

EU Commission

1. Response to European Commission's consultation on the Evaluation of Food Contact Materials (FCM) legislation

Summary

The Swedish Chemicals Agency welcomes the European Commission's initiative to evaluate the EU legislation on Food Contact Materials (FCM) and urges the European Commission to consider the following aspects:

- Expand the purpose of the legislation.
- Link action/activities on chemicals under other legislations to FCM legislation.
- Harmonise rules for various types of food contact materials.
- Assess combination effects of chemicals.
- Design food packaging for recyclability.

Comments

The Swedish Chemicals Agency welcomes the European Commission's initiative to evaluate the EU legislation on Food Contact Materials (FCM) and appreciates the opportunity to submit comments. Identifying and amending gaps and inconsistencies in the existing legislation is important to ensure a high level of protection of human health and the environment.

The Swedish Chemicals Agency urges the European Commission to consider the following aspects when revising the legislation on FCM:

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Date
2 May 2019

a. Expand the purpose of the legislation

The existing legislation on FCM focus on protecting human health and the interests of consumers. However, the legislation should also secure a high level of protection of the environment since humans are indirectly exposed to chemicals released to the environment in the different life cycle stages of the substance. For example, the continuous use of persistent chemicals will result in increasing concentrations over time in the environment and possibly reach levels that are adverse to human health.

b. Link action/activities on chemicals under other legislations to FCM legislation

There is currently no link between FCM legislation and other legislations identifying chemicals of very high concern, such as REACH and the POP Regulation. Any substances restricted or phased out under other legislations should subsequently be phased out in *all* types of FCM to protect human health and the environment.

Consequently, the list of approved chemicals in plastic material that are in contact with food should be reviewed with regard to chemicals identified as substances of very high concern (SVHCs) under REACH. For example, PFASs included on the positive list urgently needs to be reassessed for its safety. Considering the background of high concern and large amount of information around these substances, due diligence and application of a precautionary approach is advocated¹. Our recommendation is further supported by the additional knowledge that most, if not all, per and poly-fluorinated alkyl substances (PFAS) used in FCM will during their chemical life-cycle be converted to extremely persistent and potentially toxic perfluorinated carboxylic acids, similar (or identical) to PFOA, for which EFSA recently has suggested a very low TWI. Many PFASs, including PFOA, are regulated in other EU legislations, such as REACH and the POP Regulation. Therefore, we consider it indefensible to justify the use of PFAS in any type of FCM based on the large amount of evidence and/or on the grounds that it is essential to society.

In general, we are concerned that the management of endocrine disruptors are not specifically included in the legislation in order to minimise endocrine disruptor exposure of the population of all ages, genders and life stages. We, therefore,

¹ <https://www.norden.org/sv/node/35611>
<https://www.norden.org/sv/node/34339>
<https://www.norden.org/sv/node/35559>

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advocate that the European Union should move towards identical management of endocrine disruptors across all sectorial pieces of legislation and strongly recommend that the EU Commission to revise Regulation (EC) No 1935/2004 [on *food contact material*] in order to effectively reduce the content of hazardous substances therein, with specific provisions to substitute the use of endocrine disruptor chemicals.

c. Harmonise rules for various types of food contact materials

The Framework Regulation on FCM provides general safety requirements for food contact materials and the possibility to adopt specific measures for some materials. Harmonised specific measures at EU level exist for certain materials, such as plastic, but not for paper and board, including recycled paper and board, coatings, inks and adhesives, which may constitute a risk to human health today. Harmonised specific measures at EU level should also be adopted for these materials to ensure the same safety level of food contact materials in all Member States.

d. Assess combination effects of chemicals

It is a well-known issue that the current chemical assessments and regulations only consider exposure to single substances although research shows that toxicity can increase when certain chemicals interact. There is for example good evidence that groups of endocrine disruptors with similar effects produce combination effects in a dose additive manner². The Swedish Chemicals Agency therefore stress that appropriate changes to the legislative text should be considered to account for combination effects especially considering recent progress in this area i.e. publication of EFSA's Guidance on Combined Exposure to Multiple Chemicals³ and the findings that health risks of combined exposure to endocrine

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State of the Art Report on Mixture Toxicity, Kortenkamp A. *et al*, 2009
(http://ec.europa.eu/environment/chemicals/effects/effects_en.htm)

3

Guidance on harmonised methodologies for human health, animal health and ecotoxicological risk assessment of combined exposure to multiple chemicals. Adopted 20 February 2019, doi: 10.2903/j.efsa.2019.5634. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5634>

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disruptors is underestimated⁴. This is also in line with the objective in the 7th EAP that shall ensure that the combination effects of chemicals are effectively addressed in all relevant Union legislations by 2020.

e. Design food packaging for recyclability

There are ongoing discussions in EU on recycling waste to achieve a more resource efficient society. Food contact materials can be complex products consisting of several layers of different materials with the purpose to protect and preserve the food content. The complexity of the product may on the other hand reduce the recyclability of the food packaging. Thus, it is important to consider the design of food contact materials to ensure they can be recycled. However, using recycled material for FCM is currently not encouraged since hazardous chemicals may be present in such material.

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Press release and Policy Brief including key results: Health risks associated with mixtures of man-made chemicals are underestimated. 26 March 2019. Press release and Policy Brief including key results: Health risks associated with mixtures of man-made chemicals are underestimated. 26 March 2019. <https://edcmixrisk.ki.se/2019/03/26/press-release-health-risks-associated-with-mixtures-of-man-made-chemicals-are-underestimated/>, including Policy Brief: <https://edcmixrisk.ki.se/wp-content/uploads/sites/34/2019/03/Policy-Brief-EDC-MixRisk-PRINTED-190322.pdf>