



Maisons-Alfort, 21 November 2008

OPINION

of the French Food Safety Agency regarding the exposure assessment of bisphenol A in water intended for human consumption and possible resulting health risks

THE DIRECTOR-GENERAL

Context of the request

On 5 May 2008, the Directorate General for Health (DGS) asked the French Food Safety Agency (AFSSA) for an opinion regarding the exposure assessment of bisphenol A (2,2-bis(4-hydroxyphenyl)propane) in infant feeding bottles likely to be heated in microwave ovens and in water intended for human consumption and possible related health risks..

This opinion only concerns the assessment of exposure to bisphenol A (BPA) in water intended for human consumption and related health risks.

Questions

Regarding the intention of the Canadian government and the opinion of the European Food Safety Authority (EFSA) of 29 November 2006, is it necessary to

- modify the restrictions or the conditions for use of BPA in food or water contact materials or recommend particular precautions for use in materials that may be heated,
- set a maximum physico-chemical water quality value with which water intended for human consumption must comply to reduce any health risks for both adults and infants?

Background

Considering that the Canadian government intends to ban hard plastic (polycarbonate) infant feeding bottles made from BPA;

Considering the EFSA opinion of 29 November 2006 on BPA issued by the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food;

Considering the AFSSA opinion of 24 October 2008 regarding BPA in polycarbonate infant feeding bottles likely to be heated in microwave ovens;

Considering articles R. 1321-48, 49 and 52 of the Public Health Code and the amended Ministerial Order of 29 May 1997 regarding materials and objects used in installations for the production, treatment and distribution of drinking water (water contact materials);

Considering the list of products and organic materials certified as meeting public health standards, or whose formulation has been granted a certificate of conformity based on the positive lists of authorised substances (EU Classification, Labelling and Packaging of Substances and Mixtures, CLP), issued by the Ministry of Health, in application of bulletins no. 99/217 of 12 April 1999, no. 2000/232 of 27 April 2000, no. 2002/571 of 25 November 2002 and DGS/SD7A/2006/370 of 21 August 2006;

Considering the standard XP P 41-250-2 regarding the effect of materials on the quality of water intended for human consumption – organic compounds – method for measuring mineral and organic micro-pollutants.

Assessment method

The Scientific Panel on Water met on 4 November 2008 to confer on the report prepared by the working group on 'Exposure assessment of BPA in water intended for human consumption and related health risks'.

Discussion

Regarding the origin and sources of water contamination

Considering that health inspections¹ do not include testing for BPA and that there is therefore no information on BPA available in the environmental health database set up by the Ministry of Health (SISE-Eaux database; Environmental Health Information System-Water).

Considering that there are no data on the actual BPA contamination of water intended for human consumption;

Considering that BPA is found in

- plastic-/polymer-based materials and objects used in installations for the production, treatment and distribution of water intended for human consumption (epoxy resins),
- accessories and other sub-assemblies composed of at least one organic compound [acrylonitriles butadienes styrenes (ABS), polysulfones (PSU), polycarbonates (PC)]
- materials used for processing water (reusable polycarbonate [storage] tanks),
- certain membrane filtration systems used for treating water intended for human consumption (epoxy resins, PSU);

Considering that the surface area of accessories in contact with water is small, that the assumption that BPA leaches from polysulfone membrane filters has not been documented and that the consumption of water stored in tanks is trivial compared to water distributed in public water distribution systems, water contact materials and, in particular, epoxy resin linings are the main potential sources of BPA in water;

Considering that epoxy resin linings must meet public health standards for use in installations for water production and distribution, but that standards for compounds used in pipes and in linings have only been defined since 1 June 1998;

Considering that epoxy resin linings are not usually used in hot water distribution systems.

Regarding treatment processes

Considering that, although the occurrence of BPA in water resources has not been documented, some nanofiltration membrane processes, some oxidation processes and activated carbon filtration can decrease the concentration of BPA in water intended for human consumption;

Considering that the oxidation of BPA during disinfection may form by-products.

Regarding the analysis methods

¹ Ministerial Order of 11 January 2007 regarding the sampling and analysis programme for public health inspections of water supplied in distribution systems, in application of articles R. 1321-10, R. 1321-15 and R. 1321-16 of the Public Health Code.

Considering that although regulations for food contact materials (FCM) have defined a specific migration limit (SML) for BPA (0.6 mg/kg), during the certification procedure for water contact materials, testing laboratories authorised by the Ministry of Health do not always test for BPA, as there are no regulatory requirements to do so;

Considering that, in trials carried out on epoxy resin linings during the certification procedure, volatile organic compounds that migrate from materials are analysed using gas chromatography-mass spectrometry (GC-MS) and that the results are deemed satisfactory if the BPA concentration for each detected organic compound is less than or equal to 1 µg/L, relative to the closest internal standard;

Considering that the absence of a semi-quantified peak at 1 µg/L does not absolutely guarantee that the concentration of BPA is less than 1 µg/L;

Considering that the methods used when specifically testing for BPA have not been optimised (detection limits of the order of tens of ng/L and quantification limits of the order of 30 ng/L) and that the uncertainty of measurement is not known for lack of any regulatory requirements, for lack of national inter-laboratory proficiency tests and given an SML of 600 µg/kg for food contact materials.

Regarding exposure data

Considering the exposure assessment of BPA that was carried out by EFSA for its 29 November 2006 opinion showing that infants of 6 mo. or younger were the most exposed group due to the presence of BPA in breast milk or to BPA migration from polycarbonate infant feeding bottles, from food products packaged in containers with epoxy resin linings and from food in contact with polycarbonate tableware;

Considering the AFSSA opinion of 24 October 2008 specifying that microwave heating of polycarbonate infant feeding bottles under realistic conditions (heating times less than 10 min) did not bring the EFSA assessment into question because the quantities of BPA that could migrate into food are much lower than the maximum value of 50 µg/L used by EFSA for calculating exposure;

Considering that regulations for certified materials indicate that BPA leaching, measured using a semi-quantitative approach, must not exceed 1 µg/L for any one substance;

Considering that the lack of specific testing for BPA introduces a factor of uncertainty of 10 compared to this value, that a maximum value of 10 µg/L has thereby been established and that this value is sufficiently conservative for the exposure assessment of BPA in drinking water;

Considering data from the literature on BPA migration values in polycarbonate storage tanks;

Considering the data from the DONALD study (Kersting *et al.*, 1998) on consumption in infants 6 mo. and younger, which was used in the EFSA opinion of 29 November 2006.

Regarding health effects

Considering that BPA does not have any genotoxic effects;

Considering the results from studies on reproduction and development carried out in rats and used by EFSA to establish the tolerable daily intake (TDI) of BPA at 0.05 mg/kg b.w./day.

Regarding the evaluation of health risks

Considering that maximum daily intake of BPA concerns infants of up to 6 mo. and that including migration of BPA from water contact materials in the daily BPA intake did not modify the conclusion of the risk characterization in the EFSA 2006 opinion;

Considering that the estimates of BPA exposure, based on conservative assumptions, are nonetheless lower than 30% of the TDI, whatever the age group.

Conclusion

AFSSA concludes

- that the daily intake of BPA, including that from migration from water contact materials, does not lead to a risk for consumers under normal conditions;
- that these results do not contest the inspection procedures used to determine whether water contact materials meet public health standards;
- that it is nevertheless desirable that when BPA is present in a compound, that migration of BPA in water be specifically screened for during public health certification procedures of water contact materials with a target quantification limit of 1 µg/L.
- that it is not necessary to propose a maximum value for BPA in water intended for human consumption given the *a priori* absence of risk based on a conservative exposure scenario of 10 µg/L in water intended for human consumption and given the current toxicological information.

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