



# Bisphenol A (BPA) Regulatory background

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# BPA: Current regulatory status in the EU

## ■ Authorised use

- Monomer or starting substance for the manufacture of plastic food contact materials
- Specific Migration Limit (SML): 0.6 mg/kg food (**revision on-going**).

## ■ Banned use

- Polycarbonate infant feeding bottles or additive in plastic food contact materials and articles
- Commission Regulation (EU) No 10/2011)

## BPA: Regulatory status in Member States (MS)

- France
  - Banned from all food contact materials
  
- Denmark
  - Banned from food contact materials targeting children up to 3 years of age

# Recent developments

- European Chemicals Agency
  - Included BPA in **REACH SVHC Candidate List** due to its properties as:
    1. **Toxic for reproduction**
    2. **Endocrine disruptor -human health**
  - Proposed additional listing based on its endocrine disrupting properties - effects on the environment

## Recent developments 2

- European Commission
  - August 2017: draft regulation reducing the Specific Migration Limit of BPA from 0.6 mg/kg to **0.05 mg/kg** was published online (ongoing 4-week feedback mechanism)
  - To be applied to **varnishes and coatings** too

## Recent developments 3

- US National Toxicology Program (NTP)
  - Ongoing NIEHS/NTP/FDA CLARITY BPA study
  - This study addresses most of the uncertainties evidenced in EFSA's last opinion (2015)
  - The publication of the report (2018) will trigger an EFSA re-evaluation of the hazards of BPA on human health

# Overview of EFSA's work on BPA

## (1) HAZARD IDENTIFICATION



## (2) HAZARD CHARACTERISATION

ADME, acute/sub/chronic toxicity, geno/repro/immuno-toxicity, mode of action, human data, dose-response for critical effect, point of departure (NOAEL, BMDL, etc), set of TDI

2006, 2008, 2010, 2011, 2013, 2015, 2019?

## (3) EXPOSURE ASSESSMENT

Occurrence data × Food consumption =  
EXPOSURE

Relevant food groups, adults and specific groups of the population, time trends

2006, 2013, 2015

2006, 2013, 2015

## (4) RISK CHARACTERISATION

Relates exposure to a chemical in a given population with toxicological effects and concludes on the likelihood of adverse effects.

## EFSA BPA 2015 opinion

- a temporary TDI (t-TDI) of 4  $\mu\text{g}/\text{kg bw}$  day was set
- calculated human exposure 3-5 times lower than the t-TDI
  - BPA does not represent a serious risk to human health
- TDI set on a temporary basis because the ongoing NTP Clarity study was deemed critical to reduce some uncertainties



# EC mandate on BPA to EFSA



Dear Dr Url,

**Subject:** Re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs and protocol for the risk assessment strategy

## Annex

### Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002<sup>2</sup>, the European Commission asks EFSA to:

- establish a protocol detailing the criteria for new study inclusion and for toxicological evidence appraisal for the re-evaluation of BPA, to ensure an efficient and transparent re-assessment of BPA;
- re-evaluate the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. In particular, the re-evaluation should take into consideration new data available from the results of the US NTP/ FDA study due in 2017 as well as all other new available information not previously evaluated by EFSA and which fulfil the criteria laid down in an established protocol. This re-evaluation should seek to clarify the remaining uncertainties concerning the toxicological endpoints of BPA, especially those concerning the mammary gland, reproductive, metabolic, neurobehavioural and immune systems and to establish a full tolerable daily intake (TDI) on the basis of the new information available.

# Importance of current EFSA BPA activities

- The Working Group on BPA hazard assessment protocol includes experts representing their own Member State
  - Denmark, France, Germany, Sweden, The Netherlands, Switzerland, Norway.
- EFSA is committed to **engage** the public and all other relevant stakeholders in its work in an **open and transparent manner**

## TECHNICAL REPORT

APPROVED:

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## Draft Bisphenol A (BPA) hazard assessment protocol

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### Abstract

To ensure an efficient, transparent and methodologically rigorous re-assessment of the safety for consumers of bisphenol A (BPA), the European Food Safety Authority (EFSA) has undertaken the task to develop a protocol detailing *a priori* the approach and methodology for performing BPA hazard identification and characterisation. The general aim of this hazard assessment will be to assess whether the new scientific evidence (published from 2013 onwards and not previously appraised by EFSA) still supports the current temporary Tolerable Daily Intake (t-TDI) for BPA of 4 µg/kg bw per day.