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

Tuesday 18 July 2023
10h – 11h30 CEST

DG SANTE Unit E2
European Commission

Housekeeping

- Foreseen duration 1h30 minute maximum including Q&A
- Microphones and cameras are muted
- Session will be recorded and made available afterwards with presentation*. PLEASE INDICATE IF YOU ARE NOT IN AGREEMENT
- EN language only
- Please identify your organisation if relevant
- Questions on proposed ban welcome in chat box – please address to everyone (all participants)
- If you have a technical issue with WebEx, please email SANTE-visio@ec.europa.eu

NB. Please note that due to a technical issue, the webinar was not recorded

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

EFSA opinion on BPA

- Consultation on hazard assessment protocol
- Consultation on draft opinion
- Public meeting with stakeholders and EU Member States
- Discussion with other bodies (EMA, BfR, US FDA)

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

Unintentional presence of BPA in FCM & food

- FCM
  - present as a contaminant in the input waste stream used to produce recycled materials e.g. paper and board, plastic
  - unreacted monomer e.g. from process to produce BADGE
  - 'vapour-phase transfer' from outside of packaging to which a BPA-based coating has been applied
  - unknown origins e.g. in polystyrene
- Foodstuffs
  - environmental contaminants (including drinking water)
  - some bisphenols (BPF) as a process contaminant

Unintentional presence of BPA in FCM & food

- A prohibition on the unintentional presence of BPA in FCMs (often at low levels) would be disproportionate and impractical
- For certain sources, contamination levels should in any case decrease over time due to other regulatory measures (e.g. ban in thermal paper, possible further restrictions under REACH Regulation to reduce environmental sources)
- Efforts should be made to identify sources that contribute the greatest to human exposure and to address those over time

Unintentional presence of BPA in FCM & food

- Monitoring and reporting requirements to supplement the ban on the intentional use
- Cooperation and support from FCM business operators and food business operators → collection and reporting of aggregated data by Member States
- Analytical detection limit and/ or limit of quantification to be established
- Commission supports harmonised and coherent approach from Member States to any possible follow up action
- Possible future actions to mitigate potential risks e.g. GMP

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)

Estimated impacts of ban

- Plastic
  - not expected to present any significant difficulties for replacement of BPA-based polycarbonate or polysulphone plastics in FCM
  - alternatives include co-polyesters with similar properties to polycarbonate. PET, HDPE and PP may also be used as alternatives depending on the function of the FCM article
- Varnishes and coatings
  - impacts anticipated e.g. costs, shelf-life of some products, energy consumption
  - alternatives include combinations of polyester and acrylic but not all commercially available
  - transition to all foodstuffs on EU market requires development and certification
- Other FCM
  - not expected to present any difficulties

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 spring 2024; application date therefore end 2025/ beginning 2026
  - no ‘removal’ of FCM already placed on the market
- Longer transition times will be considered for specific food contact applications with solid and sufficient justification + data to support
  - some acidic foods in coated metal packaging
  - heavy duty coating on large vessels and containers

Transitional period and possible derogations

- Request from the Commission to industry – in order to request additional transitional length
  - impact on food safety (e.g. microbiological & chemical contamination)
  - impact on food security and supply chain
  - additional resources inc. costs beyond 18 months (beyond application January 2026)
  - status of development of alternatives and reasonable additional time required
  - current typical migration levels of BPA
- In writing to SANTE-FCM-CONSULTATIONS@ec.europa.eu
- Deadline Friday 15th September 2023

Compliance, controls and monitoring

- Compliance (i.e. no use of BPA in the manufacture of the FCM) can primarily be verified through a DoC, either by a business operator in the supply chain or by MSs' competent authorities when carrying out controls, including any necessary supporting documentation
- Monitoring by analytical testing, proportionate to the likely frequency and level of contamination
- Follow-up to relevant findings → investigations into the possible sources and proposed remedial action, where deemed necessary

Tentative timeline and actions

- Collection of further information from industry, specifically to support potentially longer transitional periods
- Further discussions with Member States
- 4-week feedback period on draft measure (end September)
- Possible vote SCoPAFF November 2023

Thank you

- 10-minute pause
- Q&A from chat box

European Commission