a regular or recurrent basis in the future.

The transition costs from previous legislation (i.e. the Dangerous Substances Directive (DSD) and Dangerous Preparations Directive (DPD))[173] to the CLP generated such costs for chemicals industry i.e. substances and mixtures manufactures and formulators[174]. These CLP transition costs are estimated ex-post to range from EUR 0.9 - 2.2 billion[175] with a mid-range best estimate of between EUR 1.4-1.6 billion. The range reflects uncertainties in the unit costs (± 30%), as well as uncertainties over the numbers of mixtures affected, including associated assumptions about staff training costs, IT costs, the number of mixtures subject to costs, the costs of reclassification, labelling, and Safety Data Sheet (SDS) preparation, etc.[176]

The largest transition costs were related to re-classification (a cost range of EUR 159- 295 million for individual substances and EUR 300 – 376 million for mixtures), to changes in labelling requirements (cost range of EUR 108- 200 million for substances and EUR 107 – 134 million for mixtures) and to updating and redistributing safety data sheet (a cost range of

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[170] CAPEX: occur when a company acquires or upgrades physical assets such as property, industrial buildings or equipment. Once the asset is in place, capital costs generally do not change with the level of activity and are thus functionally equivalent to "fixed costs". In cost-benefit analysis, capital costs are usually "annualised" over the period of the useful life of the equipment.

[171] Financial costs are costs related to the financing of investment, and are thus normally considered in relation to CAPEX. However, they can also emerge with respect to OPEX whenever a new legal provision changes the structure of the working capital.

[172] OPEX: include annual expenditures on salaries and wages, energy inputs, materials and supplies, purchased services, and maintenance of equipment. They are functionally equivalent to "variable costs."

[173] By 1 December 2010 for substances and by 1 June 2015 for mixtures.

[174] 1st FC Study Annex II p. 70 Table 6-8 outlines the sectors which are considered to have incurred transition costs, together with the number of companies assumed to be affected. SMEs account for 95% of all companies, whilst manufacturers / formulators of mixtures make up around two-thirds of the companies.

[175] Estimates based on the number of substances (over 99 000) and the number of mixtures (2 – 2.5 million) subject to reclassification, labelling and safety data sheets preparation. Source: 1st FC Study p. 45 and Annex II p. 58-85

[176] 1st FC Study p. 45 and Annex II p. 58-85

EUR 100- 184 million for substances and EUR 112 – 141 million for mixtures)[177]. The DSD/DPD to CLP transition costs[178] turned out higher than the original ex-ante estimates in the Impact Assessment done for the proposed CLP Regulation, where total costs were estimated at around to EUR 391 million. This difference is largely due to an underestimate of the number of affected substances and sectors in the 2006 impact assessment.[179]

Transition costs can also occur where substance specific risk management measures need to be taken because a substance previously not classified as, for example, a carcinogenic, mutagenic or toxic for reproduction (CMR) substance is reclassified as one following the introduction of the CLP Regulation leading to a ban of the substance and the need to find a less hazardous substitute. The impact of these costs, however, can vary. For example, the removal of substances from cosmetics use requires manufacturers to reformulate and, in some instances, to stop the manufacture of a particular product line altogether. Costs can be very low, for example, where a substitute is readily available, and significantly higher, where it is not, or where reformulation involves significant change to the production process. For example the costs of reformulating and remarketing a cosmetic product due to a change in a key ingredient were estimated to range from EUR 12 000 to EUR 920 000 depending on the role of the ingredient, the availability of alternatives etc.[180]

2) Recurrent costs

a) General overview

Recurrent costs are the substantive compliance costs sustained by the regulated stakeholders (chemicals industry for example) on a regular basis e.g. continual re-training of employees or repeated testing. The main recurrent costs come from:

- the obligation to identify/generate and provide data for chemical hazard classification and risk assessment;
- the risk assessment step and testing and within this the exposure assessment in particular[181];
- the implementation of risk management measures e.g. hazard communication through labelling.

More generally, the significance of the recurrent costs typically depends on the overall complexity and stringency of the legislation. The higher the potential hazard and risks of a

[177] Total classification, labelling and SDS costs for substances are estimated at around EUR 522 million (±EUR 157 million); the comparable costs for mixtures are estimated at EUR 651 million (upper bound estimate for the number of mixtures). For more details see 1st FC study, Annex II p. 75 and Table 6-16 (p. 83)

[178] The types of costs taken into account include those related to classification, labelling, SDS revision and distribution, packaging costs, upgrading IT systems, staff training, CLI notification costs and costs associated with reformulation or the withdrawal of products.

[179] i.e. 30 000 substances compared to the figure of 99 000 assumed in the 1st Fc study. In addition, the 2006 study did not cover all of the sectors which would be affected by CLP, with the 2006 analysis assuming less than 20 000 companies (1 150 large and 18 780 SMEs) would be affected compared to 31,000 for this study, with this having a significant affect on the mixture - related costs. 1st FC Study p. 45 and for more details Annex II p. 85

[180] 1st FC Study table 4-4 p. 51

[181] Interviews were carried out as part of the FC+ Study

substance for the environment and/or human health, the higher will be the level of safety requested. This also means the level of information and assessment requested will be higher: as is the case for the Plant Protection Products and the Residues of Pesticides Regulations where the substances and products, are by design, lethal to the target plants and organisms.

In addition, the importance of these costs varies depending on the procedures that industry must comply with e.g. authorisation to place on the market. The Biocidal Products Regulation, the Plant Protection Products Regulation and the Residues of Pesticides Regulation in this regard have emerged as the lengthiest and most complex regulations, implying higher cost burden than, for example, the Cosmetic Products Regulation and the Toy Safety Directive (see Figure 11). For the Biocidal Products Regulation, it shall be noted however that, in most cases, industry can place their substances/products on the market during the assessments of authorities, which also allows them to recover some costs during that period. An element of caution should be applied to this comparison as there are considerable differences in the scope and potential hazard and risks of substances and products used.

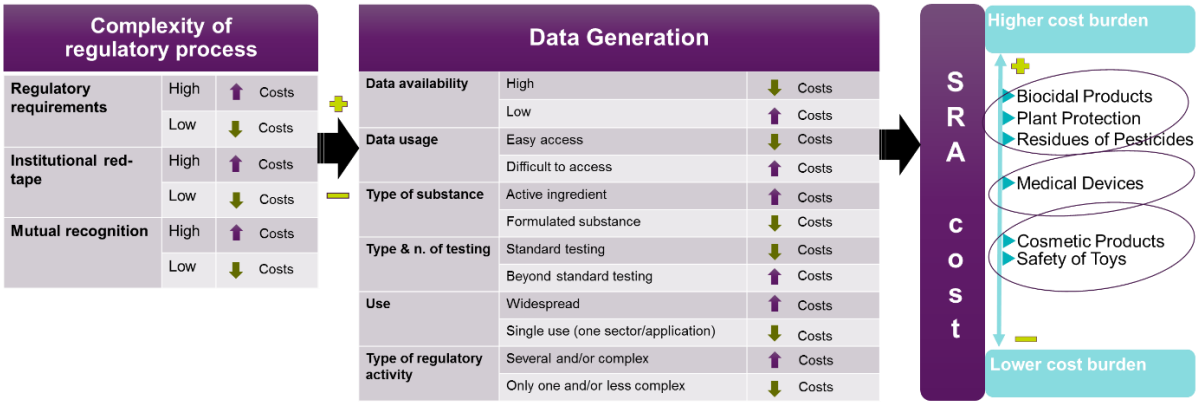

Figure 11 Legislation clustering according to cost influencers[182]

"Understanding and keeping up-to-date with changes in legal requirements" was identified during the Open Public consultation and the SME Panel Survey as a significant driver of costs by the highest number of companies (84% (147) of companies for the former and 45% of SME respondents for the latter), with the costs of risk management under the different legislation ranked second (73% or 127).[183] Training staff to ensure compliance with legal requirements was also identified as an important cost driver (61% (106) by respondents from industry associations and companies).

b) Main recurrent cost drivers

The costs of the classification of a substance are driven mainly by the CLP Regulation and are often dependent on data availability, accessibility and usability (as explained in Section 5.2.1 in the main document and Section 2.1.4 in Annex 4). The variety of cases and the conditions

[182] FC+ Study p. 84

[183] 1st FC study p. 48

of data usage and sharing vary legislation-by-legislation and according to specific cases within the same legislation[184]:

- Data on assessment of biocidal active substances and, in the future, for biocidal products, are publicly available on the ECHA website. For biocides, plant protection products and residues of pesticides, only vertebrates studies are subject to mandatory data sharing. For biocides, this mandatory data sharing is also extended to all toxicological and ecotoxicological data (including on invertebrates) for certain procedures[185]. As hazard and exposure data is lacking, companies have to undertake their own testing and, in some cases, corrections after testing. A similar problem for lack of toxicological data was reported for food contact materials.
- Under the Toy Safety Directive, publicly available information is reported fairly usable for toxicological testing.
- Under the Cosmetic Products Regulation, hazard can be obtained from the ingredient supplier (toxicological data from the product safety report) and exposure assessment data from the cosmetic producers.

In general, when data are publicly available, the risk/hazard assessment process is less costly. Similarly, low data access and usability affects costs upward. Testing as part of the data generation process to prepare and file an application for a regulatory approval of a substance or a mixture (e.g. under the Cosmetic Products Regulation, the Toy Safety Directive, the Detergents Regulation, the Biocidal Products Regulation, etc.) is another important cost driver for the industry. [186]

Annual costs arising from the CLP Regulation are estimated to amount to EUR 1.3 billion (EUR 0.97-1.7 billion).[187] The main cost element is staff costs related to compliance activities such as reviewing classifications, redesigning labels etc. (EUR 957 million[188]). These annual costs represent less than 0.1% of the total turnover for the sectors and approximately 1.1% of the value added[189]. These costs, however, do not include the poison centre reporting obligations, which currently depend on national legislation but that will be harmonised progressively at the EU level after 2020.[190] [191] Per company, the costs of the CLP

[184] FC+ Study p. 81-85

[185] Article 95 of the Biocidal Products Regulation (Regulation (EU) No 528/2012)

[186] FC+ Study p. 79-84

[187] 1st FC STUDY Annex II, p. 95

[188] 1st FC study, Annex II section 7.2.3.4 and Table 7-5 (p. 89)

[189] Based on Eurostat data for 2012-13 (for NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1, and 24.4)

[190] These costs were estimated to amount to EUR 1.7 billion (Source: Study on the harmonisation of the information to be submitted to Poison Centres; Amec Foster Wheeler; March 2015). Recent analysis, however, cast some doubt on whether the numbers of notifications used for those studies are not significant overestimates. The details will also be reassessed in a study to be launched in early 2018, which may also lead to a revision of the Annex affecting the numbers of notifications to be expected.

[191] Although there is no evidence available yet, the CLP-related costs are expected to have significantly decreased after 2015 for individual hazardous substances and from 1 June 2017 for mixtures. Source: CCA1 study p. 104

implementation are estimated at EUR 34 000 (EUR 24 000 - 44 000) for SMEs and EUR 247 000 (EUR 173 000 - 321 000) for larger companies[192].

Respondents to the Open Public Consultation[193] from Industry associations and companies were of the opinion that classification requirements for substances and mixtures (57% (100)) and chemical labelling and packaging requirements (59% (102)) result in significant costs.

In cases where a substance or a product requires an authorisation or an approval in order to be placed on the market (e.g. Plant Protection Products and Biocidal Products Regulations), the requirements associated with the authorisation process i.e. starting from the dossier preparation until obtaining the final authorisation, can impose substantial costs on the industry. The total costs for the pesticides industry are estimated at approx. EUR 122-189 million per year. The regulatory charges (fees) represent a small share of the total costs for the industry[194]. The costs for pesticides maximum residue level (MRLs) procedures are estimated at around EUR 55 million per year for the industry[195]. Industry stakeholders explained that the process can be costly and time-consuming, to a level where only the larger companies in the sector can afford to go through the authorisation process for both the active ingredients (EU level authorisation) and the plant protection product (Member State level authorisation), as they can more easily absorb and/or pass on the costs of conducting the risk assessment to the end users. [196]

According to some industry stakeholders[197], the EU Union product authorisation process under the Biocidal Products Regulation is considered to be too costly. It was explained that national authorisation is generally favoured when only a limited number of markets are served (less than 10 EU markets). Some companies (particularly SMEs), by reason of their size, due to their focus on niche markets or language barriers, may rather be interested in operating in one or few Member States only. The spatial element is also to be taken into account. Some countries may be chosen for the authorisation of biocidal products depending on the market needs (e.g. wood preservatives in northern countries). There might be different driving factors motivating the applicants' choice of the countries responsible for the assessment of the applications like the amount of the fees charged, but also the expertise on a given product-type. Nevertheless, as the EU Union product authorisation process was only introduced in

[192] Assuming that the costs are evenly spread across the 30 850 SME substance and mixture manufacturers and 1 057 larger substance and mixture manufactures. 1st FC study p. 88 Section 7.2 Annex II

[193] Question 21

[194] Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) p.126; not yet publicly available

[195] Ibidem

[196] FC+ Study p. 86

[197] This survey was carried out by Ecorys (2016), Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision, Final report to the European Commission Directorate-General for Health and Food Safety. 12 large companies and 14 SMEs participated in the survey

2013 and as it will cover all product types by 2020, it might be necessary to wait some additional time before seeing its use more widely.[198]

Annual costs incurred by the detergents industry as a direct result of the Detergents Regulation are estimated to range between EUR 63.7 – EUR 149 million (appr. EUR 764 million – EUR 1.8 billion in total since 2005). Depending on the sector, compliance with occupational health and safety legislation, e.g. investments in workers' health protection equipment, can also lead to significant costs.

Even though an in-depth analysis of the main cost drivers related to other risk management measures has not been carried out due to the wide scope of the Fitness Check and their diversity, it appears clearly that such costs exist e.g. labelling requirements (the CLP or sector specific legislation) including the label design, printing, as well as additional translation costs, or some packaging requirements such as child resistant closures that increase production costs.[199] Specific protection measures are to be taken in order to provide individual and collective protection of workers in a professional environment e.g. production or use of hazardous chemicals in products manufacturing. For the soaps and detergents sector, for example, the worker safety legislation implies the second most important regulatory cost, representing 21% of the legislation costs, equivalent to approximately 2% of the value added.[200] Most of the cost is generated by the obligations for investments on workers' safety and health protection equipment.

3) Administrative costs

Administrative costs are those borne by businesses, citizens, civil society organisations and public authorities as a result of the administrative activities performed to comply with the information obligations included in the legal rules. Administrative burden is the result of regulatory requirements: accordingly, they do not include so-called "business-as-usual costs". Given the wide scope of this Fitness Check, these costs are very difficult to assess, in particular because of the lack of monitoring at EU level and the scarcity of data.

Administrative burden represent approximately EUR 950 million for chemical sector (2004-2014)[201]. Administrative burden corresponds to:

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[198] The recent Commission's report to the European Parliament and to the Council (COM(2018) 342 final) gives some preliminary conclusions indicating that Union authorisation is attractive under the current fee rates, particularly with regard to biocidal product families. Moreover, applications for Union authorisation are serving as reference products for national applications. This will help applicants, and particularly SMEs, to obtain authorisation for their existing products at Member State level.

[199] The CLP related costs are provided in the Annex II of the 1st FC Study

[200] CCA1 Study p. 137

[201] CCA1 Study p. 115 and onwards. The identified costs cover costs for several subsectors of chemicals industry (i.e. organic and inorganic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, paints, varnishes and similar coatings and other chemicals products). The following pieces of legislation are covered: the CLP Regulation, the Plant Protection Products Regulation, the Biocidal Products Regulation, REACH, the Inland transport of Dangerous Goods Directive, the Carcinogens and Mutagens at work Directive, the Young people at work Directive, the Pregnant workers Directive, the Signs at work Directive, the Chemical Agents Directive, the IED, the Waste Framework Directive and related (ELV, Batteries, PPWD), the Seveso Directives, the Water Framework Directive, the RoHS Directive, the Export and import of hazardous chemicals (PIC) Regulation, the POPs Regulation, the Toy Safety Directive, the Cosmetic Products Regulation,

- The amount of work necessary to fulfil information obligations, retrieve data on applications from downstream users, monitor emissions data, or prepare technical dossiers for the purpose of registration, authorisation, classification and labelling[202].
- The obligation of reporting and information and the preparation of companies for inspections.[203]
- Personnel cost for the preparation of audits and carrying out regular health checks. Implementation of risk assessments and investigations e.g. for existence of hazardous, carcinogen and mutagen substances, are required and information on the findings should be communicated to the competent authorities and to workers.[204]

From a qualitative assessment perspective, the information obligations for safety reports, authorisation dossiers, etc., under regulations such as the Plant Protection Products Regulation, the Biocidal Products Regulation, the Cosmetic Products Regulation, and others, are a key driver of administrative costs. However, under the Biocidal Products Regulation there is a possibility to authorise a group of similar biocidal products ('biocidal product family') via one single application for authorisation, which reduces the administrative burden for both companies and authorities.

Another factor that can increase the administrative costs is the pace of the risk assessment process. The risk assessment processes can take anywhere between months and several years depending on the legislation and on the specific case. Laboratory/consultancy and industry stakeholders considered the risk assessment process under the Biocidal Products Regulation and to the Plant Protection Product Regulation to be one of the longest. The whole process from start to final product authorisation can take up to 10-15 years. In part, this can reflect delays both from the applicant in submitting missing data and delays caused by the evaluating authorities.[205] For the Biocidal Products Regulation, it should be noted, however, that, in most cases, industry can place their substances/products on the market during the authority assessment period which allows industry to recover some costs.

4) Hassle costs

Often linked to administrative burden measurements, hassle costs are a residual category of the direct costs. These are more subjectively felt costs related to the overlap of regulatory requirements on specific entities, be they citizens or businesses. Hassle costs can include costs related to administrative delays (when not directly attributable to an information obligation) and relatedly, the opportunity cost of waiting time when dealing with administrative or litigation procedures.

Industry stakeholders have pointed out that the potential for disagreement between the RAC and EFSA regarding the proposed classification of an active substance used in plant

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the Detergents Regulation, the Fertilisers Regulation, the Explosives Directive, the FCMs Regulation, the General Product Safety Directive

[202] CCA1 Study p.101

[203] CCA1 Study p.110

[204] CCA1 Study p. 83

[205] FC+ Study p. 82

protection products can have significant impacts for industry due to the uncertainty that it creates regarding the outcome of the assessment (approval/partial approval/no approval).[206]

They have also highlighted that the complications and delays increasing the overall costs are greater in cases where the level of mutual recognition at Member State level is generally low (or there is otherwise a differentiated approach for different parts of the EU). A lack of mutual recognition is reportedly often linked to different requirements at Member States level and to disagreements, non-acceptance or lack of trust in assessments of reference Member States, misinterpretation or misuse of emergency use of authorisation between different Member States. Data generation costs are typically influenced upward because of additional testing or information requirements from the national authorities.[207]

C. Enforcement costs

The legal rules have to be monitored and enforced by public authorities to be effective. These enforcement activities imply costs to the administration.

It is not possible to provide quantified figures of costs of enforcement of the EU chemicals legislation at national level. These costs may vary greatly amongst legislation depending also on the regulatory option chosen (e.g. self-regulation, providing information and guidelines, market-based instruments, more or less stringent and prescriptive regulatory actions). Differences in enforcement costs vary also from one Member State to another depending on the national administrative choices and the related functional costs. [208]

From a qualitative perspective, however, the costs for public authorities[209] include costs associated with:

- Implementation activities: these activities include participation in expert groups and scientific bodies, research and regulatory proposals, risk assessments, etc. The implementation of chemicals control legislation is time- and resource-intensive. Therefore, the fact that many Member States are lacking resources leads to differences in their involvement in bringing forward harmonised hazard classification dossiers, for example.
- Compliance monitoring and enforcement activities: the costs will depend on the way in which the compliance monitoring and the inspection are organised at the national level and on the regimes in place under the related chemicals legislations. Data available from the REACH-EN-FORCE projects indicate that on average over 2 000 inspectors are trained on REACH and CLP per annum, at an annual cost of around EUR 1.7 million. [210]

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[206] 1st FC Study p.62

[207] For example, for Plant Protection Products, art. 40 introduces a zonal rapporteur who should assess the application for the entire zone and not only for the Member State regarding the application. The zonal application should then be mutually recognised; however, this may be complicated where requests for additional data from other Member States in the same zone (to ensure acceptable risk) may arise. Source: 1st FC Study Annex IV p. 160

[208] Quantification of costs incurred in the EU were carried out only in respect to the CLP Regulation. See 1st FC Study Annex II p. 211

[209] 1st FC Study p. 51-52

[210] 1st FC Study p. 88

- Reporting activities (even though not all pieces of legislation are subject to reporting obligation). In this regard, Member State authorities noted that there are substantial costs incurred by the enforcement agencies related to unnecessarily bureaucratic reporting duties. For example, respondents to the Open Public Consultation noted that chemical data needs to be reported to numerous authorities due to numerous requirements. This includes the potential need for a company to undertake reporting to ECHA, the Commission (ozone depleting substances, etc.), to other national authorities (workers' safety, Seveso, the environment, VOCs, fluorinated gases, etc.). This leads to costs both for authorities and for enterprises, which are significant.[211]

For illustrative purposes, the overall costs for Member States generated by the Plant Protection Products Regulation for the approval and authorisation procedures are estimated at approx. EUR 44 million annually. The costs for the Residues of Pesticides Regulation (which sets maximum residues levels (MRLs) of pesticides on food products) procedures are estimated at around EUR 5 million annually for the 28 Member States. [212]

At the EU level, data taken from the publicly available reports setting out ECHA's budgets indicate that the average annual costs to ECHA associated with implementing CLP are estimated to be approximately EUR 2.57 million.[213] This figure constitutes the cost of providing guidance, running helpdesks, overseeing committees and forums, etc. The total cost to ECHA of implementing CLP over the period 2010 to 2016 is over EUR 22.8 million, equivalent to 17% of the combined the REACH and the CLP budget.[214] The total capital costs to ECHA of developing the Classification and Labelling Inventory (CLI) were approximately EUR 1 million, with annual operating expenditure of around EUR 0.2 million.[215]

Respondents to the Open Public consultation identified costs to public authorities as significant[216].

D. Indirect regulatory costs .

Indirect costs are costs incurred in related markets or experienced by consumers, government agencies or other stakeholders that are not under the direct scope of the regulation. These

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[211] 1st FC Study p. 52. This issue is being examined as part of Fitness Check on environmental monitoring and reporting (SWD(2017) 230).

[212] Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) p.126; not yet publicly available

[213] European Chemicals Agency, Budget 2018, MB/45/2017 Final, Brussels, 14 December 2017, Public https://echa.europa.eu/documents/10162/23601668/mb_45_2017_budget_2018_en.pdf/20014aa3-a68b-107f-ffdf-61171e273eeb

[214] 1st FC Study p. 52

[215] 1st FC Study p. 46

[216] Question 20. 40% or 17 of Group 4 NGOs and others respondents also identified significant costs for authorities at EU level and costs for authorities at national level (42% or 18). The proportion of Group 3 (representing governments and public authorities) identifying significant costs at the EU level was 25% (9) and at the national level was 33% (12). The majority of Group 3 respondents (56% or 20) to question 22 replied that there are specific requirements in the EU legislative framework which lead to particularly significant costs for authorities. Main comments received were related to market surveillance, inspections and enforcement of existing requirements.

costs are transmitted through the value chain and expressed as changes in the prices, availability and/or quality of the goods or services produced in the regulated sector.

Indirect compliance costs can arise due to the fact that, for example, a specific substance is banned for further use and therefore must be substituted. The development costs for substitution can be seen as direct one-off compliance costs even if they are occurring in downstream sectors, but they then lead to indirect costs transmitted through changes in the prices of the final goods, when the banned substance was used in their production. Changes in these prices then ripple through the rest of the economy, causing prices in other sectors to rise or fall and, ultimately, affecting the welfare of consumers.

It was possible to quantify such costs regarding the transition to the CLP Regulation costs. Indirect transition reformulation costs for manufacturers of mixtures are estimated at between EUR 67.7 million and EUR 141 million (depending on the assumptions for numbers of mixtures and the fraction of mixtures assumed to be reformulated). No estimate of the associated losses from withdrawing product lines from the market could be developed.[217]

6.1.3 Benefits

A. General overview on main aspects related to benefit assessment

Just like the costs, the benefits can be classified as direct and indirect (see Figure 12). Direct benefits will affect the stakeholders within the scope of the legislation e.g. industry, consumers, workers, etc. Indirect benefits will go beyond the target groups of the legislation and affect other groups e.g. bring benefits throughout the value chain or even become diffuse and benefit the whole society (e.g. reduced exposure to hazardous chemicals through general environment).

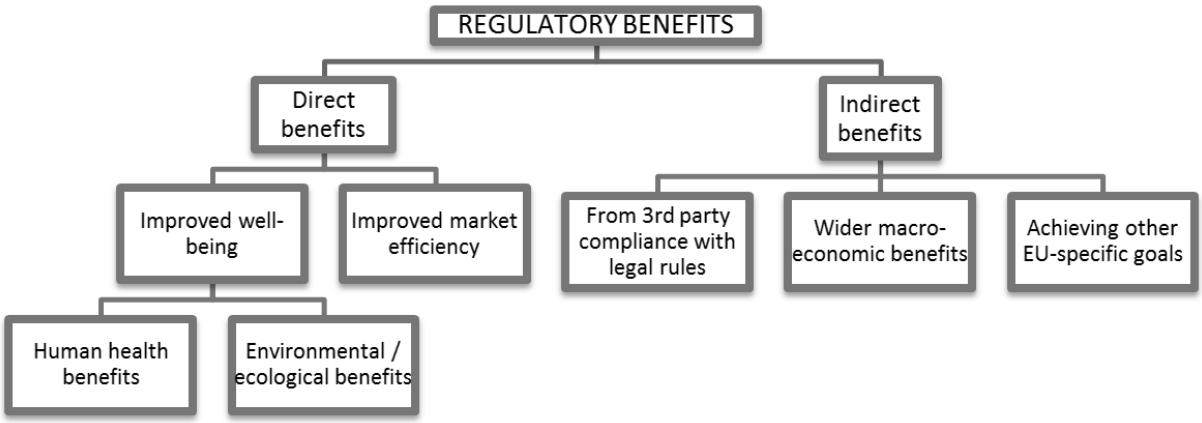

Figure 12 Categories of regulatory benefits

The direct human health and environment benefits resulting from the EU chemicals legislation are assessed below. Where the data and methodology allowed for reasonably robust and transparent benefit estimates to be calculated, quantified figures are provided. .

The benefits of improved market efficiency are typically evaluated from the perspective of market prices, competition, production and supply of goods. No estimates based on these

[217] 1st FC Study Annex II p. 83-84

criteria have been made for the purpose of this Fitness Check, mainly due to its wide scope and to the scarcity of data. Therefore, these aspects are analysed in Annex 5 Effectiveness from a wider macro-economic angle and from a qualitative perspective, including the impacts on innovation and competitiveness, as well as achieving the objective of awell-functioning internal market.

Regarding the indirect regulatory benefits for 3rd parties from compliance with the legal rules, it seems that the EU chemicals legislation has produced spill-over effects going beyond the EU borders e.g. due to the fact that imported articles shall comply with the EU legislation in order to be placed on the market. Another example is the Cosmetic Products Regulation, which is often used as a reference and a regulatory model worldwide, in particular in relation to animal testing. However, such benefits have not been assessed for the purpose of this Fitness Check.

The framework of EU chemicals legislation also contributes directly to meeting the EU's international obligations and commitments including the achievement of the 2030 UN Sustainable Development Goals (SDGs), the World Summit on Sustainable Development WSSD 2020 Goal, and the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006).

The EU chemicals legislation plays an important role in the shift towards a more circular economy, which itself contributes to achieving other EU commitments, including the fight against climate change. However, such benefits have not been assessed for the purpose of this Fitness Check. Nevertheless, the impacts of the EU chemicals legislation on achieving the circular economy goal are described in the main document (Section 8.1.2 Relevance).

B. Cumulative health and environmental benefits

Significant benefits in terms of protecting human health and safeguarding the environment have been delivered over the last 50 years by the EU chemicals legislation to industry, to public authorities and regulators as well as to consumers and citizens and to society and the economy more generally. Table 5 provides a list of benefits and direct beneficiaries.

Category of benefits		Direct beneficiaries and benefits	
Health	**'Physical' benefits**	Workers, consumers and citizens	Reduced morbidity and mortality health impacts (e.g. reduced number of cancers, cardiovascular disease, allergies, reproductive illnesses, neurological disease, etc.) from reduced exposures of hazardous chemicals. This includes avoided suffering and health effects through higher income (due to avoided lost earnings as a result of avoided illness) and longer life expectancy
	Monetised benefits	Consumers and citizens	Avoided healthcare costs, avoided suffering (assessed through willingness to pay techniques), value of avoided life years lost due to premature death, productivity losses due to lost work hours as a result of illness and/or premature death
		Industry	Avoided health costs and productivity losses; a less hazardous working environment can reduce the costs that companies face (healthcare costs, insurance costs, lost productivity, fines, etc.) .
		Member States	Reductions in the damage costs associated with chemical exposures (healthcare costs; environmental clean ups, etc.)

Avoided environmental damage	Society	Various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs
	Industry	Reductions in the costs associated with environmental remediation and clean ups.
	Members States	Reductions in the costs associated with environmental remediation and clean ups.
Regulatory	Member States	Reductions of some of the burden faced by Member States, by enabling them to share efforts (and hence resources) at the European level in the implementation of the legislative framework

Table 5 Benefits and direct beneficiaries

The available evidence suggests that the benefits of EU chemicals legislation are significant. Important benefits arise, for example, from avoided healthcare costs and productivity losses. There are, however, a number of health and a significant number of environmental benefits for which it is not yet possible to estimate the value in monetary terms. Therefore, the estimates presented for the purposes of this Fitness Check do not give the full picture of benefits.

Some of the biggest, currently measurable, health benefits of EU chemicals legislation are associated with reductions in the exposure to carcinogenic pollutants. However, one should keep in mind that, while the extent of cancer incidence due to occupational exposure has been extensively studied, the impacts from environmental exposure to carcinogens are harder to estimate. It is in an occupational setting where the link between exposure to certain chemicals and cancer is the most clear[218]:

- It has been estimated that in the EU between 91 500 – 150 500 people with past exposure to carcinogenic substances at work were newly diagnosed with cancer in 2012. Moreover, between 57 700 – 106 500 cancer deaths were attributed to work-related exposure to carcinogenic substances in 2012. As a result, cancer has been designated as the first cause of work-related deaths in the EU. Direct costs of work-related cancer in terms of healthcare and productivity losses amount at least to some EUR 4-7 billion per year. The indirect costs may reach as much as about EUR 242 – 440 billion each year.[219]
- Based on reductions in exposure to a group of 13 carcinogens since 1995 that have been targeted by EU occupational health and safety legislation, the total number of cancer deaths avoided across the EU is estimated to be around 1,4 million. [220]

Other examples below include the estimated benefits from reduced exposures to lead, hexavalent chromium, allergens, phthalates, to pesticides and polychlorinated biphenyls (PCBs) (see Table 6). Annex 5 provides more information regarding the historical and ongoing exposure.

[218] CuBA Study, p. 45

[219] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee Of the Regions, COM(2017) 12 final

[220] CuBA Study p. 18 and p. 57

The Benefits	Estimated Benefit Value (€) for the EU	What's Included?
Avoided cancers due to reduced exposures to **hexavalent chromium** at workplace	**Hexavalent Chromium: EUR 100 million/yr** and EUR **4 billion in total** between 1995-2010	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death (measured by willingness-to-pay to avoid it)
Reduced neurotoxicological disease and related deaths due to reduced exposures of children to **lead**[221] through general environment	**EUR 450 billion/yr**	• Avoided lifetime earnings losses due to reduced IQ as a result of exposure to lead during childhood
Reduced asthma cases and related fatalities due to reduced exposures to **allergens** and other hazardous chemicals attributed either to air pollution or exposure at workplace	**EUR 250 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death (measured by willingness-to-pay to avoid it)
Reduced female reproductive disease as a result of reduced exposure to **DEHP (phthalate)** via a variety of consumer products	**EUR 7 billion** cumulatively from 1996 - 2008 (i.e. approx. **EUR 580 million/yr**)	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income)
Reduced male reproductive disease (infertility) as result of reduced exposure to **DBP (phthalate**[222]**)** via **a** variety of consumer products	**EUR 6.7 billion** cumulatively from 1996 – 2008 (i.e. approx. **EUR 560 million/yr**)	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income)
Reduced cases of skin sensitisation (allergic reaction) as a result of reduced exposure to **allergens** at workplace	**EUR 160-190 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Avoided suffering/death (measured by willingness-to-pay to avoid it)
Reduced incidence of chromium VI allergy cases associated with skin sensitisation and damage due to exposure from articles of leather[223]	**EUR 350 million/yr**	• Avoided healthcare costs • Avoided productivity losses (lost working hours and income) • Increased consumer surplus

[221] Lead in European children's blood has substantially decreased over last four decades due to the removal of lead from petrol, as well as from other exposure sources such as paints and pipework. The corresponding effects regarding children are reduced damage to the intellectual development /loss of intellectual capacity, reflected in higher lifetime earnings potential and avoided disability adjusted life years (DALYs)).

[222] The reduction in the manufacture, use and exposure to phthalates in the EU has decreased significantly from the mid-1990s.

[223] Chromium VI is not intentionally used in the manufacturing of articles of leather, but may be formed during the tanning process, or can be released during storage and the lifecycle of leather articles. It is associated with skin sensitisation and damage. It was estimated that 0.84-2.31 million individuals are sensitised in the general population of the EU-27. It is also estimated that at least 45% of the new chromium allergy cases in the EU-27 were due to exposure from articles of leather. The only way of preventing allergic reactions for allergy sufferers is to avoid contact with leather goods that contain chromium (VI).

The Benefits	Estimated Benefit Value (€) for the EU	What's Included?
Reduced environmental and pollination impacts as a result of better control and management of **pesticides** (e.g. neonicotinoids)[224]	**EUR 15 – 50 billion/yr**	• Value of eco system services • Agricultural value of pollination services provided by pollinating insects
Avoided drinking water treatment costs as a result of reduced **pesticide contamination** of surface and groundwater reserves	**EUR 500 million/yr**	• Avoided water treatment costs
Avoided clean-up costs association with PCB use in the past caused by the contamination[225]	**Cumulative cost of EUR 0.4 - 1.9 billion/yr** for the period 1971 to 2018 (EUR 20 – 90 billion in total)	• Remediation and waste management costs excluding any health and environmental impact costs

Table 6 Selected monetised environmental and health benefits of reduced hazardous chemical exposures[226]

Additional benefits result from the regulatory framework on plant protection products and/or biocidal products helping to reduce the development of resistance of unwanted pests/organisms, which can have serious impacts on agriculture, health, environment, the functioning of society and the economy.

Regarding enhancement of the single market, competitiveness and innovation objectives, these benefits have been examined in the main document Sections 5.1.2 Effectiveness and 9. EU added value and in Annex 5 Section 1.2. There have been positive impacts of the EU chemicals legislation in terms of an efficiently functioning internal market. Benefits in terms of innovation and positive impact on the EU industry's competitiveness are more complex.

More generally speaking, the EU chemicals legislation plays an important role in the shift towards a more circular economy.[227] It also contributes directly to the achievement of the 2030 UN Sustainable Development Goals (SDGs[228]).

Respondents to the Open Public Consultation[229] agreed that the EU chemicals legislation and chemical-related legislation generate benefits from reducing the exposure of consumers and

[224] Bees play a significant role in the food production process and provide ecosystem services (e.g. pollination) beneficial to human nutrition. Neonicotinoids are likely to be contributing to the observed beehive collapse syndrome in Europe.

[225] These clean-up costs are associated with PCB use and waste management (remediation and waste management costs; but not including any health and environmental impact costs) caused by the contamination that could have been saved.

[226] Study on the cumulative health and environmental benefits of chemicals legislation

[227] For example, see the Interface between chemical, product and waste legislation communication (COM(2018) 32 final); 16 January 2018

[228] https://www.un.org/sustainabledevelopment/sustainable-development-goals/

[229] Question 19: What are the significant benefits generated for EU society by the EU chemical and chemical-related legislation?

citizens to toxic chemicals[230], reducing the exposure of workers to toxic chemicals[231] and reducing damage to the environment and ecosystems[232].

Respondents to the Open Public Consultation[233] indicated that EU chemical legislation and chemical-related legislation generate benefits by:

- Encouraging research and innovation, generating new jobs and improving competitiveness: NGOs and others have the highest response to this benefit at 70% (31), while respondents from the other groups are much less likely to identify this as a significant benefit of EU chemicals legislation. Only 10% (17) of Industry association and companies respondents identified this as a benefit compared with 41% (15) from Public authority and 27% (7) from Citizens.
- Stimulating competition and trade within the EU single market: the percentage of respondents from all groups is much lower for this benefit with the highest proportion identifying this as a significant benefit coming from Public authority at 22% (8). Just 5% (8) of Industry association and companies respondents identified this as a significant benefit, slightly higher than the 4% (1) from Citizens.
- Stimulating international trade between the EU and other countries: again the level of agreement that this is a significant benefit was lower, and lower than for within the EU single market for all groups except Citizens (here 8% highlighted this as a benefit but the number of responses is very low, at 2). The highest level of agreement came from Public authority at 19% (7) while just 4% (7) of Industry association and companies thought this was a significant benefit.

6.1.4 Are costs and benefits proportionate?

The inability to arrive at single overall figures for the cumulative benefits and costs of the EU chemicals *acquis*, coupled with the partial picture on the costs and benefits at the specific legislation level, means it is not possible to arrive at a single cost-benefit ratio nor is it possible to determine whether or not costs are proportionate at the framework-wide level. .

It appears from the analysis above that the benefits directly or indirectly generated by the EU chemicals legislation are significant while costs to companies and public authorities are also significant.[234] These views are shared by different stakeholders although the perception of the importance of the costs and therefore of whether costs are proportionate to benefits varies amongst different groups and even within the same category. The real question is not about the *acquis* overall, but about specific elements of it, for example:

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[230] 95% (35) of Public authority, 80% (35) of NGOs and others, 79% (140) of Industry association and companies and 54% (14) of Citizens respondents.

[231] 92% (34), of Public authority, 85% (151) of Industry association and companies, 91% (40) of NGOs and others and 54% (14) of Citizens.

[232] 89% (33) of Public authority, 84% (148) of Industry association and companies, 70% (31) of NGOs and others and 58% (15) of Citizens.

[233] Question 19: What are the significant benefits generated for EU society by the EU chemical and chemical-related legislation?

[234] FC+ Study p. 138

- Industry stakeholders from the pesticides sector (including biocides) explained that the processes of substance approval and product authorisation can be costly and time-consuming, to a level where only the larger companies in the sector can afford to go through them as they can more easily absorb and/or pass on the costs of conducting the risk assessment to the end users.[235]
- Another specific example is the EU decision to adopt changes in labelling requirements under the CLP Regulation (in line with their adoption at the UN GHS level). This is triggered by the adoption of changes under the UN Global Harmonised System (GHS) which requires all signatory countries to then implement via their respective national legislation. For EU countries this is done via the CLP Regulation. According to industry stakeholders, such changes led to significant costs while the associated health and environmental benefits were considered to be marginal (at best).[236]
- Risk prevention is commonly regarded as most effective and efficient if it is implemented from the top-down, e.g. via substitution of hazardous chemicals with safer alternatives or technologies. Depending on the situation, the effects of substitution will be perceived as proportionate or disproportionate by different stakeholders e.g. if a less hazardous alternative already exists available investments in research and development will have less of an economic impact whose absorption will also depend on the size of the company and its activity and the place in the value chain.[237]
- Amongst Member States, the UK is the only country to have tried to provide an estimate of the costs and benefits of chemicals legislation. The environment ministry quantified the costs and benefits of 428 of its environmental regulations affecting UK businesses, just over half of which were derived from EU or international legislation. The most positive cost-benefits ratio amongst the different policy area clusters was for regulations on 'chemicals and genetically modified organisms' with a ratio of 1:18.9 (with 82% of the costs coming from EU legislation) i.e the benefits outweigh the costs by a factor of 18.9.[238]

6.2 What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

This sections looks at factors that affect the efficient functioning of the EU chemicals legislation beyond the sole cost-benefit point of view.

6.2.1 Reliance on the CLP Regulation as the basis for hazard classification and labelling

The CLP Regulation is the primary basis for identifying hazards and then providing hazard classification across almost all other pieces of EU chemicals legislation. The clear separation

[235] FC+ Study p. 86

[236] 1st FC Study p. 60

[237] 1st FC study p. 61 and Annex IV p. 111

[238] "Emerging Findings from Defra's Regulation Assessment First update covering 2012 Published February 2015", DEFRA

of the hazard assessment step from risk assessment and risk management steps helps ensure the independence and objectivity of the scientific assessment of inherent properties of chemicals. Doing this on the basis of centralised hazard assessment (e.g. in CLP; or for PBT/vPvB in REACH) provides a consistent scientific base for the different legislative areas, focuses the use of scientific experts where it makes most sense and avoids duplication under different pieces of legislation. On the other hand, differing exposure, risk and socio-economic patterns depending on the uses of chemicals justify separate legislation with different approaches on risk assessment and management. This interplay between central and independent hazard assessment and the link between individual pieces of downstream legislation provides a good balance between consistency, predictability and flexibility.

The underlying principle of CLP is 'self-classification', with industry responsible for assessing, classifying and labelling substances and mixtures that it wishes to place on the EU market. For substances that are particularly hazardous and that are widely used in the EU, Member State authorities or industry itself can propose harmonised classifications on which the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) provides opinions. Based on those opinions, the Commission, through the comitology procedure, makes a decision on the proposed harmonised classification and, if agreed, the substance and its harmonised classifications are included in Annex VI of the CLP regulation. When a substance or mixture is classified for one or several hazards, the relevant information is communicated to other actors in the supply chain, including to consumers, via the labels of products placed on the market and, where relevant, via safety data sheets.

This architecture of self-classification backed up by harmonised classification for substances of concern, provides a clear and consistent approach to identifying, characterising and classifying hazardous chemicals. It ensures that the science of chemical hazard assessment and classification is done separately but then fed into decision-making in the risk assessment and risk management decision steps. It allows classification of a wide range of chemicals without creating a disproportionate burden on administration while focusing resources of public authorities to the most relevant substances for public health and the environment. With a few exceptions (e.g. PBT and vPvB and EDs), it provides harmonised hazard classifications as a basis for risk assessment under the various pieces of downstream chemicals legislation. Furthermore, where no harmonised classification exists, basing the system on self-classifications allows for faster evaluation by companies.

Criteria of hazard identification existing under other pieces of legislation are largely coherent and do not reduce the efficiency of the central hazard identification system of chemicals legislation. There is though a debate about whether criteria for PBTs and vPvBs, as well as EDs should be integrated into the CLP.

Whilst CLP is considered an efficient aspect of the EU chemicals legislation, the fact that its enforcement is not yet uniform across the EU has efficiency implications. Most industry stakeholders (64%) and a significant percentage (one third) of other stakeholders believe that the implementation of CLP is not enforced in a harmonised way in many Member States. Lack of harmonisation and enforcement can generate additional costs to industry from having to meet varying national requirements as well as lost opportunities due to unnecessary internal market barriers.

Harmonised classifications rely on the initiative of either companies or Member State authorities to create and submit a proposal to ECHA for a harmonised classification which is eventually adopted by the Commission. Resource and expertise constraints in a number of

Member States hinder their ability to make these proposals with knock-on effects, for example, on the approval of active ingredients under the Plant Protection Products Regulation. The fact that the workload in developing harmonised classification dossiers is shared unequally between Member State Competent Authorities has also been identified as a factor that negatively affects efficiency (cf. Chapter 3 Implementation and state of play).

There are inefficiencies in relation to consumer labelling under the CLP Regulation as highlighted above in terms of proportionality of costs for companies to change some aspects of labelling and the effectiveness of the communication.[239] In addition, the length and amount of hazard and precautionary statements that need to be printed on some labels lead some consumers to become inured to the hazards that mixtures (mainly) pose, reducing the ability of the hazard communication to deliver its intended benefits.[240] The existing provisions and requirements do not take into account opportunities offered by digitalisation which could help reaching consumers more effectively, increase the amount of available information e.g. via printing Q-R codes to be scanned with a mobile phone, and at the same time reduce costs related to labelling.[241]

6.2.2 Efficiency of risk management related processes

The identification and adoption of risk management measures can be taken following two different approaches, either through a specific risk assessment (SRA) or through generic risk considerations (GRC) (see Section 2.1.5 and Annex 8 for a more detailed description of the two approaches). In many instances, a combination of both approaches is tailored to, and used in, different pieces of EU chemicals legislation. For the most part, stakeholders (industry, NGO, academia and Member States) agree that it is appropriate for different pieces of legislation to have different approaches as they are concerned with different sectors and end-users. However, their views on the efficiency of use of both approaches are mixed and there has been criticism of both approaches to risk management.[242] A key consideration in the assessment of the efficiency of chemicals legislation, i.e. the interplay of different pieces of legislation that are part of this framework, is the question of when specific risk assessment or generic risk considerations approaches are most efficient. Since it is also directly and significantly related to the question of the effectiveness of the framework of EU chemicals legislation, this issue is mainly described and assessed in the main document Section 5 and in Annex 5. A more general description of the functioning of the framework is provided in Annex 8. The main discussion elements are summarised below.[243]

Risk prevention is commonly regarded as most effective and efficient if it is implemented from the top-down, e.g. via substitution. Whether or not more cost effective ways exist to achieve the same goal is difficult to judge because this is likely to differ across different cases and the application/use of a PBT/vPvB, CMR or other hazardous substance. From their perspective, industry stakeholders argue that substitution can be an expensive and resource

[239] 1st FC Study p. 23; see also Special Eurobarameter Survey 456, published June 2017

[240] 1st FC Study p. 61

[241] 1st FC Study Annex Annex II p. 134

[242] 1st FC Study Annex IV p. 122

[243] For more details see 1st FC Study Annex III p. 88 and onwards (Section 6.5) and Annex IV p. 78 and onwards (in particular Sections 5.3 and 6.3 and 6.4)

intensive exercise, especially if new chemistries or technologies are required. Research has found that applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure (see below on grouping approach). However, robust comparative risk analyses need a high level of information and can be resource and time intensive as described above and in other parts of this document.

Automatic bans on hazardous substances based on GRC can also be criticised as a more expensive form of risk management as they require immediate reformulation of products, although a possibility for derogations may exist. Moreover, the SRA approach could also result in reformulation if the substance is found to exhibit an unacceptable risk. Risk assessments will also have associated costs as they can require extensive monitoring, modelling and testing, with the latter being particularly expensive.

In terms of the speed of risk management, NGOs and Member States believe that the automatic triggers help to prevent exposure to harmful substances in a fast and efficient way and this is considered to be a benefit. They highlight that the costs of inaction can be high and this needs to be taken into account.[244] By contrast, industry associations are more generally in favour of specific risk assessment as they believe this allows for a more accurate and tailored approach to identifying any necessary risk management measures and because it avoids the potential elimination of useful applications of hazardous chemicals that would otherwise be banned using the generic risk consideration approach. [245]

The following aspects related to hazard and risk assessment efficiency within particular pieces of EU chemicals legislation merit to be highlighted:

1. The Plant Protection Products and the Biocidal Products Regulations

The risk assessment requirements under the Plant Protection Products and Biocidal Products Regulations are demanding. They reflect the fact that plant protection and biocidal products are, by design, hazardous to the target organisms or plant species which are to be controlled (agricultural pests, vectors of diseases, pathogens, organisms degrading materials, etc.). Usually their use patterns involve widespread and/or various kinds of exposure scenarios, noting that exposures in closed systems or at local level are also technically possible in some cases. This results, unsurprisingly, in a high cost and potentially lengthy risk assessment processes that are particularly challenging for SMEs. In this regard, the following efficiency factors were identified:

- The requirement to firstly approve active ingredients at the EU level and then, additionally and separately, authorise the products that are to be placed on the market at the Member State level (within a mutual recognition zonal system for plant protection products; a EU wide mutual recognition system for biocidal products) imposes additional costs and delays. It was reported by the industry stakeholders to be one of the most burdensome, and cost-variable elements. The Biocidal Products Regulation also offers the possibility for

[244] 1st FC Study Annex IV p. 114

[245] Ibidem

companies to obtain Union authorisation of their products, which allows them to place them directly on the entire EU market.

- In some cases delays make risk assessment and authorisation process lengthy (delays being attributed to delays to the applicant in submitting missing data or to the evaluating authorities). In some cases, active substances or products can be placed on the market in the meantime. However, delays can create a situation where the regulatory requirements have changed in the meantime. Additional testing and updates become therefore necessary and create additional burden leading to additional costs.
- Once a harmonised classification for an active ingredient is agreed under CLP, a transition time of 18 months from its entry into Annex VI is allowed for. During this period, industry must take the necessary measures in order to comply with the new obligations. Industry considers this period to be too short in some cases for them to manage compliance with classification and labelling obligations along complex supply chains[246]. Targeted consultation found that almost 70% of products, whether substances or mixtures, would normally retain the same labels for over 24 months with only 30% normally changing their labels within this time frame (for reasons of marketing, changes in consumer demand, reformulation, etc.).[247] One should also keep in mind that it takes some additional time to correct obvious mistakes with the Adaptation to Technical Progress (ATPs) or in the different language versions.
- In the case of biocidal products, this transition period is perceived as insufficient as the registration process may take longer. More importantly, though, it may also be too short for downstream users (i.e. formulators) to identify how best to respond. The need to act quickly (e.g. to a substance newly being classified as a carcinogen) may lead to investment in short term solutions, such as increased personal protection, or to regrettable substitutions by another substance within the same family that has a negative side effect.
- Whilst not yet widely used, the EU-level 'Union Authorisation' process under the Biocidal Products Regulation aims to reduce the cost burden of making different applications to different Member States, when commercialisation is foreseen for several EU countries. Furthermore, the Biocidal Products Regulation offers the possibility to authorise a group of similar biocidal products ("biocidal product family") via one single application for authorisation, which reduces the administrative burden for both companies and authorities.

2. The Food Contact Materials Regulation:

Regarding food contact materials (FCMs), approximately 1 000 substances have so far been approved for use in plastic food contact materials. However, in all materials around 10 000 possible substances[248] are being used. The current risk assessment rate by EFSA is approximately 50 substances per year, which suggests a major resourcing and efficiency issue.

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[246] Open Public Consultation question 33. The most common response from Group 2 Industry association/business is that the transition period is sufficient at 43% (70). However, 41% of respondents (66) of Group 2 Industry association/business consider the transition period to be too short.

[247] 1st FC Study p. 60

[248] European Food Safety Authority, Database on Food Contact Materials, available on https://webgate.ec.europa.eu/foods_system/main/?event=display

It should be also noted that the Food Contact Materials (FCMs) legislation[249], the RoHS Directive[250], the Urban Waste Water Treatment Directive[251], as well as the Plant Protection Products and the Residues of Pesticides Regulations[252] are currently undergoing their own evaluations as a part of the Commission's Better Regulation programme, where questions of efficiency, amongst others, will be carefully evaluated and examined.

6.2.3 Potential for obtaining a derogation

The availability of derogations from automatically triggered risk management measures on particular hazards (e.g. bans or restriction) based on generic risk considerations is important to ensuring the overall efficiency of the legislative framework. This aspect was identified as affecting the correct functioning of the EU chemicals legislation from the efficiency perspective.

Several regulations include the possibility of obtaining a derogation, considering proof of negligible exposure or negligible risk and based on technical/scientific grounds. For legislation within the scope of this Fitness Check, only the Biocidal Products Regulation (inspired by provisions in the REACH Regulation) and the RoHS Directive, explicitly address the broader socio-economic considerations as a part of their derogation requirements.[253] The fact that the potential for derogations from the automatic bans or restrictions vary between some EU chemical regulations creates a degree of incoherence with a potential impact on the efficiency of the framework (see in the main document Section 7.1.4).

Substances that are classified as CMR (categories 1A and 1B) are prohibited from use in cosmetic products, unless all the conditions for derogation apply. A ban also applies on substances classified as CMR category 2, unless considered safe for use in cosmetic products following an assessment by the Scientific Committee for Consumer Safety (SCCS). The timeframe for submitting evidence to, and gaining the opinion of the SCCS for derogation has been highlighted by industry stakeholders as a concern. They do not believe that there is enough time (15 months under the Cosmetics Regulation) to complete this process before a CMR 1A/B substance is banned in cosmetics, with this possibly leading to disproportionate impacts. The cosmetics industry considers that it takes around 2 years to produce the risk assessment that must be put into the dossiers.[254] However the Commission has recently drafted guidelines for the implementation of the provisions of the Cosmetics Regulation on CMR substances which shows that there is enough time for the adoption of a Commission measure to either ban or provide an exemption to the ban within that 15 month period, provided industry produces or collects data in view of an application dossier for an SCCS assessment already when the CMR classification process is at an early stage (preparation of the RAC opinion).

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[249] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en

[250] Restriction of the use of certain hazardous substances in electrical and electronic equipment; http://ec.europa.eu/environment/waste/rohs_eee/substances_en.htm

[251] http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4989291

[252] https://ec.europa.eu/food/plant/pesticides/refit_en

[253] 1st FC Study p. 71

[254] 1st FC study Annex IV p. 82

6.2.4 Use and access to data

Currently, useful hazard and risk assessment data often sit in regulatory clusters linked to particular agencies, scientific committees and legislative risk assessment processes for individual regulations and, for a variety of reasons, including data confidentiality and intellectual property rights, is not readily shared or available to other users. In addition, the exchange and re-use of information between clusters is insufficient. Given the costs of generating many of these data, the ability to avoid duplication of testing and data generation is a significant efficiency issue also helping to avoid longer-than-necessary timeframes.[255] It is the case for example when companies are seeking a derogation, as the timeframes to obtain it can be relatively short in comparison with the time it takes for new and sufficient data to be gathered to prove safe use.[256]

There are cases where one piece of legislation is dependent on another for the flow of information, particularly monitoring data. If the information flow is not fluid and timely, it can lead to delays in the decision making process In the context of the Water Framework Directive, the need was recognised a few years ago for a mechanism to generate monitoring data to inform risk assessments relevant to the review of the priority substances list when existing sources of exposure data are not adequate. This led to the establishment of a watch list mechanism in 2013 and a first watch list in 2015, which was recently revised. Several of the substances on the first list, including several pharmaceuticals, are still on the list, demonstrating how long it can take to gather the data needed to inform a decision on whether to regulate such 'emerging pollutants'.[257] The availability of adequate data might not always coincide with the review of the priority substances list or other relevant controlling legislation, leading to a delay in taking appropriate action even when a risk can be identified. Better links with risk assessments carried out under other legislation might help, i.e. better access to risk assessment (including exposure) data, faster feedback of monitoring data to that other legislation, and prompt action to introduce additional measures where necessary, as indicated in Article 7a (on coordination) of the Environmental Quality Standards (EQS) Directive[258].

The use of Good Laboratory Practice (GLP) has played an important and useful role in standardising quality requirements for test facilities and in ensuring repeatability and consistency in data generation (see in the main document Section 5.2.1). The GLP Directives have helped to avoid double testing and thereby help saving time and resources. In addition, the avoidance of double testing helps to ensure that no unnecessary animal tests are conducted. In this sense, it is considered as one the most efficient elements of the EU chemicals legislation[259]. Regarding non-GLP data, e.g. peer reviewed scientific journal papers, it can be challenging to assess whether it is robust or otherwise, meaning that potentially robust and viable data is still rejected in some cases. If this is the case, most likely

[255] FC+ Study p. 79-84

[256] Ibidem

[257] FC+ Study p. 57 (the watch list mechanism was established in 2013, the first list in 2015)

[258] Directive 2008/105/EC as amended by Directive 2013/39/EU

[259] FC+ Study p. 139

gathering additional GLP compliant data will be required. This creates additional cost and delays in reaching conclusions and leads to less efficient risk assessment process.[260]

6.2.5 Grouping approach vs. substance-by-substance approach

When considering the appropriate risk management for chemicals, a substance can be assessed in an isolated context (substance-specific; risk assessments completed on given substances under given settings) or as part of a substance group, i.e. chemicals with similar properties. The EU chemicals acquis adopts a substance-by-substance approach to risk assessment and risk management.[261]

The substance-by-substance approach is often the most pragmatic approach to conducting specific risk assessments.[262] Much of the hazard and exposure data needed are held by industry with analyses completed on single substances. Indeed, hazard data on chemicals are usually focussed on single substances rather than groups of chemicals and, equally, defined uses of chemical substances are also based on individual substances. Moreover, most OECD test guidelines and, also, alternative *in silico* approaches (i.e. performed on computer or via computer simulation) work on a substance-by-substance basis. Although the substance-by-substance approach is good at identifying the hazards of a specific substance and the risk from the situation in which it is used, stakeholders from all categories have highlighted the need for greater flexibility and a more integrated and holistic view in assessing substances as groups. The efficiency of the risk assessment process could be improved, both in terms of protecting human health and the environment, as well as in terms of avoided costs to industry for further replacement by alternatives e.g. pre-empting industry's investment in substances that are likely to be banned subsequently. However, further grouping of chemicals if envisaged, should be designed and integrated in the current framework without leading to longer decision-making processes.

6.2.6 Organisational efficiency of the EU Agencies

At the EU level, risk assessments are conducted by a number of different agencies and scientific committees depending on the chemical legislation in question. It should be noted that the EU level committees that formulate opinions on whether or not a hazardous substance is suitable for use work to different timeframes and follow different committee procedures. Moreover, the answer to the question of whether or not a process is "fast enough" is subjective and depends on stakeholder interests (e.g. possibility to commercialise a product (companies), time and effort required for process to be completed and for considering all evidence (public authorities), time allowed for taking part in discussions (NGOs) etc.). As explained above through examples, too rigid timelines and uncertainty about when a decision will be taken can have negative efficiency implications. The length of time that some elements of the legislation take to address some health and environmental impacts are also

[260] Ibidem

[261] It can however be noted that some that some grouping consideration has been made in certain cases, like for the renewal of approval of anticoagulant rodenticides (PT14) as all these substances shares more or less the same hazard properties. Similar approach has also been discussed concerning the approval and future renewal of approval of antifouling active substances (PT21).

[262] FC+ Study p. 90 and p. 143

seen as a major source of inefficiency. A key example cited is the timeline for endocrine disruptors.

Table 7 lists EU Agencies and Scientific Committees involved with hazardous chemical risk assessment.

EU AGENCY AND SCIENTIFIC COMMITTEES	KEY CHEMICALS LEGISLATION ADDRESSED	RISK ASSESSMENT ASPECTS
European Chemicals Agency (ECHA) – Risk Assessment Committee (RAC); Socio-economic assessment committee (SEAC); Member State Committee (MSC); RAC and MSC is supported by expert groups on PBTs, EDs, CMRs	• REACH Regulation • Biocidal Products Regulation • CLP Regulation	• All REACH processes (Registration, Evaluation, Restriction, Authorisation) • All Biocidal Products Regulation processes (assessment of active substances; classification and labelling of active substances) • All processes related to Classification and Labelling Regulation – maintaining inventories of self-classifications and harmonised classifications; assessing harmonised classification and labelling;
European Food Safety Authority (EFSA)	• Plant Protection Products Regulation • Residues of Pesticides Regulation • Food Contact Materials legislation • Contaminants in food and feed legislation	• All plant protection product processes – assessment of active substances for plant protection products • Assessment of the safety of substances in certain materials e.g. plastic and estimated safe levels of exposure e.g. TDI • All food and feed contaminants - Maximum residue levels for veterinary drugs, pesticides; • Emerging issues related to food/feed – scientific opinions
European Medicines Agency (EMA)	• Veterinary and human medicinal substances ('pharmaceutical') legislation[263]	• Health risks of pharmaceutical (human and animal) active ingredients. • Environmental risks partially addressed
Scientific Committee on Consumer Safety (SCCS)	• Cosmetic Products Regulation • Toy Safety Directive	• Determination of human health risks of substances used in cosmetics and toys (environmental risks addressed under REACH) • Emerging issues – questions from the Commission – scientific opinions
Scientific Committee on	• Occupational safety and health	• Risk assessment and

[263] Not within the scope of this Fitness Check

Occupational Exposure Limits (SCOEL)	(OSH) legislation (Carcinogens and Mutagens at Work Directive, Chemical Agents Directive, Pregnant Workers Directive, etc.)	determination of occupational exposure limits of chemicals in the workplace
Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)	• Toy Safety Directive	• Covering health, environmental and emerging risks and broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other European Union risk assessment bodies
Water Framework Directive Expert Group	• Water Framework Directive	• Prioritisation of substances and derivation of EQS
RoHS Expert Working Group	• Restriction of Hazardous Substances Directive	• Risk assessment of selected hazardous chemicals in the use of electronic equipment

Table 7 EU Agencies and Scientific Committees involved with hazardous chemical risk assessment

At a general level, the assessment of chemical risks to human health and the environment is divided between three independent EU agencies, namely ECHA (RAC) for industrial chemicals (including biocides), EFSA for pesticides and food contact materials, and the European Medicines Agency (EMA) for pharmaceutical products. This division of responsibilities and resources is considered to be appropriate and efficient by the majority of stakeholders. For example, the transparency and clear procedural requirements for hazard, risk and socio-economic assessments at the European Chemicals Agency (ECHA) are perceived by industry stakeholders as particularly efficient as they helped to overcome undue delays and transparency deficits of earlier legislation such as the Dangerous Substances Directive (DSD) and the Existing Substances Regulation (ESR, preceding REACH). Those procedures could also be seen as a model for other legislative areas involving regulatory agencies.

The majority of stakeholders consider the division of responsibilities and resources for the assessment of chemical risks to human health and the environment between ECHA's Risk Assessment Committee (RAC) for industrial chemicals (including biocides, also with ECHA's Biocidal Product Committee (BPC) involvement), EFSA for pesticides and food contact materials, and the European Medical Agency (EMA) for pharmaceutical products to be appropriate and efficient.

It should be noted, however, that there are a number of scientific committees and expert working groups associated with particular pieces of 'downstream' EU chemicals legislation that operate alongside and, sometimes in duplication, to the three main EU agencies, in particular to ECHA and its Risk Assessment Committee (RAC). Some examples of such cases of duplication are provided in Section 7 Coherence in the main document as well as Annex 7. Both for the sake of improved coherence and efficiency, there may be opportunities to simplify the risk assessment setup by bringing the risk assessment activities currently done by some of these scientific committees and expert working groups together under the remit of ECHA. It should be noted that the REACH Review recognised that further activities are needed to clarify the interface between REACH and other pieces of EU legislation. In this

regard, one of the announced actions was to enhance the role of ECHA's risk assessment committee (RAC), involving also social partners, to provide scientific opinions under the occupational safety and health (OSH) legislation while respecting the role of the Advisory Committee on Health and Safety at Work.[264]

6.2.7 Reporting obligations related to poison centres

Reporting obligations related to poison centres were one of the requirements under CLP that drew the highest level of concern from industry stakeholders, mainly related to the cost implications. Such reporting requirements were originally established under the Dangerous Substances Directive, but were not enforced across all Member States, which led to considerable inconsistency. This impaired effectiveness of obligations also led to a lack of harmonisation across the single market.

A new Annex to CLP adopted in 2017, which will apply as of 1 January 2020, will reduce the burden on companies due to diverging requirements in each Member State. Nevertheless, there are also concerns about certain requirements in the harmonised format which may potentially create significant costs and administrative burden. As those concerns (which are also reflected in many of the received comments) have been raised only at a very late stage in the adoption process, they will be assessed in a separate ongoing study. Moreover, as the Fitness Check is an evaluation of experiences with existing legislation, future potential impacts of the new Annex VIII are not reflected in this Fitness Check.

[264] Action 12 (COM(2018) 116 final; 5 March 2018). See also SWD p. 102-103 (COM(2018) 116 final; 5 March 2018)

7 Annex 7 Coherence of hazard/risk assessment and risk management procedures (CMRs, PBTs/vPvBs, EDs)

This Annex provides more detailed assessment of coherence of hazard/risk assessment and risk management procedures when dealing with specific substances such as carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bio-accumulative, toxic / very persistent and very bio-accumulative (PBTs/vPvBs) and endocrine disrupting chemicals (EDs). The aim was to identify inconsistencies, contradictions, duplications, overlaps or missing links in each of the risk management steps, starting from data gathering to deciding appropriate risk management measures for these substances.

Where coherence with REACH and other pieces of legislation that are, in principle, outside the scope of this Fitness Check[265] was considered important for a better understanding of the broader picture, then the relevant specific aspects of the legislation was included in the analysis.

It should also be noted that there are different information requirements and different approaches and stringency in identifying/applying risk management measures. These differences are highlighted in the assessment below. However, they do not automatically imply incoherence. Where these differences affect the correct functioning of hazard/risk assessment and risk management procedures, they are presented as coherence issues. One should also note that evidence was not always available regarding their overall, across the legislation impacts.

The assessment of hazard/risk assessment and risk management procedures when dealing with CMRs, PBTs/vPvBs and EDs helped answer the following evaluation questions:

- To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
- What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

7.1 Carcinogenic, Mutagenic and Reprotoxic Substances (CMRs)

7.1.1 Context and state of play

Substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs) are of specific concern due to the long term and serious human and animal health effects that can arise following exposure to these types of substances. Where exposure to CMRs is likely to be widespread and difficult to reliably control, the EU chemicals legislation takes a generic approach to risk management and imposes automatic bans or restrictions (sometimes with a derogation clause) on the use of such substances.

[265] Such as for example legislation covering medicinal for human use (Directives 2001/83/EC) and veterinary products (Directive 2001/82/EC) regarding PBT/vPvBs assessment

7.1.2 Coherence of criteria for identification of CMR

The CLP Regulation sets out clear criteria for the classification of CMRs in two categories with more severe (category 1) or lower hazardousness (category 2), as set out in its Annex I. A substance that fulfils these criteria is subject to harmonised classification and labelling and is listed in Annex VI of the CLP.

The Plant Protection Products Regulation, Biocidal Products Regulation, the Medical Devices Regulation, the Cosmetic Products Regulation and the Toy Safety Directive all refer to the CLP for classification of these properties. There is, however, legislation which either does not refer to the CLP for CMR identification purposes (e.g. the Water Framework Directive) or does not contain any reference to CMRs (e.g. the Food Additives Regulation, the Detergents Regulation, the General Product Safety Directive (GPSD)). This is also the case for the Occupational Safety and Health (OSH) legislation, which does not regulate the reproductive toxicants as a specific category or, alternatively, together as a group with the carcinogenic and mutagenic substances. The Carcinogens and Mutagens Directive draws mainly on the CLP for the identification of carcinogens and mutagens, however it also covers carcinogenic substances which are not classified under the CLP because they are not intended to be placed on the market (process generated chemical agents that have carcinogenic properties such as elemental carbon used as a surrogate of exposure to diesel exhaust particles, exhaust fumes and wood dust). A similar approach is adopted in the Chemical Agents Directive in the sense that it also includes those substances/mixtures/processes that would not perhaps under any circumstances be classified under the CLP Regulation but that workers might still be exposed to in the workplace.

The Pregnant Workers and Young Workers Directives both make reference to chemicals that are hazardous. In the case of the Young Workers Directive, Member States must prohibit the employment of young people for work involving exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. However, these properties are not further defined in the Directive and there is no link to the CLP Regulation.

During the public consultation, NGOs and others[266] identified a gap with respect to the identification of substances having 'properties of concern' , such as certain flame retardants and plasticisers classified as CMRs, and which are used in a range of consumer products, such as textiles, furniture, carpets, etc. On the basis of generic risk considerations, CMRs are banned or restricted under the Toy Safety Directive in order to protect children from potentially harmful exposures. However, in practice, children also play with/on carpets and furniture in which CMRs are not automatically banned or restricted. NGOs and others point out that studies have proven that chemicals such as flame retardants and plasticisers used in these product groups can be found in house dust where the inhalation is considered to be an important exposure route for children.

7.1.3 Coherence of risk assessment factors

One aspect that needs to be highlighted is the issue of non-threshold CMRs i.e. where a no-effect level cannot be established. Since, by definition, a non-threshold CMR creates a

[266] This group comprises non-governmental organisations, consumer associations, trade unions, academia or a research or educational institutes, other

potential risk at any level of exposure, it becomes important to define what the acceptable level of risk is. This issue was raised by some Member States regarding the differences in derivations of Occupational Exposure Limit Values (OELVs) between ECHA's Risk Assessment Committee (RAC) and the Scientific Committee for Occupational Exposure Levels (SCOEL). According to these consultees, the issue arises from differences in the methodologies that are adopted by the two committees, as well as their remits with respect to the interpretation of data. In this respect, consultees note that the RAC must follow the risk assessment guidance developed for use under REACH while SCOEL consists of a panel of experts which is able to interpret the scientific data and take into account broader factors when setting Binding Occupational Exposure Limit Values (BOELVs).[267] These differences have sometimes led to significant divergences, leaving downstream users confused when applying the conditions described in the exposure scenarios attached to the safety data sheets (SDS). The issue is recognised by the EU agencies and scientific committees and efforts are being made to ensure greater consistency.[268]

7.1.4 Coherence of risk management measures

When a substance is identified as a CMR, manufacturers, importers and downstream users must classify it according to the CLP Regulation.

For Category 1 CMRs (the most hazardous category of CMRs), regulations that address the use of mixtures and, to some extent, articles for consumer uses apply automatic cut-offs (bans, restrictions) based on generic risk considerations. However, for legislation that addresses medical and veterinary products and food additives, there is no automatic cut-off and the specific risk assessment approach is applied on a case-by-case basis.

Category 2 CMRs are only restricted based on generic risk considerations in regulations that specifically cover vulnerable populations (e.g. children under the Toy Safety Directive) or uses that involve direct and difficult to control exposures to consumers (e.g. cosmetics, food contact materials).

Legislation	Risk management measures	
	CMR category 1a and 1b	**CMR category 2**
CLP Regulation (EC) No 1272/2008	Labelling	
Plant Protection Product Regulation (EC) No 1107/2009	Cut–off criteria for approval of active substances covered by the Plant Protection Products Regulation No possibility of derogation for carcinogenic Category 1A	No cut-off criteria

[267] 1st FC Study Annex IV p. 92

[268] REACH REFIT SWD p. 102-103; see also Communication on Safer and Healthier Work for All (COM(2017) 12 final). Please note that from 2019, the scientific evaluation of the relationship between the health effects of hazardous chemical agents and the level of occupational exposure is conducted by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). More information is available at https://echa.europa.eu/fr/-/echa-to-provide-recommendations-for-occupational-exposure-limits

Legislation	Risk management measures	
	CMR category 1a and 1b	**CMR category 2**
	Non-threshold carcinogenic Category 1B, or toxic for reproduction category 1A	
Biocides Regulation (EU) No 528/2012	For active substances, cut-off criteria and prohibited for use in biocidal products. Derogations are foreseen (i.e. negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered). Active substances which are meeting the exclusion criteria (e.g. CMR Category 1A and 1B) will not be approved for more than 5 years, and their approval not renewed for more than seven years. Products containing those active substances can only be authorised in Member States where the conditions for derogations are met Products classified CMR Category 1a and 1b cannot be authorised for use by the general public.	No cut-off criteria, treated as any other substance which is not classified CMR 1a and 1b or PBT/vPvB.
Cosmetic Products regulation (EC) no 1223/2009	Cut-off criteria unless the use of CMRs comply with the following conditions: 1) compliant with the food safety requirements 2) no suitable alternative substances available 3) application for a particular use of the product category with a known exposure 4) and evaluated and found safe by the scientific committee SCCS, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups	Cut-off criteria unless the substance is evaluated by the Scientific Committee (SCCS) and found safe for use in cosmetic products
REGULATION (EC) No 1935/2004 on materials and articles intended to come	No cut-off criteria. The safety assessment of substances should be followed by a risk management decision as to whether those substances should be entered on a Community list of authorised substances.	

Legislation	Risk management measures	
	CMR category 1a and 1b	CMR category 2
into contact with food		
COMMISSION REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	CMRs are not automatically banned in FCMs but authorisation based specific risk assessment is required for the use of CMRs in FCMs including when used in material that is separated from the food by a functional barrier	
Toy Safety Directive 2009/48/EC	Cut-off criteria for substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or category 2 under Regulation (EC) No 1272/2008. Possible derogation or setting up of migration limits (instead of the CLP concentration limits) according to certain criteria, and assessed by the Scientific Committee(SCCS)	
Medical Devices Regulation	No cut off criteria or specific restriction, but a statement that the devices "shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles". Provisions addressed to the manufacturers when they design and produce the medical devices	
Directive 2004/37/EC carcinogens or mutagens at work[269]	If these substances cannot be substituted, the employers have to apply hierarchical risk management measure to reduce the exposure of these substances at the workplace.	
Chemicals Agents Directive 98/24		Risk management measures applied following the hierarchical approach to reduce the exposure of these chemicals at the workplace
Water Framework Directive	Annex VIII to the WFD provides an indicative list of main pollutants that should be addressed by Member States in relation to the quality of surface and ground water and includes inter alia "substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties"	

Table 8 Risk management measures for CMRs

Although the different pieces of legislation employ different explicit risk management measures, for the pieces of legislation relying on the CLP for CMRs classification i.e. the Biocidal Products Regulation, the Cosmetic Products Regulation, the Plant Protection Products Regulation, the Toy Safety Directive, the Carcinogens and Mutagens Directive, the

269 Reproductive toxins (R) are not covered by the Carcinogens and Mutagens Directive.

Regulation on Plastic Materials and Articles intended to come into contact with food, and the Prior Informed Consent Regulation, they are coherent. These differences appear justifiable as the target population and the use scenarios are different. It is clear that the Occupational Safety and Health (OSH) legislation such as the Carcinogens and Mutagens Directive will not employ the same risk management measures as the Cosmetic Products Regulation, as they have different targets. The OSH legislation focuses on reducing exposures in a work environment, whilst the Cosmetic Products Regulation focuses on reducing exposure from a product which has been placed on the market.[270]

7.2 Persistent, Bio-accumulative, Toxic (PBTs) and very Persistent and very Bio-accumulative (vPvBs)

7.2.1 Context and state of play

The EU policy for substances that are persistent, bio-accumulative, toxic / very persistent and very bio-accumulative (PBTs / vPvBs) is to eliminate, where possible and feasible, their uses given their particularly high hazard and negative long- term effects on the environment and human health. The following pieces of legislation deal with substances that have PBT/vPvBs properties:

- REACH (Annex XIII for identification criteria);
- The Biocidal Product Regulation;
- The Plant Protection Products Regulation;
- The Veterinary Medicinal Products Directive (not within the scope of this Fitness Check);
- The Medicinal products for human use Directive (not within the scope of this Fitness Check);
- The Water Framework Directive.

7.2.2 Coherence of criteria for identification of PBTs/vPvBs

The CLP Regulation does not contain criteria for PBTs/vPvBs identification as these criteria are not set under the UN Globally Harmonised System (GHS) either. Whilst the possibility of including specific harmonised criteria for the identification of PBTs/vPvBs under the GHS has been proposed, to date no decision has been taken. The lack of criteria/hazard class and labelling requirements for PBT/vPvB properties under the CLP Regulation is however not necessarily a cause of incoherence as requirements relating to PBTs/vPvBs substances in different EU chemicals legislation refer back to the well-established PBTs/vPvBs criteria set out in REACH[271]. Moreover, it was considered that both 2nd and 3rd Revisions (2007 and

[270] 1st FC Study Annex VI Case Study 11 p. 65-68

[271] The Biocidal Products Regulation refers to the REACH Regulation Annex XIII while the Plant Protection Products Regulation includes its own criteria for the identification of a PBT/vPvB, which are identical to those of REACH Annex XIII before its revision. The Medicinal Products Directive (Directive 2001/83/EC) does not explicitly include a PBT/vPvB assessment but draft guidelines for the environmental risk assessment do, and refer to REACH Annex XIII.

2009) of the GHS allowed appropriate classification and labelling of substances that meet PBT or vPvB screening criteria to take place[272].

An inconsistency exists between the Plant Protection Products Regulation and the Biocidal Products Regulation. While the Plant Protection Products Regulation includes a list of criteria for the identification of a PBT/vPvB that are identical to those set out in REACH Annex XIII before its revision in 2011, the Biocidal Products Regulation refers directly to the REACH criteria and, therefore, remains consistent with REACH Annex XIII and its updates. For the time being, there has been at least one identified inconsistency case regarding the acetamiprid assessment which was not identified as 'Persistent' under the Plant Protection Products Regulation and therefore re-approved for 15 years but was identified as 'very persistent' under the Biocidal Products Regulation and therefore identified as candidate for substitution being also 'toxic', and to be approved for 7 years only. It is therefore possible that other (not minor) inconsistencies will arise in the future.

Whilst outside the scope of this Fitness Check, some inconsistencies were identified with respect to PBTs/vPvBs and the regulations covering medicinal for human use[273] and veterinary products[274] that affect the overall functioning of the EU chemicals acquis with respect to ensuring a high level of protection of human health and the environment. Unlike the situation for industrial chemicals and for biocides and plant protection products, the medicinal products for human use and veterinary products legislation does not explicitly include an assessment of PBT/vPvB hazards and risks. PBTs/vPvBs screening and assessment in medicinal products for veterinary use can be performed if required, on the basis of different guidance documents[275]. Guidelines on how the evaluation of the potential environmental risks arising from the use, storage, and disposal of the medicinal product for human use[276] make reference to Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention) and Technical Guidance Documents for PBTs/vPvBs screening and assessment[277]. One of the intentions of the revision of this guidance (launched in 2016) was to review whether the approaches for PBTs/vPvBs are still relevant[278].

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[272] Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals; Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals; 18th session, Geneva, 9 – 11 December 2009; Proposal to consider the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances transmitted by the representatives of the European Commission; UN/SCEGHS/18/INF.4

[273] Directive 2001/83/EC

[274] Directive 2001/82/EC

[275] The current Committee for Medicinal Products for Veterinary Use (CVMP) guideline on 'Environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-Rev.1) specifies the need for a PBT screening of veterinary medicinal products. It refers to EU Technical Guidance Documents for industrial chemicals and biocides for cut-off values for each of PBT/vPvB criteria. The guidance also specifies the how the PBT characteristics should be assessed by making cross reference with the REACH guidance documents.

[276] EMEA/CHMP/SWP/4447/00 (2006) complemented by Q&A EMA/CHMP/SWP/44609/2010

[277] replaced by REACH 'Guidance on information requirements and chemical safety assessment' (ECHA, 2008)

[278] EMA/CHMP/SWP/65429/2016

Table 9 provides a summary of the PBT/vPvBs identification criteria laid down in different pieces of legislation.

Legislation	Use of the REACH Annex XII criteria?	Use of weight of evidence?	Constituents > 0.1%? If transformation products/metabolites are PBT, the parent substance is identified as PBT?
Biocides Regulation	Yes	Yes	Yes
Plant Protection Products Regulation	Criteria similar to REACH Annex XIII (i.e. the criteria listed in Annex XIII before its revision in 2011)	Yes	Metabolites/breakdown products are taken into account
Veterinary medicinal products Directive	On the basis of the draft guidance referring to REACH Annex XIII criteria (see EMA/CVMP/ERA/52740/2012[279])		
Medicinal products for human use Directive	On the basis of the technical CHMP guideline referring to REACH Annex XIII criteria (see EMEA/CHMP/SWP/4447/00 corr1[280] and EMA/CHMP/SWP/44609/2010[281])		
Water Framework, Directive	Mentions persistent hydrocarbons and persistent and bioaccumulable organic toxic substances (Annex VIII) without definition. Refers to the documents from the old TGD (Technical Guidance Document for Risk Assessment in support of Commission Directive 93/67/EEC) and REACH (1907/2006/EC).		

Table 9 Coherence of criteria for identification of PBTs/vPvBs

7.2.3 Coherence of information requirements

Under REACH, the requirement for definitive testing is done under dossier or substance evaluation on a case-by-case, stepwise approach in order to avoid unnecessary animal testing. For pharmaceuticals and veterinary medicinal products, there is no testing requirement for PBT/vPvB assessment, so only screening analysis is performed. Under the Plant Protection Products Regulation and the Biocidal Products Regulation, the authorisation dossier must contain the necessary information to allow a definitive PBT/vPvB assessment.

Industry stakeholders responding to the open public consultation were of the opinion that any differences and inconsistencies in conclusions of the PBT/vPVB hazard and risk assessments across the legislation mainly originate from the variations in the use of the weight of evidence. Under REACH, any available data including e.g. information from non-

[279] Guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products

[280] Guideline on the environmental risk assessment of medicinal products for human use

[281] Q&A on the guideline

standardised testing and monitoring data may be used in a weight of evidence approach. This also applies to the Biocidal Products Regulation, which refers to the REACH criteria and guidance documents while the Plant Protection Products Regulation defines data requirements for active substances and for products in two different Regulations and additional communications. Under the Water Framework Directive the assessment is based on "all available information", which includes several information sources, such as existing (regulatory) lists and risk assessments, data on hazardous properties, as well as modelled or measured data on environmental concentrations. The information is evaluated based on expert judgement. Some inconsistencies may also arise due to the timing of the decision making processes on PBT/vPvB properties. Due to the timelines of the Biocidal Products Regulation (and its review programme), it may not always be possible to obtain all necessary data within a substance approval procedure to finally conclude on the PBTness of a substance.[282]

7.2.4 Coherence of risk assessment

As already explained above, there has been at least one identified inconsistency case due to differences in the assessment of acetamiprid. It was not identified as 'Persistent' under the Plant Protection Products Regulation and therefore re-approved for 15 years but was identified as 'very persistent' under the Biocidal Products Regulation and therefore identified as candidate for substitution being also 'toxic', and to be approved for 7 years only. It is therefore possible that other (not minor) inconsistencies will arise in the future.

7.2.5 Coherence of risk management measures

PBT/vPvB risk management measures are summarised in Table 10.

EU legislation	Risk Management Measures (RMMs)
REACH Regulation (EC) No 1907/2006	Registration: Positive conclusion on PBTness triggers obligations (e.g. minimisation of emission, proposal of RMM) Authorisation: If identified as SVHCs and then prioritised (Annex XIV listing) PBT/vPvB substances could be subject to authorisation to be granted via the socio-economic assessment route. Restriction: Alternatively PBT/vPvB substances could be subject to restriction on the basis of a socio-economic analysis and a risk assessment (no threshold substance: any release of these substances to the environment induces an environmental risk)

Biocidal Products Regulation (EU) No 528/2012	*For active substances*:
	• PBT/vPvB :
	  ○ Exclusion criteria and prohibited for use in biocidal products.
	  ○ Derogations are foreseen (i.e. negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered).
	  ○ If the condition for derogation is met, it will not be approved for more than 5 years, and their approval not renewed for more than seven years.
	• 2 out of 3 P/B/T criteria :

[282] 1st FC Study p. 79; see also Annex III p. 35 and Annex VI Case Study 6

EU legislation	Risk Management Measures (RMMs)
	○ Identified as candidate for substitution criteria. ○ Approved, and renewed, for a maximum period of 7 years. *For biocidal products*: • PBT/vPvB: ○ Products containing PBT/vPvB active substances can only be authorised in Member States where the conditions for derogations are met (i.e. negligible risk, essential to control serious danger for human/animal/environmental health, disproportionate negative impact on society when compared to the risks; availability of alternatives is also considered). If authorised, authorisation only valid for a maximum period of 5 years ○ Products containing PBT/vPvB substances (active substances or co-formulant) cannot be supplied to the general public. Derogation possible if it would result in disproportionate negative impacts for society when compared to the risks. • 2 out of 3 P/B/T criteria : ○ Biocidal products containing active substances meeting 2 out of 3 P/B/T criteria are subject to a comparative assessment before granting an authorisation ○ If authorised, authorisation only valid for a maximum period of 5 years
Plant Protection Products Regulation (EU) 1107/2009	Active substances identified as PBT are not approved. No derogation applicable. Substitution of active substances which meet 2 out of 3 PBT criteria • Approved for 7 years instead of 10 years • Shorter period of authorization • Exception to mutual recognition
Veterinary medicinal products,Directive 2001/82/EC	For PBT/vPvB substances, an emission assessment should be performed, followed by an identification of risk management options, including risk mitigation measures. This should be taken into account in the benefit/risk analysis of the veterinary medicinal products for deciding on marketing authorisation. However, as the assessment of PBT/vPvB properties of VMP is not mentioned in the Directive text, it is not clear yet to what impact a PBT/vPvB assessment will have in the authorisation of VMPs.
Medicinal products for human use, Directive 2001/83/EC	The outcome of the environmental risk assessment (e.g. the PBT/vPvB assessment) is not considered in the benefit/risk analysis, and as such it cannot serve as a ground for refusal by the marketing authorisation. There are no consequences for human medicinal products (HMPs) for having PBT/vPvB properties. If a substance is identified as a PBT/vPvB substance, this is however communicated in the Summary of Product Characteristics (SmPC) under section 5.3, and special precautions for disposal are stated under section 6.66, again without any consequences for its application and use.
Water Framework, Directive 2000/60/EC	PBT and vPvB substances are addressed as priority substances through Annex X.

Table 10 Risk management measures

Substances that are identified as PBT/vPvBs can be dealt with under REACH (registration of the substance and authorisation/restriction). The main difference is related to the fact that under REACH and the Biocidal Products Regulation, in contrary to the Plant Protection Products Regulation, a socio-economic analysis, including an analysis of alternatives, is part of the risk assessment as this is required for the authorisation and restriction procedures for PBT/vPvB substances.

Comparing the Plant Protection Products Regulation and the Biocidal Products Regulation, both do not authorise active ingredients or products placed on the market identified as PBTs/vPvBs. The main difference lies in the possibility to gain a derogation from the automatic ban based on a specific risk assessment and consideration of socio-economic factors, which is possible under the Biocidal Products Regulation but not under the Plant Protection Products Regulation.

Regarding medicinal products, some guidance documents for Veterinary Medicinal Products (VMPs) and Medicinal Products for human use specify how the outcome of PBT/vPvB assessment should be used in the authorisation procedures. There has also been an increased focus on PBT/vPvB assessment as part of the environmental risk assessment (ERA)[283]. The European Commission adopted recently an EU strategic approach to pharmaceuticals in the environment. The actions announced include considering the findings of this and recent REACH Review as regards links with the medicinal products legislation in relation to environmental protection. This could, among other things, help to clarify the PBT/vPvB requirements.[284]

7.3 Endocrine disruptors (EDs)

7.3.1 Context and state of play

The Commission adopted its first 'Community strategy for endocrine disruptors[285]' in 1999. Several EU legislative acts – i.e. Cosmetic Products Regulation[286], the Water Framework

[283] EMA/CVMP/ERA/52740/2012 (came into force starting from 1st of April 2016) is intended to provide guidance on how PBT/vPvB substances are screened and assessed in accordance with Annex XIII of Regulation (EC) No 1907/2006 and its guideline documents (ECHA 2014a-d), with focus on the scientific data/information, parameters, test conditions and default values that should be used for the assessment. It also addresses general principles on how VMPs containing a substance that has been identified as PBT should be further assessed, within the context of the environmental risk assessment (ERA) and benefit-risk assessment of the product concerned.

[284] 'European Union Strategic approach to Pharmaceuticals in the Environment' (COM(2019) 128 final)

[285] An endocrine disruptor (ED) is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations" (World Health Organisation; Global assessment of the state-of-the-science of endocrine disruptors; WHO/PCS/EDC/02.2). ED chemicals occur in a variety of chemical classes including synthetic drugs, pesticides, compounds used in industry and in consumer products, industrial by-products and pollutants, including some metals (EFSA, 2013b). Humans are not only exposed to EDs through direct usage or consumption, but such chemicals might also be dispersed during production, use and disposal and hence lead to human exposure via the environment (Goldenman et al., 2017).

[286] Article 15(4) 'When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties'

Directive[287], REACH, the Plant Protection Products Regulation[288], the Biocidal Products Regulation, the Medical Devices Regulation[289] – contain provisions on endocrine disruptors (EDs).

Horizontal criteria for identifying substances with ED properties have not been set in EU legislation. The absence of horizontal criteria (i.e. applicable across all EU law) has been criticized by a number of different stakeholder groups including both NGOs and industry, as well as national authorities[290] and was identified as an area for action in the EU's 7th Environment Action Programme. The issue is recognised in the Commission's recently adopted strategy on endocrine disruptors which underlines the need to work on a horizontal approach for the identification of endocrine disruptors across EU legislation building on the criteria developed for pesticides and biocides.[291]

Criteria for the identification of EDs have been so far adopted under two pieces of EU chemicals legislation. Under the Biocidal Products Regulation and the Plant Protection Product Regulation the Commission set scientific criteria for the determination of ED properties in 2017[292] and 2018[293], respectively. The two sets of criteria are essentially identical and are applicable to all new and ongoing active ingredient applications for approval from 7 June and 10 of November 2018, respectively. A common ECHA/EFSA guidance document, drafted with the support of the Joint Research Centre (JRC) has been established for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009[294].

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[287] Annex VII 4. Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment.

[288] As well as Regulation 283/2013 setting out data requirements for active substances for PPPR and Regulation 284/2013 setting out the data requirements for active substances for plant protection products formulations

[289] Regulation (EU) 2017/745 Annex I 10.4.1. b) "Devices, or those parts thereof or those materials used therein that: are invasive and come into direct contact with the human body, (re)administer medicines, body liquids or other substances, including gases, to/from the body, or transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of [REACH] or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of [the Biocidal Products Regulation], in accordance with the criteria that are relevant to human health amongst the criteria established therein."

[290] FC+ Study p. 118

[291] 'Towards a comprehensive European Union framework on endocrine disruptors' (COM(2018) 734 final)

[292] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

[293] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36

[294] http://www.efsa.europa.eu/en/efsajournal/pub/5311; https://echa.europa.eu/fr/-/guidance-on-identifying-endocrine-disruptors-published

The first agreed OECD test method specifically designed to detect endocrine disrupting properties became available starting from 2007[295]. Prior to this, identification of EDs was hampered by the lack of internationally agreed test methods. There are now more than 40 test methods agreed under OECD for the testing and assessment of EDs.[296] Moreover, many methods, even if not specifically designed to identify EDs, include endpoints allowing such identification. Some of these test methods have been included in Regulation (EC) No 440/2008, laying down test methods pursuant to REACH. As announced in the Communication on endocrine disruptors[297], the Commission is working on updating data requirements in the different legislative frameworks (REACH, the Biocidal Products and the Plant Protection Products Regulations) to improve the identification of endocrine disruptors. However, these pieces of legislation contain at the moment some but limited data requirements on endocrine disruption.

For instance, according to the data requirements for plant protection products, if nervous system, immune system or endocrine system are specific targets in short term studies at dose levels not producing marked toxicity, supplementary studies, including functional testing, shall be carried out. Specific studies shall also be required if there is evidence that the active substance may have endocrine disrupting properties. Such data can also be requested from companies applying for substance approval for biocidal products. There is no such obligation under the Cosmetic Products Regulation.

In general, data on exposure to endocrine disruptors is lacking.

7.3.2 Coherence of legal provisions and of criteria for identification of endocrine disruptors (EDs)

As criteria for the identification of EDs currently exist only for the Plant Protection Products and Biocidal Products Regulations, the below-mentioned different pieces of legislation refer to ED properties with some differences in the wording used:

- The Water Framework Directive makes reference to "substances which have been proved to possess properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment".
- Under the Plant Protection Products Regulation, a substance shall only be approved if it is not considered to have endocrine disrupting properties that may cause adverse effect in humans or on non-target organism.
- Under the Biocidal Products Regulation, a substance shall not be approved for use in biocidal products if it is considered having endocrine-disrupting properties that may cause adverse effects in humans. Furthermore, a biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine disrupting properties.
- REACH makes reference to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the

[295] OECD TG 440

[296] https://www.oecd.org/chemicalsafety/testing/GD150_2017%20v3%2006122017b_clean.pdf

[297] COM(2018)734

environment which give rise to an equivalent level of concern to that of CMR substances categories 1A or 1B, or PBTs/vPvBs.

- The Medical Devices Regulation makes reference to substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in REACH or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 on biocidal products, in accordance with the criteria that are relevant to human health amongst the criteria established therein.

Although all provisions refer to ED properties, some provisions also make a reference to adverse effects and describe causal relation between the endocrine disrupting properties and adverse effect and some provisions provide additional qualifiers for the adverse effect. The language of the existing provisions in terms of strength of scientific evidence can be summarised as follows:

Provisions in (related to)	Endocrine disrupting properties	Adverse effect	Strength of evidence for causal relationship
REACH	X	X[a]	for which there is scientific evidence of probable
Medical Devices Regulation	X	X[a]	for which there is scientific evidence of probable serious effects to human health + reference to REACH and Biocidal Products Regulation
Plant Protection Products Regulation (approval)	X	X	that may cause
Biocidal Products Regulation (approval)	X	X	that may cause
Biocidal Products Regulation (consumer ban)	X	X	considered as having endocrine-disrupting properties that may cause adverse effects in humans where it has endocrine disrupting properties
Water Framework Directive	X	-	which have been proved to possess properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment
Plant Protection Products Regulation (data requirements)	X	-	may have endocrine disrupting properties

a – an additional qualifier for the adverse/serious effect exists which requires to demonstrate whether the endocrine mediated effects are of an equivalent level of concern to that of CMRs, PBT or vPvB

Such differences in wording might create uncertainty as regards which chemicals are considered by the legislative provisions and what level of evidence is required to identify such chemicals. However, there is no evidence yet suggesting that differences in the data required under these different pieces of legislation have had a significant impact on the coherence of the legislation.

7.3.3 Coherence of risk management measures

Significant progress has been made in introducing specific provisions on EDs into EU legislation. The Water Framework Directive, REACH, the Plant Protection Products Regulation and the Biocidal Products Regulation are central pieces of legislation aiming at the

protection of human health and the environment, which now include specific provisions for endocrine disruptors. It can be noted that since 1990s as consequence of the EU legislation regulating biocidal products and plant protection products, many of the adverse effects often associated to endocrine disruption have already been detected in the context of the evidence provided for approval of active substances used in these products. Where a risk was identified, those substances were removed from the market due to other toxicological properties[298]. The Regulation on medical devices has recently become the first product specific legislation that contains specific provisions laying down requirements applicable to EDs.

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
Water Framework Directive	Through Annex VIII providing an indicative list of main pollutants, including EDs that should be particularly addressed by Member States in relation to the quality of surface and ground water	The same as for human health
	Through Annex X (list of priority substances i.e. pollutants which are toxic, persistent and liable to bio-accumulate, or which give rise to an equivalent level of concern, which may include endocrine disruptors. Measures to be put in place meeting EQS in the short term and at phasing out emissions, discharges and losses within 20 years.	The same as for human health
REACH	Through placing substances on the "candidate list" and if prioritised in accordance with Article 58(3) listed in Annex XIV (List of Substances Subject to Authorisation) Once a substance is subject to authorisation, if it is possible to establish a threshold value for adverse effect, the use of the substance can be authorised via the so called 'adequate control route'. If no threshold value can be established or if the adequate control route is not feasible, an authorisation may only be granted via the so-called 'socio-economic route' when the socio-economic benefits of using the substance outweigh the risks to human health and the environment.	The same as for human health
Plant Protection Product Regulation	An active substance can only be approved if it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a	An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that

[298] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf p. 239-240

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
	plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005	may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible
	If an active substance is considered to have endocrine disrupting properties that may cause adverse effect in humans, it shall be approved as a candidate for substitution in accordance with Article 24 of the Regulation.	-
	If a substance is deemed to be an endocrine disruptor, it shall not be considered a substance of low risk	-
Regulation 283/2013 setting out data requirements for active substances for PPPR	If there is evidence that the active substance may have endocrine disrupting properties, additional information or specific studies designed on an individual basis shall be required by the competent authority (I) to elucidate the mode / mechanism of action and (II) to provide sufficient evidence for relevant adverse effects.	As regards the effects on birds, other terrestrial vertebrates and aquatic organisms, consideration shall be given to whether the active substance is a potential endocrine disruptor according to Union or internationally agreed guidelines. If as a result of this assessment, the active substance is identified as a potential endocrine disruptor, the type and conditions of the study(ies) to be performed shall be discussed with the national competent authorities.
Regulation 284/2013 setting out the data requirements for active substances for plant protection products formulations	No specific provision related to endocrine disrupting properties of plant protection products. However, it refers to Section 5 of Regulation (EU) 283/2013 (where endocrine disruptors are mentioned), indicating that in some cases of specific concern or data missing, tests referred to in Section 5 of Regulation (EU) 283/2013 need to be carried out also for formulations of plant protection products.	-
Commission Communication in the framework of the implementation of Commission Regulation 283/2013 and Regulation	Provides a list of all test methods and guidance documents relevant to the assessment of ED properties for active substances of plant protection products.	

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
284/2013		
Biocidal products regulation	Active substances shall not be approved if they are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified as substances of very high concern in accordance with REACH due to their endocrine disrupting properties.	There is no explicit mentioning of endocrine disrupting effects in relation to environmental impacts, but the procedure for the identification of substances of very high concern in REACH is applicable to substances with endocrine disrupting properties both to human health and the environment. Equally, information requirements for active substances specified in Annex II to the BPR require data sets as regards endocrine disrupting properties for both human health and ecotoxicological impacts. Following discussions with the expert group (meetings of the Competent Authorities on Biocidal Products), it has been agreed that active substances identified as having endocrine disrupting properties to the environment would normally be identified as candidate for substitution[299].
	A biocidal product shall not be authorised for making available on the market for use by the general public where it has endocrine disrupting properties.	The same as for human health
	As regards mammalian toxicity studies the Regulation stipulates that if there is any evidence from in vitro, repeat dose or reproduction toxicity studies, that the active substance may have endocrine disrupting properties then additional information or specific studies shall be required as additional data set to (I) elucidate the mode / mechanism of action and (II) provide sufficient evidence for relevant adverse effects.	As regards ecotoxicological studies, the Regulation requires "identification of endocrine activity" as an information requirement in the additional data set.
Regulation on Medical Devices	Devices, their parts or materials used that are invasive and come into direct contact with the human body e.g. administer medicines, and are used to transport or store such medicines, shall only contain endocrine disruptors in a concentration that is above 0,1 % weight by weight (w/w) where justified. The justification of the presence of endocrine-disrupting substances shall be based upon: a) an analysis and estimation of potential	-

[299] CA-March18-Doc.7.3a-final- EDs- active substances under assessment.docx

Legislation	Risk Management Measures (Human Health)	Risk Management Measures (Environment)
	patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account of whether the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines. Finally, the Commission shall mandate scientific committee to prepare guidelines for ED substances that shall encompass at least a benefit-risk assessment of the presence of ED substances.	
Cosmetic Products Regulation	When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties. The review was published together with the Communication on the ED framework.[300]	-

Despite this progress, there are still many pieces of legislation dealing with protection of human health and the environment from exposure to chemicals that do not contain specific risk management provisions as regards EDs e.g. the Cosmetic Products Regulation, the Toy Safety Directive, and the OSH legislation. NGOs and civil society representatives, as well as some Member State authorities[301] consider the regulatory action taken so far to be inadequate, and have called for stricter and broader EU measures. This could be a potential gap in

[300] COM(2018)739 final

[301] Council conclusions on the protection of human health and the environment through the sound management of chemicals (15046/16); 6 December 2016

identifying and addressing human health and environmental concerns for EDs, although legislative provisions addressing human health and environmental risks as regard chemicals in general apply also to endocrine disruptors. Gaps of particular concern could be the one in protection of vulnerable groups, such as children and pregnant women. For example, while under the OSH legislation special attention is required for pregnant workers and young workers identified as vulnerable populations, there is no specific requirement to identify and manage EDs as a risk to the pregnant workers or workers in general and, therefore, no legal obligation on employers to reduce exposures to potential EDs [302] The same is true for the Toy Safety Directive which aims to provide special protection to children but does not contain specific provisions for EDs.

[302] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding

8 Annex 8 EU Approaches to Chemicals Risk Management

This Annex provides additional elements of description of the EU approach to chemicals risk management.

The primary objectives of EU chemicals legislation are:

- A high level of protection of human health from the adverse effects of hazardous chemicals.
- A high level of protection of the environment from the adverse effects of hazardous chemicals.
- Supporting and enhancing the efficient functioning of the internal market for chemicals and the competitiveness and innovation of EU industry and business.

Specific pieces of legislation may have more specific objectives related to chemicals, such as protecting selected vulnerable groups, encouraging substitution to less hazardous alternatives, reducing the number of animals used for testing chemicals, increasing the free movement of specific products or encouraging improvements in the occupational safety and health of workers.

Furthermore, some of the legislation within the scope of this Fitness Check may also include objectives that concern other policy areas, such as ensuring agricultural productivity and sustainability or promoting products that have a high level of environmental performance.

The framework of EU chemicals legislation is based on a range of legal acts dealing with hazard identification and classification, risk assessment, and risk management. (Risk management is the determination of risk management measures such as ensuring communication of hazardous properties of chemicals towards their users, incentivising substitution where less hazardous alternatives exist, restricting the use of hazardous chemicals to uses and situations where the exposures are negligible or can be reliably controlled, prohibiting testing on animals, etc.)

In addition, the EU has committed to several objectives related to chemicals in the global context. The EU (European Parliament and Council, 2002) and its Member States, committed to the sound management of chemicals throughout their life cycle in 2002, often referred to as the 'WSSD 2020 goal'[303]. In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals and waste. The EU played a leading role in developing these agreements, which form the backbone of international policy relating to the sound management of chemicals.

In 2015, the EU committed to the United Nations' 2030 Agenda for Sustainable Development including the Sustainable Development Goals (SDG) (UN, 2015). Several of the SDGs relate directly or indirectly to chemicals and chemical policy:

- SDG 3.9: "By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination".

[303] It was expanded upon in paragraph 23 of the Johannesburg Plan of Implementation (JPOI) (UN, 2002).

- SDG 6.3: "By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally".
- SDG 12.4: “By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment”.

8.1 The framework of EU chemicals legislation

8.1.1 Historical and international dimension

The EU legal framework for chemicals comprises not only chemicals legislation in the strict sense of the word – directly regulating chemical substances and mixtures – but also legislation regulating conditions under which chemicals are manufactured, treated or used (e.g. occupational health and safety or environmental legislation) or regulating products, in which chemicals are used (e.g. toys, medical devices and food contact materials). Furthermore, there are chemicals-related provisions in several pieces of environmental legislation such as the Water Framework Directive, the Waste Framework Directive and the Industrial Emissions Directive.

The development of EU legislation on chemicals (see Figure 13) started in 1967 with the adoption of a Directive[304] that harmonised the Member States' rules for classification, packaging and labelling of chemical substances across the then European Economic Community. This enabled the free circulation of chemicals, without the need to re-classify, re-package and re-label the chemical product when trading it across national borders. The establishment of a Community-wide harmonised system of communicating hazards to the users of chemicals also made it easier for them to take appropriate safety measures.

[304] Dangerous Substances Directive 67/548/EEC

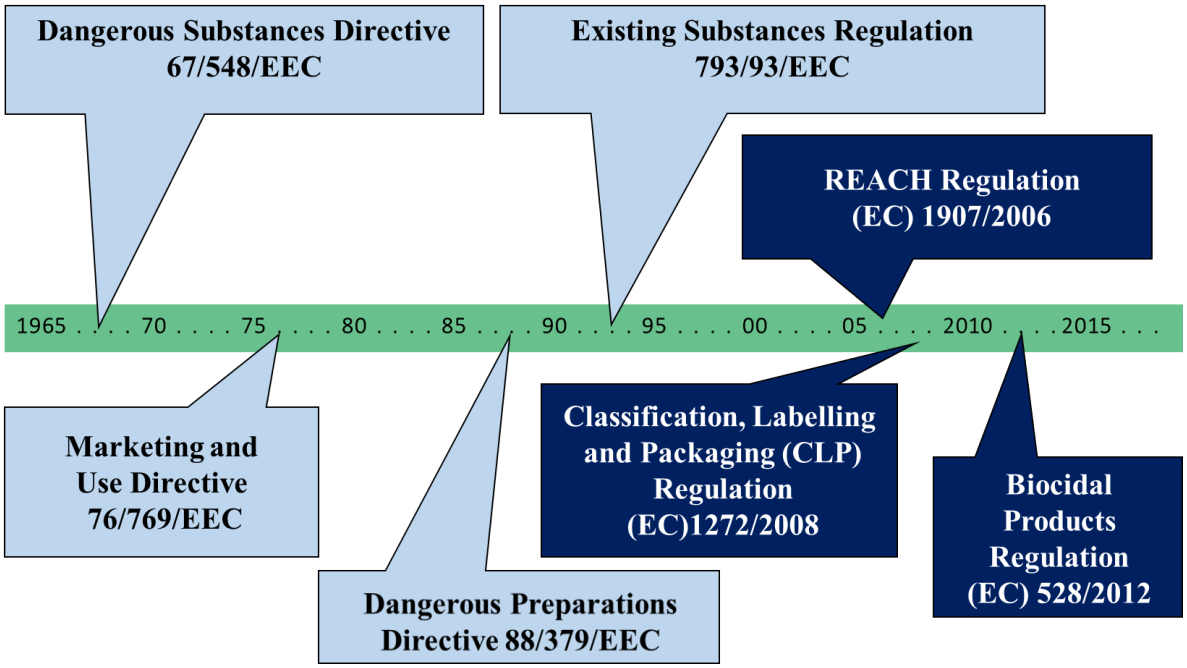

Figure 13 Development of EU chemicals legislation since 1967

In 2001 the European Commission adopted a White Paper setting out the strategy for a future chemicals policy, ultimately leading to the adoption of the REACH Regulation in 2006 and the establishment of the European Chemicals Agency in Helsinki (ECHA).

The EU has committed to a number of legally binding international agreements related to chemicals, which are implemented through EU chemicals-related legislation:

- The Globally Harmonized System of Classification and Labelling of Chemicals (GHS): an international standard that addresses the classification of chemicals by types of hazard and proposes harmonised hazard communication elements, including labels and safety data sheets, ensuring that information on physical hazards and toxicity from chemicals will be available during handling, transport and use. The GHS provides a basis for the harmonisation of rules and regulations on chemicals at national, regional and global levels, thereby facilitating trade. GHS is implemented in the EU through the CLP Regulation.
- The Basel Convention: covers transboundary movements and disposal of wastes defined as "hazardous wastes" based on their origin and/or composition and their characteristics, as well as two types of wastes defined as "other wastes" - household waste and incinerator ash.
- The Minamata Convention: limiting anthropogenic releases of mercury and its compounds. Under the treaty, new mercury mines are banned and existing mines are to be phased out, the use of mercury in a number of products and processes reduced and/or eliminated, and measures are implemented to control emissions to air as well as releases to land and water.
- The OSPAR Convention: (Convention for the Protection of the Marine Environment of the North-East Atlantic) combines and updates the 1972 Oslo Convention on dumping waste at sea and the 1974 Paris Convention on land-based sources of marine pollution. It includes a 'Strategy with regard to Hazardous Substances' which aims at the cessation of discharges, emissions and losses of

hazardous substances by 2020 in order to achieve 'close to zero' concentrations in the marine environment.

- The Rotterdam Convention: promotes shared responsibility and cooperative efforts among parties in international trade of certain hazardous chemicals in order to protect human health and the environment from harm, including legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure;
- The Stockholm Convention: is a global treaty covering chemicals that are persistent and spread widely in the environment, accumulate in living organisms and have adverse effects to human health or to the environment (so called Persistent Organic Pollutants, POPs). The parties are required to take measures to eliminate or reduce the release of POPs into the environment.

EU chemicals legislation has been a model for policy development in other parts of the world. Also, the extensive and continuously improving knowledge base resulting from the implementation of different pieces of EU legislation is, in many instances, made available to governments, industry and stakeholders beyond the EU.

8.1.2 Types of legislation within the scope of the Fitness Check

The +40 piece of chemicals and chemicals-related legislation that fall within the scope of the Fitness Check can be categorised in a number of different ways. One useful way to approach it is as follows:

1) Legislation covering chemical hazard identification and classification[305]: CLP Regulation (1272/2008/EC), Plant Protection Products Regulation (1107/2009/EC), Biocidal Products Regulation (528/2012/EU), Chemical Agents Directive (98/24/EC), Asbestos Directive (2009/148/EC), Carcinogens and Mutagens at Work Directive (2004/37/EC).

2) Legislation covering chemical risk assessment and risk management measures:

a) Worker safety and transport legislation: Carcinogens and Mutagens at Work Directive (2004/37/EC), Young People at Work Directive (1994/33/EC), Pregnant Workers Directive (1992/85/EEC), and the Chemical Agents Directive (98/24/EC).

b) Environmental protection legislation: Water Framework Directive (2000/60/EC), Industrial emissions (integrated pollution prevention and control) Directive (2010/75/EU), and the Urban Waste Water Directive (91/271/EEC).

c) Chemicals control legislation: Biocidal Products Regulation (528/2012/EU), Plant Protection Products Regulation (1107/2009/EC), Export and Import of Hazardous Chemicals Regulation (649/2012/EU), Persistent Organic Pollutants Regulation (850/2004/EC), Contaminants in Food and Feed Regulation (315/93/EEC) and Directive (2002/32/EC), and the Residues of Pesticides Regulation (396/2005/EC).

d) Products control legislation: Toy Safety Directive (2009/48/EC), Cosmetic Products Regulation (1223/2009/EC), Detergents Regulation (648/2004/EC), Drinking Water Directive (98/83/EC), Medical Devices Directive (93/42/EEC) Pressure Equipment Directive (2014/68/EU), Food Contact Materials Regulations (10/2011/EC and 450/2009/EC), and the General Product Safety Directive (2001/95/EC).

[305] sometimes together with risk assessment and risk management measures

3) Supporting and horizontal legislation: Test Methods Regulation (440/2008/EC), Good Laboratory Practice Directives (2004/9/EC and 2004/10/EC, Protection of Animals Used For Scientific Purposes Directive (2010/63/EU).

A. Horizontal Legislation Applicable to chemicals in general

There are two pieces of legislation applicable to a broad set of chemicals: the CLP Regulation and the REACH Regulation[306] (not in the scope of this Fitness Check except its Annex XIII[307]). The CLP Regulation implements the GHS in the EU and requires manufacturers, importers and downstream users to classify the hazards of a chemical, and label it accordingly, based on available data.

The CLP Regulation sets out three types of hazard classes: physical hazards, health hazards and environmental hazards. When relevant information (e.g. toxicological data) on a substance or mixture meets the classification criteria in CLP, the hazards of a substance or mixture are identified by assigning a certain hazard class and category.

The CLP Regulation stipulates the criteria and procedures for EU-wide harmonised classification and labelling (CLH) and for self-classification by industry (manufacturers, importers, downstream users, distributors, producers of articles) before substances and mixtures are placed on the market. The same obligation is upon manufactures and importers if substances, not placed on the market, are subject to registration or notification under REACH. The CLP Regulation does not cover classification for transport purposes (which is covered by Directive 2008/68/EC).

There are strong linkages between the CLP Regulation and the downstream legislation:

1. Horizontal: downstream legislation specifies properties of concern, outlines requirements for communicating properties of concern and/or sets packaging requirements for chemicals;
2. Vertical: draws on CLP classification for risk management purposes.

Some pieces of legislation in the scope of this Fitness Check do not however refer to the CLP Regulation. For examples, the Detergents Regulation sets specific rules regarding the information that manufacturers placing on the market the substances and/or mixtures shall hold at the disposal of the competent authorities of Member States. These rules on information as well as those on labelling apply without prejudice to the CLP Regulation.

Global conventions for restriction of chemicals based on the intrinsic properties of chemicals include the Stockholm Convention on Persistent Organic Pollutants (POP), the Convention on Long-Range Transboundary Air Pollution (CLRTAP), and the Minamata Convention on mercury.

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[306] REACH establishes procedures for collecting and assessing information on the properties and hazards of substances. Companies need to register their substances and to do this they need to work together with other companies who are registering the same substance. After evaluating selected substances to clarify initial concerns for human health or for the environment authorities namely ECHA and Member States, can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorisation.

[307] REACH has undergone its 2nd evaluation. The relevant document and information are available https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

While REACH is not in the scope of this Fitness Check (except Annex XIII), in practice many interlinkages exist between REACH and the various pieces of legislation covered by this Fitness Check evaluation. Assessment of the most relevant chemicals legislation would not be complete if and where these interlinkages were not taken into account. According to REACH companies (manufacturers and importers of chemicals) need to register chemicals and mixtures manufactured or imported in quantities at or above 1 tonne per year. Information requirements for the registration dossier increase with the annual quantity manufactured or imported. The registration dossier shall contain hazard information and, where relevant, an assessment of the associated risks, and suggestions for how these risks can be controlled. REACH covers in principle all chemicals and mixtures unless they are exempted, i.e. regulated under another specific legislation, such as the plant protection products regulation. Within REACH, chemicals posing unacceptable risks to health or to the environment can be restricted, subject to authorisation or phased out. REACH further defines 'substances of very high concern' (SVHC) and requires that companies request authorization for use of these substances.

B. Legislation regulating the use of chemicals or their use in products and consumer goods

Sector specific legislation (e.g. the Cosmetic Products Regulation, Toy Safety Directive) or substance specific legislation (e.g. POPs Regulation) is in place for chemicals with potentially high risks for human health or for certain categories of population e.g. workers, consumers, children, live-stock and/or the environment. Other product-specific legislation with a chemical risk management focus includes legislation for chemical products that are expressly designed to be toxic (e.g. the Plant Protection Products and Biocidal Products Regulations) or designed to be biologically active (e.g. pharmaceuticals legislation) and/or include widespread and long-term exposures (e.g. feed and food additives legislation) or direct exposure in the product use phase (e.g. the Cosmetic Products Regulation, Food Contact Materials legislation). These pieces of legislation generally require approval/authorisation of the chemical and/or product before it can be placed on the market. For cosmetics however, products need to undergo a safety assessment by a qualified assessor. There is no pre-market authorisation but products need to be notified to the Commission prior to placing on the market. There is a system of prior approval / authorisation for listed substances. Regarding food contact materials, the authorisation is required only for those made out of plastics. The authorization procedures typically include the need to conduct a specific risk assessment of the chemicals/products taking into account chemical hazards and the specific use conditions and exposure scenarios.

Product-specific legislation adopted for the following product groups in the EU: toys, electrical and electronic equipment, construction products, medical devices, and food packaging materials, generally builds on the hazard information (i.e. classifications) provided by the CLP regulation. In some cases, it is specified that products may not contain chemicals classified as having specific hazard properties, such as CMR (e.g. the Toy Safety Directive). In other cases, the use of specific chemicals in products can be restricted (e.g. the RoHS Directive on the restriction of the use of certain hazardous chemicals in electrical and electronic equipment, or the Cosmetic Products Regulation). There are also pieces of legislation that specify the allowed maximum concentration/residue levels in products (e.g. the Construction Products Directive).

C. Legislation ensuring protection of specific categories of population

One group of people distinguished from the legal perspective is consumers. The General Product Safety Directive (GPSD) aim is to ensure that only safe products are made available on the market. The GPSD applies not only safety criteria defined in EU legislation (i.e. product-specific legislation such as Cosmetic Products Regulation), but in the absence of these, any relevant national standards, Commission recommendations or codes of practice relating to the safety of products. The GPSD establishes obligations for both businesses and Member States' authorities. Businesses should place only products which are safe on the market and inform consumers of any risks associated with the products they supply. Member States, are responsible for market surveillance i.e. through different national measures and in close collaboration with customs, national competent authorities check whether products available on the market are safe, and, if proven dangerous, take any measure deemed necessary to remove them from the market, ensure that product safety legislation and rules are applied by manufacturers and business chains and apply sanctions when necessary. Member States should also send information about products posing a risk found on their markets and the measures they have undertaken to remove them to the Rapid Alert System for non-food dangerous products (RAPEX).

Another group that benefits from specific legal provisions is workers. This is addressed via the EU's framework of occupational safety and health (OSH) legislation which comprises the. OSH Framework Directive and its 23 related daughter Directives (7 of these being in the scope of this Fitness Check). At EU level, minimum standards for the protection of workers from exposure to chemicals at work are set through the Carcinogens and Mutagens Directive (Directive 2004/37), the Chemical Agents Directive (Directive 98/24) and the Asbestos Directive (2009/148). They complement action under the Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (‘REACH’) and other pieces of chemicals regulation by focusing on specific situations at the workplace.

D. Environmental legislation with a chemicals risk management component

The Water Framework Directive (WFD) and the Marine Strategy Framework Directive (MSFD) establish objectives to be reached in the aquatic environment. Rules and requirements set in the Drinking Water Directive's (DWD) can also be put in this category and linked to some extent to the protection of the aquatic environment as its objective is to protect human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean. Another example of legislation taking into account the perspective of the receiving environment is the Industrial Emissions Directive (IED).

The EU Waste legislation covers several Directives[308]. The Waste Framework Directive 2008/98/EC first adopted in 1975 and fundamentally revised in 1991, 2008 and 2018 follows a holistic approach and defines key concepts. It also made a contribution to the simplification and streamlining of legislation by integrating the Directive on hazardous waste and the waste oil Directive. The old PCB/PCT Directive 76/403 was revised in 1996. The Sewage Sludge

[308] Add references to the WFD, PPWD, ELV, WEEE

Directive prohibits use of untreated sludge on agricultural land and lists threshold values for concentrations of heavy metals. The Urban Waste Water Treatment Directive aims at protecting the environment from adverse effects of wastewater discharges from cities and the industrial sectors.

Regarding waste shipments outside Europe, the EU is a party to the Basel Convention. It is an international treaty that was designed to prevent transfer of hazardous waste from developed to less developed countries. The Basel convention was transposed into Union law by the Waste Shipment Regulation[309] in 2006, amended in 2014[310]. Amendment became applicable as of 1 January 2016 and aims at improving enforcement and inspections.

The Seveso III Directive lays down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to ensuring a high level of protection throughout the Union in a consistent and effective manner. The Directive covers establishments where dangerous substances may be present (e.g. during processing or storage) in quantities exceeding certain thresholds. Depending on the amount of dangerous substances present, establishments are categorised in lower and upper tier, the latter are subject to more stringent requirements. The Seveso III Directive relies on the CLP classification.

8.2 Main steps: from risk assessment to risk management measure

Risk assessment involves analysing the inherent hazardous properties of a substance and the extent of exposure to that substance. The human health and environmental risk of hazardous chemicals are addressed via the hazard and risk assessment procedures and requirements set out in the different key pieces of EU chemicals legislation such as the CLP, the Plant Protection Products and Biocidal Products Regulations, etc. The main steps of these procedures involve:

- Hazard identification (based on toxicity tests and other relevant information);
- Dose (concentration) – response (effect) assessment;
- Exposure assessment – exposure scenarios (based on models and measurements of the occurrence of the chemical);
- Risk characterisation; and
- Risk estimation.

Risk management measures – which can be policy-based and/or technical in nature - are then decided in light of the identified hazards and/or risks. Risk management measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.).

[309] Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on Shipments of Waste

[310] Regulation (EU) N° 660/2014

8.2.1 Risk management approaches

There are two basic approaches to risk management often used in combination, in the EU chemicals *acquis* (see Figure 14*):* one based on specific risk assessment (SRA) and the other one based on generic risk considerations (GRC).

The main difference between these two approaches is the point in time when the exposure assessment is considered and the specificity of the exposure assessment. For risk management based on generic risk considerations, the potential exposures and risks are considered generically, prior to the adoption of legislation. The GRC-based approach is built into the legislation in the form of an automatic trigger of pre-determined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of the chemical, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. For example, under the Cosmetic Products Regulation any substance classified as Carcinogenic, Mutagenic or toxic for Reproduction (CMR) categories 1A/B and 2 is banned from use in cosmetics, given the fact that direct, widespread exposure of humans is taking place through the application of a cosmetic product on the skin. Similar approaches have been taken for active ingredients in plant protection products and biocides, for substances in toys, etc.

The decision to link particular hazard properties (e.g. CMR, PBT[311], EDs[312]) to automatic risk management measures without the intervening step of a specific risk assessment is done on the basis of generic risk consideration without prejudice to performing also a full risk assessment for the other properties of the substances which are not linked to the related hazard properties. In the legislation evaluated in this Fitness Check, the generic risk consideration approach is typically applied for the following use applications and the following substances:

1. Use applications:
    - When there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management (e.g. labelling obligations under CLP, labelling requirements and use instructions under the Plant Protection Products and the Biocidal Products Regulations);
    - For use in widely dispersive or open applications which result in a significant exposure of humans or the environment (e.g. plant protection products);
    - For use in applications where the exposure is considered to be more difficult to control and monitor (e.g. plant protection products);
    - For use in applications resulting in exposure of vulnerable groups (e.g. children).
2. Substances:
    - For substances with hazard properties that result in severe adverse effects on human health or the environment should exposures occur (e.g. CMRs, PBTs, EDs, chemicals with STOT[313] properties); and
    - For substances where it is difficult/impossible to identify a safe threshold and, therefore, where most specific risk assessments are likely to identify risks that

[311] Persistent Bioaccumulative and Toxic

[312] endocrine disruptors

[313] Single Target Organ Toxicity

lead to a need for risk management measures (e.g. PBTs, vPvBs, respiratory sensitisers).

On the other hand, in the case of the specific risk assessment (SRA) approach, the exposure assessment is performed on a case-by-case basis when each substance is risk assessed under a specific legal framework. The risk management measures are triggered based on the outcomes of the specific risk assessment which considers the use of the substances and in which both the hazards and the potential specific exposure scenarios for humans and the environment to the hazardous substance or mixture in question are assessed at the same time.

The specific risk assessment approach is used more widely for uses which are not necessarily or obviously going to lead to widespread and difficult to control exposures and/or where the hazard properties of a substance are of less concern.

In many instances, individual pieces of chemical legislation use a combination of both of these approaches. For example, the Cosmetic Products Regulation applies the specific risk management approach to establish lists of authorised substances (positive lists, in case of case of no or no unacceptable risk) as well as, where necessary, restrictions on the use of certain substances in certain situations (negative lists, in case of unacceptable risks), but also the generic risk management approach to CMRs (substances identified and classified as a CMRs categories 1A/B and 2 are banned and cannot, therefore, be used in cosmetic products subject to strict derogations).

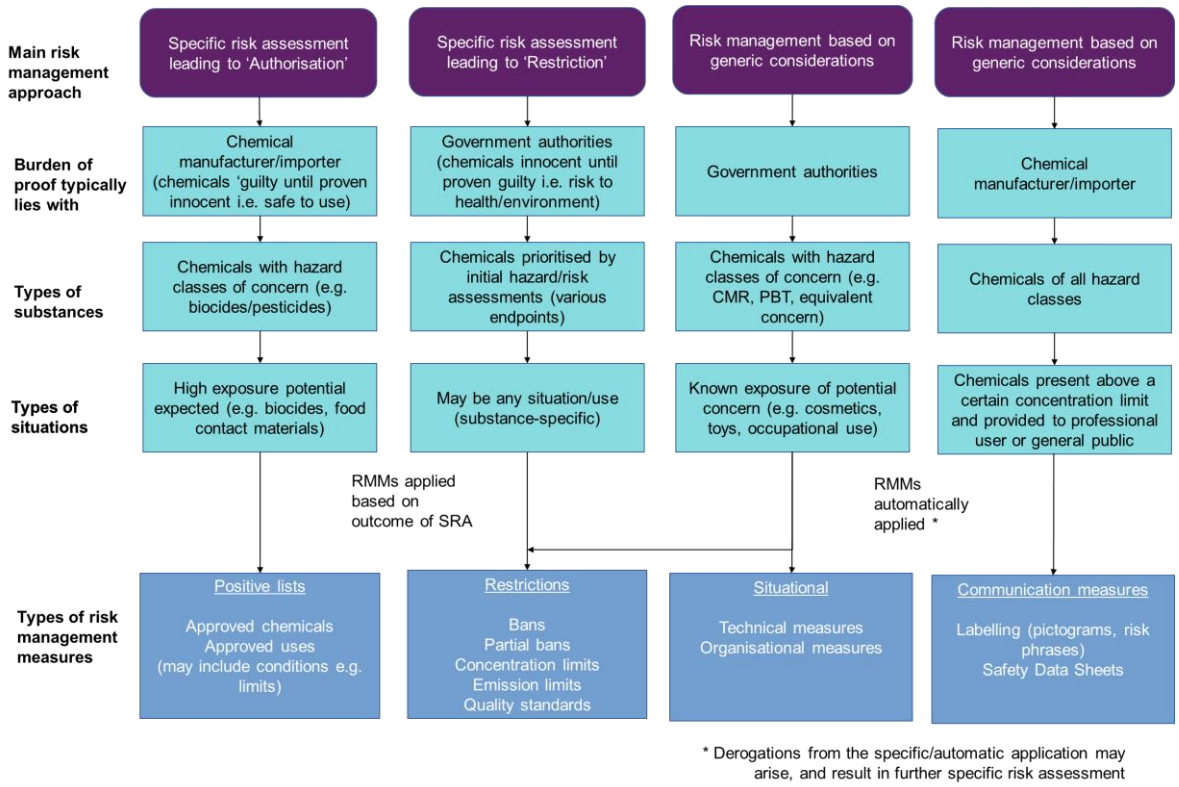

Figure 14 Main risk management approaches in the EU chemical legislation

8.2.2 Risk assessment and risk management processes and bodies involved

The necessary hazard identification, exposure assessment and risk assessment of chemicals are undertaken through a number of separate (but closely aligned) processes and EU expert committees/bodies associated with different pieces of EU legislation. As Figure 15 shows, these committees/expert groups are mainly established in association with different pieces or groups of legislation. As the same substance can be used for several different purposes/applications, it can be assessed by different committees or EU Agencies.

EU AGENCY AND SCIENTIFIC COMMITTEES	KEY CHEMICALS LEGISLATION ADDRESSED	RISK ASSESSMENT ASPECTS
European Chemicals Agency (ECHA) – Risk Assessment Committee (RAC); Socio-economic assessment committee (SEAC); Member State Committee (MSC); RAC and MSC is supported by expert groups on PBTs, EDs, CMRs	• REACH Regulation • Biocidal Products Regulation • CLP Regulation	• All REACH processes (Registration, Evaluation, Restriction, Authorisation) • All Biocidal Products Regulation processes (assessment of active substances; classification and labelling of active substances) • All processes related to Classification and Labelling Regulation – maintaining inventories of self-classifications and harmonised classifications; assessing harmonised classification and labelling;
European Food Safety Authority (EFSA)	• Plant Protection Products Regulation • Residues of Pesticides Regulation • Food Contact Materials legislation • Contaminants in food and feed legislation	• All plant protection product processes – assessment of active substances for plant protection products • Assessment of the safety of substances in certain materials e.g. plastic and estimated safe levels of exposure e.g. TDI • All food and feed contaminants - Maximum residue levels for veterinary drugs, pesticides; • Emerging issues related to food/feed – scientific opinions
European Medicines Agency (EMA)	• Veterinary and human medicinal substances ('pharmaceutical') legislation[314]	• Health risks of pharmaceutical (human and animal) active ingredients. • Environmental risks partially addressed
Scientific Committee on Consumer Safety (SCCS)	• Cosmetic Products Regulation • Toy Safety Directive • General Product Safety Directive	• Determination of human health risks of substances used in cosmetics and toys (environmental risks addressed under REACH)

[314] Not within the scope of this Fitness Check

		• Emerging issues – questions from the Commission – scientific opinions
Scientific Committee on Occupational Exposure Limits (SCOEL)	• Occupational safety and health (OSH) legislation (Carcinogens and Mutagens at Work Directive, Chemical Agents Directive, Pregnant Workers Directive, etc.)	• Risk assessment and determination of occupational exposure limits of chemicals in the workplace
Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)	• Toy Safety Directive • General Product Safety Directive	• Covering health, environmental and emerging risks and broad, complex or multidisciplinary issues that require a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other European Union risk assessment bodies
Water Framework Directive Expert Group	• Water Framework Directive	• Prioritisation of substances and derivation of EQS
RoHS Expert Working Group	• Restriction of Hazardous Substances Directive	• Risk assessment of selected hazardous chemicals in the use of electronic equipment

Figure 15 EU Agencies and Scientific Committees involved with hazardous chemical risk assessment

Risk management measures can be taken following the ordinary legislative procedure (co-decision) e.g. adoption of EU Binding Occupational Exposure Limits under the Carcinogens and Mutagens Directive, the comitology procedure for implementing acts e.g. requirements of the labelling of plant protection products and the procedure for delegated acts e.g. under the Biocidal Products Regulation specifying scientific criteria for the determination of endocrine-disrupting properties.

9 Annex 9 Glossary

ATP	Adaptation to Technical Progress
BPR	Biocidal Products Regulation
CLI	Classification and Labelling
CA	Competent Authority
CAD	Chemical Agents Directive
CARACAL	Competent Authorities for REACH and CLP
CBA	Cost-benefit analysis
CCA	Cumulative cost assessment study
CCH	Conformity check
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging
CMD	Carcinogen and Mutagen Directive
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CoRAP	Community Rolling Action Plan
COSME	Competitiveness of Small and Medium-sized Enterprises
CSR	Chemical Safety Report
CVR	Cardiovascular and Respiratory
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive
DSD	Dangerous Substances Directive
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECVAM	European Centre for the validation of alternative methods
EDs	Endocrine Disruptors
EEA	European Environment Agency
EEB	European Environmental Bureau
EEN	Enterprise Europe Network
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENES	Exchange Network on Exposure Scenarios
EOGRTS	Extended One-Generation Reproductive Toxicity Study
ES	Exposure Scenario
ESR	Existing Substances Regulation
ETS	EU Emission Trading System
EURL-ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
FCMs	Food Contact Materials
FORUM	Forum for Exchange of Information on Enforcement
GDP	Gross domestic product
GFL	General Food Law
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GLP	Good Laboratory Practice
GPSD	General Product Safety Directive
GRC	Generic Risk Considerations
HMP	Human Medicinal Products
HPVCs	High Production Volume Chemicals

IATA	Integrated Approach to Testing and Assessment
ICCM	International Conference on Chemicals Management
IED	Industrial Emission Directive
IOELVs	Indicative Occupational Exposure Limit Values
IOMC	Internet-based Toolbox for Decision Making in Chemicals Management
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
MS	Member State(s)
MSC	Member State Committee
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OJEU	Official Journal of the European Union
OPC	Open Public Consultation
OSH	Occupational Safety and Health
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PBT	Persistent, Bioaccumulative and Toxic
PBTs	Persistent, Bioaccumulative and Toxic substances
PCBs	Polychlorinated Biphenyls
PfAs	Proposals for Amendments
PIC	Prior Informed Consent Regulation
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
PPORD	Product and Process Oriented Research and Development
PPPR	Plant Protection Products Regulation
QSAR	Qualitative Structure Activity Relationship
R&D	Research & Development
RAAF	Read Across Assessment Framework
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme
RMM	Risk management measure
RMOA	Regulatory Management Options Analysis
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
ROI	Registry of intentions
SAICM	United Nations Strategic Approach to Chemicals Management
SCCS	Scientific Committee on Consumer Safety
SCOEL	Scientific Committee for Occupational Exposure Levels
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SDGs	Sustainable Development Goals
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum

SMEs	Small and Medium Sized Enterprises
SRA	Specific Risk Assessment
STOT	Single Target Organ Toxicity
SUBSPORT	Substitution Support Portal
SVHC	Substance of Very High Concern
t/y	Tonnes per year
TBT	Tributyltin
TSD	Toy Safety Directive
UN GHS	United Nations Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
UN	United Nations
US EPA	Environmental Protection Agency of the United States
US	United States
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
VMPs	Veterinary Medicinal Products
vPvBs	Very Persistent and Very Bioaccumulative substances
WEEE	Waste Electrical and Electronic Equipment
WHO	World Health Organisation
WoE	Weight of Evidence
WSSD	World Summit of Sustainable Development
WTO	World Trade Organisation

10 Annex 10 Evaluation questions

Effectiveness:

1. To what extent does the EU legislative framework for the risk management of chemicals meet its objectives?
2. What are the consequences or effects (whether socio-economic, environmental or health-related, both positive and negative) that were not originally planned (for instance, unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?
3. What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?
4. To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement, use of the safeguard procedure)?

Efficiency:

1. What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits? A specific focus will be given to SMEs.
2. What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

Coherence:

1. To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
2. What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

Relevance:

1. To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)
2. To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?
3. To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

EU added value

1. What is the added value of regulating the risk management of chemicals at an EU rather than at national level?

11 Annex 11 Overview of costs – benefits identified in the Fitness Check

OVERVIEW OF COSTS – BENEFITS IDENTIFIED IN THE FITNESS CHECK[315]					
COSTS	**QUANTIFICATION**	**STAKEHOLDERS AFFECTED**	**LEGISLATION**	**TIME PERIOD**	**SOURCE**
DIRECT COSTS					
MONETARY OBLIGATIONS (FEES AND CHARGES)	Several million EUR per year for fees to ECHA for CLP and biocides[316].	Industry and companies	CLP Biocidal Products Regulation	2004-2014	CCA1 Study
COMPLIANCE COSTS ONE-OFF COSTS	Transition costs to the CLP **EUR 1.4-1.6 billion**	Substances and mixtures manufactures and formulators	CLP	2006	1st FC Study
RECURRING COSTS	Annual costs arising from the CLP Regulation **EUR 1.3 billion (EUR 0.97-1.7 billion**)	Substances and mixtures manufactures and formulators	CLP	Since 2008	
	Annual regulatory costs for industry due to the Plant Protection Products Regulation are estimated at **EUR 122-189 million**	Pesticides industry	Plant Protection Products Regulation	Since 2009	Evaluation of the EU legislation on plant protection products and pesticides residues supporting study
	The costs for pesticides maximum residue level (MRLs) procedures are estimated at around **EUR 55 million** per year for the industry		Maximum residue levels of pesticides Regulation	Since 2005	
	Annual costs that the detergents industry has incurred as a direct result of the Detergents	Detergents industry	Detergents Regulation	Since 2005	Study supporting the Evaluation of Regulation (EC) No

[315] Please note that the quantification of costs and benefits in this table is partial. Given the broad scope of this Fitness Check, it has not been possible to provide a comprehensive assessment of all costs and benefits. Also, individual estimates as well as being partial are often subject to considerable uncertainty. The cost estimates in the CCA1 study do not relate to the same scope as the fitness check. See discussion in the methodological annex.

[316] The CCA1 study reports estimates for monetary obligations (fees) but these are approximately 10 times higher than the actual fee income of ECHA, so the estimates do not seem reliable. Moreover, the largest part of the fees is related to REACH, which is out of scope of the fitness check. Average annual ECHA fees for CLP are in the magnitude of 100 000 EUR and average annual ECHA fees for biocides have gone from approximately 300 000 EUR in 2013 to 7.6 million EUR in 2016. No information is available on fees at the national level.

	Regulation are estimated to range between **EUR 63.7 – EUR 149 million** (appr. EUR 764 million – EUR 1.8 billion in total since 2005).				648/2004 (Detergents Regulation)
	The main recurrent costs come from the obligation to provide data for chemical hazard classification, the risk assessment step and testing and within this the exposure assessment in particular and the implementation of risk management measures e.g. hazard communication through labelling	Industry and companies	Potentially all EU legislation in scope	2016	FC+ Study
ADMINISTRATIVE BURDEN	Administrative costs are those borne by different actors in complying with information obligations. They include • The obligation of reporting: • Retrieving data on applications from downstream users and labelling. Another factor that could increase the administrative costs is the pace of the processes for the specific risk assessments. Costs of reporting for MS for the CLP Regulation and the Asbestos Directive were between **EUR 30 000 and 100 000 per year**; the POPs Regulation and the Regulation on Export and Import of Hazardous Chemicals were	Businesses, citizens, civil society organisations and public authorities	Potentially all EU legislation in scope	Since 2004	CCA1 Study, 1st FC Study, FC+ Study Fitness Check of Reporting and Monitoring of EU Environment Policy (SWD(2017)230)

	under **EUR 30 000 per year**				
HASSLE COSTS	Costs related to delays and diverging requirements at national level	Industry and companies	Potentially all EU legislation in scope	2000-2016	1st FC Study
TOTAL DIRECT COSTS:	SEVERAL BILLION EUROS PER YEAR				
ENFORCEMENT COSTS (RECURRING)	CLP related activities by ECHA approximately **EUR 2.57 million**	EU and national authorities, ultimately borne by taxpayers	CLP	2000-2016	1st FC Study
	CLP (and REACH) training for inspectors around **EUR 1.7 million**				
	MRL procedure costs for EFSA and the Commission **EUR 3 million** The overall costs for Member States generated by the Plant Protection Products Regulation for the approval and authorisation procedures are estimated at approx**. EUR 44 million annually**. The costs for MRL procedures are estimated at **around EUR 5 million** annually for the 28 Member States		Residues of pesticides Regulation Plant Protection Products Regulation Residues of pesticides Regulation	Since 2005	Evaluation of the EU legislation on plant protection products and pesticides residues supporting study
	From a qualitative perspective, however, the costs for public authorities[317] include costs associated with: • Implementation		Potentially all EU legislation in scope	Since 2000	1st FC Study

317 1st FC Study p. 51-52

	activities: participation in expert groups and scientific bodies, research and regulatory proposals, risk assessments, etc. • Compliance monitoring and enforcement activities: • Reporting activities (even though not all pieces of legislation are subject to reporting obligation).				
INDIRECT COSTS	Indirect regulatory costs of the EU chemicals legislation were impossible to assess due to the large number of pieces of legislation and to the complexity of the value chains.	Companies, ultimately at least partially passed on to consumers	Potentially all EU legislation in scope		
	Indirect transition reformulation costs for manufacturers of mixtures are estimated at between **EUR 67.7 million and EUR 141 million**. No estimate of the associated losses to removing product lines from market could be developed.[318]	Industry and companies	CLP	2006	1st FC Study
BENEFITS	**QUANTIFICATION**	**STAKEHOLDERS AFFECTED**	**LEGISLATION**	**TIME PERIODE**	**SOURCE**
DIRECT BENEFITS					
HEALTH IMPACTS	Reduced morbidity and mortality health impacts (e.g. reduced	Workers, consumers and citizens	Potentially all EU legislation in scope	Since 1970s	CuBA Study

[318] 1st FC Study Annex II p. 83-84

	cancers, cardiovascular disease, allergies, reproductive illnesses, neurological disease, etc.) from reduced exposures of hazardous chemicals Avoided healthcare costs, avoided suffering (assessed through willingness to pay techniques), value of avoided life years lost due to premature death, productivity losses due to lost work hours as a result of illness and/or premature death	All			
	Reduced poisoning incidents, occupational skin and respiratory diseases and occupational cancers **EUR 391 – 512 million per year** **EUR 217 – 338 million per year**	Citizens, workers Ultimately also beneficial for companies	Dangerous Substances and Prepares Directives CLP	2000-2008 Since 2008	1st FC Study
	Avoided cancers due to reduced exposures to hexavalent chromium at workplace **EUR 100 million per year (and EUR 4 billion in total)**		The Carcinogens and Mutagens at Work Directive The Chemical Agents Directive	1995-2010	CuBA Study
	Reduced neurotoxicological disease and related deaths due to reduced exposures of children to lead through general environment **EUR 155-183 billion per year**		1st Directive concerning the lead in petrol (78/611/EEC; not in the scope of the Fitness Check) Lead in paints (Directive 76/769/EEC amended in 1989; not in the scope of the Fitness Check) Toy Safety Directive (1988)	Since 1970s	CuBA Study

		Waste legislation Dangerous Substances and Preparations Directives and CLP		
	Reduced asthma cases and related fatalities due to reduced exposures to allergens and other hazardous chemicals attributed either to air pollution or exposure at workplace **EUR 250 million per year**	CLP REACH (not in the scope of this Fitness Check) Chemical Agents at work (and Occupational Safety and Health (OSH) Framework Directive in general) Industrial Emissions Directive (combined with Air Pollution legislation that is not in the scope of the Fitness Check)	2004-2013	CuBA Study
	Reduced female reproductive disease as a result of reduced exposure to DEHP (phthalate) via a variety of consumer products **EUR 580 million per year (EUR 7 billion cumulatively)** Reduced male reproductive disease (infertility) as result of reduced exposure to DBP (phthalate) via a variety of consumer products: **EUR 560 million per year (EUR 6.7 billion cumulatively)**	Legislation on consumer products (cosmetics (2005), food contact materials (2007), electrical equipment (2015), medical devices) The Water Framework Directive (2000) The Existing Substances Regulation (not in the scope of the Fitness Check) 1994-2006	1996 – 2008	CuBA Study
	Reduced cases of skin sensitisation (allergic reaction) as a result of reduced exposure to allergens at workplace	CLP (preceded by the Dangerous Substances and Preparations Directives) REACH	2004-2013	CuBA Study

	EUR 160-190 million per year				
	Reduced incidence of chromium VI allergy cases associated with skin sensitisation and damage due to exposure from articles of leather **EUR 350 million per year**		CLP REACH (not in the scope of the Fitness Check)	Since 2012	CuBA Study
ENVIRONMENTAL IMPACTS	Various ecosystem services, recreational values, increased fishing revenues and avoided water treatment costs	All	Potentially all EU legislation in scope	Since 1970s	CuBA Study
	Reductions in the costs associated with environmental remediation, waste management and clean ups	Industry and companies Public authorities			
	Reduced environmental and pollination impacts as a result of better control and management of pesticides (e.g. neonicotinoids) **EUR 15 – 50 billion per year**	All	Plant protection products related related legislation	Since 1980s	CuBA Study
	Avoided drinking water treatment costs as a result of reduced pesticide contamination of surface and groundwater reserves **EUR 500 million per year**		Plant protection products related related legislation Water related legislation (1st Water quality legislation and the Water Framework Directive, Drinking Water Directive, Ground Water Directive, EQS Directive) POPs Regulation	Since mid-1970s	CuBA Study
	Avoided clean-up costs associated with PCB use in the past caused by the contamination Cumulative benefit of **EUR 20 – 90 billion**		CLP Directive 96/59/EC on the disposal of PCBs and PCTs (not within the scope) The POPs Regulation	1971-2018	CuBA Study

			(2004) Hazardous Waste List		
OTHER DIRECT BENEFITS	Encouraging research and innovation, generating new jobs and improving competitiveness	All	Potentially all EU legislation in scope	Since 1970s	CuBA Study
	Stimulating competition and trade within the EU single market	Industry and companies			
	Stimulating international trade between the EU and other countries	Industry and companies			
INDIRECT BENEFITS	Contribution to achieving objectives defined in other policy areas (Circular Economy, agriculture)	All	Potentially all EU legislation in scope	Since 1990s	CuBA Study
	Contribution to achieving the EU international commitments (the UN Sustainable development goals, fight against climate change, resource efficiency etc.)				