

The Health and Environment Alliance (HEAL) welcomes the possibility to comment on the European Commission roadmap for the evaluation of food contact materials (FCM).

In HEAL's view, such an evaluation is long overdue, since the legislation has been in place since 1976. Many of the synthetic chemicals involved in packaging and storing the food we eat can leak into it, and researchers have alerted to potential harm to long-term health for three reasons: 1) consumers are exposed to known toxicants; 2) hormone production-disrupting chemicals, such as bisphenol A (BPA), tributyltin, triclosan and phthalates, can also be present in FCMs and 3) the number of known chemical substances intentionally used in FCMs is over 4,000. (1) This evidence combined with the JRC's recent assessment and other studies demonstrates that **the regulation falls short of meeting its two main objectives: the high level of protection of human health and the interests of consumers on the one hand, and the effective functioning of the internal market on the other hand.**

PROBLEMS WITH THE CURRENT LEGISLATION

HEAL's most immediate concerns relate to the lack of adequate provisions in the current regulation to achieve the protection of human health. We regret that the context description included in the roadmap does not highlight this aspect prominently and we call on the European Commission to ensure that the protection of human health is a guiding aspect of the upcoming evaluation. This is particularly critical, when we know that vulnerable groups such as babies, young children, pregnant or breast-feeding women are most at risk from the adverse health effects of an inadequate regulation (for instance because of loopholes for certain toxic substances in food packages). Unwanted chemicals present are routinely found in various food packages, without consumers knowing it and regulatory bodies acting upon those findings to fully ban those substances from food contact materials. (2) On the contrary, addressing food contact materials in a health-protective way will benefit citizens, workers in the food packaging sector and contribute to significant economic savings. (3)

Our concerns about the regulation's inadequacy to protect human health add to and overlap with the inadequacy of the regulation to ensure the functioning of the single market. This is because member states currently adopt different regulations to fill in the gaps of the European framework. In practise, this means that citizens are not protected equally across Europe from the risks arising from the presence of chemicals used in food packaging. Moreover industries have to abide by different standards depending on the countries in which they sell their products and workers in the food packaging industry are also exposed to different risks depending on the country of their workplace.

The European Parliament 2016 resolution on food contact materials (4) identified severe shortcomings on the functioning of the current regulation and clear demands for how the

European Commission could improve the current legislation and its enforcement. HEAL regrets that the present roadmap does not acknowledge this resolution and strongly supports that it should be an important basis for the evaluation to come, in addition to the JRC report already referenced in the roadmap.

HEAL'S VIEW ON WHAT THE UPCOMING EVALUATION SHOULD DELIVER

In HEAL's view, it is urgent for the European Commission to identify the existing loopholes in the regulation that currently put citizens' and workers' health at risk and draw on the most protective regulatory frameworks that might already exist in individual member states in order to overhaul the European framework. Doing so will benefit citizens' and workers' health and translate into higher regulatory certainty for businesses so that they can operate in better conditions. Finally this will stimulate innovation towards safer alternatives, giving the EU industry a competitive advantage over the rest of the world and an opportunity to set a golden standard in terms of regulation for others to follow.

In HEAL's view, the biggest regulatory gaps (4) that the evaluation should cover include the following:

- Most materials currently used for food packaging are not covered by the current regulation. Only five materials are covered: these are ceramics, regenerated cellulose film, active and intelligent materials, plastics, recycled plastics. Widely used materials such as paper and boards are overlooked.
- Many chemicals are not assessed for safety by public authorities, the so-called non-intentionally added substances (NIAS) that are present as impurities or by-products of manufacturing processes.
- Numerous chemicals harmful to human health are overlooked – including substances identified as of very high concern (SVHC) under the REACH legislation.
- Endocrine disrupting chemicals are not addressed at all.
- Recycled inputs are not assessed for their adverse health effects.
- The real-life exposure conditions to chemicals as well as the additive effects between the various chemicals used in one single food package are overlooked in the current risk assessment process.
- The current regulatory process for FCM is not transparent enough and suffers from an unbalanced stakeholder access, with limited access for civil society groups.
- By not being aligned with the REACH regulation, the FCM regulation is not delivering on the better regulation objectives set by the European Commission itself.

In HEAL's view, the evaluation of the regulation should allow to take measures in order to achieve the following:

- Regulate all types of food contact materials in a health-protective way;
- Contribute to a toxic-free circular economy;
- Prohibit or phase out "Substances of Very High Concern" (or SVHCs) as identified under the REACH legislation;
- Ban all endocrine disrupting chemicals (or EDCs) from FCMs;

- Address the cocktail effect of chemicals when assessing the safety of the substances present in FCMs;
- Support innovation for safer and less resource intensive materials and health-protective alternatives.

HEAL'S VIEW ON THE EVALUATION PROCESS

In terms of the proposed evaluation logic:

- The current regulation's failure to protect human health and the need to change this situation should be the departing point of the intervention logic. The presence of substances with health-adverse effects in food packages currently sold on the European market should be acknowledged.
- Likewise the failure of the risk assessment process to address the cocktail effect of chemicals and the potential toxicity of the mixtures present in packages should be acknowledged.
- Finally and related to the previous point, the intervention logic should shift away from the sole focus on food contact materials in order to also integrate the finalised food packages (that composed of different materials). Both individual materials and final packages should be assessed for safety.

In terms of the process for the evaluation to be carried out, particular attention should be given to the following points:

- Ensure full transparency throughout the entire evaluation process (who is being consulted, how, when, by whom, on which points);
- Ensure balanced consultation between public interest and industry stakeholders in order to guarantee that the evaluation fairly reflects fairly on how the regulation performs on both of its objectives. The protection of human health should not be considered as a secondary objective when compared to the functioning of the single market.
- All the data mentioned in the 'data collection and methodology' box (including the information held 'concerning audit and fact-finding work carried out by DG SANTE' and 'information on the use of compliance documentation in the supply chain' should be made publicly available.

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Notes:

- (1) Journal of Epidemiology and Community Health
<https://www.medicalnewstoday.com/articles/272910.php>
- (2) See for instance <http://kemi.taenk.dk/bliv-groennere/fast-food-packaging-contains-unwanted-fluorinated-substances> ; <http://kemi.taenk.dk/bliv-groennere/test-chemicals-plastic-food->

- [containers-migrate-warm-fatty-foods](#) ; <http://kemi.taenk.dk/bliv-groennere/test-unwanted-chemicals-found-pizza-boxes> ; <http://www.env-health.org/resources/press-releases/article/two-thirds-of-food-can-linings>
- (3) See for instance: https://ehp.niehs.nih.gov/wp-content/uploads/2017/09/EHP644.alt_.pdf ; <http://www.chemtrust.org/wp-content/uploads/chemtrust-foodcontactchemicals.pdf>
- (4) <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2016-0384>
- (5) Details about HEAL's views on the gaps in the existing regulation and our recommendations are detailed here: http://www.env-health.org/IMG/pdf/15022016_-_heal_briefing_fcm_final.pdf

The Health and Environment Alliance (HEAL) is a leading European not-for-profit organisation addressing how the environment affects health in the European Union (EU). With the support of more than 70 member organisations, HEAL brings independent expertise and evidence from the health community to different decision-making processes. Our broad alliance represents health professionals, not-for-profit health insurers, doctors, nurses, cancer and asthma groups, citizens, women's groups, youth groups, environmental NGOs, scientists and public health research institutes.