PlasticsEurope
Association of Plastics Manufacturers

Polycarbonate/Bisphenol A group
Epoxy Resin Committee

July 2015

Background information :

ANSES conclusions regarding exposure to BPA in food contact

based on the new EFSA TDI, as written in ANSES note of 16 June 2015

Upon publication of the comprehensive EFSA opinion on BPA in January 2015, ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, on February 25, had been requested by the French Minister of Environment, Sustainable Development and Energy, to provide a respective opinion. The ANSES response has now been published (16.6.2015) in form of a note "of scientific and technical support".

In the description of "Background and purpose of the request" (p.1) the document summarises the questions raised by the Minister. These include, among others, for the Agency to decide on *"the protection of the health of populations of any age group and the most sensitive populations under the new provisional reference values recommended by EFSA for food."*

A careful and thorough reading of the document shows that ANSES indeed provides a response to this issue. The topic is related to on pages 10, 11, 12 and 13, and specifically at the end of Annex 2, the title of which repeats word by work the Minister´s question. Unfortunately, no summary of these answers was included in the chapter "Analysis and conclusions" (p. 3) of the note. Similarly, ANSES did not repeat in its note what it had already written in 2013, namely that so far BPA has not been proven to have any adverse effect on humans.

In Annex 2, the note states that *"The question here is whether the modeled exposures by ANSES in 2013 may be higher than the provisional reference value EFSA*" (p.10). In other words, it is necessary to verify whether exposure to BPA - as estimated by ANSES in 2013 - exceeds the new t-TDI (tolerable daily intake) set by EFSA, or not.

To do so, ANSES first converts the EFSA t-TDI of 4 µg/kg bw/day to an internal dose. The internal dose describes the "free" amount of BPA that remains potentially active in the body after the overall ingested dose has been rapidly metabolized and converted into an inactive sugar. ANSES applies a conversion rate (also called "bioavailability factor") of 3%, resulting in an internal dose of 0.12 µg/kg bw/day.

ANSES then compares the exposure levels modeled in its 2013 opinion for cumulative exposures through air, dust and food, with this new internal dose of 0.12 µg/kg bw/day using the EFSA t-TDI. The conclusions in the ANSES note are unambiguous:

- for pregnant women
  "None of the BPA exposure situations through air, dust and food exceeds the provisional reference value recommended by EFSA. Ultimately, no risk situation is observed with regard to EFSA's reference value."

- for children over 3 years (3-18 years):
  "None of BPA exposure situations exceeds the provisional reference value recommended by EFSA. No risk situation is observed with regard to this value. "

- for adults (men and women):
  "None of BPA exposure situations exceeds the provisional reference value recommended by EFSA. No risk situation is observed with regard to this value. "

Link to the ANSES document :
https://www.anses.fr/fr/system/files/SUBCHIM2015sa0049.pdf

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Elements not mentioned in the ANSES note

In the chapter "Analysis and Conclusions", ANSES avoids to refer to its conclusions on food contact as described in Annex 2, and prefers to argue that the *'Danish Food Institute (DTU) takes a critical view on of the value proposed by EFSA, considering that on the basis of these values, a risk related to exposure to BPA through food cannot be excluded."* (p.3). Contrary to what is suggested by the beginning of paragraph (*"Since its publication, different national agencies have taken a position on the opinion of EFSA,")* the DTU is not the Danish counterpart of ANSES or the German BFR, which are cited in this context, but is a research department of the Technical University of Denmark. The equivalent to the French and German authorities in Denmark is the Danish Veterinary and Food Administration (DVFA), a service unit to the Ministry of Food, Agriculture and Fisheries.

DTU did not submit comments during the public consultation organized by EFSA on its draft opinion (see the full report of the EFSA on the subject: http://www.efsa.europa.eu/ in / Supporting / pub / 740e.htm) but was heard as a stakeholder. If the DTU was the Danish health safety agency, EFSA must have held a consultation with them to discuss and resolve differences in views between the agencies so as to ensure that the opinion issued by EFSA is authoritative throughout the European Union. Such a consultation indeed took place between ANSES and EFSA (meeting of 3 December 2014 in Paris, English transcript available here: http://www.efsa.europa.eu/fr/fip/fipmsmeetings.htm).

Also in the chapter "Analysis and Conclusions", ANSES notes that "*in its Opinion of March 2013,* [it] *pointed with a level of "moderate" confidence related to the available knowledge to a risk to the unborn children of pregnant women exposed to BPA during pregnancy particularly via food, …"*

ANSES fails to recall the note of its opinion of 2013 (Bisphenol A Risk assessment for human health / Vol 1 / p7) more completely. There it says: *"The level of trust associated with these results* [editor's note: a risk to the mammary gland of the unborn child] *is described as" moderate "by the majority of experts. Some experts of the working group on endocrine disruptors consider this confidence level as "limited", especially because of the sensitivity of the model to the bioavailability factor. If lower bioavailability data in humans were used, those situations exceeding the level could be revised downwards."*

For clarification

In its report 2013 Vol 1, in the chapter on the mammary gland, ANSES states at the outset that *"In humans, the only study available does not allow to conclude on a link between exposure to BPA and breast cancer."* (p. 86) In dismissing this study, the agency focused on studies in animals (rats and mice). The 3% bioavailability factor retained by ANSES is the bioavailability factor established in rodents (rats/mice) that metabolize less BPA, and more slowly, than humans. ANSES itself mentions recent studies in primates indicating much lower free BPA levels, in the order of 0.5%. Now, with the latter value, the health risk from the diet would have been considered "negligible" on the basis of a health risk assessment of an internal dose. Consistent with the latest EFSA findings in 2015.

Being aware of this limitation, ANSES recommended in its 2013 report (p. 12): *"In terms of estimating the internal dose and to better assess BPA exposure of the unborn child: Given the strong influence of the bioavailability factor of unconjugated BPA orally ingested by humans on the results of the health risk assessment, and the lack of available data to confirm the value of 3% used, to conduct a kinetics study to determine that* [bioavailability] *value in humans."*