CHEMTrust
Protecting humans and wildlife from harmful chemicals

Consultation response
May 2021

CHEM Trust response to the Commission's Inception Impact Assessment "Revision of EU legislation on hazard classification, labelling and packaging of chemicals"

1 Introduction and context

CHEM Trust would like to take this opportunity to comment on the Commission's plans for revising the EU CLP legislation. CHEM Trust welcomed the commitments made in the Chemicals Strategy for Sustainability (CSS) for strengthening the identification and control of chemicals with properties that are endangering public health and the environment. However, we are very concerned that some of these policy commitments in the CSS seem to have become optional as described in the Inception Impact Assessment.

It will be very important to focus the revision of the EU chemicals policy framework on those policy areas where the greatest potential for protecting health and environment can be expected. In CHEM Trust's view the emphasis should be placed on introducing new hazard classes for endocrine disruptors (EDs) with different sub-categories. Together with our campaign partners from the EDCFree-Europe coalition we have advocated for many years for a better identification of EDs, followed by necessary protective measures to minimize exposure.

CHEM Trust also strongly supports the introduction of new hazard classes relating to persistent, bioaccumulative and toxic properties (PBT, as well as vPvB properties) and persistent, mobile and toxic properties (PMT, as well as vPvM properties).

We also support a greater emphasis on the identification of substances with developmental neurotoxic- and immunotoxic properties, as mentioned in the CSS. If the EU Green Deal is supposed to live up to its aims to result in more prevention and precaution, this will require a more efficient identification of harmful substance properties and subsequent control measures that provide for long-term benefits and go beyond window-dressing.

2 Our comments on 'B. Objectives and policy options"

2.1 Introduction of new hazard classes and corresponding criteria

The identification of substances with hazardous properties such as endocrine disrupting, neurotoxic, immunotoxic, as well as substances that are PBT, vPvB, PMT and/or vPvM is a prerequisite for taking regulatory measures to obtain adequate protection of human health and the environment. Therefore, the first bullet point on the introduction of new hazard classes under Part B is by far the most important of the long list mentioned as options for the CLP revision. However, it is important to underline that an increased protection level can only be obtained, and substances with these hazardous properties can only be identified, if data are available. Therefore, it is essential to update the REACH information and registration

requirements as outlined under Part B in the inception impact assessment for the revision of REACH. For more details see CHEM Trust response.[1]

The inclusion of new hazard classes in the CLP Regulation will ensure more consistency and transparency in legislation. The horizontal approach ensures that harmful substances will be addressed by all relevant EU legislation referring to chemical substances and products. It will be an important step forward to increase the protection level and live up to the EU Commission's Green Deal ambition of zero-pollution leading to a toxic-free environment.

2.1.1. Endocrine disruptors

Until now only around 20 substances have been officially identified as endocrine disruptors/endocrine disrupting chemicals (ED/EDCs) since the REACH legislation entered into force in 2007. This is mainly due to the lack of sufficient data on chemical substances, the burden of proof required to meet the WHO definition, and the very strict criteria for identification under the biocides and pesticides legislation. However, endocrine disruption is especially harmful to the developing foetus leading to deleterious effects after birth or later in life or even in the next generation. Thus, the identification of, and regulatory action on substances that are suspected to be endocrine disruptors is crucial to ensure increased protection from exposure to these chemicals. Regulatory action must no longer be postponed, and it should be emphasised that immediate protective measures to compensate years of inaction in the protection of the unborn child are needed.

CHEM Trust has called for regulatory action on EDCs to be strengthened urgently for many years, and in July 2020 we presented the publication `A new path for EU control on Endocrine disruptors´ to illustrate a new approach to protect people and wildlife in the EU.[2] It highlights how CLP, REACH and other legislation need to be amended to result in a more protective framework with regard to endocrine disrupting substances. In September 2020, the EDCFree Europe coalition once again called on EU regulators to finally strengthen protection from endocrine disrupters.[3]

Building on this, CHEM Trust, together with the NGOs HEAL and ClientEarth, has recently outlined in a joint policy paper how horizontal identification of EDCs should be included in the CLP Regulation.[4] Here we have explained why 3 subcategories are needed as part of the new hazard classes for EDs. It is important to align the horizontal ED criteria with the criteria for substances that are carcinogenic, mutagenic, or toxic to reproduction, to ensure consistency in legislation. In a nutshell, we propose the introduction of the following hazard classes in CLP.

- **Category 1: Endocrine disruptor** *(Known Cat. 1A and Presumed Cat. 1 B based on the source of evidence)*
- **Category 2: Suspected endocrine disruptor** (*Substances for which there is some evidence but not sufficient to meet the Category 1 criteria)*

To be consistent with the CMR approach and to be transparent on the source of the evidence, it seems most advantageous to split Category 1 into 1A (information largely based on evidence from humans or

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/F2330024_en

[2] https://chemtrust.org/wp-content/uploads/CHEMTrust-newEDPolicy-July2020.pdf

[3] https://www.edc-free-europe.org/articles/position-papers/edc-free-europe-demands-for-a-protective-european-framework-on-endocrine-disrupting-chemicals

[4] https://chemtrust.org/wp-content/uploads/Joint-CT_HEAL_CE-proposal-on-CLP-ED-criteria-March-2021-final-with-date.pdf

animals living in the environment), and 1B (information largely based on data from experimental studies in vivo).[4,5]

In addition, we make the suggestion to classify substances that are shown to have endocrine activity, as endocrine activity is a strong indicator of a potential for ED properties. Further, it can inform companies and the public about chemicals that may have a potential for being endocrine disruptors.

- **Category 3: Substance showing endocrine activity** (*Substances that show endocrine activity in specified in vitro tests)*

2.1.2 Persistent, bioaccumulative, and toxic (PBT, vPvB) or persistent, mobile and toxic (PMT, vPvM)

CHEM Trust supports the inclusion of new hazard classes for PBT/vPvB as well as for PMT/vPvM chemicals. In analogy to the discussion on ED criteria, we support a sub-category which lists those substances with 'suspected´ properties. As we presented in the context of the 3rd international PMT workshop organised by the German Environment Agency "Getting Control of PMT and vPvM substances under REACH", a sub-category allows for more transparency, better reflects the available data and provides a heads-up to all actors in the supply chain.[6]

2.1.3 Chemicals with immunotoxic and/or (developmental) neurotoxic properties

The Commission has promised in the CSS to investigate the *modalities and timing for extending a generic risk management approach to chemicals that affect the immune, neurological or respiratory system as well as chemicals toxic to a specific organ* (page 10). This important measure first requires a proper identification and therefore, we welcome efforts to create separate hazard classes also for these groups/subgroups. CHEM Trust has already warned about the lack of protection from neurotoxic substances and in particular from developmental neurotoxicants in the report `No Brainer: The impact of chemicals on children's brain development: a cause for concern and a need for action.´[7]

2.2 Other points

Speeding up harmonised classification: CHEM Trust supports the introduction of a mandate for the Commission to request ECHA to develop new harmonised classification and labelling dossiers to speed up the process of agreeing EU-wide classifications for harmful substances.

Updating information requirements: Another important issue to stress is the relation with the REACH revision process regarding the update of the REACH information requirements in Annex VII to X. The revision must ensure that registration dossiers contain all information needed for adequate hazard identification, and in particular for substances with endocrine disrupting properties. For more details see CHEM Trust submission on the REACH inception impact assessment[1] and our comments on the Commission proposals discussed within the CARACAL subgroup on EDs.[8]

[5] https://chemtrust.org/action-on-suspected-edcs/

[6] https://chemtrust.org/wp-content/uploads/CHEM-Trust-UBA-conference-PMT-March-2021.pdf

[7] https://chemtrust.org/brain/

[8] https://chemtrust.org/wp-content/uploads/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_final.pdf

Ensuring the right expertise and resources for the identification work in ECHA committees: The new processes and hazard classes for identifying substances under CLP will mean a shift in responsibility of different scientific committees. This will require a careful assessment of resources and expertise needs in ECHA Risk Assessment Committee (RAC) and ECHA Member State Committee (MSC).

Making identification future proof and less reliant on animal data: Identification should be based on all available data, including peer-reviewed academic studies, in a weight-of-evidence approach and be conducted by experts in the respective scientific areas and assessments. The criteria should be able to include a variety of *in vitro* and non-test methods for the identification of the inherent properties for chemicals. In the future, such methods will become more and more accessible and 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.[1]

Clarifying the obligations to classify mixtures: It makes sense to clarify the obligations for classifying mixtures and some complex substances. When it comes to classifying mixtures of endocrine disruptors, it should be underlined that endocrine disruptors should by default be considered as non-threshold substances. Therefore we would find it problematic from a scientific point of view to introduce general concentration limits for EDs. Some of the special characteristics of endocrine disruptors include the fact that protective thresholds cannot be set with sufficient certainty, the existence of low dose effects, and non-monotonic dose responses. Moreover, because substances have various modes of action, the usual principles in toxicology cannot always be used for endocrine disruptors. We therefore propose to refrain from setting a general concentration limit. See joint HEAL/CHEMTrust comments on the proposals made in the CASG ED.[9]

3 Our comments on "Preliminary Assessment of Expected Impacts"

It will be very important for the impact assessment to properly balancing costs and benefits for certain companies as well as costs and benefits for society. Experience has shown that impact assessments are often not properly considering both likely impacts in the future, and uncertain impacts which were not fully understood. The NEF report: "Discounting Future Damage" describes how important this is for any socio-economic assessment and how to ensure a less biased approach.[10]

For context and starting point of the expected impact analysis we note:

- Only around 20 substances have been officially identified as EDs in the EU since 2007. However, several analyses have led to over 1000 substances being listed as potential EDs so new horizontal criteria via a new hazard class for identification of EDs and Suspected EDs will represent an important step to increase the level of protection.[11]
- Horizontal criteria will lead to a more efficient ED identification process and support other regulatory processes, facilitating the work of industry, downstream users, and authorities.
- Regulatory burdens for companies may increase due to new requirements, however, the savings of companies by not having to follow regulatory identification processes in many different sectors should not be underestimated.

[9] https://chemtrust.org/wp-content/uploads/2021.04.26.HEAL_CT_comments_CLP_proposal_EDCs_final.pdf
[10] https://chemtrust.org/putting-a-price-on-health/
[11] https://chemtrust.org/2021-eu-edc-policy/

- It should also be emphasised that the introduction of an ED hazard class may lead to substitution to less problematic substances and facilitate and foster innovation, thereby creating new business opportunities.
- It should also be highlighted that the expected positive social and environmental impact will take years to obtain. First, it will take many years before the new legislation is fully implemented but not least because endocrine disruption is most harmful when the foetus is exposed, so the real positive impact of a regulatory intervention today will only be fully achieved, after yet another generation.

To increase the protection level and obtain an immediate positive impact, we find it necessary to establish transition measures to ensure swift identification and control of EDs based on current data.[2]

4 Our comments on Evidence Base and Data collection

The Commission Staff Working Document on the Fitness Check on endocrine disruptors[12] highlighted very important points which should form the basis for the ED hazard class under CLP:

- A need for a horizontal approach for identification of EDs based on the WHO-definition and building on the criteria developed for biocidal products and plant protection products while ensuring it is fit for purpose for other relevant legislation.
- The strengthening of information requirements in the relevant legislation is key to improving identification of EDs.
- There is a need to explore options to strengthen the legislative framework to further minimize exposure to EDs, both for consumers and the environment.
- It was confirmed that the current approach of considering data from scientific literature alongside those obtained by regulatory testing is needed.
- Efficiencies could be gained by developing a horizontal approach to EDs, including increased use of grouping approaches and new approach methodologies to avoid the use of animal tests.

The Commission Staff Working Document on the Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries[13] identified the CLP regulation as:

> "*one of the most efficient aspects of the functioning of the EU chemicals legislative framework, as it allows hazard classification of a wide range of chemicals without creating a disproportionate administrative burden for public authorities while focusing their resources on the most relevant substances for human health and environmental protection*" (page 108).

It also highlighted important areas for future improvement or further assessment. These include e.g. assessing the benefits of the introduction of additional hazard classes in the CLP Regulation for PBTs/vPvBs and endocrine disruptors and the protection of vulnerable population groups, including those that are particularly sensitive to endocrine disruptors. More generally, it mentions the need for addressing risks posed by endocrine disruptors, in particular the need for a coherent approach for the identification of endocrine disruptors across all relevant Union legislation.

In CHEM Trust view it will be crucial to adequately estimate the enormous costs and burden on society of remedying/treating health effects and the impacts on the environment. This is particularly relevant given

[12] Commission Staff working document: SWD_on_Endocrines_disruptors.pdf (europa.eu)
[13] Commission Staff working document: swd_2019_0199_en.pdf (europa.eu)

the serious and irreversible effects endocrine disruptors, PB(M)T and neurotoxic chemicals may cause, including their potential impacts on the next generations. Previous assessments useful in that context are:

a) The Nordic Council: The Cost of Inaction - A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, 2014.[14]

b) Health impact studies on several ED endpoints, published in 2015.[15]

However, it should be noted that these studies only cover a limited range of effects or group of chemicals, respectively.

5 Conclusions

The CLP Regulation is a key piece of EU law which helps to identify, communicate and trigger the regulation of hazardous chemicals in Europe. The inclusion of legally binding hazard identification of endocrine disrupters for EDs in the CLP Regulation was one of the Commission commitments set out by new European Chemicals Strategy for Sustainability. Equally, the Commission promised to *propose new hazard classes and criteria in CLP to fully address environmental toxicity, persistency, mobility and bioaccumulation*.
Therefore the CLP revision must focus on these main aspects in order to improve the efficiency of identifying harmful substances and thus lay the basis for speeding up the measures to reduce human and environmental exposure to toxic chemicals.

[14] https://www.norden.org/en/publication/cost-inaction
[15] https://chemtrust.org/health-impacts-from-hormone-disrupting-chemicals-cost-eu-countries-billions/