BUSINESSEUROPE

POSITION PAPER

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REACH REVIEW: BETTER IMPLEMENTATION IS NEEDED, NOT A REVISION

MAKING REACH FIT-FOR-PURPOSE

BusinessEurope fully agrees with the objectives of REACH to protect human and environmental health, reduce animal testing, and promote innovation in the chemical value chain. REACH has brought about greater risk management and communication across industrial sectors, which has improved the management of substances in Europe. BusinessEurope applauds the aim to fully harmonise chemical legislation in the European Union to ensure a free circulation of substances on the internal market, rather than having chemical management legislation diverge between the 28 Member States. In addition:

- REACH has led to a wider collection of data on chemical substances and enhanced cooperation in the chemical value chain. This has generated a greater knowledge of substances, which helps to strengthen the health protection of workers, consumers and the environment.
- REACH has incentivised market players in an industry to engage with each other through a consortium in compliance with anti-trust regulation. For example, the aerospace industry established a cross-sectoral industry consortium to prepare joint authorisation dossiers for the use of chromium trioxide.
- REACH has been instrumental in the development of a good practice named “Risk Management Option Analysis” (RMOA), which allows for an early exchange between involved actors and helps to reach a common understanding and to take pragmatic decisions.

REACH is a very complex regulation, and the quality of its enforcement tends to differ between the Member States. These differences can distort competition on the internal market and reduce the effectiveness of the legislation. Furthermore, the costs of chemicals legislation for most of the chemical industry[1] in Europe has doubled between 2004 and 2014 to EUR 9.5 billion according to a recent Commission report, representing about 30% of the industry’s gross operating

[1] The study looks at the subsectors of “inorganic basic chemicals”, “organic basic chemicals”, “plastic in primary forms”, “pesticides & other agrochemicals”, “specialty chemicals”, and “soaps and detergents”. Together they represent 79% of the chemical industry in turnover, 73% in value added and 70% in employment.

surplus (GOS). Lowering these costs while respecting the objectives of REACH is therefore a key pillar for the competitiveness of Europe's industries.

BusinessEurope calls for efforts to improve those aspects of the regulation creating costs and uncertainties without generating clear benefits. Having said this, the following elements illustrate a series of unintended consequences of REACH:

- **Impact on the competitiveness of European companies**. A key unintended impact on competitiveness is the legal uncertainty around which substances will be targeted, and under which procedures they will fall (candidate list, restriction, evaluation, compliance check, automated screening etc.). While REACH cannot fully prevent different processes from occurring in parallel, it is difficult to understand why the same substance would be targeted under different processes led by different national competent authorities. Industry also struggles with different lists, making the daily management of chemicals costly and time consuming. This makes it difficult for producers and downstream users to anticipate which substances may or may not be used in their products, which can have a large economic impact. BusinessEurope acknowledges the fact that predictability can never be perfect. REACH does not require a revision to overcome this issue, but there needs to be a:
    - Clear timeframe in which business can expect clarity regarding substance management plans.
    - Formalisation of the RMOA process wherever possible, with coherent processes throughout the EU. This allows for clear and logical decisions to be taken as to which REACH process is proposed and applied. The RMOA should include a thorough assessment on the use of a substance if it is to be included in the candidate list. For example, molten lead (Pb) has been proposed to be included on the candidate list, without any public and transparent assessments explaining the option choice or decision.
    - Pragmatic management of different lists and greater transparency and communication between producers, downstream users and policymakers.
    - Stronger role for ECHA and the Commission to clarify the obligations and rights of all actors.

- **Impact on smaller companies.** Many smaller companies fall under the 2018 registration deadline as it concerns substances in the 1 to 100 tonnes per year band. As SMEs simply have less capacity and fewer resources than other actors, the process of registering and authorising adds a significant burden both in terms of time and costs on them. This burden is further exacerbated for both SMEs and other actors by the recent ECJ ruling. It obliges companies to inform the supply chain (article 33) and in principle also ECHA (article 7.2) of the presence of a substance of very

high concern (SVHC) in a concentration above 0.1% by weight of any 'simple article' which is used in a more complex article, such as the colour film behind the glass of a television screen or the screws on a bicycle seat. For article manufacturers and importers, it is very difficult to find out whether all of the products contain any substances that have to be notified. This is due to highly complex products that can include thousands of components and due to the complexity and length of their multi-tier supply chains. It is therefore very important to:

  - Ensure a proportionate and workable implementation of the requirements of substances in articles. For the safe use of complex articles by their recipients, it is not necessary to require a complete breakdown of a complex article into all of its components. Small and big companies should be allowed to provide aggregated information that ensure safe use and is workable and usable for their customers.
  - Further simplify the authorisation process, for example by allowing downstream users to rely on applications issued earlier by upstream chemical manufacturers. Simplification would benefit all companies. Information and data should in such cases not be demanded on a company-by-company basis.

- **Impact on innovation.** Substance substitutions are inherent to producers and users of chemicals regardless of regulation. Research looking at substance alternatives also occurs in the absence of the candidate lists, authorisation, or other compliance mechanisms as proposed by REACH. Furthermore, such mechanisms will very likely not have an additional impact if it has already been demonstrated before (e.g. through an RMOA process) that economically or technically feasible alternatives are currently not available. Rather, REACH may unnecessarily be diverting expert resources away from R&D, process improvement and product testing towards compliance if the regulation is not implemented correctly. Furthermore, requesting an authorisation requires a thorough analysis of all possible alternatives and justification for their non-suitability or availability. R&D departments have to dedicate considerable time to contribute to the argumentation, as the scope can be very broad. The public consultation on alternatives often generates a significant second workload for those departments, in order to bring factual answers to alternative suggestions that often prove to be theoretically rather than practically feasible, or out of scope. The time and resources spent on this administration is taken away from the researchers that are working on the R&D of the real promising substance alternatives.

- **Impact on supply chain communication**. In general, REACH has improved communication throughout the supply chain, especially about SVHCs. Safety Data Sheets (SDS) are crucial for such communication. To be of best use to downstream users of chemical substances, SDSs should

be easily readable and include high quality information. Concerning the Article 33 communication on SVHCs, BusinessEurope notes that for (very) complex articles, which may contain thousands of components and parts along a rather complex supply chain, becomes a significant and costly effort, especially when the "once an article always an article" principle would be improperly defined and applied. For example, for medical MRI equipment, no less than 120,000 components and parts are connected together forming the final product. In turn, a single component may contain many articles according to "once an article always an article". Therefore, a manufacturer will need to ensure that almost a tenfold of articles are declared and flow along the very complex supply chain – thus declarations of more than 1,000,000 articles. And this is only for one product, which may also vary over time or in its individual constellation (also the case in car manufacturing). Additionally, because the list of SVHCs changes every 6 months, the same exercise has to be performed repeatedly along the very complex supply chain, and for an almost infinite number of products. The risk is therefore again that a large amount of industry resources for R&D have to be used for compliance instead, with only limited positive impact for the end-user.

- **Impact on implementation due to regulatory overlap**. Several important efforts have already been made to enhance the consistency between REACH and other pieces of legislation, notably on the risk management options analyses (RMOAs). Nevertheless, legal uncertainty in terms of practical compliance by companies is still present due to overlaps and inconsistencies between REACH and other chemicals legislation. RMOAs would run more efficiently if the question of substitution and qualification was dealt with in a systematic manner, as well as the assessment of socio-economic aspects. For example, if workplace legislation rules or other RMOAs identify and manage risks regarding worker exposure to a certain substance, then it would not make sense to spend additional resources on the candidate list or authorisation if no additional impact is expected. It is therefore important to prevent overlap between REACH and workplace safety rules, so that duplication can be avoided. This is also the case for the Restriction on Hazardous Substances (RoHS) Directive and the Classification, Labelling and Packaging (CLP) processes, which should be fully consistent with REACH. Furthermore, the current revision of the Waste Framework Directive has given rise to potential inconsistencies. References have been made to "hazardous chemicals" in amendments tabled by Members of the European Parliament's Environment (ENVI) Committee; these amendments unfortunately lack consistency with existing chemical legislation. Although they may not become part of the final revised legislation, there is a tendency to include chemical provisions in waste and product legislation that are not aligned with obligations foreseen under REACH. Finally, REACH still shows inadequate alignment with the circular

economy objectives, in particular on the re-use of resources (recycled materials that might contain new regulated substances). This would consequently show an impact on the capability of article manufacturers incorporating such recycled materials in their articles to comply with sector-specific product legislation, namely restrictions on the article. During the identification of SVHCs, it should be evaluated whether this measure will not block re-use of, say, recycled materials. Furthermore, it must be assessed whether article manufacturers will remain in a position to comply with other product legislation existing in parallel with REACH. This topic does not require revision of the regulation, but rather better interpretation of its requirements through exposure scenarios and improved communication with stakeholders. BusinessEurope would therefore appreciate the Commission's intention to evaluate how chemical, product and waste legislation can consistently co-exist. Finally, RMOAs should be streamlined and used in the framework of REACH and other legislations.

- **Impact on animal testing.** Animal testing may have increased rather than decreased, because companies need to adhere to the "one substance, one registration" requirement to show that their substances or mixtures will not have detrimental effects on human or environmental health. Instead, REACH should allow faster approvals for alternative non-animal testing methods. Furthermore, better implementation and more transparency should minimise the occurrence of repetitive testing and further ensure the use of animal testing is only applied where appropriate, justified and takes into account the animal's welfare.

MOVING FORWARD

- **REACH should not be revised.** The issues addressed above are serious, but they do not require a complete overhaul of the regulation. Preference should be given to strengthening the guidance documents and updating annexes. Improved enforcement will provide an important boost to the effectiveness of REACH. Furthermore, BusinessEurope stresses that the objective of the REACH review is not to revise, but to assess its functioning and identify where improvements are needed. The final phase of the REACH registration will only be completed in 2018 and implementation will continue after that date. Companies require a stable regulatory environment, and therefore a revision at this time is not appropriate.

- **REACH is just one of the many drivers of substitution**. Substance substitutions are inherent to producers and users of chemicals regardless of regulation. Research looking at substance alternatives also occurs in the absence of the candidate lists, authorisation, or other compliance mechanisms. Furthermore, such mechanisms will very likely not have an

additional impact if it has already been demonstrated before that economically or technically feasible alternatives are currently not available, for example through a RMOA process. REACH may unnecessarily be diverting resources away from R&D spending because of the many compliance requirements. Similarly, breakthrough technologies may not be investigated to their fullest potential due to uncertainties surrounding the REACH regulatory regime. It is therefore very important to make the authorisation obligation more cost effective, and to avoid overlaps with other EU legislations.

- **Improve data gathering and selection of risk management options**. In order to better ensure REACH is achieving its objectives, BusinessEurope believes that robust, evidence-based risk and hazard assessments need to be carried out. This allows for better risk management options to be identified and for better standardised laboratory testing. RMOAs can also best assess whether substance alternatives are technically and economically feasible, provided they are specific to the different uses of a substance and take industry data into account.

- **Ensure greater regulatory predictability** through clearer timeframes on substance management plans, formalised RMOA processes and more transparency between policymakers and stakeholders.

To conclude, BusinessEurope members do not dispute the added value of REACH; they clearly see an added value. It is however important to find ways to achieve more efficiency, effectiveness and coherence as well as decrease costs for business and, in turn, for society. In dialogue with stakeholders, BusinessEurope firmly believes that the Commission can bring down the costs of complying with REACH, as well as support investments and innovation. It can do so by streamlining key elements on REACH, such as better and more realistic guidance documents and annexes, increasing the time between candidate list updates and improving predictability of the regulatory regime.