



Health and Environment Alliance (HEAL) - Response to the European Commission public consultation on the inception impact assessment for the review of the Food Contact Materials legislation

January 2021

Current situation

The Health and Environment Alliance (HEAL) welcomes the opportunity to comment on the European Commission's plans for revisions of the EU Food Contact Materials (FCM) legislation. HEAL has long called on the EU authorities to close the loopholes in the legislation, which put the health of Europeans at risk through potential leaching of chemicals of concerns from the food contact articles and materials into the food.

Among others¹, these loopholes include the following:

- Numerous chemicals that are harmful to human health are currently not restricted in strict enough a way to fully protect human health, including substances already identified as of very high concern (SVHC) under the REACH legislation.
- Endocrine disrupting chemicals are currently not assessed. Considering specific properties of these substances, such as effects at very low doses and non-monotonic dose responses, they should not be tolerated in food contact materials and articles.
- The legislation currently focuses heavily on the chemical presence in the starting materials, but non-intentionally added substances (NIAS), which are present as impurities or by-products of manufacturing processes, are not assessed. This means that the final food contact articles put on the market and through which consumers are mostly exposed to chemicals are not thoroughly enough assessed for safety.
- The real-life exposure conditions to chemicals as well as the additive effects between the various chemicals used in one single food contact article are overlooked in the current risk assessment process.
- Harmonised rules are lacking for all types of materials in use under EU legislation (for 12 out of 17 materials). It is urgent to develop rules that offer the same level of protection for all Europeans, starting with widely used materials such as papers and boards as well as printing inks. A recent testing undertaken by the Swedish chemicals agency KEMI in paper and cardboards found known hazardous substances in numerous food contact articles, including the phthalate DEHP in over 80% of the tested packaging materials².
- Recycled materials are not assessed for their adverse health effects.

¹ Further descriptions of the limitations of the current EU legislation on food contact materials can be found in: HEAL's response to the public consultation on the evaluation of the legislation https://www.env-health.org/wp-content/uploads/2019/05/HEAL-response-to-FCM-public-consultation_May2019.pdf
HEAL's briefing on food contact materials https://www.env-health.org/wp-content/uploads/2019/05/Food-Contact-Materials-Briefing-Health-and-environment-Alliance-HEAL-PRINT_final.pdf

² As reported by Chemsec, "Testing finds that 8 out of 10 packaging materials for food contain highly toxic chemicals", 19 January 2021, <https://chemsec.org/testing-finds-that-8-out-of-10-packaging-materials-for-food-contain-highly-toxic-chemicals/>

A recent scientific consensus statement, based on more than 1,200 peer-reviewed studies, has further underlined the urgency to address the risk of chemical contamination for the population through exposure to food contact materials and articles³.

Problem formulation and proposed approach to revise EU FCM legislation

For all the reasons mentioned above, we welcome the European Commission's problem formulation and its acknowledgement of some of the important limitations of the current regulation. **We believe that those issues justify undertaking a significant overhaul of the legislative framework for FCMs, and we therefore support proposed option (2): "Develop a new regulatory framework, replacing the current Regulation".**

Regarding the options for action presented in the document under consultation:

- We welcome the proposed shift onto the final material and/or combination of materials, which we have long called for. We would however welcome the clear additional mention of the final article, of which safety needs to be addressed through the new provisions.
- In the context of the estimated 8,000 substances coming into play on the European food contact market, we support the proposal to prioritise the assessment and management of substances, which is coherent with the EU Commission commitments under the Chemicals Strategy for Sustainability – including that to extend the generic approach to risk assessment.
- The aim of the revision of the EU FCM legislation should be to minimise the presence of all harmful substances in the food contact materials used for the production and at play in food contact articles. Therefore, we would welcome further clarifications as regards the consequences of the proposed tiered approach:
 - As regards tier 1, as a matter of principle, all identified category 1A/1B or 2 carcinogens, mutagens or reprotoxicants as well as identified endocrine disruptors, PBTs or vPvBs should be fully banned in food contact materials. This is necessary in order to minimise the presence of harmful substances rather than mere migration thereof in food contact materials in view of enhanced health protections.
 - Flexibility must allow the addition of substances of concern under tier 1 in the future, as scientific knowledge as well as regulatory provisions under other EU Chemicals laws evolved. For instance, the future development of hazard classes for endocrine disruptors must make it possible for the substances covered under such classes to be reflected in the list of substances covered under tier 1.
 - It is currently unclear from the Commission's document where non-intentionally added substances fit (which tier under the proposed strategy?) and how they will be taken into account according to the proposed plan. We would welcome clarifications on this aspect.
 - The approach proposed for tier 3 seems to suggest a significant involvement of industry players into the actual risk assessment. We would welcome clarifications about the proposed approach and the guarantees proposed to protect the integrity of the safety assessment.

³ Jane Muncke et al., Impacts of food contact chemicals on human health: a consensus statement, March 2020 <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-0572-5>

- Besides mentioning the reliance on the most up-to-date scientific information and the promise to clarify the roles of EFSA and ECHA respectively, the document is vague regarding the concrete steps that the Commission considers taking in order to close important safety loopholes that exist in current risk assessment methodologies and practice. For instance:
 - o How in practice endocrine disruption or other critical health endpoints such as neurotoxicity will be accounted in safety testing requirements;
 - o For endocrine disruption in particular, how the Commission intends to address the issues of effects at low doses and non-monotonic dose responses;
 - o Which options for accounting of cocktail effects of mixtures of chemicals at play in materials and final articles are considered;
 - o How the proposed 'one substance one assessment' is thought to look like when it comes to evaluations of substances already classified for health concerns by ECHA...

We look forward to clarifications on those points, which are crucial to the effectiveness of the revised legal framework in better protecting health.

- We welcome the commitment to support the development of safer and more sustainable alternatives, which is overdue. We will be looking for clarifications for how in practice the Commission intends to translate this commitment into action and stress that objectives of circularity must be thought together with, not at the expense of, the aim of minimising the recourse to harmful chemicals at the source and all throughout the lifecycle of materials and articles.
- When it comes to enforcement, we are wary at the proposed recourse to delegated and/or notified bodies to contribute to compliance checks. This could put the integrity of the compliance system at risk, especially on such a sensitive area as food safety. We would therefore favour the development of options designed to support the increase of capacities of national public authorities as well as better sharing of information and analytical methods among them.
- Finally, while we acknowledge efforts to better address communication and information throughout the supply chain, we note with concern that information towards consumers seems to be absent from the document under consultation. Consumers are exposed to chemicals through the handling of and/or direct consumption from food contact articles and materials on a daily basis. Besides the obvious aim to reduce consumers exposure to harmful chemicals, the revision of the EU FCM legislation is the opportunity to empower them to make informed choices and to promote their right to know.

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