



EU ban on the use of bisphenol A (BPA) in food contact materials (FCMs)

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MAC meeting

DG SANTE Unit E2

European Commission

EFSA opinion on BPA

- Published 19 April 2023
- Based on all new scientific evidence assessed, EFSA established a TDI of 0.2 nanograms/kg of body weight (previous temporary TDI → 4 µg/kg bw)
- EFSA concluded that consumers with both average and high exposure to BPA in all age groups exceeded the new TDI, indicating health concerns
 - TDI → estimate of level of substance which can be consumed over a lifetime without presenting an appreciable risk to health
 - Above this does not necessarily equate to an immediate risk but indicates a need to act to ensure consumer protection
- EFSA noted that a similar dose range also caused adverse effects for reproductive and developmental toxicity and for metabolic effects, which are therefore also relevant for human health

Current EU rules on BPA in FCM

- Authorised as a monomer in plastic FCM with SML of 0.05 mg/kg
- The same SML applies to varnished and coated FCMs
- A prohibition on BPA in FCMs specifically for infants and young children also applies based on the precautionary principle since 2018, except in the case of the ban on BPA in polycarbonate infant feeding bottles, which has applied since 2011

Uses of BPA in FCM

- Used to manufacture polycarbonate plastic for use in applications such as food moulding or processing equipment, water dispensers and some reusable drinking bottles for consumers
- Still used extensively to manufacture epoxy resins for coatings to line food and drink cans, metal lids and caps and some large-scale storage tanks for the food industry
- May also be found as a component in other FCMs e.g. inks, adhesives, rubber

Risk management of BPA in FCM

- Authorisation of BPA in FCM plastic no longer justified
- An SML is not practical – non-compliance + no reliable analytical methodology for compliance and enforcement purposes
- Prohibition on the intentional use of BPA in FCMs [where it can be used]
 - plastic
 - varnishes and coatings
 - inks
 - adhesives
 - rubbers

Avoiding other hazardous bisphenols

- Legitimate questions on what should and shouldn't be used to replace BPA → avoid substances with similar and/ or specific hazardous properties to maximise consumer safety and provide regulatory predictability/ legal certainty
- As well as BPA, BPS and 2,2-bis(4'-hydroxyphenyl)-4- methylpentane are classified in accordance with CLP Regulation as Repr. 1B.
- ECHA has also adopted an opinion on BPAF and its salts; further information generation and investigations on a number of other bisphenols
- Support commitments given as part of the EU's Chemicals Strategy for Sustainability → ban of CMRs and endocrine disruptors (EDs)

Main requests from industry

- Ban should target intentional use of BPA
- Sufficient time to transition from currently formulations using BPA (particularly for all varnished and coated articles)
 - development and qualification process to ensure suitability, functionality, quality and safety of replacement
 - some applications will take longer than others
 - avoid waste and destruction of materials and eventual food waste
 - avoid high costs
 - replacement in the case of long-life [repeat-use] applications

Transitional period and possible derogations

- A fixed transition period of 18 months is foreseen for the [first] placing on the market of affected FCM from the date of entry into force of the measure
 - entry into force currently estimated late 2024; application date therefore mid 2026
 - no 'removal' of FCM already placed on the market
- Longer transition times
 - Canned fish and fruit and vegetables
 - Exterior of cans
 - Repeat use equipment for professional food manufacture

Tentative timeline and actions

- 4-week feedback period on draft measure (Feb – March)
- Further discussions with Member States
- Vote SCoPAFF April or June

Thank you

- Questions?

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