FIT FOR FUTURE Platform Opinion

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		No
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		No
	☐	Other
		No
Have your say: Simplify!	*No relevant suggestions on this topic have been received from the public.*	
Commission follow up	REFIT Scoreboard:	REACH
	Have your say portal:	Revision of REACH Regulation
	Annual Burden Survey:	The EU's efforts to simplify legislation (2022)
	Other:	ECHA 2023 Annual report

SUGGESTIONS SUMMARY

Suggestion 1:	Improve communication up and down the supply chain in relation to safety-data-sheets, other risk-/hazard-communication and worker protection
Suggestion 2:	Facilitate registration and evaluation by optimizing resources and procedures
Suggestion 3:	Develop IT-tools more adequate for SMEs
Suggestion 4:	Enhance transparency supporting regulatory actions and innovation by optimizing enforcement, decision-making-procedures, data-foundation and applied R&D
Suggestion 5:	Strengthen enforcement by focusing on problematic areas and dedicating more resources for concrete activities of enforcement bodies
Suggestion 6:	Streamline authorisation and restriction by better focusing on problematic areas, introducing incentives for the development and marketing of substitutes and streamlining regulatory procedures

SHORT DESCRIPTION OF THE LEGISLATION ANALYSED

The EU's Regulation on the registration, evaluation, authorisation and restriction of chemicals (referred to as REACH) entered into force in 2007. REACH provides a comprehensive data generation and assessment system for chemicals manufactured and used in the EU, designed to improve the protection of human health and the environment. REACH places the burden of proof on companies, based on the motto 'no data, no market'. It puts obligations on industry to collect chemical safety information, to use this information to develop and apply appropriate risk management measures, to communicate these measures to users of chemicals and, finally, to document this in registration dossiers submitted to the European Chemicals Agency (ECHA).

In practice, REACH establishes procedures for collecting and assessing information on the properties, uses and hazards of substances. Companies need to register their substances in order to be able to place them on the market and, to do this, they need to work together with other companies who are registering the same substance (*registration process*). ECHA receives and evaluates individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment (*evaluation process*). Authorities and ECHA's scientific committees assess whether the risks of substances can be adequately managed. Authorities, including EU Member States or the Commission through ECHA, can ban hazardous substances if their risks to human health or the environment are considered to be unacceptable (*Restriction process*). They can also decide to impose a general ban a substance of very high concern, or, in the contrary, make a use subject to a prior authorisation (*Authorisation process*), in which case companies will need to demonstrate in order to be able to use the substance, either that the use is adequately controlled, or otherwise that there are no suitable alternatives and that the benefits of using the substance outweigh the risks.

REACH impacts on a wide range of companies across many sectors, even those who may not think of themselves as being involved with chemicals, such as manufacturers, importers, downstream users or companies established outside the EU. It covers all sectors, as well as different stages in the supply chain: manufacturing, importing, distributing or using chemicals as raw materials or finished products companies, regardless of the size of the company. This includes for example large chemicals manufacturers or distributers, as well as painters, hardware stores or surface treatment professionals.

Further sources of evidence:

Legislation framework webpage

Chemicals Strategy for Sustainability towards a Toxic-Free Environment

REACH revision under the Chemicals Strategy

Call for evidence

Public consultation

Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions, COM(2018) 116 final

European Chemicals Agency

PROBLEM DESCRIPTION

Existing Commission evidence suggests the following issues:

The Chemicals Strategy for Sustainability recognises the need for a targeted revision of REACH to achieve its objectives by addressing amongst others the following main **problems that have been identified in the Call for evidence, which relate** to burden reduction and simplification but in order to increase protection of citizens and the environment.

REACH is the most advanced knowledge base globally but there are still gaps in knowledge of many relevant substances. The information required on certain critical hazard classes does not always allow a sufficiently thorough hazard assessment, including for carcinogenicity, neurotoxicity, immunotoxicity and endocrine disruption.

The communication in the supply chains is inefficient. As identified and reported in the latest REACH Review, the communication up and down the supply chain on uses and necessary risk management measures lacks accuracy and clarity, which has a significant negative impact on the control of risks.

The evaluation of registration dossiers and substances is too complex and insufficient. The procedures for evaluation of registration dossiers and substances are complex, with several bottlenecks delaying the request for information from registrants and the conclusions on possible hazards and risks. In addition, the procedures are insufficient to ensure compliance of all registration dossiers. Furthermore, the current level of non-compliance causes a high burden on authorities. This hampers the assessment of substances and it also delays the regulatory control of harmful chemicals. Authorities spend a high level of resources by ensuring the still

existing data gaps are filled. The lack of consideration by registrants of the combination effects of chemicals in mixtures also hampers evaluation.

The authorisation procedure is too heavy and inflexible. The authorisation process has imposed a heavy burden on both companies and authorities. A multitude of applications for the use of small quantities of substances, unclear criteria for authorisation and information gaps (in particular for uses where competitors have already implemented alternatives), as well as unclear information in applications (in particular from applicants up the supply chain and from only representatives) have led to prolonged discussions and delays in decision making. In many cases, this has placed EU-based companies at a competitive disadvantage compared to their non-EU competitors.

The current restriction process is too slow to sufficiently protect consumers, workers and other professional users against risks from the most hazardous substances. The normal restriction procedure, through specific risk assessment, puts a high burden on authorities to document unacceptable risk for health or the environment. Although REACH already enshrines the use of a generic approach (i.e. assuming that the use constitutes a risk) for restricting certain carcinogenic, mutagenic or reprotoxic (CMR) substances in consumer products, this procedure cannot be used for other critical hazard classes including endocrine disruptors, persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances, immunotoxicants, neurotoxicants, respiratory sensitisers or substances that affect specific organs. Moreover, professional users are often using the same products as consumers, but much more frequently and during longer periods of time. Yet, they are unlikely to benefit from the same risk management as in industrial settings. Hence, they should get a level of protection at least at the level of consumers.

The control and enforcement is not equally effective in all Member States. Considerable differences exist between Member States depending on available resources and different policies leading to inconsistent effectiveness of controls. The increasing import of products from countries outside the EU, including by consumers' direct purchases through online portals, allows for import of goods that are not subject to the necessary controls to ensure compliance with EU law. These differences represent a risk for consumers and the environment and they negatively affect the competitiveness of compliant European industry.

(**Source**: Call for evidence)

The Fit for Future Platform has acknowledged the issues raised by the legislation concerned as follows:

Regarding: modernisation and future proofing of existing laws, including via digitalisation, the efficient labelling, authorisation and reporting obligations, the simplification of EU legislation:

The Platform has acknowledged the issues as presented in the problem description. While individual stakeholders gave different priorities to some of the topics, still the Platform jointly concluded on a set of suggestions to modernise and improve the REACH-regulation by optimising or more deeply changing the existing regulatory framework. In this document the

Platform suggests some concrete measures that could be implemented swiftly and others that need a more thorough preparation. The objective was not to necessarily create new legislation or tools, but rather to make a more efficient use of what is already available. The Platform also analysed the situation of SMEs and consequently considered their situation in its suggestions. Finally, the Platform identified several areas, where digital tools could support the implementation of the REACH regulation.

If relevant, specific issues on the local and regional level:

At several occasions, the Platform in its suggestions addressed the role of enforcement. This is almost exclusively the competence of Member States.

SUGGESTIONS

Suggestion 1: Improve communication up and down the supply chain

Description: REACH, being the largest data-collection framework for chemicals globally, has very sophisticated communication instruments up and down the supply chain. Based on this, suppliers of chemicals and their users, should in a joint effort collect and regularly fine-tune the data on their chemicals. This concept triggers a complex communication-process in countless supply chains. Actors in these supply chains are very different in relation to e.g. size, sector, usage of supplied chemicals etc. At the beginning of a supply chain there is very often a large manufacturer or importer of chemicals. The submitted safety-data-sheets (SDS) are of varying quality, especially extended safety-data-sheets (eSDSs) are usually data-rich and technical. These aspects can make especially eSDSs hard to understand for actors further down the supply chain, for example to small end-users, formulators or retailers.

However, safety data sheets are the main vehicles for communicating safety information in the supply chain. If they are deficient, workers and professionals may not receive adequate information to use hazardous substances and mixtures safely. It is therefore crucial that the quality of SDS is improved and communication concerning them streamlined.

Another challenge is the communication of chemicals-data up the supply chain as regulated in articles 34, 37 and 38 of REACH. For example, when a user discovers weaknesses/errors in the safety-data-sheet of his supplier or the user wants to inform the supplier about a new use, so that its safety can be assessed. In addition, more communication to authorities by downstream users on the substances of very high concern they use, could prove useful.

To address these shortcomings, ECHA should assess, how and which tools could make communication in the supply chain downstream and upstream more efficient and targeted to the audience. This assessment should take into account already existing effort of authorities, industry and the ENES work program.

Furthermore, the interaction between REACH and health and safety at work (OSH) legislation could be improved. REACH applies without prejudice to OSH legislation. It means that

employers have to comply with both set of legislations. REACH and OSH do complement each other and what is needed is finding synergies and trying to avoid duplications. For example, the hierarchy of risk management measures should be taken into account in the exposure assessment tools to prevent conflicts between OSH and REACH and to create more realistic and useful exposure information for the supply chain.

Expected benefits: Improved quality of SDS as well as improved communication in the supply chain supports the safe use of chemicals and consequently contributes to a better protection of human health and the environment. Furthermore, better communication upstream as well as the use of targeted reporting and notification of selected data to authorities will improve the general knowledge about chemicals in the EU and make necessary regulatory actions more targeted and efficient. Finally, a more structured communication in the supply chain may foster the cooperation of different actors and with this new business opportunities and/or innovation.

Suggestion 2: Facilitate registration and evaluation

Description: REACH regulatory processes like registration or evaluation are complex and costly. However, they are also the pillars on which risk management measures are built under REACH. Authorities face growing workload to assess the information provided by companies. But also companies, - in particular SMEs - are very often overburdened by these processes. At the same time, SMEs need to compete with large competitors, who, proportionally, have significantly more resources for regulatory compliance. To manage registration, well trained people from various areas, e.g. IT-knowledge, toxicology, risk-assessment, etc. are needed. These qualifications are not always available to SMEs, which leads to an unequal level-playing-field. Exploring existing training and funding possibilities, at EU and national level, for directly supporting SMEs and associations supporting them could change the tide and would alleviate the administrative burden on SMEs.

Furthermore, the “No Data, No Market” principle needs to be implemented more strongly by giving ECHA more tools to evaluate quality and adequacy of the registered data at registration, as well as to make sure that dossiers are adequately updated by the registrants. Non-compliance of registrants could end in the revocation of the registration number, which should follow a clear and transparent procedure, including the right of the registrant to be heard and in justified cases an option for a subsequent dossier update. The interaction between dossier and substance evaluation should be improved with the objective to speed up the overall evaluation under REACH. A more effective grouping of substances could further improve the speediness of evaluation.

Current data requirements for problematic substances, especially those with high production volumes or wide-spread uses, should be reviewed with the objective to improve environmental and worker protection, while at the same time, the burden for low-tonnage substances up to 100 t/a should be reduced to the widest extend possible, in particular taking into account their hazard and risk profile. Critical data gaps exist, in particular, for specific polymers and for combination effects of certain substances in mixtures. To reduce testing-costs especially for SMEs, obligatory data-sharing should be applied as efficiently as possible, for example by extending it to read-across-data.

Expected benefits: SMEs would improve compliance with legal information requirements and could also have a stronger focus on their core business. This would untie resources for production, innovation and education of apprentices. Finally, this would strengthen the competitiveness of the EU. Authorities would evaluate dossiers quicker and with less resources, close data gaps and improve the general protection in the EU by having more resources to focus on areas of known non-compliance.

Suggestion 3: Develop IT-tools more adequate for SMEs

Description: In the past ECHA has already implemented some measures to make IT-tools more adequate for SMEs, e.g. IUCLID Cloud. However, one of the main issues is still not systematically resolved, which is the availability of IT-tools like the Classification and Labelling Inventory, the DU-notification acc. Art. 66 REACH or SCIP in other official languages than English. Because the majority of workers in SMEs do not master English in technical jargon, this has direct resource-impacts for SMEs. In practice this means, that also administrative work needs to be performed by experts who master English, usually a higher qualified employee. This employee is then missing in other vital parts of a company, like for example production.

Expected benefits: Reduction of costs and more fairness for SMEs.

Suggestion 4: Enhance transparency supporting regulatory actions and innovation

Description: Comprehensive and qualitative data is crucial for the safe use of chemicals, a proper assessment of hazards/risks and for setting regulatory actions. Dossiers need to be compliant and regularly updated, also after a registration was submitted. This requires a stable legal basis, and also an efficient cooperation between authorities and businesses. Effective sanctions - including the possibility to revoke a registration number – play an important role as well.

It should be explored to which extent and how existing evaluation processes – namely completeness check, dossier evaluation and substance evaluation – could be merged or synchronized to make evaluation faster and more resourceful. Consequently, improving the evaluation process itself should make the database better and more consistent.

During the preparation of a restriction, a targeted requirement for downstream users to provide information on use and exposure could be helpful and make a restriction better targeted. Targeted obligatory information requirements for users of substances of very high concern could further prove useful to improve the knowledge base about chemicals and support regulatory actions. However, such an obligation needs to respect the Think-Small-First-principle, while ensuring the burden of proof on companies and polluter pays principle.

Additionally, for this purpose, a better data-collection could be supported by improving consultations to make them more inclusive for smaller businesses and suppliers of alternatives for the chemicals being restricted. This could be achieved by making a more targeted use of existing tools to increase the participation in REACH-related consultations of suppliers of

alternatives, smaller businesses, etc. with relevant alternatives/substitutes to e.g. restricted chemicals or substances of very high concern (SVHC).

Finally, a one-stop-shop for funding opportunities for R&D around SVHC, safety, sustainability and similar should be developed. It should cover funds at national and EU-level. And it should be kept up to date.

Expected benefits: The evaluation of data submitted by businesses could become faster, more effective and less burdensome for authorities. The data basis for regulatory actions would improve and make such actions more targeted. This way administrative costs could be kept as low as possible, while at the same time the database on chemicals could be improved. Based on this, more targeted regulatory actions could be taken, what would reduce unnecessary negative impacts on EU's businesses and keep the same level of benefit for the protection of health and environment.

More transparency could promote R&D on alternatives/substitutes for SVHC and other substances of concern and support the marketing of already available alternatives/substitutes. Furthermore, authorities would collect more information about uses, including small niche-applications of SMEs.

Suggestion 5: Strengthen enforcement

Description: Just like every law, also REACH requires an effective enforcement. While this is necessary to ensure that chemicals can be used safely, it also protects law-abiding enterprises from competitors, who want to benefit by ignoring the rules. Controlling and ensuring compliance with EU chemicals legislation for online sales, in particular via online marketplaces and web shops established in third countries, is a significant challenge, as evidenced by the 2021 Forum report[1] on enforcement of online sales.

The general lack of resources and divergences of enforcement approaches across the National Enforcement Authorities (NEAs) has led to very high levels of non-compliance under REACH and the presence of unsafe products on the EU. Clearly, enforcement of REACH is a Member States' obligation. ECHA's Forum can play a meaningful role in coordinating, harmonising and facilitating it. For example, it is to be considered how ECHA's Forum has a better role in assessing the enforceability of restrictions or developing guidance – including on the use of methods of analysis and monitoring to improve the enforcement of restrictions.

Furthermore, enforcement authorities are highly and practically experienced. This knowledge could be used systematically to complement the more theoretical support of the national helpdesks. Such support would be very valuable for SMEs and help them to navigate through the complexity of REACH.

Finally, enforcement could be made more effective, protecting all actors on the internal market better. Cooperation at different levels (e.g. between Member States, ECHA, the Commission

[1] https://echa.europa.eu/documents/10162/17088/project_report_ref-8_en.pdf/ccf2c453-da0e-c185-908e-3a0343b25802?t=1638885422475

and/or stakeholders) could be further strengthened and enforcement further harmonised, whilst considering the specificities of the national enforcement system of each Member State.

Strengthening cooperation between Member State competent authorities and civil society is particularly key to improve compliance with EU chemicals legislation. Inspiration could – as recommended by the High-Level Roundtable on the Chemicals Strategy – come from the Consumer Protection Cooperation (CPC), such as empowering consumer organisations to issue external alerts to national authorities and the Commission of suspected infringements. In line with the new EU Consumer Agenda, the Commission and Member States should further support consumer organisations to develop their capacities for collective redress actions related to breaches of EU chemicals legislation.

Transparency requirements regarding control and enforcement activities could help to ensure protection, information, scrutiny, fair competition and incentives for compliance. Furthermore, it could be analysed to which extent more harmonised sanctions/penalties would improve consistency across the national enforcement authorities and which instruments could ensure the economic sustainability of the control and enforcement system under REACH.

Finally, the REACH revision should enable a comprehensive, future-proof and enforceable regulatory approach, particularly for online sales. This will require new elements, including a clear definition covering the role and responsibilities of online marketplaces with respect to non-compliant substances, mixtures, and articles. For example, online marketplaces could be given the same status as 'importers', while a possibility to hold these actors liable for non-compliance where no other responsible economic operator can be identified should be introduced. The benefits would be threefold: it would increase the level of consumer protection; enable market surveillance authorities to take effective enforcement actions; and create a level-playing field for companies in the EU single market.

Expected benefits:

SMEs would additionally get more practical support from experienced enforcement officers, while at the same time cooperation between these two actors would be strengthened. Introducing a possibility to hold 'online service providers/marketplaces' liable in certain circumstances would significantly contribute to reduce non-compliance for products sold online, thus ensuring stronger consumer protection and increasing fair competition between all players. Effective control and enforcement are key to ensure health and environmental protection as well as fair competition since it ensures that all companies respect the law.

Suggestion 6: Streamline authorisation and restriction

Description: Any reform of the authorisation and restriction processes should have the objective to simplify the regulation of relevant chemicals, while further improving the protection standards for health and the environment. Such a reform should promote substitution by creating the appropriate legal environment for companies investing in the development and the implementation of alternatives. It should also explore possible synergies between the existing authorisation and restriction schemes.

As recognised by the European Commission in the 2017 REACH review, restrictions are too slow. One delay factor is the high burden of proof required by authorities before they can restrict harmful chemicals. Simplifying the restriction system for authorities would be to improve the data basis on how to demonstrate "unacceptable risks at EU level". Such information has often proven to be insufficient in the past. Furthermore, a smarter grouping could make the restriction system more effective. Unlike consumers, professional users should be primarily regulated by OSH-legislation, which has already in the past proven to be an effective way to ensure protection of workers. Additionally, more transparent and concrete deadlines when for example a restriction proposal will be delivered by the European Commission would make the process better plannable.

Furthermore, authorisation and restriction processes need to be made fitter for SMEs. On the one hand this requires that SMEs should be better able to participate in these processes. This could be achieved by extending obligatory data-sharing rules to authorisation and promoting simplified schemes for the application for authorisation (e.g. low-tonnages, niche-applications, large group of small applicants with similar use), while not compromising health and environmental protection. Furthermore, there should be clear criteria, when professional users are not considered to be equivalent to industrial users and/or when they are considered comparable to consumers. On the other hand they should be supported in the research and development of substitutes. For this purpose a dedicated infrastructure would be needed. Such a substitution centre should have sufficient financial resources based on the polluters pay principle and should remain independent while involving relevant stakeholders. Its primary objectives would be to support SMEs in finding technical solutions to substitute problematic chemicals, to promote B2B-contacts and provide training opportunities in the field of chemicals regulation. To improve consumer protection, the generic risk management approach should be extended as the default option for the most harmful chemicals in consumer products. This simpler and less granular approach could in addition free resources to address other chemical risks, in turn contributing to speeding up implementation of REACH.

Expected benefits: By making the authorisation and restriction systems more efficient, the burdens could be significantly reduced while protection of health and environment promoted. A systematic approach to substitution and which chemicals are targeted for phase-out would support the phase-out of the most harmful chemicals, while creating new business opportunities especially for SMEs.

DISSENTING VIEWS

EEB regrets having to dissent from suggestion number 6. For the same reasons outlined by EEB, WWF wishes to dissent from suggestion 6 as well.

Rationale for dissenting views on the suggestions:

We cannot agree with the sentence "promoting simplified schemes for the application for authorization" as we cannot support simplified applications for large group of companies since this may translate into large amounts of substances of very high concern, in other words, wide exposure to the most damaging chemicals to our health and environment. We do agree that joint applications should be promoted for regulatory efficiency reasons and saving costs for companies, but the level of proof that these chemicals are properly controlled and no safer alternatives exist should remain as high as for other high production volume cases.