# ChemSec input to the REACH Revision

*April 2022*

The REACH regulation has been the benchmark of chemicals regulation since the start, with ambitious aims and substitution mechanisms. It has, however, failed to deliver to the expected extent and therefore we welcome the Commission initiative for a revision. REACH needs to change to be in line with the Green Deal in general and the Chemicals Strategy for Sustainability in particular.

The aims of the strategy are ambitious and necessary to sufficiently protect human health and the environment. It's therefore of utmost importance that the Commission show leadership and fulfil the promises from the Chemicals Strategy and changes the REACH regulation in line with the aims of the Chemicals Strategy. These objectives must be fully incorporated in the legal texts as well as in the implementation.

Chemicals regulation must be based on some key principles to properly protect human health and the environment while driving substitution. The principles are:

- No Data No Market
- Polluter Pays Principle
- Precautionary Principle
- Substitution Principle
- The Right to Know

While the current REACH regulation intends to incorporate these core values, it has failed to do so in practice and the revision must ensure that this is not the case once the new text is adopted.

Based on the suggestions in this consultation and after attending many meetings and workshops connected to the revision, we fail to see how the Commission proposals on the table now will induce the necessary changes that the current text fails to deliver. Below, we elaborate on the different topics covered by the consultation and highlight important aspects in each part. However, we want to stress that all parts must be seen in the full light of what REACH should be delivering. Every aspect of the REACH revision is important on its own but defined by its weakest link. We trust in the process forward to keep the main focus on the end result, supported by strong components.

## REGISTRATION

### Increased information on critical hazards, Q1

There is a great need for information on further hazard properties, including PMT/vPvM and EDC properties. Also, for low-volume substances, current information requirements are not sufficient.

On the issue of animal testing, the general rule should be that for a substance to be allowed on the market, there should be reliable data on its intrinsic hazard properties. At this point, and for a foreseeable future, it is not possible to obtain this information completely without animal tests. We do support the general direction to reduce, refine and replace animal tests with non-animal tests. However, there needs to be a rigorous evaluation of new methods before adoption, preferably on an OECD level.

It is also important to make better use of the Precautionary Principle as a way to reduce the need for animal tests, which are often triggered by a so-called "paralysis by analysis". So far, when there is not a complete understanding of how a problematic chemical acts, the general rule has been to ask for more data. With support from the Precautionary Principle, we can accept a higher level of uncertainty when it comes to restricting the use of a chemical. It is ok to ban chemicals even when there are uncertainties! The opposite, however, is not acceptable. To allow the use of a chemical based on uncertainty is to risk human health and the environment.

Two other important ways to reduce the need for animal testing is to make better use of the wealth of independent academic peer-review data that is available. To regulate chemicals by groups also reduces the need for animal testing of each individual chemical.
https://chemsec.org/how-to-reduce-animal-testing-without-compromising-chemical-safety/

### Information on substances marketed at the lowest tonnage level, Q2-4

ChemSec has for many years pushed for more information to be required from the low tonnage substances since the information provided today is very limited. It does not give enough information to identify critical hazard properties and this means the risks from these are not managed.

We support non-animal test methods where such methods are available and provide the same level of information. But we do not support non-animal test methods if that would mean we will obtain less complete information on critical hazards for the low tonnage levels. We have a clear position on how to reduce animal testing without compromising chemical safety.

### Information requirements to provide information on EDCs, Q5

The issue of Endocrine Disrupting Chemicals has been lagging behind in regulation for much too long time. While since 2012 some EDCs have been identified under SVHC criteria, the slow regulation still causes irreversible damage to people and wildlife as these chemicals are still widespread in consumer products.

We welcome the introduction of EDC classification under CLP, however for this to be an efficient process, we need the industry to provide information on ED properties already under registration.

### Information requirements for Polymers, Q6-7

Huge amounts of polymers are being produced, imported and used in Europe. The plastic converter demand for the main types of polymers raised to over 51 million tons in 2017 and this represents only part of the total demand. Polymers are the basic ingredients of a very wide range of materials and products (plastics, resins, paints etc.) to which people and the

environment are widely exposed every day and will increasingly be exposed in the future as plastics and other polymeric products continue to build up in maritime and ocean ecosystems and production is predicted to continuously grow.

Despite this wide, growing exposure and rising concerns about their impact on health and the environment, there is no obligation to register polymers under REACH - and therefore provide information on their health and environmental hazards. The REACH Regulation is based on the precautionary principle, shifting the burden of proof on the safety/risks of chemicals to industry and introduces the principle of "No Data No Market": The manufacture, import and use of polymers should follow the same principles as other chemicals. Without registration, it is impossible to ensure safe management of polymers.

### Information on environmental footprints, Q8

ChemSec has put forward suggestions for how the criteria for "Safe and sustainable by design" should be developed. In our view, information on environmental footprints should link to the Safe and sustainable by design concept being developed by the Commission.

In general, we support the inclusion of information on environmental footprints in REACH but not the inclusion of all the 16 PEF endpoints from the start. We believe it would be wise to commence by requesting information on climate impact and natural resources and add more parameters at a later stage. If too many parameters are added from the start we believe there is a risk the data provided for these parameters are not accurate or just calculations (and not "real data"). Moreover, we don't think a full life cycle analysis is relevant to be included in the REACH regulation.

To make sure the information provided will add value to investors and downstream users, the information needs not only to be substance but also production site-specific. Moreover, all information connected to the environmental footprint added by companies should be public. Only then can the footprints drive companies to become more sustainable and improve their work in this area. If the numbers are confidential that would not be the case.

### Information requirements on use and exposure, Q9

Information on uses and exposures is key in REACH, but the information received up to now has not fulfilled the expectations. It is therefore very important to improve this part in the REACH revision.

While information on uses and exposures is very important for the evaluation and risk management of chemicals, it is also important for finding and evaluating alternatives. It's useful for companies wishing to develop alternatives, to understand where the chemical in question is used. Companies further up the supply chain, who often do not have a full declaration of what chemicals are found in their products, would also benefit from knowing where different chemicals are used to be able to ask their suppliers the right questions.

Many consumer close companies spend much resources to find out what chemicals are used in their products. If that kind of information was more easily available it would be very helpful for them.

### Introduction of a Mixture Assessment Factor (MAF), Q10

We see the introduction of a Mixture Assessment Factor as the most realistic and pragmatic approach to, at least to an extent, tackle the cocktail effect and all the unknowns contributing to it. We do not see how it can be justified to use different MAFs in different situations as the concept itself is a response to unknowns.

Our proposal, along with other environmental NGOs is to use a MAF of 100. This is the result of two factor 10s. One for the combination of exposure from different chemicals (10) and one for the exposure from different sources (10).
https://chemsec.org/the-sober-way-to-tackle-the-cocktail-effect/

### Simplifying communication in the supply chain (improving SDS etc) Q10

The lack of relevant information being passed along the supply chain is a major roadblock to substitution. This is true both for information currently required in safety data sheets and for additional hazard information requested by brands to suppliers. All efforts that can benefit from increasing the transparency of information on chemical content are positive and should be included in the REACH revision.

The Chemical Strategy highlights the fact that frontrunners should be supported, and our conclusion based on discussions and workshops shows that incentivizing transparency is the most important assistance to progressive companies with ambitious chemicals management.

## EVALUATION

### Changes to the provisions on the evaluation process, Q11-12

REACH has been in place for more than 15 years and still, a large proportion of the dossiers are incomplete and incompliant. In fact, information from REACH dossiers is generally not regarded as reliable.
However, several chemical producing companies have done their homework and provided complete and compliant dossiers, and this is a costly task. To not reward these companies by somehow "punishing" the companies by ignoring their obligations is working against all efforts to have a more transparent chemicals market.

The lack of reliable registration information leads to delays in all other parts of the REACH processes, as these are built with the expectation that there should be complete and compliant dossiers. As a result, Member States and the Commission have needed to spend many resources on evaluating substances and arguing with industry on the need to provide data, often at the level of the Board of Appeal.

Meanwhile, the substance in question has just been used and produced as if nothing happened, leading to unnecessary exposure (in the cases where the chemical is hazardous) of people and the environment, while the finances of the company have been unaffected.
The “no data-no market”-principle needs to be revisited.

For many other reporting obligations, like financial reporting, yearly reporting has become accepted and part of the routine. In the same way, yearly assuring that the registration

dossiers for what you produce and sell are up to date and compliant is a very reasonable demand to put on companies.
https://chemsec.org/the-ultimate-guide-to-cheat-regulation-and-sell-toxic-chemicals-in-the-eu/

AUTHORISATION & RESTRICTION

## Including the concept of essential use in authorisations and restrictions, Q13

The idea behind including the Essential use concept in authorization and restriction is to come to terms with substitution not happening at the expected pace and restrict the most harmful chemicals more effectively. The aim of the concept is also to make sure public resources are spent on only the important cases. **In order to make REACH more efficient, it is crucial that the essential use concept is used in the strictest sense, ensuring predictability of areas where the industry should avoid investing in further use.**

ChemSec has put forward concrete suggestions on how the essential use criteria should be implemented in the following publications/ paper (including a proposed decision tree) as well as a Q&A.

ChemSec supports the inclusion of the essential use concept and believes it has the potential to speed up the regulation if applied strictly. There are some key points regarding essential use we like to bring forward:

- Do not include or connect "safe use" to the essential use concept in any way. "Safe use" is a risk-based approach, proven less efficient than the hazard-based approach. To fulfil the aims of the Chemical strategy and phase out the most harmful chemicals (not all chemicals as some industries claim), apart from where their use is critical to the functioning of the society or necessary for health, the inclusion of the essential use concept is key.
- Regard if something is essential use early in the process to make sure not to spend public resources discussing cases that are not essential uses.
- Make sure the criteria for what is and isn't essential use is very clear to provide predictability for the industry as well as to limit the cases brought up for discussion.
- Keep incentives for substitution also for the essential uses. When something is regarded as essential use this should not mean a blank check to continue to use most harmful chemicals. Incentives and obligations to research and innovate to find and develop alternatives need to be included.

## Reform of authorisations and restrictions, Q13

The goal of the revision of the authorisation and restriction processes is to have a more efficient system to regulate chemicals, a system that drives substitution as well as provides better protection of human health and the environment from substances of concern. The options put forward by the Commission so far are in our view not enough to achieve this goal.

A cornerstone of the EU chemical regulation is the Substitution Principle and this principle must be applied to make sure to have an efficient regulation. One of the very difficult parts of REACH Authorisation process has been to conclude: "are alternatives available?". This question has resulted in endless discussions and has proven how difficult it is to judge if

alternatives are available. Even if the regulation will have a different setup the need for determining if alternatives are available or not will still be needed. Here, the essential use concept has an important role to play - to ensure that public resources are only focused on uses essential for society. But this is not enough. None of the options presented in the consultation properly addresses the crucial point of alternatives. Instead of SEAC analyzing alternatives, we propose to resource ECHA with a group of experts in alternative assessment. These experts should scrutinize the applications for derogations and authorisations, as well as make a market analysis and an outreach to the market of what alternatives are available and feed this information to the Commission. Even if the service of these efforts should be performed by experts, it is important that the cost is covered by the users of the harmful substances, in line with the Polluter Pays Principle.

To make §68.2 an efficient route for regulation of the most harmful substances, it must be very clear when derogation is possible and limit the possibilities for derogation only for essential uses and not for safe use. To include "Safe use", which is based on risk and not hazard, would contradict the idea of the CSS to phase out the most harmful chemicals in ALL consumer products (see GRA below) except for essential uses (see essential use above).

We support the expansion of §68.2 but would like to see this process being open also for Member States to use. The provision must also be supported with clear and time-limited obligations on the Commission to propose restrictions, rather than it being a voluntary option to do so.

Even if §68.2 will be expanded (due to GRA), §68.1 will still be a much-needed route for regulation. Based on the performance of §68.1 it's clear changes are also needed for this restriction route to protect human health and the environment more efficiently. For example, §68.1 fails to ban the most harmful substances in baby diapers due to the difficulties in proving risk.

The main overarching changes that should be included in the REACH revision of §68.1 are:

- Lower the burden on Member States as dossier submitters
- Increase obligations on industry to provide information to the dossier, such as uses and hazard information
- Change the requirements for risk assessment and proportionality- meaning lower the burden to prove risk when a restriction is about a most harmful substance.

### Generic risk management approach, Q14

The Chemical strategy promises that no consumer products should contain substances of very high concern and additionally not the most harmful chemicals by the introduction of the Generic risk management approach (GRA). The introduction of GRA requires in our view much more than adding additional hazard classes in §68.2 as the Commission proposes. It requires an introduction of an obligation for the Commission to restrict all these chemicals in consumer products, not just a possibility to do so (as is the case of applying §68.2 today).

To fulfil the aim of the chemical strategy the future §68.2 restrictions need to be covering ALL consumer products and not substance groups per substance group. A gradual approach to phase-in GRA cannot be accepted unless some fundamental elements are ensured. It must be

focused on gradual phase-in of hazard endpoints, not of product categories since this would mean the aims of the Chemical strategy are not fulfilled within a reasonable timeline.

We support also including professional products in GRA. We would also like to see Member States being able to apply §68.2 (today it's only the Commission who has this opportunity).

## ENFORCEMENT

### Establishing a European Audit Capacity & Enhance the Enforcement of national controls, including stricter border controls, Q14

We support the recommendations brought forward in the High Level Round table on the Chemical Strategy for Sustainability report on Enforcement and compliance of chemicals legislation launched in November 2021 and encourage the Commission to take all of these recommendations into account when working to improve the Enforcement of REACH.

During the work of the report mentioned above industry pushed for the inclusion of "100% Enforceability". We are very concerned with this approach since it might risk regulation not being put in place due to that enforcement is not possible. Many new restrictions are difficult to enforce but that doesn't mean we should not do the restriction to protect human health and the environment. We have written a longer piece on this where we elaborate more on the problem with this ask from the industry.

## ADDITIONAL FEEDBACK

### Efficient mechanisms for substitution and support to industry frontrunners are needed

One of the major failures of REACH in our view is that the regulation has missed opportunities to support and promote frontrunners, alternative providers and companies in transition but rather focused on the ones having difficulties (or not wanting) to change.

In addition to supporting frontrunners, it is imperative for an efficient chemicals regulation to make the continued use of the most harmful substances a non-profitable choice. It must be less profitable for companies to i.e. apply for authorisation/derogation than to substitute the use.

We need a system that drives substitution of the most harmful substances efficiently. The companies working towards this change need attention and support. The most efficient support is to give them market opportunities.

The options in the REACH revision put forward so far from the Commission are in our view now enough to support the right companies. Efficient mechanisms for substation (economic incentives and strict regulation for example) need to be put in place to achieve the aims of the Chemical strategy.

### Socio Economic Analysis

The socio-economic analysis (SEA) done in the REACH process today has proven to slow down the regulation and the phase-out of SVHCs. The way SEA is implemented in REACH has also been shown to work against many incentives for substitution. Therefore, we believe that to

deliver on the aims set out in the Chemical Strategy, SEA needs to be taken out of REACH or substantially change.

### Timeframes and Obligations

Time limits and automated processes would make REACH more efficient. Automated processes make sure the process moves forward and require few public resources. We encourage substances classified under CLP to move directly to the Candidate List in an automated process. We also encourage a requirement on the Commission to apply risk management measures on the Candidate list substances within 5 years.
Moreover, including obligations for the Commission to act and regulate the most harmful chemicals would also make the regulation more efficient and valid.

*If you have any questions regarding what is stated in this paper please do not hesitate to contact frida@chemsec.org or theresa@chemsec.org*