

HEAL's input on the CLP revision roadmap consultation



1st June 2021

The Health and Environment Alliance (HEAL) welcomes the opportunity to **comment on the inception impact assessment for the revision of the EU legislation on hazard classification, labelling and packaging of chemicals (CLP)**.

We are pleased with the Commission's commitment under the Chemicals Strategy for Sustainability (CSS) to reinforce the CLP Regulation (together with REACH) in order to rapidly respond to scientific findings and address ongoing and emerging health and environmental concerns. However, we regret to see that **the IIA roadmap falls short in delivering the Commission's commitment**.

CLP is a cornerstone of the EU chemicals legislation and its purpose is to ensure a high level of protection of health and the environment as well as the free movement of substances, mixtures and articles. The assessment at the basis of classification determines whether a substance or mixture meets certain classification criteria to be considered as hazardous for human or environmental health. It triggers policy action under other legislations, and determines manufacture, use, distribution and trade of the substance. Consequently, **it is of utmost importance that substances or mixtures that are hazardous to human health and the environment are properly identified via CLP and that this classification can feed into other chemical legislations.**

CLP is currently missing hazard classes. As a result, certain hazardous substances that can give rise to human diseases and environmental degradation are still placed on the market, without being properly identified and without adequate restrictions being implemented under other legislations. In parallel, there is a need to increase the quality and transparency in the hazard assessment process, to make more resources available to the authorities in charge of it and to enhance safeguards for its integrity.

To our disappointment, the IIA roadmap does not mention all the important European Commission commitments foreseen for the CLP review in the EU CSS. It focuses considerably on the quantification of the potential economic impacts of the CLP review for companies at the expense of protection needs. **There is indeed only little emphasis on the creation of new hazard classes and the strengthening of the hazard evaluation procedure in Europe** – which should be the main aim of this revision process in view of delivering the European Commission commitments under the CSS.

According to HEAL and on the basis of the CSS commitments, **the IIA should focus on what elements the CLP review must include to increase human and environmental protection from chemical substances and mixtures, always in line with the latest scientific knowledge**. Increased human and environmental health protection will inevitably result in significant long-term economic benefits for society. Saving on health costs associated with chemical exposure¹ and on resources dedicated to mitigating impacts of chemicals and pollution clean-up pollution (e.g. drinking water companies) will not only protect the health of future generations, but it will also increase the overall wellbeing and functioning of our society and economy.

Development of hazard categories

According to the CSS, the Commission is committed to ensuring that "*CLP* is the central piece for hazard classification and allows the Commission to initiate harmonised classifications", in particular by "adding

¹ According to the Endocrine Society, estimated Costs of Endocrine-Disrupting Chemical Exposure Exceed €150 Billion Annually in EU. Trasande et al 2015, J Clin Endocrinol Metab. 2015 Apr;100(4):1245-55. doi: 10.1210/jc.2014-4324

endocrine disruptors, and PBTs/vPvBs, assessing the need for specific criteria for immunotoxicity and neurotoxicity, currently under the hazard endpoints 'Specific target organ toxicity' and 'reproductive toxicity', and amend them if necessary".

HEAL is however concerned that PBTs/vPvBs as well as neurotoxic and immunotoxic compounds are not mentioned at all in the current IIA for development of new hazard categories.

More specifically, new hazard categories should include:

- Endocrine disruptors (EDs): the Commission should introduce categories in line with the classification system of other hazard classes; Cat1A, 1B for known and presumed ED and ED Cat2 for suspected EDs. HEAL proposes the introduction of an additional class for endocrine active substances (Cat 3)².
- **<u>PBTs/vPvB substances</u>**: these are of high concern for the environment, and in the long-term for health, and are currently not identified properly under EU hazard identification systems. A harmonized classification system, through the creation of a hazard class under CLP is urgent.
- **Neurotoxic and immunotoxic substances:** In line with CSS, the commission should update the hazard endpoints 'Specific target organ toxicity' and 'reproductive toxicity' in order to include the ones relevant for neurotoxic and immunotoxic substances. A creation of a new class could be considered in the different IIA options.

Hazard assessment procedure

Under the CSS, the Commission has also committed to building greater trust in the scientific underpinning of EU decision-making processes for chemicals, and proposed to build on the important steps taken regarding transparency in the EU food safety sector. To achieve this, it committed to extend the principle of open data and the relevant transparency principles from EU safety sector to other pieces of chemical legislation.

In HEAL's view, a crucial first step to improving the **objectivity and transparency** of the hazard assessment procedure and strengthening public trust in it is to make the toxicity studies provided by the companies publicly available as part of the process. This would reduce the inherent bias of these studies that are performed by companies that have commercial interests in the approval of the substances being assessed.

We are therefore concerned at the **absence of measures to promote transparency in the hazard assessment procedure** in the current IIA.

In the long term, HEAL supports a system where the toxicity studies of a substance or mixture are not provided by the companies any longer but are commissioned by an independent institution (e.g. ECHA or a public authority) and are carried out in independent laboratories. The costs are paid by funds supported by the companies, in line with the 'polluter pays' principle.

Furthermore, CLP should provide clear guidelines to guarantee that **all available scientific knowledge is taken into account in the hazard assessment** and the competent authorities have the scientific expertise required as well as the necessary financial and human resources. In order to ensure that the decisions are objective, scientific and impartial from commercial interest, the CLP Regulation should consider to promote the endorsement of **an independence policy** across competent authorities involved in the procedure.

² HEAL, ChemTrust, ClientEarth (March 2021), Identification of EDs under CLP. [https://www.env-health.org/wp-content/uploads/2021/03/Joint-CT_HEAL_CE-proposal-on-CLP-ED-criteria-March-2021final-with-date.pdf]

The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 70 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

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