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Comments on the draft regulation on the use of BPA and other bisphenols and their derivatives with harmonized classification for specific hazardous properties in certain materials and articles intended to come into contact with food

Plastic Change is a Danish NGO working to fight plastic pollution, with specific focus on significant reductions of the production and use of single-use products, regardless of material, as well as the elimination of all known and potential/suspected harmful chemicals associated with the manufacture, use and disposal of plastic products and products of other materials.

We much welcome and generally support this draft regulation on the use of BPA and other bisphenols in FCMs. This revision is urgently needed, due to the known harmful effects of bisphenols.

Denmark has been a front-runner on this topic with BPA in FCMs, e.g. by prohibiting its use in all packaging for food items for children up to 3 years of age since 2010. Also in other uses other than FCM, Denmark was leading a ban on BPA in certain items intended for small children, and the EU followed suit with similar legislation. We are generally happy that Denmark can be a leading example in the EU in stricter chemical regulation that protects human health and environment.

Some issues of concern with this draft does apply, in our view. We welcome regulation that protects human health and environment in the best way possible, and thus we see some issues and loopholes that need to be addressed.

Strengthen the scope of bisphenols ban

Although BPA has been the most extensively researched bisphenol, and data on other bisphenols is still somewhat limited, there is growing evidence that confirms the urgent need to limit exposure to all bisphenols. Thus, we are happy that this draft includes a wider scope of bisphenols. However, for a full protection against the potential harmful effects from all bisphenols, from a precautionary principle perspective, and because data gaps causes limitations for classifications of harmful chemicals (also for long periods of time), and the risk of substitution from one harmful bisphenol to another, we would like to see an expansion of the scope of the 'other bisphenols' ban to those meeting the criteria for classification as CMRs and EDCs for human health of Category 2. FCMs for children and pregnant women, who are particularly vulnerable to the harmful effects of bisphenols, should be taken especially into consideration in this regard. It would indeed also be welcomed to instead not to distinguish between BPA and other bisphenols, but instead cover all bisphenols as one group of chemicals, for which the conditions as stated for BPA specifically in the draft would apply for all bisphenols. This would be the best way to future-proof the avoidance of regrettable substitutions.

Remove currently authorized bisphenols from the list of authorized substances for re-application

BPS is one example of known substitutions for BPA. This is a regrettable substitution to BPA, since evidence suggest similar harmful effects on health. While BPA is removed from the authorizations list, BPS remains. This risks regrettable substitutions of BPA with BPS. The removal of BPS from the list of authorized substances in Regulation 10/2011 is therefore highly encouraged, in order for the companies to re-apply in accordance with this new regulation for authorization for very specific

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applications, where alternatives are not possible and the continued use is critical. In this regard, there should be a review clause in order to be certain that the authorization of the bisphenol only results in negligible exposures.

Broaden the scope of monitored bisphenols for recycled material

In the draft only the presence of BPA should be monitored in recycled material, and we believe this to be to narrow a scope to protect human health. We thus encourage the Commission to broaden the scope of the monitored substances potentially contaminating recycled material to cover all bisphenols. ECHA has documented that the EU paper industry is already substituting BPA with BPS, and other bisphenols may also be used or applied in the future. Thus it is highly relevant also to monitor other bisphenols, and ideally all bisphenols should be included in the monitoring program.

Limit the sell-off period for "use up stocks"

In the proposed draft there is no limit as to when stock items that contain bisphenols can be put on the market. For public health reasons this is not acceptable, and we encourage to include a 12 month limit in this regard.

High priority on a defined low detection limit for monitoring BPA contamination

In the proposed draft with respect to monitoring the presence of unintentional presence of BPA a detection limit is not clear. Standards on such detection limit should be described and should be adequately low in order to protect human health. If such analytical methods for adequately low detection limits are not currently available, it should be highly prioritized to develop such methods. Otherwise, BPA contamination could still present an actual risk to human health for many years to come, despite stricter regulation on bisphenols in FCMs.

Regards,

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