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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 3

{COM(2018) 116 final}

Annex 3: Methods and analytical models

The purpose of this Annex is to summarise the main methodologies applied and the information sources used for this evaluation. As described in the methodology section, a number of thematic studies have been carried out by external consultants for the Commission services. In addition, the evaluation uses the regular reports from Member States Competent Authorities and ECHA submitted in accordance with Article 117 of the Regulation, which cover the implementation of all REACH processes and their enforcement.

Studies on the operation of REACH

A first set of reports provides a detailed account of the implementation and enforcement of REACH at European and national level.

The ***Analysis of the Member States' reporting questionnaire 2015*** provides a comparative analysis of the 2015 Member States reporting questionnaires on the implementation of REACH at national level for the period 2010-2015, and CLP for the period 2011-2014, as per Article 117(1) of the REACH Regulation and Article 46 of the CLP Regulation. The questionnaire covers all activities to be carried out by Member States including the enforcement activities. Reports published by the ECHA and focussing on the implementation of certain REACH processes have also been included in the evidence base.

The ***Report on the Operation of REACH and CLP 2016*** is the second five year report the Agency has published in accordance with Article 117(2). It gives an overview of the implementation of REACH and CLP, the progress to date, impacts, successes and areas needing further work or improvement. It also presents a list of recommendations to the European Commission, Member States and industry.

The third report on the ***Use of Alternatives to Testing on Animals for the REACH Regulation***, published by ECHA as per Article 117(3), describes the implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment. The report is based on the information provided in the registration dossiers held by ECHA on 31 March 2016. Most of the analysis is based on a data pool covering 6 290 substances in 6 911 dossiers. The ***Analysis of higher tier studies submitted without testing proposals*** investigates the reasons why some registrants have submitted new higher-tier studies on vertebrate animals without submitting a testing proposal. These cases have been identified through the research conducted for the second report on the *Use of Alternatives to Testing on Animals*.

In addition, the ***annual reports on evaluation under REACH*** 2012, 2013, 2014 and 2015 describe the progress made in the dossier and substance evaluation activities according to the objectives defined in the Agency's work programme, the compliance check (CCH) strategy and the Community Rolling Action Plan (CoRAP). The 2015 and 2016 ***annual reports on the SVHC Road*map** monitor the implementation of the SVHC Roadmap to 2020 Implementation Plan. The reports contain a summary of activities carried out in the previous year, an outline of activities planned for the following year, and an overview of related regulatory risk management activities.

The ***Final report on the first Forum pilot project on authorisation***, presents the outcome of the first pilot project undertaken by the Forum on the Authorisation process, which aimed at checking compliance with the REACH Regulation on the marketing and use of MDA and Musk xylene after their sunset date, in order to gather experience and building practice and processes for enforcing the authorisation-related obligations. 18 Member States participated

in the project.

The study on ***Substance Identity in REACH*** analyses approaches applied by the industry in identification of substances for registration under REACH. The study consists of a substance identity screening of 223 complex substances selected as a representative set of substances with different challenges in their identification, with the aim of identifying key challenges in the identification of complex substances and comparing approaches taken by registrants of different groups of substances. The study is based on information contained in registration dossiers reported in the ECHA database of registered substances as of August 2014.

Finally, the ***Study on 'Development of enforcement indicators for REACH and CLP'*** proposed indicators that can be used to monitor and measure the performance of the enforcement of the REACH and CLP regulations. The study defined indicators at the levels of the individual Member States, the Forum and the EU as a whole. Enforcement indicators at Member State level aim at assessing how REACH and CLP enforcement is functioning within the Member States; indicators at Forum level aim at assessing the level of implementation of the activities of the Forum; and indicators at EU level aim at providing an overall insight on how the enforcement of REACH and CLP is functioning within the EU and the European Economic Area (EEA). A total of 50 indicators were developed, including 44 key indicators that were fully developed and six additional indicators, which require further development before they can be implemented. The majority of the indicators developed are outcome indicators.

Studies related to the scope of REACH

A second set of reports examines the relevance of extending registration requirements or more stringent information requirements to certain substances currently excluded from REACH or benefitting from lighter requirements. These reports have mostly been commissioned following the requirements of Article 138 of the REACH Regulation.

Since 2012, four studies have been commissioned to review information requirements for 1 to 10 tonnes substances and the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) for 1 to 10 tonnes CMRs 1A/1B, as required by Article 138(1) and 138(3) of REACH. After the 2012 study that had defined a methodology to address these questions and some first options, the second study (2014) on the extension of the obligation to perform a CSA and to document it in a CSR considered the changes introduced by extending the CSA/CSR requirement to 1 to 10 tonnes CMRs 1A/1B and provided an estimation of the costs and benefits of extending it. A third study (2015) on the extension of registration requirements proposed options for refining information requirements and assessed their costs, business impacts and benefits on a per substance basis. The fourth study (2017) built on the results of these previous studies and updated the evaluation of five selected options taking into consideration the combination of the information options with the CSA/CSR option and also any changes in context and timing since previous studies have been conducted. The options and the baseline are compared by using an Excel based Monte Carlo model and simulation that analyses, for each of the options, the number of substances with hazardous properties that would be detected, the usefulness of the information generated, the cost of registering/updating the registration dossiers, the likely impact of the registration costs at a company level and, to the extent possible, the likely impacts on SMEs, competition and innovation.

Two studies have been conducted since 2012 following the requirement of Article 138(2) to review registration requirements on polymers. The first study from 2012 described the

polymer market and hazards posed by polymers compared with those posed by monomers and other substances, summarised previous impact assessment conclusions on the registration of polymers and assessed some policy options for the future registration of polymers. A second study from 2014 providing ***Technical assistance related to the review of REACH with regard to the registration requirements on polymers*** assessed two potential approaches for the registration of polymers: grouping polymers for registration and defining a category (or categories) of Polymers of Low Concerns (PLCs), and aimed to develop alternative approaches for registering polymers based on this analysis. The study collected information on the approaches for polymers in non-EU jurisdictions and compared them according to the parameters used to identify polymers, type of approaches, and criteria used to define PLCs. Third countries approaches were then assessed in terms of hazard assessment and in terms of cost-effectiveness.

In addition, the ***study to support the 3rd regulatory review on nanomaterials*** compiled information on nanomaterials and advanced materials in the environment and explored further the regulatory implementation challenges. One component of the study was to review the application of environmental and other key legislation to nanomaterials, including the REACH Regulation, to assess the coverage of nanomaterials in EU environmental legislation.

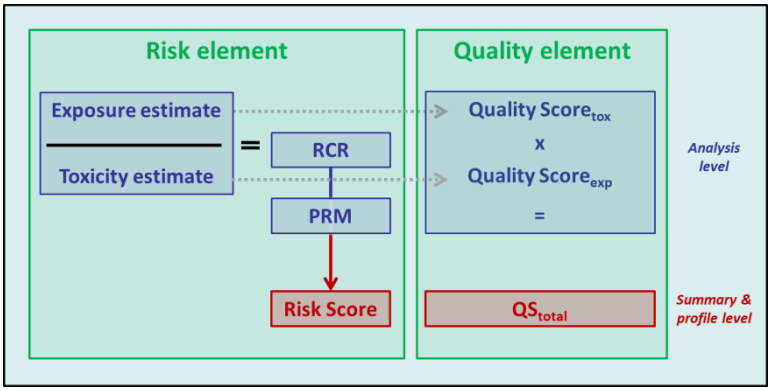
Studies on the impacts of REACH on human health and the environment

The ***Study on the calculation of the benefits of chemicals legislation on human health and the environment*** proposed indicators measuring the links between chemical substances and their impacts on human health and the environment, and measured the role that chemicals legislation, in particular REACH and CLP, has had in reducing such impacts in the period 2004-2013. They defined indicators at three different levels of objectives (operational, specific and general), resulting in output indicators, results indicators and impact indicators. The study also proposed monetary estimates of certain impact indicators. However, the suitability of these estimates was considered by the authors as very limited as they rely on assumptions that are likely to be changed over time.

The ***REACH Baseline study*** aims at monitoring the effectiveness of REACH as regards risk reduction and improvement of the quality of data available for the assessment of chemicals by means of Risk and Quality indicators. The methodology to derive the Risk score (risk posed by a substance) and the Quality score (quality of the data available to assess the risk associated with a substance) was established in 2007[1] and applied for the first time in 2009 to a set of 237 reference substances considered a representative sample of the chemicals available in the EU market before REACH entered into force. The assessment was repeated after five years for the substances which had been registered by August 2011 to feed into the first REACH review. The ***REACH baseline study: 10 years update*** analyses changes in the Risk Scores and Quality Scores based on registrations until September 2015, including registrations from the second registration phase (by May 2013) as well as updates from dossiers registered previously.

The Risk & Quality Indicator system consists of an element assessing the nominal risk and an element assessing the quality of the underlying data.

[1] The REACH baseline study, A tool to monitor the new EU policy on chemicals - REACH (Registration, Evaluation, Authorisation and restriction of Chemicals), Eurostat, June 2009



The Risk Scores and Quality Scores are calculated for four impact areas:

- ✓ workers,
- ✓ environment,
- ✓ consumers and
- ✓ human health via the environment

The study ***Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH*** aims at identifying specific priorities that ECHA and other public authorities could support in the short term to advance substitution programs and practices among Member States and the Commission, including specific needs related to analysis of alternatives capacity. The study is based on a review of applications for authorisation and restrictions proposals, surveys and interviews involving industry, Member State and Commission authorities, and NGOs.

The study on the ***Interpretation of the World Summit on Sustainable Development (WSSD) 2020 Chemical Goal and assessment of EU efforts to meet the WSSD Commitment*** developed a series of 20 indicators to measure EU progress towards achieving that goal from a baseline year of 2002 up until the end of 2012, assessed progress and provided recommendations for future EU actions.

Studies on the impacts of REACH on the internal market, competitiveness and innovation

The study on the ***Cumulative Cost Assessment (CCA) for the EU Chemical Industry*** aims at identifying the structure of the cumulative costs incurred by EU chemical companies because of EU legislation during the period 2004-2014. The study does not aim at providing overall figures of costs or at assess the benefits of EU legislation. Only pieces of legislation incurring high cost directly to chemical companies have been included in the study. These comprise: chemicals, energy, emissions and industrial processes, workers' safety, product-specific, customs and trade, and transport legislation. Chemical legislation is not limited to REACH and includes as well CLP, the Persistent organic pollutants (POPs) Regulation and legislation related to pesticides and biocides. Costs have been calculated only for the subsectors of the NACE classification for which some data were available, e.g. inorganic basic chemicals, organic basic chemicals, plastics in primary forms, pesticides and agrochemical products, soaps and detergents, and cleaning and polishing preparations, paints, varnishes and similar coatings and other chemicals products. Data on costs for the past 10 years were collected

from a limited panel of 31 typical companies from different sectors, and an online survey with a sample of 90 companies, from which a cross-sector extrapolation was done to the whole of the European Union. The cost estimates provided, and in particular the conclusions about the change of these costs over time, need to be treated with caution because they are based on the extrapolation of data from a limited number of companies and their recollections of past costs.

The study ***Monitoring the impacts of REACH on innovation, competitiveness and SMEs*** aims at 'evaluating changes to the operational conditions and the structure of the chemicals industry and downstream industries focusing on the implementation of the REACH Regulation' during the 2010 – 2013 period. The study focuses on assessing the impacts on the trade exchanges and the harmonisation of the single market, on the external competitiveness, on business opportunities, on innovation, on small and medium enterprises (SMEs), and evaluates the costs of the 2013 registration deadline on dutyholders and provides an estimation for the costs of the 2018 registration deadline. The information was collected from five sources: a computer aided telephone interview (CATI) business survey, covering 15 Members States with a sample of 1 076 responses (38% large firms, 62% SMEs) - 47% of which are downstream users; an online business survey (OBS), which gathered 566 responses from all 28 EU, EEA and non-EU based firms (45.6% large, 54.4% SME); 104 interviews with stakeholders (Commission, ECHA, industry associations, Member States authorities, Environmental and consumer group and trade unions); 56 in-depth interviews with firms with different roles, sizes and countries of operation (57.1% large, 42.9% SME); and 5 thematic cases studies. Both the OBS and the CATI surveys requested estimates of the cost of the registration 2013. The survey data collected included the number of substances registered, the estimated cost of registering substances in different tonnage bands, as well as different components of the registration costs (fees and costs associated with undertaking the Chemical Safety Assessment, liaising with the downstream users, safety data sheets, etc.). The data from both surveys were presented separately to allow comparison between the results and to check consistency.

The study in 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*** aims at assessing the impacts on international competitiveness of the general legislation governing the conditions for marketing and use of chemicals in the EU and the following countries: China, Japan, the USA, Canada, and South Korea. The study focuses on the REACH Regulation in the EU, and in the other five countries, on the main legislation dealing with horizontal conditions related to the placing chemical substances on the market to guarantee safe use and protection of human health and the environment. The study is based on collecting secondary data through literature review on the impacts of REACH and corresponding third-country chemicals legislation, particularly with respect to comparisons of similarities and differences; an interview programme with stakeholders (4 European business associations, 4 Business associations of concerned sectors in the third countries); case studies on 12 companies from EU and third countries representing the chemicals sector and three downstream sectors (textile, automotive, rubber and plastics).

The report from ECHA on ***Cost and benefit assessments in the REACH restriction dossiers*** assesses costs and benefits of the restrictions included or proposed to be included in Annex XVII of REACH. It summarises and aggregates the information on costs and human health and environmental benefits provided in the restriction dossiers and opinions of the Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC). The analysis covers the 18 restriction proposals on which RAC and SEAC have adopted their

opinions by April 2016. In addition, one case where the RAC opinion and SEAC draft opinion were finalised, although not adopted, is covered in the report. The main cost category assessed in the restriction cases is substitution costs, i.e. investment and recurring costs to switch to alternative substance.

The ***study on the impacts of REACH authorisation*** evaluates the performance of the REACH authorisation process. It is based on evidence to assess if it is working as intended and achieving its objectives in terms of progressive substitution of SVHCs by less hazardous alternatives and control of the risks. The study is focusing on five areas: costs of authorisation, benefits of authorisation, changes in the market structure for SVHCs and alternatives, progress on substitution and affordability of authorisation for SMEs. Finally, the study intends to evaluate the adequacy of current guidance for stakeholders to facilitate the preparation of the authorisation applications while reducing their costs, to search for alternatives and to provide input on alternatives during the process. The study gathers evidence through an initial literature review, followed by an extensive data collection through desk research (Eurostat data), stakeholder surveys (companies, NGOs, Member States, ECHA and Commission) and case studies.

The ***presentation by ECHA at the 9th annual meeting of the Society for Benefit-Cost Analysis in Washington D.C. in March 2017*** provided some figures on the benefits and the costs of authorising the use of Substances of Very High Concern under REACH for the first 60 opinions adopted by ECHA.

The article on '***Socio-economic benefits and risks of the use of carcinogenic substances subject to authorisation under REACH***' quantifies the benefits and risks (and benefit-risk ratio) of industrial uses of hazardous chemical substances (carcinogens), for which applications for authorisation have been submitted under the REACH Regulation. The article is based on the opinions of SEAC, which were adopted until July 2016, and cover 32 uses of 9 carcinogenic substances. Applications for threshold substances have been excluded from the scope of the article, as well as ancillary uses such as formulation and packaging and one application for a persistent, bioaccumulative and toxic (PBT) substance.

Studies related to other EU legislation

The ***Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States*** assesses the implementation of the OSH directives with a view to evaluating their relevance, effectiveness and coherence and identifying possible improvements to the regulatory framework. The section on the coherence of OSH directives with other measures and/or policies at the European level addresses the coherence with the REACH Regulation, especially regarding occupational exposure limit values (OELs) and derived no-effect levels (DNELs) in CSR and exposure assessments. The evaluation focuses on the 24 OSH directives and their implementation in 27 Member States (Croatia not included) in the period 2007-2012. The evaluation is based on the National Implementation Reports, on an extensive mapping and analysis of transposition and implementation of OSH legislation in each Member State, official statistics at the national and EU levels, scientific literature, existing studies and interviews with national and EU stakeholders.

Other studies

The ***Evaluation of the European Chemicals Agency (ECHA)*** assesses the performance of ECHA, covering the full range of ECHA's operations and processes: REACH, CLP, BPR and PIC. The evaluation of ECHA was conducted based on the intervention logic of the Agency and a comprehensive analytical framework comprising the evaluation questions to assess the effectiveness, efficiency, coherence, relevance and EU added value of ECHA's work and their respective judgement criteria, indicators and information sources. The study maps and compares the obligations stemming from each of the Regulations mentioned above and compares those to the activities implemented. The Agency's organisation, its resource allocation, the use of tools and results achieved were compared to what was expected from the Agency. The data collection tools used to gather the relevant information consisted in document review, stakeholder interviews, an online company survey, a comparative analysis with similar EU Agencies and a limited process analytics exercise. Document review covered ECHA's planning, reporting and monitoring documents, organisational strategies, policies and procedures, as well as internal and external audit reports and other relevant documentation of the Agency's bodies. In addition, the perception of stakeholders was assessed by analysing the results of ECHA's Stakeholder Annual Surveys and staff surveys as well as position papers of external stakeholders. Interviews were conducted with ECHA staff and management, member of the Agency's bodies, Commission officials, EU Agencies, Member States Competent Authorities (MSCAs), peer agencies in third countries, OECD, industry associations and individual companies and NGOs. The online survey covered a representative selection of companies involved in ECHA's activities. A comparative analysis with similar organisations was carried out to compare the functioning of ECHA on specific indicators with practices implemented by other EU Agencies, such as the organisational structure, management and governance as well as on communication resources and activities. The limited process analytics exercise allowed to assess the efficiency of ECHA at process level, by comparing a documented process, as described in the Agency's standard procedure, with the process that occurs in practice.

The ***Eurobarometer survey on chemical safety***, which aims to understand EU citizens' awareness and perceptions of chemical products, including comparisons (where appropriate) with similar surveys conducted in 2012 and 2010. The survey covers public awareness and information about chemicals; public perceptions about the safety of chemicals, whether this has improved in recent years and the relative safety of chemical products manufactured both within and outside of the EU; perceptions of who is currently responsible for the safety of chemicals in the EU and who ought to be responsible for such activity; awareness and understanding of chemical hazard pictograms. This survey was carried out 28 EU Member States. Some 27 929 EU citizens from different social and demographic categories were interviewed face-to-face at home and in their native language according to the methodology established for Commission's Eurobarometer surveys[2].

[2] http://ec.europa.eu/COMMFrontOffice/PublicOpinion/