



CHEMTrust
Protecting humans and wildlife
from harmful chemicals

Consultation Response

EU Commission Draft Regulation “Bisphenol A in varnishes and coatings and plastics intended to come into contact with food”

Comments from CHEM Trust

20th September 2017

Summary and Introduction

CHEM Trust welcomes the opportunity to comment on the European Commission’s draft regulation “*on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials*”¹.

We have been concerned about the health and environmental impacts of Bisphenol A (BPA) for many years²; BPA was first identified as a hormone mimic in 1938³. There is evidence that BPA could affect health at low doses, and BPA is suspected of having neurodevelopmental effects⁴.

We also welcome the fact that the Commission have produced this proposal in reaction to EFSA’s opinion published on 21 January 2015 recommending a decrease in the tolerable intake of BPA’s⁵. However, we had a number of criticisms of the EU Commission’s road map for this regulation in 2015⁶, and these concerns continue.

In our view there should be a ban on all food contact uses of BPA, and DG Health must also address other bisphenols, not just BPA. In addition, the BPA example exposes the lack of focus on substitution in the EU’s laws for regulating chemicals in food contact materials.

¹ https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4140854_en

² See: <http://www.chemtrust.org/bisphenol-a-bpa/>

³ Dodds, E. C., & Lawson, W. (1938). Molecular structure in relation to oestrogenic activity.

Compounds without a phenanthrene nucleus. *PRSL. Series B, Biological Sciences*, 125(839), 222-232.

⁴ CHEM Trust, *No Brainer: The impact of chemicals on children’s brain development: a cause for concern and a need for action*, March 2017: <http://www.chemtrust.org/brain/>

⁵ EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids, *Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs*, 21 January 2015

⁶ See: <http://www.chemtrust.org/bpa-roadmap-food-contact/>

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Our comments in detail

1) BPA should be banned in coatings and varnishes in food contact materials

- The draft regulation proposes a ban on BPA migrating from coatings and varnishes in food contact materials (FCM) intended to be used for young children, and a reduction in the migration limit for those FCMs intended for use by other groups.
- In CHEM Trust's view this proposal does not go far enough, as there should be ban on BPA in all food contact materials, not just a ban on migration from coatings "*applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food or food for special medical purposes developed to satisfy the nutritional requirements of infants and young children*".
- The proposed regulation of coating and varnishes FCMs and the amendment to the regulation of plastic FCM (EU) No 10/2011 proposes a specific migration limit (SML) of 0,05 mg of BPA per kg of food (mg/kg). CHEM Trust does not consider that this is protective.
- Young children may be still exposed to BPA through, for example, food contact materials which are not designed for them. Similarly, pregnant women will be still exposed to BPA from FCMs not covered by the draft regulation, potentially putting at risk their unborn children's health⁷.
- The EFSA opinion of 2015 has estimated that adolescents had the highest aggregated exposure⁸, but this group potentially vulnerable to endocrine disrupting chemicals is not specifically protected by the regulation.
- Several studies have convincingly demonstrated a mixture effect from exposure to multiple chemicals, which is what we are all always exposed to. For example, a study published in August 2017 showed that the BPA effect on testosterone in foetal human tissues was multiplied by 10 when combined with seven other chemicals⁹. The reality of the mixture effect should lead regulators to reduce BPA exposure to a minimum.

⁷ Members of the European Parliament "*Calls on EFSA and the Commission to extend the concept of vulnerable groups to pregnant and breastfeeding women and to include the potential effects of low-dose exposure and non-monotonic dose responses in the risk assessment criteria*": Committee on the Environment, Public Health and Food Safety, Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004) (2015/2259(INI)), 18 July 2016, Rapporteur: Christel Schaldemose: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bREPORT%2bA8-2016-0237%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN>

⁸ EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids, *Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs*, 21 January 2015

⁹ Pierre Gaudriault, Séverine Mazaud-Guittot, Vincent Lavoué, Isabelle Coiffec, Laurianne Lesné, Nathalie Dejuq-Rainsford, Martin Scholze, Andreas Kortenkamp, Bernard Jégou, "Endocrine Disruption in Human Fetal Testis Explants by Individual and Combined Exposures to Selected Pharmaceuticals, Pesticides, and Environmental Pollutants", *Environmental Health Perspectives*, vol.125 issue 8, August 2017: DOI:10.1289/EHP1014 <https://ehp.niehs.nih.gov/ehp1014/#tab1>

2) BPA should also be banned in other FCMs, including paper and card

- The report on FCMs from the European Parliament¹⁰, called for a better harmonisation of the regulation of all FCMs at EU level. Regarding the Commission's proposal to reduce the BPA SML for plastics, varnishes and coatings FCMs, they "[regret] that, owing to a lack of specific measures, there are no corresponding migration limits for all FCMs".
- We also commented in this issue in our response to the 2015 road map¹¹:
 - *"the fact that less is known about BPA levels in paper and card is not a rationale for inaction, this is rather an indication of an ineffective regulatory system for these materials."*
 - *"The plastics industry and the coatings and varnishes industry are apparently already working well within the current BPA in plastics EU migration limit and therefore able to comply with the proposed lower migration limits. CHEM Trust does not see why the paper and board sector should be exempted from control. For some people, who regularly eat certain products wrapped in recycled cardboard, exposure via such food contact material may be significant. However, without sufficient data this is difficult to evaluate."*
- Research has shown that BPA is present in card and board packaging, possibly due to recycled materials¹². This exposure route needs to be addressed. The Commission has announced that it plans to draft rules for regulating chemicals in printed paper and board, though the exact scope of these planned regulations is not yet clear¹³. As the European Union is implementing a circular economy, solutions have to be developed to ensure that exposure to chemicals in recycled paper and board FCMs does not increase in the coming years.
- Extending the scope of the draft regulation to all FCM would also avoid disruption of the internal market. BPA is banned in all types of FCMs in France, and so it would be less disruptive for the EU to adopt the same approach

3) Regulation of FCMs should be more integrated with REACH, including promotion of substitution

- One key provision of REACH is the identification of substances of very high concern, and encouragement – and in some cases an obligation – on industry to substitute such chemicals. This substitution-focussed approach is based on the fact these chemicals have particularly problematic properties and it would therefore be better to replace them with safer alternatives. Many of these

¹⁰ Committee on the Environment, Public Health and Food Safety, Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004) (2015/2259(INI)), 18 July 2016, Rapporteur: Christel Schaldemose: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bREPORT%2bA8-2016-0237%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN>

¹¹ See: <http://www.chemtrust.org/bpa-roadmap-food-contact/>

¹² Rosenmai, A. K., Bengtström, L., Taxvig, C., Trier, X., Petersen, J. H., Svingen, T. et al. (2017). An effect-directed strategy for characterizing emerging chemicals in food contact materials made from paper and board. *Food and Chemical Toxicology*, 106, 250-259.

¹³ <http://www.chemtrust.org/chemicals-packaging-fcm/>

chemicals become more regulated over time, as more is understood about their toxicity (this is the case with BPA). The focus on substitution encourages the development of safer alternatives. There is no equivalent focus on substitution in the EU's regulations on chemicals in food contact materials.

- BPA is now classified in the Candidate list of Substances of Very High Concerns under the REACH regulation, for both its toxic for reproduction and human endocrine disrupting properties (Article 57c and f)¹⁴. This classification aims at progressively substituting the use of BPA if safer alternatives are available. CHEM Trust suggests that there needs to be a clear signal now to eliminate exposure to BPA and similarly acting substances wherever possible, anticipating a likely future ban of BPA under REACH and incentivising companies to develop safe and innovative alternatives.
- This approach has been supported by Members of the European Parliament in their report on the implementation of the Food Contact Materials Regulation¹⁵, which *“Calls on the Commission to ensure better coordination and a more coherent approach between the REACH and FCM legislation, in particular as regards substances classified as CMRs (categories 1A, 1B and 2) or SVHCs under REACH, and to ensure that harmful substances phased out under REACH are also phased out in FCMs”*.
- The Campbell Soup Company announced a transition to cans that do not use BPA linings by mid-2017¹⁶, showing that the use of alternative materials in certain circumstances is certainly feasible, including for can coatings.

4) The draft regulation should address chemicals similar to BPA

- BPA is one of a group of bisphenols, and there is growing evidence that other chemicals in this group, for example Bisphenol S (BPS) have similar problematic properties. In the context of the REACH restriction on BPA in thermal paper (e.g. till receipts), the European Commission asked the European Chemical Agency ECHA in June 2016 to investigate whether BPS in till receipts could be a risk to human health¹⁷.
- We are not aware of any similar request from DG Health to EFSA, even though it is well known that BPS is being used as a replacement for BPA in a wide range of applications.
- CHEM Trust believes that the industry should always adequately test alternative chemicals to ensure that the substitute substances that are brought

¹⁴ See the ECHA's Candidate list of Substances of Very High Concern:

<https://echa.europa.eu/candidate-list-table>

¹⁵ Committee on the Environment, Public Health and Food Safety, Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004) (2015/2259(INI)), 18 July 2016, Rapporteur: Christel Schaldemose: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bREPORT%2bA8-2016-0237%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN>

¹⁶ See: <https://www.campbellsoupcompany.com/newsroom/press-releases/campbell-to-remove-bpa-from-packaging-by-mid-2017/>

¹⁷ *Request to the European Chemicals Agency .. to assess whether the presence of bisphenol S in thermal paper could pose a risk to human health...*, June 2016:

https://echa.europa.eu/documents/10162/13641/echa_rest_proposals_rubber_granules_en.pdf

in to replace BPA are indeed safer. If the alternatives used have similar health concerns then further legislative action will need to follow.

- It is notable that there has already been an unnecessary delay to bring down the SML for BPA in plastic food contact materials in line with the EFSA updated opinion of 2015. Extending the ban to all bisphenols suspected of having similar EDC properties at this point would avoid further delays and continued exposure to harmful substances in the future.

For more information on CHEM Trust's work:

CHEM Trust is a charity that works mainly at EU level to prevent man-made chemicals from causing long term damage to wildlife and humans, by ensuring that harmful chemicals are substituted with safer alternatives.

- <http://www.chemtrust.org>
- [@CHEMTrust](#) on twitter

For our work on chemicals in food contact materials, see:

- <http://www.chemtrust.org/food-contact/>

For our work on bisphenol A, see:

- <http://www.chemtrust.org/tag/bpa/>