CHEMTrust
Protecting humans and wildlife from harmful chemicals

Consultation response
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CHEM Trust response to the Commission's Inception Impact Assessment "*Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals*"

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1 Introduction

CHEM Trust welcomes this opportunity to input into the Commission's discussions on the revision of the EU's crucial REACH chemicals regulation. CHEM Trust is an NGO that focusses on EU-level regulation of chemicals, in particular endocrine disrupters and persistent, bioaccumulative and/or mobile chemicals. Our team includes people who worked on the processes around the creation of REACH, so we have a great deal of experience of the good and bad points of this important law.

- See also: https://chemtrust.org/reach-10-years-on/

REACH is a crucial element of the EU's environment and health policy, but unfortunately there are many areas where it has not provided enough protection, often due to the combination of a lack of safety data and an unwillingness to act on this limited data. In many cases this means that exposure to a hazardous chemical continues for many years, with many opportunities for companies to use legal challenges to delay protective action.

CHEM Trust welcomed the commitments made in the Chemicals Strategy for Sustainability (CSS) for the strengthening of EU chemicals regulation. However, we are very concerned that some of these policy ***commitments*** in the CSS have become policy ***options*** in the Inception Impact Assessment, and also that certain new policy options (like deleting the Authorisation Title) have appeared which would weaken protections, not strengthen them.

We have structured this response in the same order as the inception impact assessment. We have focussed our comments and evidence contributions on those areas which are particularly important to CHEM Trust. However, REACH is a complex and inter-locking system, and it is vital that it is strengthened, not weakened – see submissions from other environmental and health NGOs, for example EEB, HEAL and others.

2 Our comments on 'Objectives and policy options"

2.1 A general point on grouping:

In our report "*From BPA to BPZ: a toxic soup? How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them*"[1] published in March 2018 we looked in depth at the bisphenols as an example of a group of chemicals where increasing controls on one member, Bisphenol A, was leading to market shifts towards other chemicals in the same group, which appeared to have very similar hazards to bisphenol A.

Our first recommendation in this report was:

> *"Regulators should regulate groups of related chemicals, rather than taking a substance by substance approach. In the absence of good data to the contrary, chemicals with similar structure should be assumed to have the toxicological properties as harmful as those of the most toxic known substance in the group. This approach needs to be used in the main EU chemicals law REACH, and also in other chemical regulations, such as laws on chemicals in food contact materials. ECHA should also investigate the effectiveness of the industry's self-classification of chemicals, and whether this is being done in accordance with the legal requirements."*

The implications of taking a grouping approach would lead to changes in registration, evaluation, restrictions, authorisation and classification and labelling.

Groups should include all related chemicals, and are treated (in terms of CLP, restrictions etc) as having the properties of the most hazardous member, unless industry comes forward with substantial data to show that a chemical does not have these properties.

[1] https://chemtrust.org/toxicsoup/

Such an approach reverses the burden of proof & encourages industry to move away from problem groups. It also means that you need less test data, unless industry wants to defend a chemical in which case they need to pay for tests.

Clearly there are still questions about exactly how you define a group, though microplastics and PFAS will have useful lessons, and it may be possible for a chemical to be part of more than one group. The key issue is applying the precautionary principle, where a lack of data means the chemical is viewed to have the most hazardous properties in its group. This is in contrast to the current approach, where the absence of data is one of the best ways to keep a chemical on the market, which then incentivises companies to challenge any attempt to get more data (e.g. in Substance Evaluation).

2.2 Revision of the registration requirements:

The problem definition of the REACH inception impact assessment clearly states that current information requirements do not allow a sufficiently thorough hazard assessment, including for carcinogenicity, neurotoxicity, immunotoxicity and endocrine disruption. The lack of information occurs in all tonnage bands and is in particular significant for substances produced between 1-10tpa and polymers. Closing these information gaps should be one of the most important priorities for the REACH revision as the information provides the basis for subsequent control measures. Without enhanced information requirements there will be no improved protection for human health and the environment.

The Commission Communication on the REACH review in 2018[2] stated: that "*incentives are lacking for companies to update their registration dossiers and work is still needed to rectify important data gaps or inappropriate adaptations to testing*". (...) This failure to fulfil obligations from the companies' side should be addressed and the legal text should be clarified and options for enforcement improved.

The other important findings from the REACH review should guide the considerations for adding new information requirements to the REACH Annexes, in particular on those endpoints needed to clarify whether a substances has SVHC properties. Quoting once more from the Commission Communication:

> *"Compliance with the information requirements by registrants is considered insufficient. This is related to two main causes: (i) the legal requirements to avoid animal testing may push registrants to use alternative methods to animal testing, even if not justified; and (ii) difference in the assessment of hazard between registrants and authorities"*

These insights have to be at the centre of the new provisions and the different options developed should all have the purpose of rectifying these problems.

It will be important to link the new proposals for REACH data requirements very clearly to the CLP provisions and new hazard classes so that sufficient data are available to make the hazard identification possible. Previous analysis from regulators[3] has found that "REACH will hardly generate sufficient information for classification of substances as category 1B for mutagenicity and carcinogenicity. Therefore, indications of very severe hazards of substances are missed and health risks could occur."

In addition, for endocrine disruption endpoints there is a huge gap which needs to be filled and companies will have to update their dossiers accordingly to fulfil their obligation to ensure safe use. CHEM Trust, together with HEAL, has already provided comments to the first suggestions under discussion as part of the CARACAL subgroup on endocrine disrupters (CASG ED):

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

[3] Woutersen et al., Human and Ecological Risk Assessment 25(1):1-20, DOI: 10.1080/10807039.2018.1480351.

It will also be crucial to include new data requirements/new endpoints in order to be able to improve the identification of substances with immuno- and neurotoxic properties, and in particular developmental immuno- and neurotoxicants to protect children's brain development and immune system. See our recent blog on this subject: https://chemtrust.org/edcs_brain_development/

The new REACH information requirements are likely to include a combination of in vitro, in vivo and non-test methods for the identification of the inherent properties for chemicals. In the future, more methods will become accessible to partly replace animal test methods. Therefore, there is an urgent need to develop regulatory identification approaches based on in- vitro methods and other methods, like grouping and read-across. Still, it would not be acceptable to leave dangerous substance properties unidentified. The benefits of REACH for human health and environment will depend on the extent harmful substances are identified and regulated.

As the Commission Staff working document on the REACH review in 2018 stated:[4] [our emphasis]

> *"REACH has also promoted alternative methods for testing though the legislative requirements to only test on animals as a last resort* ***has been implemented at the expense of hazard information relevant for the protection of human health and the environment****."*

2.3 Introduction of a Mixtures Assessment Factor (MAF):

- The Commission Staff working document on mixtures published as part of the CSS in 2020 has highlighted very clearly that current EU laws systematically underestimate the risks from multiple exposures to chemicals. Therefore this crucial protection gap should finally be given a high priority in the REACH revision after it has been neglected for many years.
- Results from EU research projects like HBM4EU or SOLUTIONS have illustrated the concern for health and environment resulting from the exposure to combination of chemicals. EDCMixRisk has demonstrated that prenatal exposure to mixtures of EDCs was associated with various effects in children's health and development. Tested mixtures affected hormone-regulated and disease-relevant outcomes in a variety of experimental models at the same concentrations found in the pregnant women.
- The introduction of a MAF in REACH registration is one important tool so that companies take combination effects into account in their chemical safety assessment. This should apply to all registered chemicals above 1 tpa. As we emphasized in joint NGO submissions to CARACAL in January 2021 we support the introduction of a generic MAF as there is little evidence to support different sizes of MAFs for different scenarios. Furthermore, we see the added value of the MAF in its generic nature given the multitude of exposure routes and situations. It is also important that the MAF should be large enough to account for the plethora of exposures to chemicals from different uses in different sectors and should be at least 100, see this talk for more details.
- In addition to the introduction of a MAF in REACH the other important commitment of the CSS to "*introduce or reinforce provisions to take account of the combination effects in other relevant legislation*" should be prepared in parallel. What is needed is the development of a legal framework and a mechanism to improve the co-ordination across regulatory areas to address the exposure to a combination of chemicals subject to different pieces of legislation.

[4] https://eur-lex.europa.eu/resource.html?uri=cellar:2834985c-2083-11e8-ac73-01aa75ed71a1.0001.02/DOC_1&format=PDF

2.4 Simplifying communication in the supply chains

- CHEM Trust is very supportive of more information flow in the supply chain, including to consumers and workers. Any simplification must ensure more flow of information, not less.

2.5 Revision of the provisions for dossier and substance evaluation:

Given that REACH puts the responsibility on industry to provide information on the properties of their chemical, if sufficient information is not available then there should be enforcement action taken. Unfortunately REACH has largely given a free ride to those companies who have not provided sufficient data, so rather than 'no data no market' the reality is 'no data no problem'. This incentivisation against providing data must change.

Looking specifically at Substance Evaluation, CHEM Trust has just published a blog looking at the example of Decabromodiphenyl ethane (DBDPE), where a substance evaluation was initiated in 2012, but nine years on there is no EU regulatory action on this substance and it remains in widespread use in our homes, in spite of the fact that research has shown that contaminates wildlife across the world.

The principle of group assessments for dossier and substance evaluation should be formally enshrined in REACH. The group should be treated as having the property of the most hazardous member, and the burden of proving that specific chemicals should be excluded from the group should be on industry. This would be a better implementation of producer responsibility, rather than the current approach where lack of data leads to inaction, as regulators are not prepared to sanction the deficiencies.

In addition, it should be considered whether substance evaluation is the appropriate tool to deal with chemicals that are potentially members of groups of concern. As we point out in our blog on DBDPE, the group Restrictions on PFAS and micro-plastics bypass the Substance Evaluation process and instead focus on justify group membership and known hazardous properties of certain substances in the group.

Classification and labelling inventory

It's also worth highlighting how poorly industry takes its responsibility to classify and label its chemicals. As our blog on DBDPE points out, almost every notifier has stated that this chemical has no hazards in their submissions to the Classification and Labelling Inventory (CLI), in spite of the fact that it is accumulating in polar bears and human breast milk.

In the case of bisphenol S (BPS), our 'Toxic Soup' report identified that in February 2018 the majority of notifiers to CLI claimed that BPS had no hazards, in spite of the fact that RAC said in 2015 that BPS "*may have a toxicological profile similar to BPA*". Since our report was published RAC has agreed at the end of 2020 that BPS should be classified as a Reproductive Toxin (1b).

Commissioning tests

We support giving the opportunity for authorities to commission test to obtain hazard information, as it is clear that in some situations – for example DBDPE – years are wasted in attempts to get the registrants to deliver data. Tests commissioned by authorities also give an opportunity for the properties of multiple chemicals to be established in one set of tests, which will be more rapid and efficient in some circumstances.

However this should not take away from the legal responsibility of registrants to deliver data, including updating data and delivering anything requested in substance evaluation. We would like to see effective enforcement of these legal responsibilities.

2.6 Reforming the authorisation process

We support reforming the authorisation process to clarify the current provisions and improve the interface with the restriction process. Both should remain separate, complementary processes as they have distinct aims and merits. Restriction puts the burden of proof on the authorities to demonstrate risk, while authorisation puts the burden on applicants to demonstrate safe use

However, we are opposed to the idea of removing the authorisation title from REACH, as any such deletion would be a weakening of EU chemicals legislation, which is not what the CSS states that it will achieve.

In addition, any removal or the Authorisation title would also remove the articles that define SVHC substances, which would be totally unacceptable.

We are surprised that the IIA does not mention the Commission's plan to extend the hazards covered by SVHC status; it is clearly stated in the CSS that the Commission will *"introduce endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances as categories of substances of very high concern*". CHEM Trust is supportive of this extension of SVHC status.

CHEM Trust has emphasised the importance of addressing the persistent and mobile PFAS group of chemicals. The simple reality is that if persistent and mobile chemicals are released into the environment it is impossible to remove them if they are later found to be toxic. The contamination caused by the PFAS group should be viewed a severe lesson of what happens when persistent and mobile chemicals are allowed to be used – it is also an indictment of both industry irresponsibility and regulator inadequacy. **If the Commission wishes to impact assess action on persistent and mobile chemicals they could start by calculated the cost of removing PFAS from the world's environment.**

We would also make the following general points on authorisation:

- Authorisation provides information on uses of chemicals that is not present in registration dossiers, which causes problems in the Restrictions process
- CHEM Trust do not see any merit in national authorisations, though we would welcome stronger compliance inspections within Member States
- Any modifications to the Authorisation system must create a more protective system, with rapid action to control the use of the most hazardous chemicals. For example, ensuring that they are always time limited, with the need for an active Commission decision to end them.
- Authorisation has not been properly applied, and there is a need to correct mistakes in the implementation, for example upstream authorisations and a failure to properly consider the availability of alternatives/

2.7 Reforming the restriction process

CHEM Trust would certainly agree that the Restriction process has been too slow; as the 2018 REACH Review staff working document states: [our emphasis]

> *"As stated in the legal text, REACH's provisions are underpinned by the precautionary principle, however, since the entry into force of the legislation,* ***the risk management actions proposed by the Commission have been limited****"*

We are also very supportive of an extension of the Generic Risk Assessment (GRA) approach, as this is proven to be a faster and more protective approach.

The GRA approach should be expanded to cover the following hazard classes:

- Endocrine disrupting chemicals – for more details, see our paper "A new path for EU control of Endocrine Disruptors" published in July 2020.
- PBT/vPvB chemicals, and also PMT and vPvM chemicals – as mentioned above, these are chemicals that cause widespread contamination and cannot be removed from the environment once release.
- Neurodevelopmental toxins, our March 2017 report looking in detail at the issue "No Brainer: The impact of chemicals on children's brain development: a cause for concern and a need for action."
- We are also supportive of the extension to immunotoxicants (an issue that has been highlighted by PFAS), respiratory sensitisers or substances that affect specific organs.

The CSS commits the Commission to extending the GRA approach to Food Contact Materials, which we have welcomed, but in addition REACH Restrictions should also routinely cover uses in food contact materials, rather the current inconsistent approach.

As mentioned above, group restriction should become the normal approach. This is to speed up the Restriction process and also to prevent industry moving from one problem chemical to another e.g. BPA to BPS or even BPZ, as examined in details in our report "*From BPA to BPZ: a toxic soup? How companies switch from a known hazardous chemical to one with similar properties, and how regulators could stop them*" published in March 2018.

2.8 Revision of provisions for control and enforcement:

Options include establishing minimum requirements for national controls and enforcement, including stricter border controls; and establishing a European Audit Capacity to audit Member States enforcement.

It is very clear from numerous studies that control and enforcement is a pervasive weakness of REACH, affecting many different aspects.

For example, there is little evidence of compliance action against a failure to deliver data before the deadline in substance evaluation, for example in the case of DBDPE.

The IIA also doesn't mention important policy measures like strengthening the completeness check and requiring regular, mandatory registration updates (or regular re-registration). As all chemicals have been phased-in since 2018, it is now time to strengthen the provisions for the completeness check: the completeness check should ensure that registration dossiers contain all information needed for hazard identification.

3 Our comments on "Preliminary Assessment of Expected Impacts"

3.1 Economic & social impacts

There is a long history of reports that exaggerate the economic impacts of REACH, with some particularly poorly research but heavily promoted reports during the formation of the REACH, for example those by Arthur D Little for German BDI and by Mercer in France. ChemSec's 2016 Cry Wolf report includes a critical analysis of these reports as well as others.

One of the key issues in chemicals policy is the importance of encouraging substitution. Older chemicals tend to be cheaper due to fact that investment in plant etc has already happened. Newer, safer alternative chemicals or technologies are frequently more expensive, and so strong regulatory measures are needed to enable them to compete and scale up.

It is also vital that the EU economy avoids stranded assets when the economy is moving out of from fossil fuels. It is counter-productive to have a transition to more use of hazardous substances, as this just creates the need for a further transition to safer and more sustainable substances in the future. In its deep transformation toward net zero the chemical sector needs clear safety, health and environmental guidance to avoid lock-in and stranded assets.

Safer alternatives are often non-chemical solutions which provide a safer and better service. Many of these are more labour intensive (creating jobs) and can also help shorten allow shortening of overly long supply chains. Any claims of overall job loses should be treated with great suspicion.

3.2 Health and Environment impacts

It is important to consider health and environmental benefits of a stronger chemicals policy, though the Commission should also be aware that such assessments are inevitably limited, with many environment and health impacts ignored. This issue is examined in more depth in the study that we commissioned from the New Economics Foundation.

3.3 Likely impacts on fundamental rights

We support the assessment that a strengthening of REACH will improve the protection of consumers and environment as enshrined in the Charter of Fundamental Rights of the European Union – but this requires the measures we describe in this submission at a minimum.

3.4 Likely impacts on simplification and/or administrative burden

More use of grouping throughout REACH and regulatory action based on in vitro tests will reduce registration costs, as discussed above.

Increasing the overall speed of REACH processes will also reduce the resources spent in delayed and repeated processes.

4 Conclusions

REACH is a vital and world-leading piece of EU legislation, however it has many deficiencies. This revision provides an opportunity to correct these deficiencies and create a system that will truly encourage the development and use of safe and sustainable chemicals, and help solve the problem of polluting and hazardous chemicals.