SUBMISSION PAPER

April 2022

Cefic supports the goals of the Chemicals Strategy for Sustainability and we are ready to work with the EU institutions, national competent authorities and downstream users to improve REACH and propose solutions that build on the current strong framework.

The overarching goal of this revision process is to continue reducing the exposure to the most harmful chemicals. It should lead to a predictable regulatory system which will enable industry to prioritise actions that would substantially improve health and environment protection, allow to develop safe and sustainable alternatives where needed while at the same time offering flexible, efficient and straightforward processes.

With REACH and 40+ pieces of EU chemical legislation, the EU has the most comprehensive chemical legislation in the world. REACH has been shown to be fit for purpose[1] and to ensure a high level of protection of people's health and environment despite few gaps in its implementation and enforcement (Second REACH Review, 2018, see Section 2.1 note 13; REACH baseline study 10 years update, 2016).

Since the adoption of REACH, the European chemical industry has invested significant efforts in ensuring compliance and improving its implementation, including a voluntary Action Plan[2] for review/improvement of registration dossiers to help assess and fill data gaps, if any. In doing so, the European chemical industry wants to cooperate and maintain a constant dialogue with stakeholders and work on areas that require improvement.

Our industry supports the European Green Deal and the EU's ambition to become climate neutral by 2050. Reaching this goal will only be possible with the help of climate-neutral and circular economy solutions developed by our industry.

Unlike other sectors that are facing a twin "digital and green" transition, our industry's challenge is in fact quadruple. In addition to climate neutrality and digitalisation, we must also factor in circularity objectives and implementation of the Chemicals Strategy for Sustainability (CSS) – all happening at the same time, and all requiring significant investments.

At the time of writing our industry is also facing another existential challenge: uncertainty regarding energy supply following Russia's invasion of Ukraine and the economic sanctions imposed by the EU on Russia, with possible economic consequences for the EU as a whole.

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[1] "The evaluation has identified a number of shortcomings and key issues that hamper the achievement of REACH objectives…The issues requiring most urgent action are: non-compliance of registration dossier, simplification of the authorisation process, ensuring a level playing field with non-EU companies through effective restrictions and enforcement, clarifying the interface between REACH and other EU legislation , in particular that on occupational safety and health (OSH) and on waste."

[2] REACH Dossier Improvement Action Plan: https://cefic.org/policy-matters/reach-dossier-improvement-action-plan/

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Considering all these elements, we strongly believe that maintaining policy coherence, prioritising action and promoting incremental change during this REACH revision vs. completely overhauling the current well-functioning system is creating a strong business case for investments into modern and sustainable EU chemical industry.

We believe that the current REACH revision is an opportunity to further improve the current framework by making it more efficient, consistent and coherent with other pieces of EU product safety and environmental law and focus on elements that truly need improvement as identified by the Second REACH Review.

In this document you can find our input on several key changes to REACH proposed by the European Commission. Our input takes into account information made available by the European Commission during the past few months[3] and builds upon publicly available data and evidence[4]. Where needed alternative policy options are being suggested.

[3] For example proposals for policy options presented at CARACAL and/or information shared in the context of several stakeholder workshops organised by the European Commission.

[4] See reference list at the end of our submission.

Contents

1. Information requirements for critical hazards and Information on substances marketed at the lowest tonnage level

Need for a paradigm shift in safety assessment and transition towards new approaches to safety and hazard assessment

Animal-based approaches are rapidly becoming unacceptable to large parts of society[5]. New Approach Methodologies (NAMs) and integrated assessment to testing approaches (IATA) are reflective of 21st century science and already today form the basis for assessing pharmaceuticals products, cosmetics, food, transport and energy systems (Fentem et al., 2020). They are applied in tiered, flexible regulatory framework without sacrificing the robustness of the decisions made.

While acknowledging that it is not possible to fully move away from *in vivo testing*, we believe a similar mindset shift is needed in the area of chemicals policy for the further development, use and regulatory acceptance of NAMs that are protective and predictive of human and environmental safety. This is particularly important for the upcoming registrations of certain polymers and new, innovative chemicals. It can be a triple win for industry, regulators and society at large.

A progressive vision towards a change in regulatory thinking and application, as articulated by the European Commission's Joint Research Center (JRC) when presenting options to the Competent Authorities for REACH and CLP (CARACAL) (CA/09/2022), should be tackled and specific actions taken beyond the current REACH revision, towards this vision, in the form of a roadmap.

Make every effort to identify where animal-based testing may not be necessary in maintaining a high level of protection

Legal barriers to the use of NAMs for replacing animal tests and the lack of confidence in the ability of the new methods to predict safety are the most challenging hurdles impeding the shift to using modern safety science (Fentem et al., 2021). In the short term, the REACH revision offers an opportunity to give more prominence to New Approach Methodologies (NAMs) so that the principle of animal testing as last resort is taken to the next level.

Without compromising on the protection of humans and the environment, we recommend that:

- **Data** are required and generated if they are of value **for informing on safety**.
- Latest scientific advances are exploited, and **use of predictive and validated NAMs maximised**. To be successful in the current regulatory framework, NAMs are **best applied alongside human/environmental- relevant and exposure considerations.**
- Huge amounts of (eco) toxicological data and the knowledge from 10+ years REACH are used effectively. Such data should remain available for **incorporation into future NAM toolboxes** for designing and assessing new molecules (e.g in read across, QSARS and quantitative *In vitro* to *in vivo* extrapolation)
- Unnecessary **animal testing is avoided**. The development of effective baseline and metrics can help track progress on the use of vertebrates, build the basis for a shared accountability of ECHA, Member States and registrants to use animal testing as last resort.

[5] European Parliament's call for an EU-wide action plan to phase animals out of science and regulation

Current scientific and technological advances allow for generating data that are protective and predictive of human and environmental safety without relying on additional animal testing (Ball et al., 2022) (Paul Friedman et al., 2020). New Approach Methodologies (NAMs, defined as any technology, methodology, approach, or combination of them that can provide information on chemical hazard and safety assessment to avoid the use of animal testing (Wheeler et al., 2020)) have the potential to achieve faster and easier regulatory review (Ball et al., 2022). Whilst acknowledging that animal studies cannot be fully avoided now, we need to accept that the regulatory framework for chemicals safety evolves (Fentem et al., 2021). We believe that NAMs should not be validated (and compared) to animal tests, given that the goal is to predict effects on humans, and not on animals.

We support Europe's Beating Cancer Plan and NAMs have a role to play in this context. The understanding of the mechanisms by which substances elicit genotoxic or non-genotoxic carcinogenicity is increasing. Tools, methods and methodologies are becoming more available to investigate key events of carcinogenicity. NAMs offer value in providing information related to mechanisms of biological activity. Since it is recognised that the information obtained from the rodent chronic bioassay cannot be replaced by one single NAM, a framework to organise the evidence is required: thereby, NAMs are used within a larger process that integrates data from multiple sources in decision-making frameworks (Felter et al., 2021). NAMs can provide benefits for assessing more chemicals against critical hazards (in this case carcinogenicity), and circumvent the critical question of transferability of animal data to humans by replacing it with a more human-relevant approach.

With more chemicals being assessed for safety against critical new hazards, any new test battery is most effectively used in exposure-led approaches (including grouping, read across and optimised use of existing, historical data) ensuring that unnecessary animal testing is truly avoided (ECETOC Technical report TR-137, 2020; Hernández-Jerez et al., 2021; Masjosthusmann et al., 2020)

We suggest to ***change the legal text of REACH Annex XI 1.1.2 bullet point 1) into "Adequacy for the purpose of ~~classification and labelling and/or~~ risk assessment"***.

We share the views of the Joint Research Center[6] that the legal text could specify the endpoints in a generic manner to avoid the need for frequent ATPs to Regulation EC 440/2008, while the methods and test batteries themselves could be specified more efficiently elsewhere. Classification and labelling is not a goal in itself, it follows from data. The goal is robust safety assessment. Developing performance criteria, taking into account the uncertainties and limits inherent of both conventional (animal-based) methods and NAMs could additionally provide flexibility to apply the best available techniques. Such adaptations to the current framework are required also as a single NAM will rarely be applicable to all REACH substances.

[6] Doc. CA/ 09/2022 at ad-hoc meeting of the Competent Authorities for REACH and CLP (CARACAL)

We need NAMs to support innovation

Last but not least, NAMs have the potential to boost innovation: already today companies apply NAM-based predictive tools for pre-assessing new chemicals (Redman et al., 2021). If applied wisely, we expect further development and regulatory acceptance of NAMs to accelerate development, hazard and safety assessment of new molecules under REACH (see EU Chemical Industry transition pathway[7]). In addition, the assumption that adoption of validated and human relevant NAMs would harm competitiveness (Q 1.4) is speculative.

Chemicals safety assessment (CSA) for all registered substances driven by exposure considerations

We support conducting a proportionate chemicals safety assessment (CSA) for all registered substances if the requirements for such a CSA are driven by exposure considerations (the hazard characterisation needs arising from there) (ECETOC Technical report TR-137, 2020). An approach that is just asking for more hazard data for low volume chemicals is insufficiently targeted and incompatible with the principle of animal testing as last resort. It is also a barrier to innovation as new chemical development always starts at small scale. The Impact Assessment needs to look specifically at small businesses and start-ups from an innovation perspective.

[7] https://cefic.org/media-corner/newsroom/the-eu-chemical-industry-embarks-on-a-green-deal-transition-pathway-in-a-make-or-break-moment-for-the-sector/

2. Information requirements for polymers

Align with globally harmonised approaches for polymer assessment and focus resources on what matters

Polymers are different from and more complex than traditional substances, both in composition and in properties. This means **the current substance registration scheme under REACH cannot be re-applied to polymers**. The fundamental question is how to **group and compare polymers**: this determines if and how registrants can work together and whether data are representative. Combined with the fact that polymers, due to their large molecular weight, have reduced bioavailability and potential for hazards, Cefic strongly advocates that any polymer registration scheme needs to be **pragmatic, workable and harmonised with current approaches used in other areas of the globe**. As such, any proposal to register should focus only on Polymers Requiring Registration (PRR) defined by **properties associated with a higher likelihood of hazard.** Polymers recognised globally as Polymers of Low Concern (PLC) based on the experience of other (non-EU) agencies following a multi-year evaluation process, have to be excluded from REACH registration not to jeopardise the globally aligned approaches for polymer assessment, and to avoid assigning EU agency resources on polymers which present a low likelihood of hazard and risk.

Whilst the exact number of polymers on the European market is not known precisely, previously conducted estimations have identified roughly around 200 000 individual polymers on the market (however estimations can go as high as 400 000). With this high number of expected polymer notifications, the **requirements of a polymer notification step need to be chosen extremely carefully.** In addition, there will be a need to **build expertise and capacity at ECHA and within national authorities** on polymer chemistry to support polymers under REACH. The Impact Assessment should take this into account.

The registration of polymers is also an opportunity for better generation of data in a **targeted approach that supports risk management** and applying the principle of **animal testing as a last resort**.

The current approach of REACH for non-polymeric substances practically disregards exposure during the registration and (dossier) evaluation steps. The default approach for human health is to test all substances based on formal volume triggers regardless of whether there is any exposure or whether the testing results could result in changes to the risk management measures or not. The REACH processes are set up in a way that they almost always result in the default approach following tonnage which is not necessarily a proxy for exposure to humans. Also, the current formal provisions for derogations or waiving are rarely effective in avoiding non-value-added animal studies. To make polymer registration efficient towards its protection goal and act responsibly towards experimental animals, the approach cannot be that testing is the default for high volume polymers. The only effective approach to prioritise testing for human health endpoints is a combination of a base set of hazard data and additions triggered by exposure considerations, as already in place for environmental and ecotox endpoints. Additionally, both uncertainties in risk management and animal testing should be reduced by allowing group registrations of PRR with similar hazards. Depending on the approach for grouping, the final number of registrations could be around 12 000. A polymer grouping and testing framework, with no limits placed on the size of groups, needs to be developed considering the complexity of the polymer universe, building on the work from ECETOC (ECETOC Technical Report TR 133-1, 2019; ECETOC Technical Report TR 133-2, 2020; ECETOC Technical Report TR 133-3, 2021).

Adopting such framework will allow a targeted approach that supports risk management and sets animal testing as a last resort based on state-of-the-art methodology.

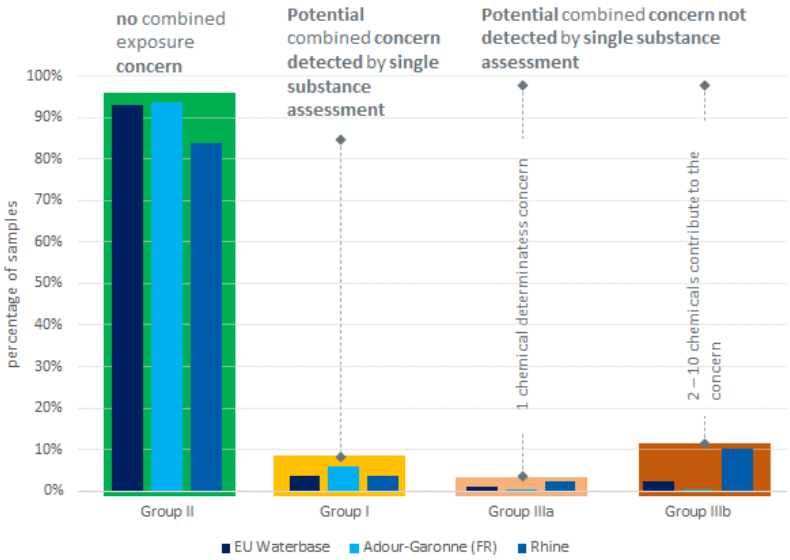
Once grouping is established and confirmed using a base set of hazard data, depending on exposure, further testing may be needed. Animal testing should be considered only in a second stage, after grouping is confirmed and co-registrants can get together to generate animal testing, if needed.

Such an approach would ensure a high level of protection while significantly reducing the number of animal tests required to register polymers.

3. Introduction of a Mixture Assessment Factor

Available data supports a targeted implementation of the Mixture Assessment Factor (MAF) for environmental risk assessments

Over the past decade, considerable research has been carried out to gain a better understanding of the issue of combined exposure to unintentional mixtures. One of the latest and most comprehensive research in this field, conducted by Arche Consulting, made a detailed review of monitored mixtures of chemicals in surface waters (the study was commissioned by Cefic; Arche Consulting & VITO, 2021).
The study shows that only **in a limited number of cases**, environmental levels of chemicals might point to a **potential combined exposure risk** that would not be identified by applying currently applicable assessments and regulatory regimes [see p. 30 – results graphically represented below].



In case a potential combined exposure concern is identified (ca. 10% of all samples), half of these would be detected by the current single substance assessments. Where this is not the case, combined exposure risk estimations are dominated by **a few substances** already largely managed by specific regulatory frameworks[8] [see p. 25] and heavily depend on local factors [see p. 19].

The study provides evidence that a broad-brush approach such as **a generic mixture assessment factor** (MAF) to be applied to all chemicals, **is not the right solution**. It would not provide for the targeted work needed to identify combined exposures of potential concern.

Cefic has developed a decision tree to help decide whether the application of MAF for a chemical is justified or not when running an environmental risk assessment (see Appendix A). The decision tree includes a combination of straightforward hazard and exposure criteria and can easily be integrated into environmental risk assessments done under a REACH registration.

[8] For example the Water Framework Directive, Industrial Emission Directive or REACH authorisation.

If the outcome of the decision tree justifies the application of a MAF for a specific substance, the magnitude of the mixture assessment factor(s) to be applied must be underpinned by data. Different methods have been suggested to derive assessment factors using surface water monitoring data. All methodologies apply their own logic and assumptions and thus result in different outcomes. A review (Arche Consulting, 2021) of different methods **to derive assessment factors** shows that the so-called **'Maximum Cumulative Ratio' (MCR) is by far the most robust method** [see p. 36-38]. The size of a MAF must reflect the findings that in a reasonable worst-case, only 2-3 substances contribute to combined exposure concerns [see p. 19 - 20].

More work needed to develop knowledge on relevant combined exposure to humans

Most of the information on exposure of humans to chemicals (including legacy chemicals such as dioxins and PCBs) originates from human biomonitoring (HBM) studies. The Flemish Institute for Technological Research (VITO) did a review of available HBM studies, including the data collected under the HBM4EU project (Arche Consulting & VITO, 2021). The review indicates that available studies have gaps in reporting transparency, data accessibility and availability. These deficiencies hinder the assessment of relevant combinations of chemicals to which individuals are exposed. Nor do available data allow suggesting an appropriate regulatory approach. Similar conclusions were drawn by the JRC[9].

Several EU-funded research projects[10,11] are ongoing to obtain more precise information on human exposure to chemicals. The JRC is taking a leading role in this. It can be expected that screening and refined risk assessment approaches will become available in the next couple of years.

In this context, it is important to keep in mind that the scenarios where high combined exposure of humans to chemicals can occur, are already addressed today. EU Occupational Health and Safety legislation includes a legal obligation to assess and control combined exposure to chemicals at the workplace, complemented by EU rules to protect vulnerable groups[12]. Guidance documents[13] have been developed by the European Food Safety Agency (EFSA) to support risk assessment of combined exposure to chemicals for all relevant areas within EFSA's remit. The European Commission's staff working document on mixtures (European Commission SWD, 2020) does not indicate that these existing practices are failing and should be replaced or complemented by another approach such as a MAF. So building on what exists is a better starting point.

[9] Supporting the Commission in developing a proposal for introducing a Mixtures Assessment Factor in REACH, workshop organised by Wood, 24/11/2021.

[10] European partnership for the assessment of risks from chemicals. One of the objectives of PARC is to develop practical approaches for regulatory risk assessment of single, aggregated or combined exposure: https://www.anses.fr/en/content/european-partnership-assessment-risks-chemicals-parc

[11] PANORAMIX-project to develop an innovative tool or chemical mixtures exposure assessment - https://cordis.europa.eu/project/id/101036631

[12] For example adolescents or pregnant and breast-feeding women.

[13] EFSA various guidance documents for human risk assessment of combined exposure to multiple chemicals: https://www.efsa.europa.eu/en/topics/topic/chemical-mixtures

A generic MAF can result in significant business impacts

A case study analysis done by Ricardo (Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability, 2021) assessed the potential impact that businesses may face from the application of a generic MAF. This analysis reveals that the introduction of a MAF of 10 could have substantial implications on the chemicals industry, with knock-on implications across the supply chain and wider economy (see p. 16-19].

These two case studies show that the introduction of a MAF of 10 could result in significant turnover losses against the baseline. For example for those 2 case studies, in the year 2040, central estimates would suggest turnover (or market) losses valued at around 50 million euros and 3 billion euros (in constant 2020 EUR), or 18% and 50% lower than the baseline scenario respectively. These impacts would only be exacerbated by the additional regulatory burden that the registrants would face and would have direct implications on the EU-27's GDP - potentially resulting in direct losses of billions of euros in value added.

Further, the effects on the chemicals industry would also result in potential negative impacts on competitiveness and strategic dependency of the EU-27 industry, when compared to the baseline. There would likely be a shift towards increasing imports of final products, increasing the dependency on third countries for chemical substances and/or products previously manufactured and used in supply chains across the EU. As a result, many supply chains would be affected and potentially disrupted.

Major concern on the increased need for animal testing

One result of industry attempting to accommodate the introduction of a MAF will be the generation of new hazard data (Ricardo 2021; ECHA presentation 2020; Wood workshop report 2021). Doing so would reduce the use of assessment factors for deriving reference values and, hence, compensate for the MAF. Generating new hazard data will most likely increase animal testing. This is in direct contradiction to REACH legislation making animal testing the last resort for filling data gaps. The actual impact on animal testing will be directly proportional to the size of a MAF, therefore, the potential impact of a MAF on animal testing must be integrated in the ongoing Impact Assessment.

4. Reform authorisation / restriction

Introduce an overarching vision of how to regulate the use of chemicals

Options to reform authorisation/restriction largely focus today on reconciling existing practices and processes (CA/03/2022). In doing so there is a clear risk that feasibility and workload for authorities and industry, which are the key drivers for reforming the current processes (European Commission background paper; 2021) will not be adequately addressed. We fail to see how current suggested policy options will bring the envisaged improvements.

For example, by changing the procedure to ban Substances of Very High Concern (SVHC) from Annex XIV listing to fast-track restrictions, there is a risk of transferring the administrative burden linked today to authorisation to the restriction process. A high workload for processing derogations (authorisations) will remain which is one of the most resource intensive parts of the current processes (European Commission background paper; 2021). Some suggestions are made to simplify processes for assessing authorisations/derogations. They rely heavily on the essential use concept as a way to regulate chemicals, which would overturn the precautionary principle. It is also unclear whether the essential use concept would lead to the necessary simplification.[14]

To bring real improvements on efficiency and effectiveness one needs to move to a system which can, more effectively, enable industry and authorities to prioritise actions with the highest protection benefit, and allows to choose and practically implement the best solution to control exposure or risks to humans and the environment.

The regulatory approach sketched out in Appendix B seeks to introduce an overarching vision of how to regulate the use of chemicals. It builds on the European Commission thinking and the REACH Review findings, draws upon today's available regulatory toolbox[15], introduces a system of continuous improvement and covers the different stages of the life-cycle of a substance, from manufacturing to waste management and recycling.

If well implemented, the proposed approach will:

- identify the cases where regulatory action brings the biggest benefit taking into consideration available resources,
- generate additional detailed information in a targeted manner on uses, exposure at different life cycle stages, alternatives etc., early on into any regulatory process (addressing a well-known area for improvement under REACH),
- support the "one (group of) substance one assessment" (OSOA) approach[16],
- limit the need for ex-post derogations and the workload for authorities to process them through implementation of the most effective regulatory action for all life-stages,
- Enhance the existing process of candidate listing and hence significantly reduce the need to gather information on uses and exposure via substance evaluation as it would be collected during the process.

[14] see comments on using the essential use concept as a screening approach in paragraph 6.

[15] As to some extent already applied by ECHA when publishing 'Assessment of regulatory needs list' https://echa.europa.eu/assessment-regulatory-needs

[16] Cefic views on OSOA approach: https://cefic.org/library-item/cefic-view-on-one-substance-one-assessment-osoa/

5. Generic approach to risk management

Need for a comprehensive impact assessment

The Commission has presented several options to implement the extension of the generic approach to risk management in the REACH Regulation (CA/19/2022). The options presented will be subject to an Impact Assessment.

As the envisaged extension of the generic approach to risk management can have a significant impact (see below) it is critical that the Impact Assessment looks into the benefits of existing generic approaches to risk management and clearly indicate the expected and substantiated benefits of extending it.[17] On the impact side, consequences for the whole value chain must be mapped including consequences of indirectly banning certain end-products. In addition, the Impact Assessment must integrate the European Commission proposals to reform authorisation/restriction, the extension of bans to exports[18], and to introduce the essential use concept. It is crucial to evaluate and discuss the implementation of all proposals holistically and not in isolation.

Only by doing so will the Impact Assessment allow to clearly indicate if the proposed changes would bring the anticipated results with regard to proportionality, efficiency, transparency and predictability and how it would impact authorities' resources.

If the European Commission were to move forward with the generic approach to risk management, the only feasible implementation scenario would be a careful phased approach differentiating between mixtures and articles, consumer and professional uses as well various hazard classes and categories.

A phased implementation based on clear priorities is key

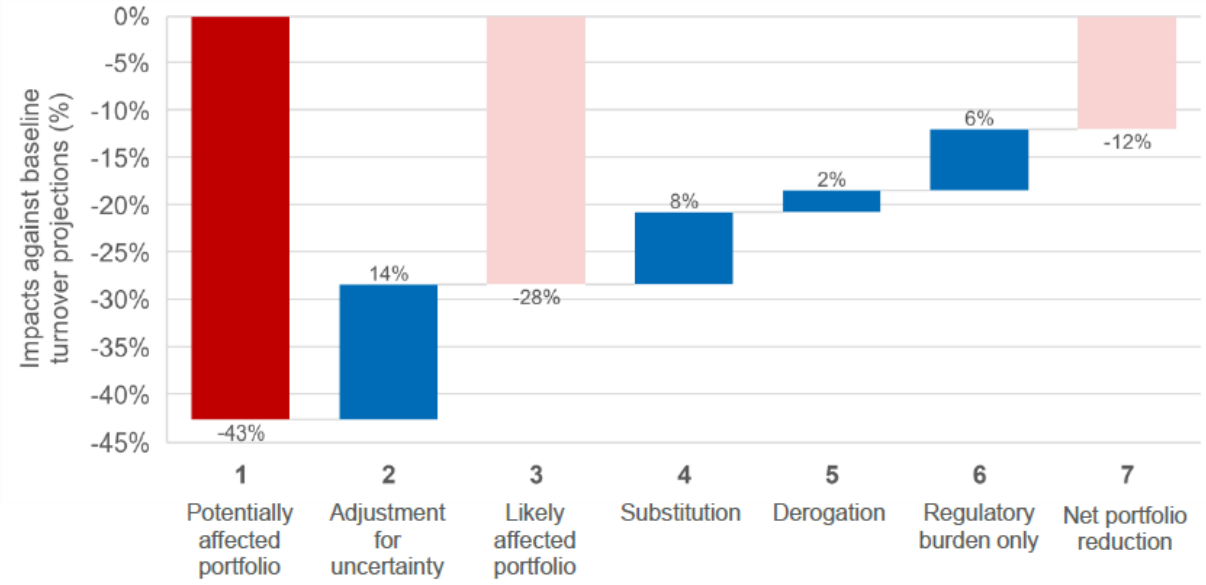
The first in a series of studies conducted by independent economic research consultancy Ricardo Energy & Environment on the business impacts of the Chemicals Strategy for Sustainability, showed that as many as 12 000 substances[19] could be impacted by this planned regulatory action [see p. 106]. The consultants concluded that the most likely impacted portfolio would be as much as 28% of the industry's estimated annual turnover. The companies consulted indicated that around one third of this most likely affected portfolio could potentially be substituted or reformulated. Even when substitution, reformulation and derogations are taken into account, the EU chemical industry could face a net market loss of around 12% of its product portfolio by 2040.

[17] Neither the CSS nor the Commission paper uploaded for CARACAL, contain any information on the expected benefits of extending the generic approach to risk management.

[18] Action from the CSS: "ensure that hazardous chemicals banned in the European Union are not produced for export."

[19] From Ricardo Energy & Environment report: "A total of 25,433 unique substances, i.e. duplicated removed, were identified." https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf

Figure 1-2 Static stepwise representation of the portfolio in scope of being affected by the policy changes and expected responses from businesses (in percent of baseline turnover)



Source: Ricardo analysis based on Eurostat data and a bespoke survey to chemical companies.

However, the ability of companies to substitute potentially affected products will largely depend on the details of the upcoming regulations, on what might be technically and economically feasible, and especially on how customers will react to the substitutes or reformulated products.

Therefore, prioritising and sequencing the extension of the generic approach to other hazard classes is a key condition to enable the industry to develop substitutes and focus on those products where these substitutes could be available first. To keep the whole process proportionate and manageable, focus must be on the most severe hazard classes (SVHCs) in certain consumer uses. Our proposed approach is explained below.

A gradual implementation for consumer uses

Building on the European Commission's intention to gradually implement the GRA and to develop a work plan, Cefic's recommendation is to prioritise consumer uses with a high likelihood of exposure (particularly of vulnerable groups) and to focus on the most severe hazardous chemicals. As suggested in the CARACAL paper (CA/19/2022), further differentiation can be made between substances on their own and in mixtures, and selected article types.

To protect consumers and the environment in a pragmatic, accelerated manner, the current generic approach for CMRs Cat 1A/1B under REACH (art. 68 (2)) for **substances/mixtures** sold to the general public could be extended to Endocrine Disrupting substances category 1, and PBT/vPvB substances if the use leads to emissions to the aquatic environment.

Regarding articles, a first step should be to identify those article categories and uses that lead to 'hard-to-mitigate' exposure and exposure of vulnerable groups to CMRs 1A/1B and Endocrine Disruptors category 1. Once identified, targeted restrictions for articles can be developed. For articles, it is reasonable to assume that articles should not be released to the environment, therefore PBT/vPvB substances in articles would not be a priority area of focus.

Extension to other hazard endpoints such as STOT, respiratory sensitisers, immunotoxic and neurotoxic substances should be only considered in a subsequent phase, after a review, if positive experience from restrictions to ED and PBT/vPvB has been demonstrated (incl the number and complexity of essential use derogations), depending on the outcome of discussions at UN GHS level on immune- and neurotoxicity and monitoring data e.g. generated under the PARC project.

For the future development of and roll out of generic restrictions according to Art. 68(2), a **stepwise and transparent legal procedure** must be inserted into REACH. This procedure should include the development of a background document by ECHA followed by a consultation as suggested in the European Commission's paper on the reform of authorisation and restriction. Appendix C outlines a suggestion for a legal process.

In addition generic restrictions must be accompanied by **a clear derogation mechanism for essential and/ or safe uses** under REACH.

Any future generic restriction set under art. 68(2) should follow the same basic principles as the existing generic approach to risk management for CMRs 1A/1B in consumer mixtures:

- The scope is limited to substances for which a **harmonised classification** has been agreed by authorities. This is crucial to secure legal certainty and level-playing field in the market. Whether a regulatory measure would apply cannot depend on a classification assigned by a market actor or pending discussions on classification.
- Only substances with a **hazard classification category 1** (where applicable) should be targeted, which is also in line with the concept of SVHCs and approaches taken in other legislations (e.g. the Carcinogens and Mutagens Directive (CMD)).
- Each restriction (proposal) must include **a list of (groups of) substances** falling in the scope of the restriction and define **generic and/or substance specific thresholds** allowing the restriction to be workable and enforceable.

An alternative approach for professional uses

Concerning **professional uses, we would like to propose an alternative way forward**.

We fully understand the need to take a more preventive approach for consumers, with a particular focus on vulnerable groups, but the situation with professional users is different.

Applicable occupational health and safety (OSH) legislation contains a large set of measures[20] to secure safe handling of chemicals by workers. A continuous, sustainable improvement of the EU OSH framework for hazardous substances will enhance the protection of professional users, including self-employed workers. This can be done by :

- Making safe handling of chemicals a mandatory element of professional training courses and apprenticeships.
- Making easy-to-understand safe use instructions available to professional users for example via IT-tools and platforms.
- Developing guidelines setting out good practices for risk prevention and control, building on existing EU and national guidance.
- Developing tailored measures for professional uses with increased incidence of occupational diseases linked to the use of chemicals e.g. mandatory training and certification schemes or sector-specific best-practice guidelines. Existing publications can support in identifying professional categories with higher risks and incidences (e.g. UK Health and Safety Executive 2010; Montano 2014).
- Expanding EU OSH legislation to ensure coverage of self-employed workers without employees in all EU member states.
- Reinforcing and strengthening OSH-legislation by setting EU-wide binding OELs for substances of very high concern

[20] See Chemical Agents Directive 98/24/EG and Carcinogens, Mutagens and Reprotoxic substances Directive 2004/37/EG. Measures include risk identification, risk prevention/elimination/minimisation, training, exposure monitoring and health surveillance.

6. Including the concept of Essential Uses in authorisation and restriction

A simple idea on paper, a high-risk of entanglement in reality?

The term “essential use” is mentioned in the EU's legal commitments to the Montreal Protocol and the Stockholm Convention[21]. It has not been used to any great extent in EU regulatory law. It has limited basis in international or European law.

It does not exist in the REACH Regulation and it is not part of the existing REACH governance[22]. The other 40 legal acts dealing with European chemical substance regulation, whether on sector-specific issues, health and safety at work, or environment issues, do not include the narrow reference to the 'essential use' concept

It has not been taken up in the main in the EU and elsewhere (Garnett, Kathleen and van Calster, Geert, 2020) because it runs counter to the basis of chemical regulation: risk analysis. Risk analysis includes hazard assessment, threshold/dosage levels, and quantitative risk assessment and risk management measures. This has been the established EU (and international) approach to chemicals management since 2003 and the publication of the Commission Communication on the Precautionary Principle (2000).

At the workshop organised on 3 March 2022, the European Commission suggested to use the essential use concept as a tool to screen out (non-)essential uses chemicals considered for regulatory action (Wood workshop background document; 2022). With this proposal, qualitative function and end use of a chemical would be driving regulatory control. It introduces an element of normative evaluation and judgement as opposed to relying on purely scientific, expert evaluation of the risk and hazard and management through stringent control measures. It is unclear who would make this judgement and take the responsibility for it.

The European Commission’s Chemical Strategy for Sustainability does not provide any evidence on why such a fundamental change is needed nor on the benefits this concept would bring to the current regulatory system. It would be interesting to run a retrospective analysis. If the concept had been applied in the past, would it actually have changed previous decisions taken on regulatory measures and would it have led to more efficient decision-making? The European Commission assumes that applying the suggested screening approach would simplify procedures but does not address the potential impact on resources. This ignores the complexity of a screening approach applied to regulatory measures covering hundreds of uses[23] where for each use a decision on essentiality has to be made. The Impact Assessment should carefully assess the consequences of the suggested approach on resources.

[21] See EU POP Regulation Annex I part A

[22] Considerations of ‘essentiality’ are included in the BPR exclusion criteria and implicitly considered within the socio-economic assessment under REACH. It is important to note, however, that when ‘essentiality’ is considered in these assessments, it is one of many other aspects with risk assessment and management topping the ‘hierarchy’.

[23] With the planned extension of the generic approach to risk management and grouping of chemicals the Commission intents to make complex and broad in scope regulatory measures the standard. Restrictions such as on microplastics and PFAS will become more and more the rule.

Smart integration into REACH will be key

Despite its current limited use and identified challenges, if well-defined and applied to existing procedures[24], the concept could become a supplementary tool for assessing **case by case** whether or not to continue a use of a substance subject to a ban or restriction. How such smart integration can look like is outlined in our publicly available paper "How to introduce the Essential Uses concept under REACH (graph available in Appendix D).

The concept **should complement** - **not replace** - existing processes by looking at the broader consequences of banning the use of a certain chemical or groups of chemicals. In other words, exploring the implications for society if certain uses for certain substances cease and certain products or applications are no longer available. How this can be done in practice is described in our publicly available paper "Conducting an Essential Use assessment"(example of assessment available in the Appendix D).

The very discussion about what is essential and what is not is by definition subjective. Defining what is essential for society is a matter of political choice. A Committee with a political mandate and accountability to decide on this needs to be created and empowered to make this choice. Suggestions on how such a committee could like and operate are included in our abovementioned papers.

[24] For example the socio-economic analysis under REACH.

7. Changes to the provision on the evaluation process

Build upon lessons learned

The European Commission has presented a set of policy options to improve evaluation processes (CA/08/2022). In doing so, it would be beneficial that changes to the REACH Evaluation processes consider **practical experience and lessons learnt**[25] and are assessed against proportionality, transparency, predictability and impact on authorities' resources to truly bring improvement. This is all the more important now that registration of certain polymers is foreseen in the future, which means the level of complexity will only increase. According to an initial estimation from 88 companies in the sector[26], around 14 000 polymer substances would need to be registered (if polymers of low concern are excluded), compared to ca. 13 000 substances fully registered since the beginning of REACH (excluding intermediates)[27]. All polymer registration will be complex. Therefore, after extrapolation of these numbers to the entire market, polymer registration is likely to at least triple the amount of work for ECHA and other evaluating authorities.

Added value of commissioning of testing by authorities is unclear

Neither the CARACAL paper (CA/08/2022) nor the Chemical Strategy for Sustainability elaborate on the need and added value of the proposed commissioning of testing by authorities.

First of all, **when commission testing, authorities would face the same hurdles as companies**.[28] Thus, it would not accelerate testing. This goes against the aim of the REACH revision to streamline and coordinate the processes.

Secondly, **the responsibility to generate data under REACH is with registrants** (linked to access to market). The question is who would own the data/have access to studies if the authorities were to perform testing of substances, as we understand registrants would financially contribute to the testing but not run it themselves? We recommend to run an in-depth legal assessment before such change is introduced in REACH.

Revocation of registration numbers needs a transparent legal process

We support the revocation of registration numbers in line with the 'no data, no market' principle, subject to a transparent legal process. Revoking registration numbers in case of persistent failure to comply is a powerful tool that needs to include clear conditions, legal rights and due process (suggestion on the legal process and examples of conditions outlined in Appendix E). It should be applied as "the last remedy".

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[25] E.g. Generating the necessary information and filling the registrations dossiers is a very thorough and time-consuming process (some studies take 3-4 years to complete). Most of the difficulties the industry faces is with complex dossiers for groups of substance that rely on read-across or on other adaptations to standard information requirements. Interaction with ECHA to review the grouping approach and jointly agree on a testing strategy (prior to launching the test) is valuable.

[26] Cefic has commissioned Phase 2 of an Economic Analysis of the impacts of CSS on businesses. One of the modules in Phase 2 deals with polymers requiring registration. This initial assessment remains to be confirmed (mid-2022)

[27] https://echa.europa.eu/registration-statistics

[28] For instance, timelines for approval (animal studies), adequate justification for animal testing, lab capacity, writing and sending Requests for Proposals (RFP), working with other MSCAs, assessing GLP of the labs, obtaining test material, getting approval by the Member State Committee.

The revocation mechanism needs to be coupled with **effective and coordinated enforcement** of the revocation decision: this means all registrants (including all Only Representatives) and all legal entities established in different Member States concerned by the revocation decision need to be equally controlled /sanctioned – not only lead registrants. In this respect, we see **a role for the Forum on Enforcement** to ensure joint enforcement of revoked registrations.

Limiting Testing Proposals (TPs) for Annex IX-X studies[29]

We **support the proposal to maintain limiting Testing Proposals (TPs) to for Annex IX-X studies** as one mechanism to streamline the processes and accelerate testing. Extending TPs to other animal studies in all annexes would lead to further delays in developing or updating dossiers. We would rather recommend to retrospectively assess the added-value of Testing Proposals based on experience gained so far. To make sure this does not result in unnecessary animal testing under Annexes VII-VIII, reflection is needed on whether other, less cumbersome mechanisms can be devised to ensure that validated and predictive non-animal alternatives have been considered before running animal testing.

Sequencing and streamlining of procedures for compliance check and grouping

Generating the necessary information and filling the registrations dossiers is a very thorough and time-consuming process (some studies take 3-4 years to complete). Most of the difficulties the industry faces are with complex dossiers for groups of substance that rely on read-across or on other adaptations to standard information requirements. In such cases, it is extremely valuable to have interaction with ECHA to review the grouping approach and jointly agree on a testing strategy prior to launching the tests. Therefore, **agreeing on grouping, categories and read-across justification early in the process** would smoothen the next steps for industry and for authorities. For that reason, we propose **sequencing and streamlining of procedures** (see Appendix F).

[29] Standard information requirements for substances registered at above 100 T/y and 1000 T/y respectively

8. Enforcement

Need to step up enforcement

Cefic fully supports the European Commission acknowledgment to strengthen a zero-tolerance approach to non-compliance with EU chemical legislation, including revocation of registration numbers (Joint Statement on Enforcement of EU Chemical Legislation, 2021; Cefic discussion paper on enforcement and enforceability, 2020). It is evident from the CSS High Level Roundtable (HLRT)[30] discussion that the topic is of high interest for all stakeholders.

There is sufficient evidence showing that **the vast majority of goods containing banned or restricted substances are imported from outside the EU**.[31] The data represent the tip of the iceberg, as many cases do not get reported in the EU Safety Gate. The issue is even more exacerbated with the **rise of online sales** (Postnord report "E-commerce in Europe", 2020). A recent European Commission report on the reform of the EU Customs Union (Wise Persons Group on the reform of the EU Customs Union, 2022) has identified that growing complexity of legislation, fragmentation of data, lack of modern technologies and skills to cover a wide range of risk areas, among others, pose a serious challenge to the EU Customs Union [see p. 22].

This clearly shows that **enforcement of current EU chemical legislation is an issue**.

As legislation will become more complex with broader and more generic approaches to risk management[32], new restrictions will need to be thoroughly assessed for enforceability. New mechanisms and policy coherence with other legislation are needed to strengthen controls both offline and online.

Stronger role of the ECHA Enforcement Forum needed

As the legal complexity will increase, it will be essential to strengthen and formalise the role of the ECHA Enforcement Forum to examine proposals for their enforceability and prepare an Opinion (as indicated in document CA/03/2022). For example, today the ECHA Enforcement Forum can advise on enforceability for draft restrictions, however, their advice is not fully considered.[33] We think **their advice should have a stronger role.**

To facilitate the work of the Forum, we propose the following **set of enforceability criteria** to be defined in the new legal text:

- Availability of standard analytical methods (if these are not available, there should be a specific and coordinated action to develop the test methods during the transition period)

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[30] Second meeting of the High Level Roundtable on the Chemicals Strategy for Sustainability: https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=29575&fromExpertGroups=true

[31] Cefic analysis of EU Safety Gate data from 2020: https://cefic.org/media-corner/newsroom/2020-enforcement-data-reveals-increasing-number-of-hand-sanitiser-imports-violating-eu-chemical-safety-laws/

[32] The CSS announces: extension of generic approaches to risk management to additional hazard classes (PBT,vPvB, ED, Resp.Sens., Immunotox, Neurotox, STOT and professional uses; while the generic approach to risk management is not in place, prioritise all the above-listed substances for restrictions for all uses and through grouping, instead of regulating them one by one.

[33] For instance during the ongoing restriction on skin sensitisers in textiles, the ECHA Enforcement Forum advised that the "enforcement of this restriction could be challenging" due to high number of substances under the scope, problems involving sampling, sample preparation and analytical methods: Compiled RAC and SEAC opinion

- Legal clarity in terms of substances covered under the scope (with their chemical identifier whether it is EC or CAS number) and their respective thresholds
- Laboratory capacity
- Member States' budget and resources
- Representative number of samples selected (these should be representative of what is being supplied to the market)

The role of the ECHA Enforcement Forum should be to identify if any of these elements are missing/what needs to be done to close to gap to ensure a restriction delivers on its objective.

We also see a **stronger role for the Forum to ensure joint actions on enforcement of revocation decisions** (reference section on Evaluation).

Making online platforms comply with EU chemical legislation

Digital world and the volumes of traded goods[34,35] have progressed faster than the EU legislative framework (Wise Persons Group on the reform of the EU Customs Union, 2022) [see p. 20]. Certain evidence suggests a high degree of inspected products purchased online to be non-compliant with EU chemical legislation: in the latest ECHA Enforcement Forum (REF-8) project, 78 % of products checked for REACH restrictions were non-compliant (REF-8 project report on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online, 2021; BEUC report "Is it safe to shop on online marketplaces", 2021).

Online platforms with an operational seat in the EU can be held liable when selling their own branded products. The real issue lies with those marketplaces and web shops established outside the EU, so called intermediaries, for which the current EU laws do not apply.[36] This creates a legislative loophole, providing a window for unsafe and non-compliant products to reach EU consumers.

Online platforms need to be seen as duty holders. The REACH revision should consider appropriate linkages with other policy mechanisms (Market Surveillance Regulation, Digital Services Act, General Product Safety Regulation) to close any legal loopholes.

General comments on the REACH revision survey questions (from customs angle)

From our understanding, the REACH revision survey suggests ideas to ramp up security and administrative measures rather than strengthening enforcement. In our view, the suggestions would add administrative burden to already compliant businesses and not targeting the *free riders*. We believe that more attention should be given to ensure that articles and mixtures comply with EU chemical legislation.

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[34] Between 2010 and 2020, extra-EU imports have increased by 16.5 percent while exports have grown by 34.6 percent. Source: EUROSTAT: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fec.europa.eu%2Feurostat%2Fstatistics-explained%2Fimages%2F4%2F46%2FExtra-EU_main_features_2020.xlsx&wdOrigin=BROWSELINK

[35] It is estimated that e-commerce represented 490 million customs declarations for a total value of EUR 4.8 billion while traditional trade in goods represented over 220 million import declaration for a value of EUR 1,250 billion. Data from July to December 2021 – the first six months of compulsory customs declaration for all goods imported into the EU irrespective of their value

[36] Market places have three different roles: 1) intermediaries between suppliers and consumers; suppliers are often located outside EU; 2) online marketplaces can store, package, ship and address customer care issues; 3) online marketplaces can be themselves retailers, selling their own brand (BEUC report "Is it safe to shop on online marketplaces?")

In addition to the above recommendations, in general we see more benefit in working with third countries directly, having criteria to prioritize products/groups of chemicals being at risk of high non-compliance (smarter/targeted controls), boosting the knowledge and exchange of information across the Member States, involving online sales platforms in the discussion (e.g. at ECHA Enforcement Forum). It is also important to modernize and equip customs authorities: there needs to be more data sharing among different law enforcement bodies, linking of relevant databases (for instance REACH and customs) and development of more efficient and modernised tools[37] coupled with serious investments (certain recommendations mentioned by Wise Persons Group on the reform of the EU Customs Union, 2022, see p. 25). We look forward to discussing further these ideas in the follow up session of the DG GROW HLRT breakout group.

[37] For instance, Single Window electronic tool allows parties to submit information in electronic format and it is very useful for customs to verify compliance a the EU market entry point. It allows to exchange data between authorities. However, it is operational only in a few Member States: https://ec.europa.eu/taxation_customs/eu-single-window-environment-customs_en

9. Information requirements for uses and exposures

New digital technologies for a more efficient collection of information

Robust and sufficiently granular data on uses and exposure at different life cycle stages are critical to identify the needs for regulatory follow up and to support effective regulatory action. During the past decade, registrants and downstream users spent a lot of effort in getting the necessary data from the value chain into the registration dossiers, but the complexity of supply chains and Confidential Business Information (CBI) concerns have proven to be challenging.

As a general comment on policy options presented in document CA/12/2022, it will be important that any new reporting requirements focuses on substances considered for regulatory action, actually solves data gaps on use and exposure allowing registrants and authorities to refine their assessments.

Should the Downstream User (DU) reporting become mandatory, it should be done under specific conditions[38] to ensure the system is workable and manageable. Detailed information on uses and exposure should only be requested if needed for developing regulatory measures. Any new processes should explore the potential of new digital technologies, consider user friendliness and avoid duplication to limit administrative burden. Reporting would preferably be web-based, targeted and standardised. The notification requirements should be clearly defined in the legislation.

The option of integrating more granular information on registered volumes per use has been explored in the past (Cefic-VCI report 2016). Despite several approaches developed by sectors facing severe regulatory constraints on their substances, there is no uniformly applicable method for identifying and aggregating information on tonnage per use and any method is labor-intensive. Thus, such information may only be provided by industry in specific cases. Also, EU Competition Law and the fact that distributors are much involved in the chemical sector further limit options for identification and aggregation of such information. Whereas past assessments focused on data gathering and aggregation by industry, similar hurdles would affect data aggregation by authorities.

Technical optimisation of already available tools and reporting mechanisms can always be explored. The impact of this action on existing dossiers could be high. Therefore, any kind of “technical optimisation” would benefit from involving registrants to come up with workable solutions.

[38] E.g. reporting should be mandatory when an industry actor uses the substance in certain quantities; de minimis threshold need to apply for reporting; limiting regular reporting to the identity of the hazardous substances used.

10. Derived Minimal Effect Level (DMELs) for non-threshold substances

Risk-based exposure limit setting for workers: workers' legislation must set the scene

The recently agreed update of the Carcinogen and Mutagen Directive[39] mandates the European Commission to develop Union guidelines on the methodology for establishing risk-based limit values. It will build upon input from the Advisory Committee Safety and Health and existing national practices.

The outcome of the upcoming discussion under workers' legislations should determine where to go on this issue.

Cefic supports the practice to derive and use of risk-based exposure limits for non-threshold carcinogenic (NTC) chemicals if considered alongside data related to the substance (i.e., its mode of action), the technical feasibility[40] and a Socio-Economic assessment (e.g., the Occupational Exposure limit, OEL). In this respect, the approach adopted in the Netherlands when deriving DMELs (i.e., the Dutch approach[41]) provides a good starting point.

A DMEL approach for non-carcinogenic endpoints to be considered case-by-case

We support the conclusion from Wood /Ramboll[42] recommending no default extension of DMELs to other hazard classes. The conclusions remind that "for respiratory sensitisation the issue is complex (particularly with regard to the limited data-availability), and for immunotoxicants and neurotoxicants, high variability from substance to substance and/or non-linear dose response would make the application problematic and possibly not appropriate. Multiple modes of action and target organs, meaning high variability in dose-response relationship would make the application to endocrine disruption highly complex and possibly limited on a case-by-case basis."

[39] Revised Carcinogens and Mutagens Directive (2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L0431

[40] When proposing an OEL, good practices are that the feasibility for industry to meet the value is considering best available techniques and that the feasibility of the measurement is verified by securing sampling and analytical methods are available (Limit of Quantification of these methods do allow for at least 10% of the expected OEL).

[41] https://rivm.openrepository.com/rivm/bitstream/10029/557055/3/2014-0153.pdf

[42] Wood presentation at CARACAL: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/6c370f26-fcce-46a9-8f19-4b0bb6237481/details

11. Information requirements to provide information on Endocrine Disruptors (EDs)

Presence of adverse effects as key for ED identification

Currently existing information requirements in REACH already enable the identification of endocrine disruptors. As a result, a number of chemicals have already been identified as EDs.

New data requirements to provide information on endocrine disruptors should remain proportionate, take into account the need to minimise animal testing and follow a tiered approach in line with OECD's Conceptual Framework Guidance Document 150.

According to the WHO definition, information on adversity is a key criterion for the ED identification. As there are several existing REACH information requirements allowing the identification of adverse effects related to potential endocrine Mode of Action. Cefic does not see an added value in performing additional studies immediately without any proper assessment of existing information. To reduce additional higher-tier animal testing to a minimum, existing data have to be re-assessed from that perspective, and if necessary, further studies should be envisaged to fill in the gaps.

In view of the wide diversity of cases/chemistries/substances, differing data availabilities and complexity of ED assessment, modification of the REACH annexes should not be seen as the sole mechanism to recommend if/when a more in-depth assessment and additional studies may be needed. Technical Guidance should be considered as an alternative.

Making use of REACH SVHC listing and substance evaluation work for ED identification

The Substance Evaluation process can also be used to allow further studies to be considered, on a case-by-case basis, in case of uncertainty or specific concerns. It would be important to have a common understanding of which information or data may trigger an "ED-concern". This will inform a consistent approach and give industry the ability to identify and address defined regulatory concerns, as well as get a better understanding of which studies/data are the most appropriate to confirm or rule out the concern. A retrospective assessment of the REACH SVHC listing and substance evaluation work related to ED would generate useful information about the most useful lead studies on ED identification. Similarly, we recommend that the European Commission and ECHA find a mechanism to ensure the experience gained in the ECHA ED Expert group is reflected in future ED identification scheme.

Finally, Cefic would also like to clarify that some questions on impacts for industry, such as the impact on competitiveness (Q 5.c)) are difficult to answer properly as currently the European Commission is proposing two distinctive options to Amend the REACH Annexes to include information to identify EDs. In that sense, the impacts are heavily dependent on the option chosen and so a proper answer could not be provided.

12. Information on environmental footprint

Environmental Footprint data yes, but not linked to REACH registration

Robust and high-quality data information on substances are increasingly requested by downstream actors in the value chain, who need this information to assess the sustainability of their materials, products and services (as applicable) or perform LCA assessments.

We support the development of a central repository/common database that builds on existing, publicly accessible life-cycle inventory and environmental footprint (EF) datasets.

For this, a suitable, interoperable and harmonised format is required to successfully achieve the collection and use of such information.

We also see a need for Environmental Footprint data gaps to be addressed: industry associations can facilitate the generation of datasets at sector level (examples are ESIG, PlasticsEurope, EPDLA, …) which can be complemented by individual B2B communication between suppliers and customers for company specific EF data, aligned with the Commission Recommendation (C(2021) 9332 final) on 'PEF'. At chemical/substance supplier level, such information can only follow a cradle-to-gate approach, as the use stage is very hard to model, and there are too many uses and downstream production processes possible. Each actor in the value chain should integrate EF footprint data from the previous actor in the value chain.

However, the REACH registration is not fit for this purpose for the following reasons:

- The environmental footprint is supplier-specific as EF varies depending on type of production process, energy efficiency, locations, feedstock etc. Thus, any such data could only be linked to individual registrations and even so, it would lead to a proliferation of environmental footprint information and generate an unmanageable database as well as a high frequency of updates. The major effort it would require would deviate from the main purpose of REACH, which is safety information.
- In addition, providing such information could lead to revealing confidential business information. So it is likely ECHA would need to deal with many new confidentiality claims.
- A registration cannot provide the level of specificity that B2B communication between suppliers and customers allows.
- We fail to see how such information can be verified for compliance. There is a risk such a measure would not be enforceable and it would require a significant increase in ECHA resources.
- More generally, it goes against the simplification objective of the 'targeted' REACH revision.

We see the Digital Product Passport (DPP) announced under the proposal for the Ecodesign for Sustainable Products Regulation as a key tool to increase transparency, both for supply chain businesses and for the general public, as well as improve the efficiency of information transfer. DPP can be used by suppliers to transfer information to their customers, including on EF.

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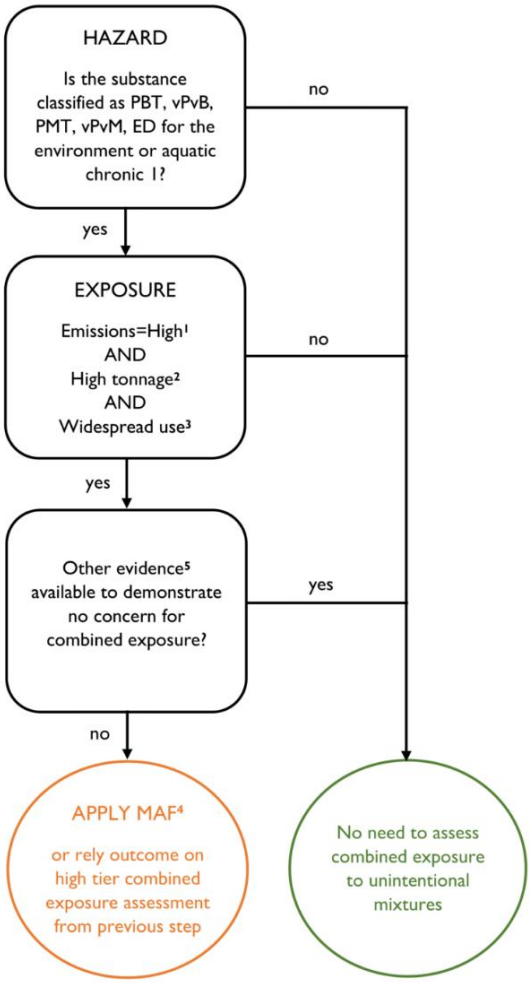
Appendix A

Mixture Assessment Factor (MAF) – Cefic suggestion for a decision tree



[1] High emissions would typically include uses where Environmental Release Categories 4,8a,8d,10b,11b are used in the chemical safety assessment as a basis to predict emissions to the environment. See ECHA's Use Descriptor guidance for more info on environmental release categories.

[2] To be specified. One could use cut off values >= 1000 tpa (Non-Readily Degradable substances) or >= 10000 tpa (Readily degradable substances) – thresholds apply to the tonnage registered at EU level

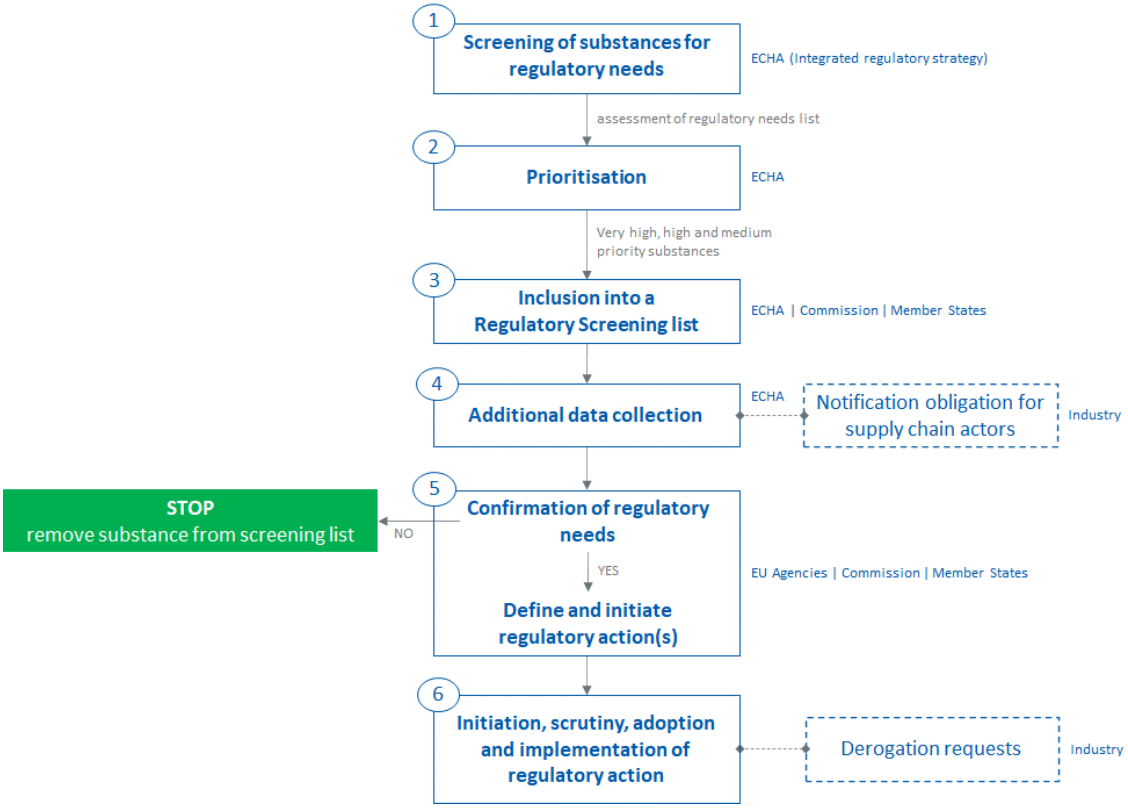
[3] A review of monitoring data has shown that wide dispersive uses typically drive potential combined exposure risks. Wide Dispersive uses would typically include uses where Environmental Release Categories 8,9,10,11 are used in the chemical safety assessment as a basis to predict emissions to the environment ERC. See ECHA's Use Descriptor guidance for more info on environmental release categories.

[4] Value to be specified. To be discussed if one would define one value or multiple values linked to the hazard properties.

[5] To be specified: incl. assessing actual co-exposure scenarios, monitoring data, MoA, actual emissions, …

Appendix B

Reform of authorisation and restriction – Cefic suggestion on new regulatory approach for risk management



Appendix C

Generic Approach to Risk Management (GRA) - Cefic suggestion for a legal process

Today, there is no legal process for development of restrictions under art. 68(2)/generic approach to risk management (GRA). Until now art. 68(2) has mainly been used for updating the list of CMR substances captured by the pre-REACH restriction on CMRs substances and mixtures sold to the general public. Only 2 new restrictions have been adopted under this procedure (PAHs in rubber and plastic and CMRs in clothing, textiles and footwear).

We propose the following legal process detailed below. It takes into account lessons learned and experience from the recent art. 68(2) restriction for CMR 1A/1B in clothing and textiles[43] which included a stepwise approach and stakeholder consultation:

1. The Commission would ask ECHA to develop a preparatory/background document.
2. At the same time, ECHA would launch a "call for information"[44] for stakeholders to provide input on relevant chemicals, uses and exposure(s). This would feed into the ECHA preparatory document. The background document would contain publicly available information and would aim to map out substances and uses in scope, identify non-relevant/no exposure uses, collect information on availability of alternatives and analytical methods and define exemptions and scope of derogations.
3. Once the ECHA preparatory document is published, it would be subject to a consultation. The aim of the consultation would be to confirm/refute and/or provide any additional information. Such upfront collection of information would ensure a solid basis for drafting a restriction proposal later on.
4. At the same time, the ECHA Enforcement Forum is to be consulted on the enforceability of the restriction(s) (based on the suggested criteria outlined in the enforcement chapter of this document).
5. The draft restriction(s) proposal would be submitted to the REACH Committee.
6. Generic restrictions must be accompanied by a clear derogation mechanism for safe or essential uses under REACH. Applying for 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) could serve as a basis (with modifications to accommodate the new system).

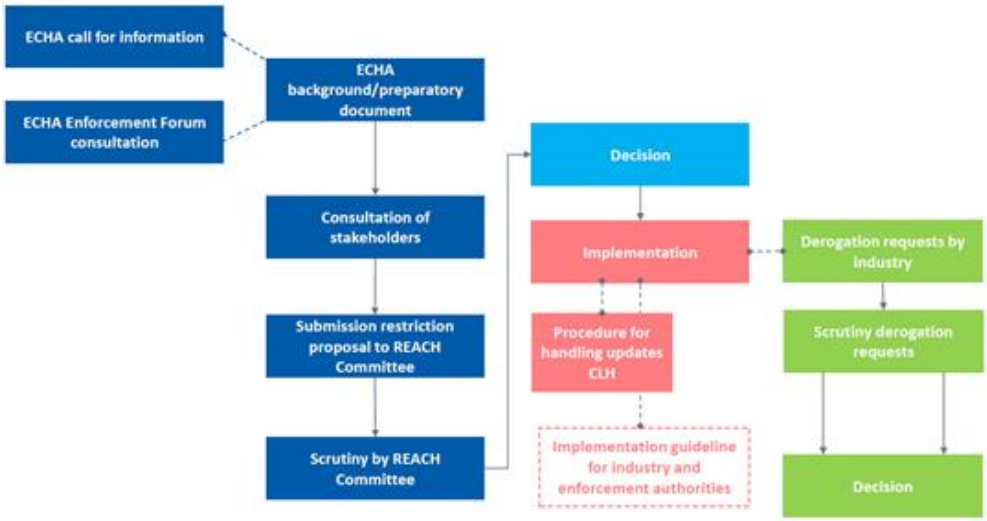
7. Regarding the procedure for handling new updates to CLH, we suggest that relevance and concentration limits of newly classified substances need to be assessed (with input from

[43] REACH restriction on CMR 1A/1B in textiles and clothing via art. 68(2): https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1539328475031&uri=CELEX:32018R1513

[44] Whether this preliminary input is needed will largely depend on how the Commission will implement its ideas on uses and exposure

stakeholders) for the GRA restriction under discussion. The relevant substances would then be added to the appendix of Annex XVII under REACH as it is currently done for CMRs.[45]

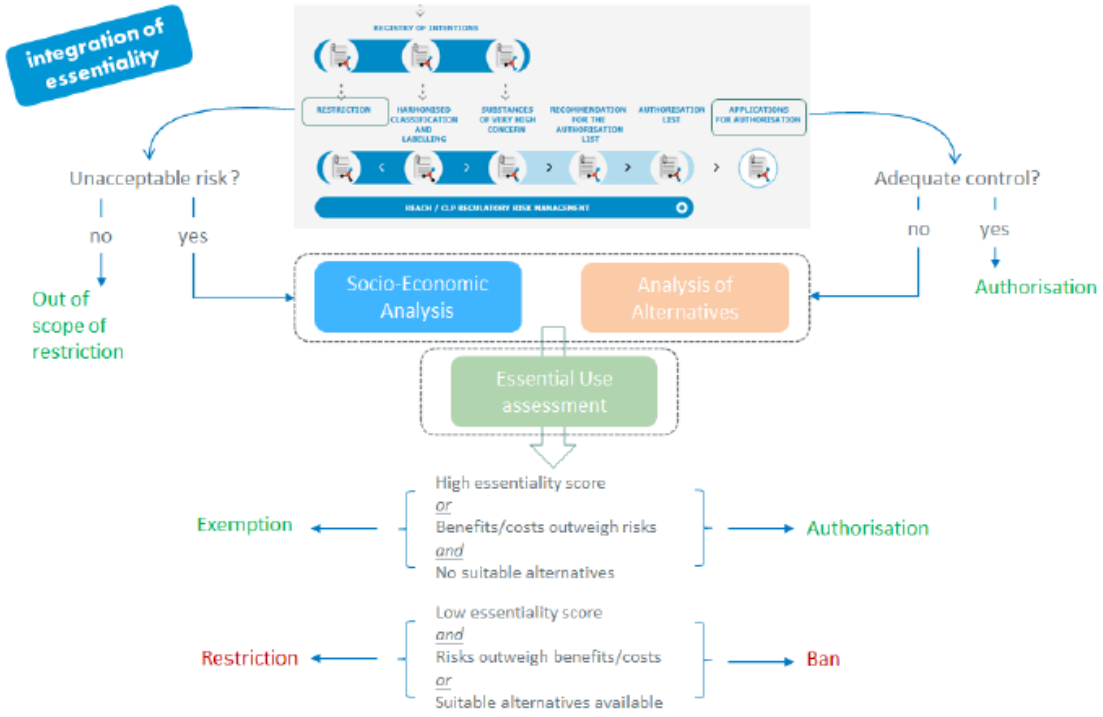
8. The final restriction would be accompanied with an explanatory guide listing chemicals in scope (with their EC or CAS identity), relevant analytical methods and non-exhaustive list of articles in/out of scope (for restrictions targeting articles).[46] This would help both businesses and enforcement authorities.



[45] Entries 28, 29 and 30 of Annex XVII to REACH Regulation prohibit the placing on the market or use for supply to the general public of substances that are classified as CMRs 1A/1B and mixtures containing such substances in specific concentrations. Once new CMR substances are harmonized classified and added to Annex VI of CLP Regulation, the Appendix to Annex XVII of REACH regulation is amended accordingly to add the new substances, in accordance with the procedure referred to in Article 133(4).
[46] Similar was done for the art. 68(2) restriction for CMRs 1A/1B in textiles and clothing: https://ec.europa.eu/docsroom/documents/32006

Appendix D

Essential use – Cefic suggestion on including the essential use concept in REACH and running an essential use assessment



Essential Use Matrix	Yes/No or score?	Comment
Does the substance have a suitable alternative in this use (considering performance in technical and economic terms, product market requirements, availability of volumes or technical standards)?	Y/N	• If yes, assessment can be stopped for this use (substance in this use could still be authorised under SEA) • If cost of regulatory measure is high, longer derogation due to essential use could be justified.
Possible Industry Sectors where Essential Use could be justified: (Note – responding yes to any single category below is sufficient to justify an Essential Use Assessment)		
Sustainable development: Link to Sustainable Development Goals and Circular Economy	Y/N	If yes - document how
i.e. Would removal of this substance from this use impact the achievement of the UN SDG or circular economy?		
Climate neutrality goals and environmental protection	Y/N	If yes - document how
i.e. Would removal of this substance from this use impact achievement of climate neutrality goals, or negatively impact on environmental protection or conservation?		
Objectives of Sustainable Finance Taxonomy	Y/N	If yes - document how
i.e. Climate change mitigation, climate change adaptation, the sustainable use and protection of water and marine resources, the transition to a circular economy, pollution prevention and control, the protection and restoration of biodiversity and ecosystems		
Energy supply	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact energy supply or security in the EU?		
EU digitalization agenda	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact digitalization in the EU?		
Food and drinking water security and supply	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact on food or potable water supply?		

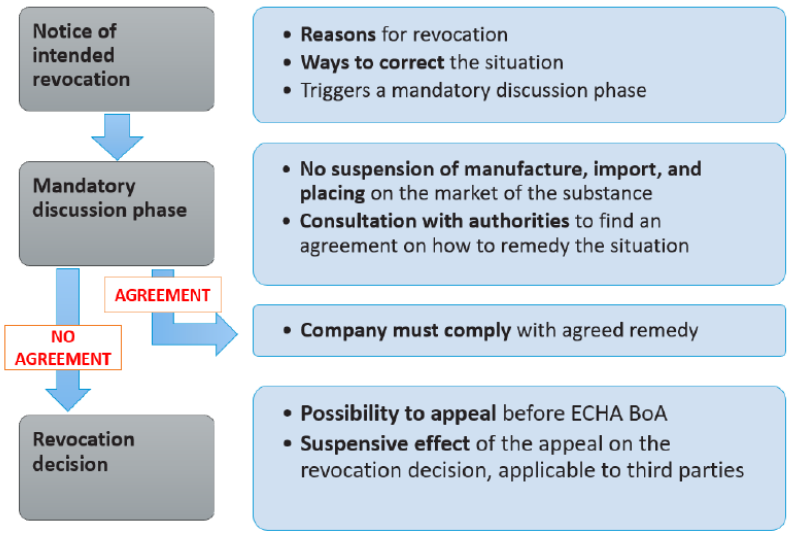
Transport and mobility	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact transport of people or goods within the EU?		
Health and Disease Control	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact health outcomes, disease treatments, or disease control?		
Innovation, research and development	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact research and innovation activities in the EU?		
Social practices, culture and representation, art and aesthetics	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact cultural practices of EU citizens or minorities, inhibit traditional social practices or negatively impact the production or art and/or culture?		
Law & fundamental rights	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact on the legal or fundamental rights of citizens or minorities of the EU?		
Defence and National Security	Y/N	If yes - document how
i.e. Would removal of this substance from this use negatively impact national security, operational readiness or public safety in the EU?		
European sovereignty		
i.e. Would removal of this use negatively impact the autonomy of Europe and increase its dependence to non-EU countries ?		

Appendix E

Revocation of registration numbers – Cefic suggestion for legal process and examples of conditions subject for/against revocation

We believe that the new system of revoking registration numbers needs to be based on the following principles:

- **Revocation as last resort.** Withdrawing a registration number is a powerful tool and should be considered as the last remedy.
- **Right to be notified and heard.** Companies should have the right to be informed and heard before a decision on revocation is taken as the ultimate remedy/last resort. The right to be informed could take the form of a notice of intended revocation specifying the reasons for revocation as well as possible ways to correct the situation.
- **Mandatory discussion phase.** Receipt of the notice of intended revocation would trigger a right to be heard in the form of a mandatory discussion phase with ECHA, during which companies would also be given the opportunity to consult with their national enforcement authorities on how to remedy the situation and find an agreement. During this "intermediate" step, the manufacture, import, and placing on the market of the concerned substance would not be suspended.
- **Possibility to appeal.** Companies should be able to appeal a revocation decision before the ECHA Board of Appeal. Such appeal should have a suspensive effect on the revocation decision, meaning new rules (revocation decision) would become effective only after the appeal procedure was concluded and in circumstances where the appeal outcome was in favour of ECHA. The suspensive effect should also benefit third parties[47], as they may rely on the registration dossier for their own compliance and would be impacted by a revocation decision.
- **No retroactive effect of revocation.** Revocation decisions should not have a retroactive effect as it should not impact past decisions. For downstream users, whether formulator or article producer, the registration number must remain a clear indication that a substance has been legally placed on the market before the revocation date.



[47] Co-registrants or other companies relying on data; Cefic notes that this is already a standard BoA practice in appeal proceedings for Substance Evaluation final decision where not all addressees appeal the decision.

Potential triggers for revocation of registration dossiers may include[48]:

- **Non-compliant behavior with empty dossiers and no changes.** It is crucial that the new legal provisions allow for a distinction between *intentional violations* by repeated offenders and *unintentional administrative errors or delays.*
- **No-longer existing registrant.** In cases where registrants continuously fail to reply within a given deadline, revoking a registration number is justified. However, substantial time should be given to the affected company via different communication channels.
- **Upon requests from registrants for their own dossier.** A registrant may ask ECHA to revoke their own registration number.

Cases where revocation may not be justified:

- **Co-registrants depending on lead-registrant's responsibilities.** In cases where the lead registrant is not responding or not fulfilling his/her obligations to update the dossier, co-registrant's dossier should not be subject to revocation. Instead, co-registrant should be able to alert their Member State Competent Authority or ECHA to act.
- **Administrative delays or technical difficulties caused by testing laboratories.** Revocation of registration dossiers should not happen in cases of justified delay with deadlines set by the authorities for which the registrant is not responsible. This includes cases where test results cannot be delivered because of non-availability of test slots, technical difficulties in the laboratories, necessity to repeat the test, or non-availability of test samples.
- **REACH IT issues.** ECHA's current and frequent technical changes in IUCLID (web based as well as the classic system) may have an impact on technical performance and companies' ability to update their respective registration dossiers on time; such delays caused by non-conformity with the latest IUCLID version should not trigger a revocation.
- **Disagreement on additional data.** There are situations when companies and authorities cannot agree if additional data are necessary during the evaluation process. Efforts should be made to facilitate agreement without that being an immediate trigger for revocation.

[48] These represent an early stage in the thinking process and Cefic welcomes further discussion on this with ECHA, the European Commission and other parties. These preliminary situations are provided by way of examples for discussion purposes only. In reality, each situation should be determined on a case-by-case basis according to its own circumstances.

Appendix F

Evaluation: Cefic suggestion for a 3-step approach

We propose the following sequential steps to streamline evaluation:

1. Where grouping or read-across is involved, or when exposure-based waiving is used, first find agreement with ECHA on the grouping approach. Industry has a lot of internal experience with their products, sometimes additional information, to contribute to a robust, scientific grouping approach. Practical experience shows that we often face discrepancies between ECHA and registrants on the grouping approaches, on underpinning data and on how to assess other substance properties beyond structural similarity. Early resolution of discrepancies would help for the next stages.
   Further details on Cefic views on grouping are explained in our previously published paper.[49]

2. Run Compliance Checks (CCH) where needed, in line with the priorities established under the Commission-ECHA Joint Evaluation Plan, in line with the Chemical Universe and in line with Article 41.

3. Consider Substance Evaluation, if a concern remains, after CCH is completed to avoid overlaps or duplication. This has become a fairly standard practice but is still not consistently applied.

[49] Cefic views on grouping: https://cefic.org/app/uploads/2021/06/Cefic-views-on-grouping-of-substances.pdf