

Maisons-Alfort, 24 October 2008

THE DIRECTOR GENERAL

OPINION

of the French Food Safety Agency regarding bisphenol A in polycarbonate baby bottles likely to be heated in microwave ovens

Context of the request:

On 5 May 2008, the Directorate General for Health (DGS) requested that the French Food Safety Agency (AFSSA) respond to the Canadian government's decision to ban hard plastic (polycarbonate) baby bottles made from bisphenol A (BPA). According to information provided by the DGS, the Canadian authorities have deemed that, after an initial assessment report, the gap between exposure and health effects due to BPA migration from baby bottles heated to high temperatures or from inner linings of baby formula cans was not large enough.

The DGS requested that the following issues be addressed: a) evaluate the quantities of bisphenol A that migrate into food from polycarbonate baby bottles during microwave heating; b) indicate whether it is necessary to modify the conditions under which BPA may be used in food contact materials or recommend particular precautions for use for materials that may be heated.

Assessment method:

Collective expert assessment was carried out by the Scientific Panel on 'Food contact materials', regarding the risk associated with migration into food of BPA found in baby bottles.

Basic information on bisphenol A:

BPA (2,2-bis [4-hydroxyphenyl]propane) is used to make polycarbonate and epoxy-phenolic resins. Due to its transparency and high impact-resistance, polycarbonate is widely used to manufacture many types of food containers and utensils, such as baby bottles. Epoxy-phenolic resins are used to line the insides of some food cans and in water distribution systems and reservoirs (water pipes and water storage tanks).

In the European Union, BPA is authorised for use in food contact materials with a specific migration limit (SML) of 0.6 mg/kg of food (Directive 2004/19/EC).

Results from the risk assessments of bisphenol A:

The toxicity of BPA has been evaluated by different international bodies and numerous reports and scientific articles have been published on the subject.

Among the most recent assessments in 2006 and 2008, the European Food Safety Authority (EFSA) established a tolerable daily intake (TDI) of 0.05 mg/kg bodyweight for BPA (50 µg/kg bw), based on a No-Observed-Adverse-Effect Level (NOAEL) of 5 mg/kg body weight/day in a multi-generation study in mice. Using conservative scenarios, the levels of exposure of infants to BPA, through infant food and the use of polycarbonate bottles, were estimated at 11 µg/kg bw/day for 3 mo. infants and at 13 µg/kg bw/day for 6 mo. infants. These levels are much lower than the TDI of 50 µg/kg bw (EFSA, 2006).

The September 2008 report from the United States National Toxicological Program (NTP) does not propose any toxicological reference values for BPA, but offers general conclusions on the effects attributed to BPA on reproduction and development in humans and in animals (NTP, 2008).

The United States Food and Drug Administration (FDA)¹ recently concluded that the available toxicological data show that at the current exposure levels, BPA does not constitute a safety concern. The FDA used a value of 5 mg/kg bw/day as the NOAEL for BPA. Based on this value, the FDA considers that the level of exposure to BPA from food contact materials, including those intended for infants and children, is lower than the toxicological reference values and that the products currently on the US market that contain BPA are without risk.

The draft report published in April 2008 by the Existing Substances Assessment Program carried out by Health Canada and Environment Canada departments concluded that the experimental data in animals may suggest increased sensitivity to BPA during early developmental stages, especially neurological development. As a precautionary measure, BPA should thus be considered as likely to constitute a health hazard for pregnant women, fetuses and infants. This report did not carry out a risk assessment on this hazard and, consequently, did not propose a toxicological reference value for BPA (Environment Canada, 2008).

More recently, in Germany, the Federal Institute for Risk Assessment (BfR) considered that the use of polycarbonate baby bottles in household situations does not constitute a hazard for infant health.

Consequences of microwave heating on the quantities of bisphenol A that migrate from polycarbonate baby bottles into food

For its conservative estimation of infant exposure, EFSA used a concentration of 50 µg of BPA per litre of liquid in baby bottles, a value that could be considered as the maximum quantity that can migrate into food. This value is much greater than the experimental data derived from studies under various nearly realistic use conditions (contact duration, temperature, cleaning, repetitive use, ageing) (EFSA, 2006; Brede, 2003; Tan and Mustafa 2003).

Some studies have shown that water hardness² or the presence of washing-up liquid residues influence the quantities of BPA that can migrate into food from polycarbonate baby bottles (Biederman *et al.*, 2008). The results remain lower than the value used by EFSA (50 µg/L) for estimating exposure.

The Health Canada and Environment Canada report confirms that the value of 50 µg BPA per litre used by EFSA is very conservative, based on migration values of the order of 0.4 to 8 µg of BPA per litre from bottles containing liquids (distilled water, ethanol/water mixtures, acetic acid solutions) heated to 80°C for 2 hours. These values are at least six times lower than those used by EFSA.

¹ <http://www.fda.gov/oc/opacom/hottopics/bpa.html>

² Water hardness is an indicator of the mineral content of water. Minerals in hard water consist primarily of calcium and magnesium cations. Water hardness is expressed in ppm w/v (or mg/L) of CaCO₃ or, in France, in French degrees (symbol, °f, not to be confused with °F, the symbol for degree Fahrenheit). 1 French degree equals 10⁻⁴ mol/L or 4 mg Ca²⁺ or 2.4 mg Mg²⁺ per litre of water. Between 0 and 7°f, water is very soft; 7-15°f, soft; 15-25°f, moderately hard; 25 - 42°f, hard; and above 42, very hard.

The potential influence of microwave heating was not taken into account by EFSA, as mentioned in its 2006 opinion.

It must be stressed that the energy delivered by microwaves (10^{-2} eV) is not high enough to influence or modify the structure of food contact materials. In polymers, especially polycarbonate, bond energies are of the order of 3 to 6 eV (Clegg and Collyer, 1991).

The quantities of BPA contained in the structure of contact materials and that migrate into food after microwave heating can be assessed by considering data on BPA migration under different experimental conditions in food-simulating liquids, with the official simulant for milk being distilled water according to Directive 85/572.

Two studies (Ehlert, 2008; Kawamura, 1998) assessed the quantities of BPA that leached from baby bottles into distilled water, heated in a microwave oven under realistic conditions, either:

- 3 cycles of heating for 3 minutes (Ehlert, 2008) or
- 5 minutes of heating (Kawamura, 1998).

These studies report values of the order of 0.1 to 0.7 μg of BPA per litre. These values are at least 70 times lower than the value of 50 $\mu\text{g}/\text{L}$ used by EFSA.

In one particular experimental situation, the German consumer magazine *Oeko-Test* (2003) reports that 157 $\mu\text{g}/\text{L}$ leached into baby bottles filled with tap water (City of Berlin) and heated in a microwave oven at a temperature close to 100°C for 2 hours. These experimental conditions are far from realistic bottle heating conditions.

Finally, AFSSA emphasises that the maximum BPA migration value used by EFSA (50 $\mu\text{g}/\text{L}$) for calculating exposure is much less than the value that would lead to the TDI for an infant being exceeded. Indeed, to reach the current TDI of 50 $\mu\text{g}/\text{kg}$ bw/day, a 3 mo. infant weighing 6.1 kg has to drink daily 1060 mL^3 of water or milk from a bottle leaching 287 μg of BPA per litre, a value that is practically six times higher than the value used by EFSA to estimate exposure.

Conclusions:

Regarding heating polycarbonate baby bottles in the microwave and the risk of BPA migration, given the current knowledge and after analysing the latest publications and reports, AFSSA deems that:

- * when the contents of polycarbonate baby bottles are heated in a microwave oven in realistic conditions (heating for less than 10 minutes), the quantities of BPA that migrate into food are much less than the maximum value of 50 μg BPA per litre as used by EFSA as a conservative estimate of exposure. As a consequence, the conclusions of the EFSA opinions issued in 2006 and 2008 are also applicable when polycarbonate baby bottles are heated in the microwave and do not justify any particular precautions for use.
- * water hardness or washing-up liquid residues are factors that favour BPA migration from polycarbonate containers; this migration level is still lower than the maximum value of 50 μg of BPA per litre used by EFSA.

Keywords:

Bisphenol A, polycarbonate, plastic, migration, baby bottles, microwaves, food contact materials

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