BUSINESSEUROPE

POSITION PAPER

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Revision of the REACH Regulation

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1. Key messages

- **Chemicals are key components of materials used in every-day life**, from the food we eat to the medicines we take, from the cosmetics we apply to the devices we use or the clothes we wear. They are present in all industrial ecosystems and are as such crucial to the green and digital transformations of the EU's economy.

- The envisaged revision of REACH represents a paradigm shift, **away from a proven risk-based approach towards an unproven hazard-based approach**. The impact assessment must therefore thoroughly assess the cost-benefits of this reform, as manufacturers and users of chemicals along the whole value chain would be significantly impacted.

- For volumes below 10 tonnes per year, **information requirements for registration** must remain proportionate and targeted, otherwise important substances could disappear from the market due to disproportionate costs.

- The report by the European Commission according to art. 138(2) of REACH is necessary to give a framework to assess whether certain **polymers** should become subject to registration.

- The generic introduction of a **Mixture Assessment Factor (MAF)** would massively curtail substances and uses even without relevant combination effects. Any further requirements should target the cases of substances and uses where a combined exposure has been identified.

- The extended use of the **generic approach to risk management (GRA)** must be based on a stepwise and transparent process, with upfront data collection, and ensure targeted and proportionate regulatory action without restricting substances for which safe use is secured. Given the different framework conditions, an equalisation of GRA for professional use and consumer use would not be justified.

- On the **'authorisation and restriction' reform**, a combination of the different options should be considered. In principle, some positive aspects of the authorisation procedure should be maintained and not replaced completely by a generic restriction process. Advantages of the two procedures must be maintained, in particular when combined with the GRA and the 'Essential Use' concept.

- It is important to keep **REACH and OSH legislation** separate, giving OSH legislation precedence when it comes to worker protection, whilst acknowledging that REACH can provide complementary measures in specific cases. Decisions on which is the most appropriate framework should be based on a binding list of criteria.

- The mere presence of a hazardous substance in a process or product is not a sufficient reason to apply the "essentiality" assessment. **The 'Essential Use' concept** (EUC) could therefore be a valid solution only if applied in a targeted manner, i.e., in case of proven risks to the health and environment, difficulties in managing these risks and if no acceptable alternatives or substitutes exist.

2. Introduction

Chemicals are present in our everyday lives and key for the well-being, high living standards and prosperity of modern society and economy. Moreover, chemical processes and products are present in all industrial ecosystems and are as such crucial, among other things, to the green and digital transitions of the EU's economy. In light of the EU's ambition to become the first climate neutral continent by 2050, it is important to note that chemicals are integral components of low-carbon, zero-pollution and energy- and resource-efficient technologies, materials, and products (e.g., wind turbines, solar panels, chips). All technological advancements needed to deliver on the EU Green Deal objectives will thus be relying on broad range chemicals in some shape or form.

As part of the EU's zero pollution ambition, the European Commission published the Chemicals Strategy for Sustainability (CSS) in October 2020. The CSS recognises the crucial role of chemicals for businesses and the society at large and aims at protecting citizens and the environment, while enhancing innovation for safe and sustainable chemicals through its 85 planned actions.

As one of the actions announced in the CSS - and aiming to reflect the strategy's ambition - the European Commission has begun its work on a revision of the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), envisaging major changes in multiple key areas, such as revising the registration requirements, introducing mixture assessment factor(s), reforming the current authorisation & restriction process, extending the generic approach to risk management as well as introducing an essential use concept.

While the revision aims at improving regulatory decision-making and efficiency, many of the envisaged changes represent a fundamental paradigm shift in EU chemicals legislation, away from a proven risk-based approach towards an unproven hazard-based approach. The planned impact assessment (IA) must take careful consideration of the risks associated with this fundamental overhaul of the REACH Regulation, as manufacturers and users of chemicals along the whole value chain will be significantly impacted. Furthermore, the overall reform of risk management for chemicals and its impact on industry cannot be assessed holistically, as the European Commission does not present at this stage clearly enough the interplay between an extension of the general approach to risk management (GRA), the introduction of an 'Essential Use' concept (EUC) and the reform of authorisation and restriction. With the current REACH Regulation, the EU already has one of the most sophisticated and protective chemical legislations globally.

Moreover, the safe and sustainable use of chemicals at the workplace is enshrined in the existing legislative framework, i. a. the Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to Carcinogens or Mutagens at work (now the Carcinogens, Mutagens and Reprotoxic substances Directive, which is subject to national transposition by 5 April 2024.

A revision of REACH must occur in a way that can enhance the system's ability to regulate harmful substances without blocking innovation and competitiveness of industry. Furthermore, investment security must be ensured, with a stable regulatory environment for companies.

To develop and use innovative solutions and socially relevant technologies in the future, it must remain possible to produce and use hazardous chemicals if there are safe use conditions, which sufficiently prevent damaging impacts on human health or the environment. Only if the broad availability of substances is maintained, the production of sustainable products and value creation may continue to take place in Europe.

This paper aims to contribute to the European Commission's work on the revision of REACH within the framework of the public consultation. Specifically, it will address key areas for industry as mentioned above. The broad spectrum of manufacturing industries and downstream users as well as their value chains, which strongly depend on the availability of chemicals, is particularly interested in the revision of REACH as their activities could be heavily impacted by the future framework of the EU's most extensive piece of chemical legislation.

3. Registration requirements

EXTENDED REACH INFORMATION REQUIREMENTS

The EU Chemical Strategy for Sustainability (CSS) has committed to increase the information requirements under REACH for all chemicals, in particular for so-called 'critical hazards' such as carcinogenicity, mutagenicity and reproductive toxicity, endocrine disruption, respiratory sensitisation, immunotoxicity, neurotoxicity, and other STOT (Specific Target Organ Toxicity). This may imply the need for companies (registrants of substances, i.e. manufacturers and importers of substances) to test more chemicals for more hazardous properties. At the same time, the European Commission intends to maximise the use of New Approach Methodologies (NAMs), thereby exploiting the latest scientific advances in hazard and risk assessment to avoid unnecessary animal testing.

Specifically, the European Commission is tabling detailed options entailing the following common provisions to be further evaluated in the impact assessment:

- A chemical safety assessment (CSA) shall be conducted at all tonnage levels.
- Annexes VII and VIII shall be merged.
- The intention to further encourage the use of NAM-based adaptations of the Standard Information Requirements (SIRs) by revising some of the provisions of Annex XI.
- An intention to reduce the administrative burden of the testing proposal (TP) process. At a minimum, this implies removing the need to submit a TP for non-vertebrate studies.

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While we appreciate the overall direction being taken by the Joint Research Centre (JRC) and the European Commission on the possible extension of REACH standard information requirements (SIRs) and on the increased use of New Approach Methodologies (NAMs), the tabled options in the current form miss the opportunity to address fundamental requirements for a transition towards a modern, fit-for-purpose and effective safety assessment.

→ *Conducting a chemical safety assessment (CSA) for all tonnage levels*

Especially for volumes below 10 tonnes per year, the information requirements must remain proportionate and targeted (e.g., exposure-led bioactivity/exposure ratio approach are considered in test designs). If data requirements at the lowest tonnage level become too high, important substances could disappear from the market due to disproportionate costs, and it would particularly impact SMEs.

A simplistic approach of just asking for more data for low volume chemicals is insufficiently targeted. The requirements for the CSA must balance exposure considerations and the hazard characterisation needs arising therefrom. An assessment of risk relative to volume that takes available use and exposure data into account would be a way to usefully determine which low volume substances require less or more data. Derogation criteria for substances of low risk - for both the CSA and SIR - are crucial to be defined. This is the only way to ensure that data requirements are proportionate to

the potential risk for low volume substances used e.g., in the absence of exposure, when used only on an industrial scale, in a well-controlled environment (compliance with occupational health and safety regulations) or as industrial intermediates.

→ *Additional information requirements for Annex VII substances (<10 tonnes/year)*

In addition to merging Annexes VIII & VII, the European Commission also proposes to increase the information requirements for low-tonnage substances (<10 t/a) to provide a basis for a Chemical Safety Assessment (CSA), including derivation of no effect levels (DNELs) and Predicted No Effect Concentration (PNECs).

→ *Modification to Annex XI (NAM-based adaptations of SIR)*

It is positive the European Commission takes a new course and reflects scientific advances on NAMs in chemicals legislation. However, more data does not necessarily lead to better protection of health and environment. Data should only be required and generated if it is of value for risk management.

Today, NAMs primarily address hazard assessment and are not linked to exposure considerations. A fundamental condition to increase their uptake is to consider upfront exposure considerations. It is not necessary to have trade-offs in protecting health and environment e.g., exposure considerations can help to inform whether additional hazard characterisation is necessary. Overall, testing resources need to be used more wisely for chemicals with relevant exposures. NAMs will only be successful in reducing animal testing when applied alongside with exposure considerations. In conclusion, we do support inclusion of NAMS for those endpoints and methods for which there are OECD validated protocols available (or become available in 2 or 3 years), provided that industry is properly involved in this process and that there is a follow up action foreseen on the basis of the outcome of the NAMs.

OBLIGATION TO REGISTER POLYMERS

Polymers, which are the fundamental building blocks of plastics, are currently exempted from the provisions on registration (under Title II of REACH Article 2(9)). The European Commission is assessing the REACH Regulation in order to require registration of certain polymers (Polymers Requiring Registration, PRR).

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Only a workable, well justified, and proportionate scheme can be implemented by all stakeholders and will foster sustainable developments in Europe. Non-EU competitors can bring articles made from polymers onto the EU common market without additional burden. The anticipated regulatory action needs to be proportionate and achieve all three objectives of REACH: a high level of protection, minimisation of animal testing and maintaining competitiveness of EU industry. High care should be given to the practical workability of all the parts of the scheme and the targeted benefit.

The following should be considered for a workable framework to consider registration of polymers:

- Article 138(2) of REACH requests the European Commission to first publish a report and therefore gives the framework for assessing whether certain polymers should become subject to registration.
- Use of practicable and cost-efficient way of selecting polymers i.e., a grouping approach adapted for polymers (chemical similarity but also phys-chem properties and hazard information.
- Application of sound technical, valid scientific criteria, risk-based considerations (selection of polymers based on reports, that demonstrate that certain types of polymers pose an increased risk compared to others).
- Make the best use of knowledge already gathered by other jurisdictions, such as US, Canada or Australia, and propose a set of criteria that identify PRRs in Europe that are in line with internationally accepted criteria, thus ensuring a harmonised international system.

MIXTURE ASSESSMENT FACTOR(S)

To consider adverse (eco)toxicological effects when humans or other organisms are exposed to several substances together or subsequently i.e., when they are exposed to an "unintentional" mixture, the European Commission intends to introduce a Mixture Assessment Factor (MAF). When applying a MAF, exposure levels that are considered sufficiently safe for single chemicals are reduced by a certain generic factor (i.e., by MAF).

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The benefit of introducing a generic MAF has not been clearly demonstrated yet. MAF-studies and assessments presented e.g., in the MAF-workshop organised by the European Commission (24 November 2021) have shown, that combination effects of chemicals only occur in a limited number of cases.

The generic introduction of a MAF would massively curtail substances and uses even without relevant combination effects. This would have massive consequences for the safe use of chemicals without being associated with an improvement in the level of protection. Therefore, any further requirements should target the cases of substances and uses where a combined exposure has been identified. Moreover, specific values of the MAF should be adjusted to the different effects caused by the various substances and to the specific use of substances.

DERIVED MINIMAL EFFECT LEVEL FOR NON-THRESHOLD SUBSTANCES (DMELS)

The European Commission is further assessing how DMELs for non-threshold substances, aiming at improving the risk assessment, could be implemented more widely. To date, the use of DMELs (and comparable approaches) has primarily focussed on carcinogens and germ cell mutagens (Cat. 1A/1B). The European Commission aims to widen the use of DMELs to quantify risks to other non-threshold hazard endpoints such as respiratory sensitisers, immunotoxicants, neurotoxicants, and endocrine disruptors. Moreover, to ensure safe usage levels, a traffic-light / two-tier approach, adopting both acceptable and tolerable risk thresholds is being assessed.

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Overall, BusinessEurope evaluates the approach to widen the use of the DMELs concept as not very realistic given the lack of data for some hazardous endpoints and lack of capacity for companies to develop DMELs with the same quality as ECHA or the Committee for the Risk Assessment (RAC). These scientific bodies need around 12-24 months to develop such information, based on existing scientific studies. If this work has to be undertaken by companies (incl. SMEs), it is safe to assume that it will take them at least the same time and effort. Consequentially, there is a limitation in the number of DMELs that can be derived.

BusinessEurope supports the risk-based approach for non-threshold carcinogenic substances. If certain prerequisites such as a comprehensive database, detailed knowledge about Mode of Action (MoA), studies to derive a dose response relationship, are given, DMEL calculation is in principle possible and can be an option.

Moreover, there is no strong evidence of the benefits an extension of the DMEL approach to further hazard categories (e.g., endocrine disrupters, neurotoxicants, immunotoxicants and respiratory sensitisers) would bring, as these substances are not per-se non-threshold substances. Even if it may be - in some cases - difficult to quantify the threshold, they should not be treated systematically as non-threshold substances.

The DMEL-approach is meant for non-threshold endpoints/mutagenic carcinogens and should not be used without the explicit knowledge that a substance exerts a non-threshold toxicity. Decisions, whether scientific dose response relationships allow for a sound DMEL calculation, must be made carefully, and evaluated on a case-by-case basis.

4. Generic Approach to Risk Management (GRA)

The application of the "generic approach to risk management" (GRA) has so far been restricted to CMR substances in private consumer products (Article 68 (2)). In these areas, the European Commission can apply a simplified procedure to prohibit the use of substances due to their intrinsic properties (CMR) without a use-related risk assessment.

The European Commission now envisages to extend the generic approach to risk management to more hazard classes, namely the 'most harmful chemicals' as defined in the CSS[1], as well as to professional users to ensure their safety. Accordingly, professional users would no longer be allowed to work with any substances that are either carcinogenic, mutagenic or toxic to reproduction, category 1A and 1B – independent of the individual risk and in the absence of an individual risk assessment. Furthermore, as the GRA is likely to be extended to additional, new hazard classes, such as EDCs and PBT, it would further broaden the impact on consumers and professional users.

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The current restriction process under REACH allows for an appropriate risk management, targeting those substances and uses that pose an unacceptable risk. The existing procedure should therefore not be replaced by a generic approach, whereby substances and uses can be banned and restricted solely based on their intrinsic hazardous properties, irrespective of whether there is a risk to health or the environment. Regulatory decisions must continue to consider benefits, risks, and safe use conditions. In addition, there is an urgent need to keep restriction procedures transparent and comprehensible. Affected companies and industries must therefore be included in all steps of the process and be involved in comprehensive consultations.

→ *Need for a stepwise and transparent legal process*

With the extension of the scope, both in terms of hazard classes and use, there needs to be a full understanding of the impact that the GRA-based restrictions could have across different value chains. Having a stepwise and transparent process in place with upfront collection of data should ensure targeted and proportionate regulatory action without restricting substances for which safe use is secured. In addition, consultation on due time by the ECHA Enforcement Forum should be part of the legal process.

We welcome the European Commissions' suggestion for a preparatory document and stakeholder consultation to support refining of a generic restriction. We believe that these steps should be compulsory for any type of generic restrictions. For instance, upfront information collection would help to focus on the articles where there is a likelihood of a consumer being exposed to a particular substance. Upfront information might also demonstrate cases with no or limited exposure (e.g., when a substance is contained in a matrix). Preparatory work will ease further decision making, limit derogation requests and make sure the measure is proportionate and manageable from an enforcement perspective. The impact assessment should integrate all this to understand the net

[1] 'Most harmful' substances are defined in the EU Chemicals Strategy for Sustainability (CSS) as chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative; chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.

impacts of adding some steps at the early stage of the process, not only on efficiency but also on transparency. The GRA must be effective and focus on areas where a problem has been identified, with a focus on consumer uses with a high probability/frequency of exposure. The challenge must remain the control of risks according to the conditions of use, and therefore exposure.

→ *Extension of GRA to professional users*

While we understand the need to take a more preventive approach for consumers, particularly regarding vulnerable groups, the same level of exposure and therefore risk (i.e., combining hazard potential and exposure) should not be assumed for all professional uses. The activities performed by professional workers and the respective "professional use conditions" can be very similar to or even identical to those in the industrial sector. Professional use requires specific education, training, including task-specific instructions on how to safely manage hazardous materials. Some examples of professional uses include life-science business, medical personnel, physicians, pharmacists, auto-mechanic repair shops, construction workers, either in SMEs or in large businesses. Moreover, extending the GRA from consumers to all professional users ignores the significant difference in training, experience and risk management options accessible to those professional users e.g., through occupational health and safety measures: task-specific risk assessment, risk management according to the hierarchy of controls, mandatory instructions of workers and monitoring of potential exposures. Companies with business models on professional uses are responsible that the uses in their responsibility are described with operating conditions and risk management measures in the REACH registrations and communicated in the supply chain (with the safety data sheets)

In view of these different framework conditions, an equalisation of professional use with consumer use would not be justified. Rather, the focus should be on strengthening implementation and enforcement of existing OSH regulations, e.g., by establishing best practice guidance that helps practitioners and national enforcement bodies to interpret the regulation in a more harmonized way.

To strengthen the minimum level of protection for professional workers at risk, ensuring that the training of workers in line with the OSH framework directive considers safe chemicals management is also important. Occupational disease data should be used to identify professional user groups at risk.

Alternatively, specific criteria/qualifiers should be defined to assess whether a proper level of safe handling for different users is implemented or whether adjustments are required. In any case, the focus should be first on enforcing existing legislation such as OSH to improve education and safe handling of chemicals by professionals before considering banning the use.

If regulation is necessary in specific and exceptional cases, the use or risk management can be regulated within an individual restriction based on the existing REACH provisions (e.g., regular REACH restriction process (following article 68.1 of REACH), and only if regulatory options under OSH and related provisions are fully exploited. Only in this way can it be prevented that those professional uses are massively restricted without this being associated with an actual benefit for health and environment.

→ *Possible risk of lack of material availability for innovation & technical development*

Restricting the access of professional users to certain chemicals limits their innovation power and further technical development. This is particularly relevant for SMEs, dramatically impacting their competitiveness, while in turn failing to enhance the necessary expertise in safe chemicals management.

→ *Group approaches*

The use of group approaches could be beneficial. However, it is particularly important that substances or groups of substances are not banned independently of an unacceptable risk and, in the case of downstream users, that the timing of a group restriction allows for a data collection from the supply base. To make group approaches transparent and comprehensible, it must be clear which substances fall under the regulation (e.g., via substance lists with CAS numbers). Group approaches are also only justified if the substances in a group have homogeneous properties and a comparable risk profile, otherwise a restriction or another regulation of the entire group would be disproportionate. To be able to consider the effects of far-reaching group approaches in advance, impact assessments, in which socio-economic and technical aspects are also considered, are of particular relevance.

→ *Holistic discussion on risk management needed*

The extension of the generic approach to risk management (GRA) is part of the commitment of the EU's Chemical Strategy for Sustainability but currently not part of the revision of the restriction and authorisation process, even if it will have an enormous implication on the efficiency of these processes. In our view, the reform of authorisation and restriction cannot be adequately discussed without considering the parallel work on GRA and EUC, as both elements carry the potential to radically impact the framework of risk management under REACH. BusinessEurope thus advocates for a holistic discussion and assessment including GRA, EUC as well as the reform of the authorisation and restriction processes.

→ *Information on the environmental footprint of substances*

We do not consider that there is a clear added value in introducing an environmental footprint information into REACH registration dossiers. In contrast to physico-chemical properties or hazard properties, the environmental footprint of a substance may strongly depend on the actual production conditions (used upstream raw materials, environmental protection measures, use of by-products, re-use of resources). Furthermore, such a disclosure may allow to derive production costs for individual registrants as well as other commercially sensitive information and therefore risks falling under confidentiality rules. Lastly, the assessment would duplicate other work/databases or methodologies that are available elsewhere such as the product environmental footprint, ISO standards on life-cycle analysis, environmental product declarations for construction products, etc.

5. Authorisation & Restriction reform

The proposed reform of the REACH authorisation and restriction processes aims at a more efficient, less burdensome and faster system for regulating chemicals as well as more focused requirements for request for derogations and/or applications for authorisation. To achieve these aims, the European Commission has tabled various options in the inception impact assessment, some of which would result in major changes to the way REACH works today. BusinessEurope supports the overarching goal of the authorisation and restriction reform enabling authorities and industry to prioritise actions with the highest impact, while offering a flexible, efficient and straightforward process.

The impact assessment should clearly analyse for each of the different options whether the proposed changes would bring the anticipated results about proportionality, efficiency, transparency and predictability. Careful considerations about downstream users and especially the manufacturers of articles using chemicals is necessary to avoid further penalization of the European economy. For example, today, as articles are exempted from authorization, manufacturers can use substance listed in Annex XIV outside Europe to produce their articles and export them to Europe whereas a Europe-based manufacturer cannot.

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→ *Proposed options*

None of the three options as currently proposed for the reform provides enough clarity on how authorisation and restriction will be applied in practice. Rather than assessing and developing these options individually, we propose to combine elements of the different options that would help to meet the defined criteria/goals. The final "preferred option" could be foreseen to be a combination of different elements of the presented three options. In any case the preferred option must result in a regulatory system able to focus where regulatory measures brings the most benefits on prioritised substances. In particular, the following aspects should be considered.

In principle some positive aspects of the authorisation procedure should be maintained and not be replaced completely by a generic restriction process. In the past, the authorisation process has led to a controlled substitution of substances. In addition, the authorisation process offers companies the possibility to maintain uses if they are adequately controlled and no suitable alternatives are available. This must also be possible in the future.

Experiences from the past[2] show that the authorisation process would benefit substantially from simplification and clarification. The procedure has proven to be too lengthy and too resource-intensive for all parties involved. Furthermore, particularly short review periods pose a challenge for companies.

[2] E.g., the authorization process of Chrome VI and the individual and upstream (group) application requests that are partly due to various delays 5 years after the sunset date of the substance still not decided.

If the authorisation process is maintained, simplification for small quantities is urgently needed. Furthermore, it should be evaluated how efficiency, transparency and workability could be enhanced, particularly for SMEs.

For spare parts, the principle of "repair as produced" should be introduced. A simplified approval procedure for a few spare parts for very long-lived and complex products is still associated with too high barriers for the companies concerned and is not proportionate. A possibility to apply for exemptions even after the latest application date (as known in today´s authorisation process) should be introduced to take latest developments and information into account.

Regarding other options, any combination must be done very carefully and the advantages of the two procedures must be clearly maintained. This is especially important when the procedure is combined with the Generic Risk Assessment Approach and the 'Essential Use' concept. Under these conditions, it can be possible to establish a level playing field between EU and non-EU companies and to maintain the well-functioning parts of the processes. In order to always select the best and most efficient risk management measure/regulatory option, a transparent procedure must be established right at the beginning of the regulatory process (e.g., RMOA).

→ *Proposed reform of Candidate List and fee system for Substances of Very High Concern (SVHC)*

Envisaged as a horizontal option, potentially applicable to all reform proposals, the future role of the Candidate List is seen as a tool to prioritise substances for regulatory action, in particular for restrictions, but also for non-REACH regulatory measures.

The European Commission also suggests a mandatory notification for all actors in the supply chain using substances of the candidate list to collect more data on uses and exposures. BusinessEurope understands that to make more tailor-made regulatory decisions and confirm potential concerns and regulatory needs, more data may be required. However, it would be too early in the process and too inefficient to collect data for all substances on the candidate list and from all downstream users on a regular basis. In addition, questions remain on how it would apply to parts of the supply chain outside of Europe. Therefore, to keep the process of data collection manageable, only substances where there is a need for regulatory action identified should be added to the candidate list, looking at elements such as hazard, uses and potential exposure.

Another proposal aims to introduce an initial notification and annual fee for manufacturing or using SVHCs of the Candidate List to incentivise substitution. BusinessEurope has strong cautions against this, as continued production and use of certain SVHCs may be deemed essential in certain applications. It is not clearly demonstrated that fees will help to incentivise substitution activity in industry sectors. Unnecessarily penalising manufacturers and downstream users would undermine the competitiveness of EU actors on the global stage and potentially result in premature obsolescence of substances and formulations (as well as products making use of the substances), many of which may be low volume and therefore already a risk for obsolescence by formulators. Moreover, this approach would involve considerable bureaucratic effort. This would pose unreasonable challenges for SMEs in particular.

→ *Exemptions and derogations*

For regular restrictions under Article 68.1, the option for both authorities and industry (either jointly or individually) to apply for derogations should be evaluated in the impact assessment to see which benefit this would bring to the system.

For fast-track restrictions under Article 68.2, the CARACAL paper limits derogations only to those uses which are essential for the society. Firstly, essential use should not be the only factor for granting derogations. It should also be possible to request derogations where safe use is demonstrated (both for generally applicable derogations and for individual derogations). Secondly, applying for a derogation should be possible upfront and after the adoption of a restriction.

The process for requesting derogations has not been defined yet. Potentially, elements from the current authorisation scheme (timing, content, scrutiny and decision-making) can serve as a basis, with modifications to accommodate the new system. This should include the possibility for exceptions even after the last application date (see comment above).

6. Interface between REACH and OSH legislation

The review of the REACH regulation is clearly linked to other bodies of EU legislation, in particular occupational safety, and health. We welcome the European Commission's intention to clarify the interface between REACH and the Occupational Safety and Health (OSH) framework, as this causes confusion for employers and workers in terms of the applicable rules. It is important to recognise that OSH legislation is part of EU social policy and is therefore based on the setting of minimum EU level standards, complemented by national legislation. It is also important to see the specific OSH chemicals legislation (e.g., the Chemical Agents Directive and the directive protecting workers from exposure to Carcinogens, Mutagens and Reprotoxic substances) in the broader context of overall EU OSH legislation, in particular the framework directive, which sets employers' obligations on risk assessment for all OSH risks at the workplace.

In general, the review should aim to improve the coordination between the different pieces of legislation, whilst clearly distinguishing between them. This should include developing transparent procedures and criteria to be used when selecting the most appropriate substance specific regulatory options. Where risks for workers are identified, OSH regulatory and non-regulatory options should be the preferred choice to achieve an adequate protection level for both professional and industrial workers. In turn, if a substance is deemed a general risk to people and the environment, REACH allows for a holistic review of all use cases based on the available exposure scenarios. Should this analysis demonstrate the need for additional protective measures for professional and industrial uses, REACH only allows for complementary options to an OELV, e.g. mandatory training programs, without relegating the specific OSH regulation.

It is crucial to note the adoption of limit values in the form of restrictions that cover the same scope as an occupational exposure limit value (OELV) will be detrimental to their effective implementation. In particular, restrictions establishing derived no-effect levels (DNELs) would completely bypass the long-standing procedures to develop OSH legislation by most notably foregoing the crucial contributions of the social partners in the tripartite Advisory Committee on Safety and Health. This would furthermore contradict the European Commission's previous statement that REACH is not intended to set occupational exposure limit values, as reflected in the explanatory memorandum to the second revision of the Carcinogens and Mutagens Directive.

Concerning DMELs, it is important to note that the determination of an acceptable level of excess risk to be implemented cannot be carried out across all substances, as a substance-specific impact assessment and evaluation of the feasibility are required.

Developing a DMEL means to develop risk-dose relationships that are accurate enough to provide for confidence. The scientific bodies need around 12-24 months to develop such information, based on existing scientific studies. If this job has to be undertaken by companies (incl. SMEs), it is safe to assume that it will take them at least the same time and effort. Consequentially, there is a limitation in the number of DMELs that can be derived.

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REACH restrictions and OSH directives should be viewed as complementary tools, with different existing legal procedures and scopes. In the context of REACH, the primary

objective of the implementation of Exposure Scenarios is to contribute to the safe use of a chemical through a generic approach, whereas the OSH legislation's key aim is to demonstrate that all risks, including risks associated to all chemicals covering Process Generated Agents, are adequately controlled for task specific workplace activities. Safety Data Sheets and exposure scenarios are a key tool for OSH practitioners.

Instead of moving the OELVs process entirely or partly under REACH, it is crucial that this procedure remains under the responsibility of DG EMPL and subsequently the Advisory Committee on Safety and Health. In this regard, the substantial expertise that the tripartite Working Party on Chemicals (WPC) provides to the OELV-setting process of priority chemicals should not be undermined or side-lined as the tripartite dialogue between employee representatives, employer organisations and national governments is required specifically to address the feasibility of proposals as well as socioeconomic issues.

For OSH-related REACH restrictions, the proof of an unacceptable level of risk for workers is an essential prerequisite for demonstrating that action is necessary beyond any measures already in place, quoted from REACH Art. 69. Therefore, for substances regulated by the CMRD, harmonized limit values should always be set as BOELVs pursuant to the CMRD and not by way of a REACH restriction. Similarly, BOELVs can be set for substances, which are regulated by the CAD. The need to set harmonized limit values can be fulfilled using OSH instruments. If in addition to OSH legislation, occupational limit values are in practice set also by REACH restrictions, the coherence of the legislation is disrupted. This risk causing confusion, administrative burden and legal uncertainty.

In conclusion, there is a need to keep separate REACH and OSH legislation except for particular reasons evaluated case by case and on the basis of a binding list of criteria to be used when determining when OSH-related REACH restrictions are expedient or not. This list should be developed by appointed representatives from the WPC (all interest groups) and ECHA/ENV/GROW/EMPL and agreed by the three policy Directorates General (EMPL/ENV/GROW). A valid alternative would be to give preference to OSH legislation for the risk assessment and risk management of professional and industrial uses of chemicals in relation to worker protection.

7. The 'Essential Use' concept

The 'Essential Use' concept (EUC) was originally established within the legal framework of the Montreal Protocol for a very homogeneous group of substances with proven toxic and very environmentally damaging properties leading to unacceptable risks.

Whilst the Montreal Protocol has a narrow scope and addresses unacceptable risks (not simply hazards), the European Commission intends to take a more precautionary approach (no longer on an *ad-hoc* basis) and apply the EUC on a hazard basis, i.e., all 'most harmful' chemicals, and ban their consumer and professional uses, except essential ones, regardless of whether they actually present a risk.

In other words, the European Commission is expected to implement the concept in the context of the exemptions from restrictions (following Art. 68 of REACH) to only admit those uses of substances that are needed for health, safety or is critical for the functioning of society and if there are no alternatives. The decisive factor would therefore be the hazardous properties of the individual substances or the substance group.

In the context of the upcoming revision aiming to improve the decision-making, it is paramount to ensure the possible integration of the EUC in a way that can enhance the system's ability to regulate harmful substances without putting brakes on much needed innovation and competitiveness of industry.

BUSINESSEUROPE RECOMMENDATIONS

→ *A robust definition of 'essential use'*

The definition of what the term "essential use" could mean, or which uses are "essential" to society, is a difficult exercise. It inevitably leaves the door open to different interpretations, which sometimes can be linked to societal choices considerations. Also, from a practical point of view, it is difficult to define ex-ante what is deemed to be essential today and what might become essential later. It is safe to assume that we cannot know definitively on which technologies the progress of our society will be relying on decades from now.

Uses to be considered "essential" to society should not be arbitrarily defined by regulators. Defining essentiality should be a matter of societal debate and at the end political decision. It thus requires a proper assessment and discussion in a committee with representatives of the European institutions, industry, including SMEs, as well as civil society and academia. This committee could be specifically empowered to assess essential use and give recommendations to the European Commission.

This discussion must be initiated before the concept is used for the first time and should continue to reflect the evolution of the "essentiality" definition: any EUC framework will need to account for the fact that essentiality is dynamic and subjective, and its impact not limited to the EU. With this objective, the European Commission should establish a transparent and accountable dialogue, i.e., all relevant stakeholders should be involved, and the discussions should be science-based. What is more, the assessment process itself should also be reliable, transparent, and proportionate to the identified risk.

Further, the essential use definition must not be a barrier to innovation. Research and development need transparent, stable and understandable regulation. It must be ensured that a definition of essential use defined today does not restrict emerging and future technologies, incorporating changing scientific and technological developments and considering availability of substitutes.

The criteria for 'Essential Use' should be broad without excluding entire industry sectors and assessed specifically for substance by substance and use. Besides the functionality and wellbeing of the society, societal and cultural aspects should be considered as well as sustainability criteria. In addition, the aspect of safe use should be considered in this new concept.

The difficulty to define clearly the 'Essential Use' concept e.g., through unambiguous criteria, could lead to unclear and sometimes arbitrary decisions in regulating substances, which could force EU companies to invest into research and innovation outside of the European Union. It could also considerably reduce the availability of substances on the EU market which can have a negative impact on the innovative capacity of Europe's industry in all sectors.

→ *Risk of regrettable substitution and undermining regulatory efficiency*

The automatic application of the EUC based on hazard classifications could lead to the possible substitution of products by less sustainable, less performant or less durable materials. How so? With this concept, the market would be pushed towards using alternatives that may be less sustainable (environmental impact through e.g. higher lifecycle CO_2 emissions, an increasing amount of waste or lack of recyclability) and thus lead to a substitution that would be regrettable from a broader sustainability perspective and potentially in conflict with the EU Green Deal objectives (e.g. lead in bearings and lead-acid batteries, use of fluoropolymers for heat and abrasion resistant non-metallic components in machinery, cobalt in hydrodesulfurization catalysts). Applying the EUC independent of a risk assessment, only based on hazardous properties will lead to the fact that safe uses and products can no longer be realised.

Finally, the international competitiveness of EU's industry could be severely hampered. An unfounded ban of the use of a hazardous substance means reducing the technological toolkit available to EU manufacturers. This would lead to a substantial performance gap between products manufactured within and outside the EU, thus reducing the competitiveness of the former on the global market. In addition, an essential use exemption/derogation could bring about severely reduced volumes and therefore question the economically reasonable production within the EU. This would lead to higher vulnerability in case of disruptions of the supply chain.

→ *Slowdown of regulatory processes*

The CSS envisions to streamline, facilitate and speed-up current processes. Contrary to the good intentions of improving the efficiency and speed of authorisation / restriction, there is a risk of delaying regulatory decisions. The wide application of the EUC to all substances with certain hazardous properties would lead to the need for an assessment of the different uses of all these substances. Considering the different applications of each substance used for many different applications, the regulatory process will be

delayed as requiring a strenuous and granular “essentiality” assessment per individual substance and its subsequent use along various value chains. The impact on the regulatory process and its duration cannot be underestimated and the effects on regulatory efficiency necessitate a realistic assessment of applying the EUC, carefully examining all the hurdles this process would encounter.

However, these delays are unjustified as there are products which can be safely used and recycled regardless of the toxicity profile of included substances. If the EUC is introduced in the way envisaged in the CSS, the already limited regulatory resources would therefore be deployed to assess essentiality of uses and would not be dedicated in a more focused manner to address risk in consumer uses. Hence, the resource issues identified in the REACH authorisation/restriction process would only become worse.

→ *Implementing the EUC in a targeted manner*

Considering the ongoing work of the European Commission and having in mind the risks of a broad application of the EUC, including unclear concepts and provisions in legislation, we recommend maintaining the exceptional approach of the Montreal Protocol. This means implementing the EUC in a targeted manner complementing the existing risk-based regulatory approach and therefore only in case of:

(1) unacceptable risks to health and environment,
(2) lack of adequate control measures and
(3) feasible alternatives with the same characteristics including the sustainable profile exist.

The EUC should be used to prioritize and manage GRA substances. When a clear demonstration of safe use of a substance classified as a substance of very high concern is possible, based on the scientifically valid risk assessment – the subsequent assessment of essential use is not necessary. The purpose of chemicals legislation is not to limit the use of chemicals to what is considered "essential", but to ensure that the chemicals are safe to use. According to the "safety first" principle, if the use of a substance is safe, the essential use analysis is not applicable. Lastly, uses for which safety is regulated otherwise, e.g., intermediate use by occupational health and safety regulations, in general do not need to be covered under this concept.

Further information about BusinessEurope’s views on the EUC can be found here.

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