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

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1 Introduction

CHEM Trust is grateful for this opportunity to provide input into the Commission's proposal for a Regulation that restricts the use of Bisphenol A (BPA) and 'other bisphenols' in food contact materials (FCM).

CHEM Trust is an NGO that focusses on EU-level regulation of chemicals, particularly endocrine disruptors and persistent, bioaccumulative and/or mobile chemicals, including in FCMs.

2 General comments

CHEM Trust welcomes the Commission's initiative to prohibit the use of BPA and 'other bisphenols' in FCMs.
Following the EFSA's decision to lower the tolerable daily intake (TDI) by 20,000 times and stating that "dietary exposure from BPA is a health concern for European citizens across all age groups", it is essential that exposure is limited by the planned prohibition of BPA and 'other bisphenols'.

We welcome the inclusion of 'other bisphenols' in the proposal as there is a high risk of regrettable substitution of BPA by other bisphenols, which we outlined in our report From BPA to BPZ: a toxic soup? The ECHA has assessed the regulatory needs of the group of bisphenols and concluded that 34 substances require restrictions. We have long asked for the regulation of bisphenols as a group and, therefore, support the idea of grouping bisphenols in restrictions under the FCM legislation.

CHEM Trust furthermore strongly supports the proposal's approach of a dynamic scope, which automatically covers bisphenols after they are included in Annex VI Part 3 of Regulation (EC) No 1272/2008 due to the specified properties. This approach is new to the FCM legislation and very effective in achieving a high level of protection, as it ensures immediate regulation after relevant hazards of bisphenols are recognised.

In addition to the many good approaches in the draft regulation, CHEM Trust believes that additional efforts should be taken to ensure a high level of protection and make the regulatory conditions for the use of bisphenols in food contact materials more predictable.

As a core improvement, we ask to **expand the scope** of the prohibition regarding the covered substances by including 'other bisphenols' that are **CMRs and EDCs for human health of category 2** (Article 1.2.b and 4.1)

In addition, it is essential for the protection of human health and the environment to **expand the prohibition scope to all FCMs** in which BPA and other bisphenols are currently used, may be used in the future, or may be present due to the use of contaminated recycled materials (Articles 1.2.a, 1.2.b, 3.1 and 4.1). Due to such inclusion of recycled FCMs (in particular plastics and paper and board), limit values are needed that make the prohibition of marketing contaminated FCMs enforceable.

Finally, the **legislation's transition periods should be shortened** to stop human (and environmental) exposure to hazardous bisphenols as soon as possible.

We also want to remind you of the **urgent need to revise the FCM framework legislation**.

3 Specific comments

3.1 Include category 2 of all relevant health hazard classes

CHEM Trust asks to include the hazard category 2 for CMRs and EDCs in the list of 'relevant hazards' to include further hazardous bisphenols in the regulation's scope.

We already stated in our comments to the consultation of the German restriction proposal for bisphenols that, in order to be effective, future-proof and precautionary, group approaches for bisphenols should not be too narrow. Otherwise, hazardous bisphenols will stay in use (in FCMs), during the frequently long periods of time taken for data generation and chemical producers who have inadequate safety data for their products will be rewarded. Including more bisphenols on a precautionary basis would, in turn, incentivise either innovation to find alternatives or data generation to clarify a suspected hazard and potentially change the classification.

As data gaps are likely to remain a limiting factor to the classification of chemicals as CMRs and EDCs, the inclusion of category 2 in the Articles 1.2.b and 4.1 of the regulation would:

- Ensure a high level of protection from known, presumed and suspected CMRs and EDCs and incentivise data generation rather than discourage it,
- Implement the precautionary principle in the particularly sensitive application of food contact materials with potentially high human exposures,
- Ensure that the goals of the chemicals strategy for sustainability to ban substances of very high concern in consumer products are implemented,
- Promote a consistent regulatory approach, following the scope of restrictions as currently undertaken in the revision of the Toy Safety Legislation.

Including category 2 of the hazard classes of CMR and EDC in the list of 'relevant hazards' would be a clear signal to the market to avoid bisphenols in general and thus contribute to preventing regrettable substitution and promoting innovation towards safer alternatives.

3.2 Expand the scope to any FCM

CHEM Trust asks to expand the scope and simplify the wording of the prohibitions by including 'all FCMs' in Articles 1.2.a, 1.2., 3,1 and 4.1 of the draft regulation, rather than providing different lists for BPA and 'other bisphenols' and excluding materials which contain BPA or 'other bisphenols' or might contain them in the future.

The list of FCMs in which BPA and 'other bisphenols' should be prohibited differs in the current text regarding the use in plastics. This may be due to the need to have uses in plastics authorised under Regulation 10/2011 but it is confusing, as a difference is made for BPA and 'other bisphenols'. There should be a clear signal that any future uses of 'other bisphenols' in plastics or other FCMs should be avoided wherever possible.

Bisphenol S, which is currently authorized for used in plastic FCMs, needs to be removed from the Union list. A paragraph covering this issue under Article 9 of the draft regulation is very important to prevent regrettable substitution of BPA with BPS in plastics.

Including "all FCMs" would also mean that the prohibition covers any recycled materials used in contact with food, including in plastics and paper and board. According to the recitals, paper and board is currently excluded because BPA is

currently not intentionally used in paper and board, and that prohibiting the use of bisphenol-contaminated recycled paper would be disproportionate to control and implement. A similar situation may exist for recycled plastics.

Exposure levels of European citizens with BPA and 'other bisphenols' are already high. Mixture effects from bisphenols are likely increasing the current risks from bisphenols. And it is known that recycled materials may be contaminated with BPA and 'other bisphenols'. **Therefore, exposure from all sources in FCMs must be eliminated or at least reduced, including from recycled FCMs**. CHEM Trust considers the safety of FCMs more important than ensuring recycling rates are maintained. We need a clean circular economy, not a dirty one!

As indicated in our comments to the German bisphenols restriction, the discussion about harm from bisphenols has been ongoing for decades. The (recycling) industries should be aware of this problem, and when supplying the food industries they may already have invested in technologies to ensure bisphenol-free input wastes to their processes or will do so in the future.

3.3 Include limit values for BPA and 'other bisphenols' in the regulation

Expanding the scope to all FCMs, including those which may be produced from recycled materials, requires **setting limit values for the content of BPA and 'other bisphenols'.** Such limit values are needed to clarify above which levels of a material or an article in contact with food are non-compliant, regardless of the origin of the bisphenols.

These limit values should be as low as possible to ensure a high protection level but must also be implementable and enforceable. There could be a limit value for the group of the covered bisphenols as well as specific limit values for the individual compounds. The limit values should relate to the concentration in FCMs rather than their migration (i.e. no specific migration limits) to facilitate compliance checking by the industry and the enforcement authorities. If analytical methods to measure bisphenols in FCM are missing, they must be rapidly developed – these are chemicals that have been in use for many decades.

3.4 Revise timelines

The timelines in the draft regulation are very long, e.g. 18 and 36 months, respectively, particularly for uses where alternatives should be available and implementable much faster than that, e.g. single-use food contact articles in Article 10.2.a and 10.2.b. These long transition periods unnecessarily prolong human exposure and should be shortened considerably.

3.5 Authorisation of uses of 'other bisphenols'

According to Article 4.3 of the draft regulation, 'other bisphenols' that are included or may be included in the future in Annex VI of the CLP regulation may still be used if an application for authorisation according to the FCM framework regulation's

Article 9(1) is submitted. The use may continue until a decision is made and, if the use is authorised, even beyond.

CHEM Trust acknowledges that in the future, there may be a few uses for which an authorisation could be necessary to allow more time for substitution. However, we consider the current criteria and conditions for granting an authorisation under the FCM framework regulation as insufficient (c.f. next paragraph). We are concerned the authorisation could endanger protection through too many exemptions from the prohibition.

3.6 Revise EU legislation on food contact materials

We want to use the opportunity of this consultation to highlight the urgent need for the revision of the European legislation on food contact materials, to harmonize provisions on all FCMs across Europe, ensure high protection standards, to better address final FCM articles and non-intentionally added substances, and to increase transparency on hazardous substances in FCMs, among others.

In the context of this prohibition of BPA and 'other bisphenols', **we would like to highlight the need to include the concept of "essential use" in the authorisation procedure under Article 9 of Regulation (EC) No 1935/2004.**

This would ensure that the availability of alternatives and the need of society for the functionality of harmful substances in the to-be-authorised use(s) is considered in the authorisation decision. This might be particularly useful as an assessment of risk may be challenging for many of the prohibited bisphenols due to a lack/uncertainties of effect thresholds.

In addition, we also expect the FCM revision to include a requirement for EFSA to define time limits or review periods for any granted authorisation (and hence also for any bisphenol authorisations) to push for substitution and ensure an eventual phase-out of the respective bisphenol(s).

We would also like to repeat our request in the former consultation input that FCM legislation should address all substances of high concern, including PBT/vPvB, PMT/vPvM, as well as EDCs to the environment (Category 1 and 2), because they:

- Eventually lead to human exposure as they accumulate in the food chain or reach drinking water. The chemicals strategy for sustainability suggests regulating all SVHCs under the generic approach to risk management, including in food contact materials.
- The increasing efforts to implement a circular economy may result in the recycling of hazardous chemicals as part of the materials they are included in, such as food contact materials ('toxic cycling').
- The Treaty of Amsterdam (1999) established the duty to integrate environmental protection into all EU sectoral policies with a view to promoting sustainable development." Hence, covering all SVHCs in FCM legislation contributes to the EU's policy integration aim.