AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

AFSSA – Request no. 2010-SA-0040
Related Requests nos. 2009-SA-0270 and 2010-SA-0041

Maisons-Alfort, 2 March 2010

OPINION

of the French Food Safety Agency regarding clarification of the AFSSA Opinion on bisphenol A issued on 29 January 2010

THE DIRECTOR GENERAL

1. REVIEW OF THE REQUEST

On 17 February 2010 the French Food Safety Agency (AFSSA) received a request from the Directorate General for Health (DGS) for an Opinion regarding clarification of the AFSSA Opinion on bisphenol A issued on 29 January 1010.

2. BACKGROUND

This request follows the AFSSA Opinion of 29 January 2010 on the critical analysis of the results of a study on the toxicity of bisphenol A on the development of the nervous system, together with other recently-published data on its toxic effects, with a view to clarifying the following points, within fifteen days:

- the critical period of exposure to bisphenol A,
- European and international studies on the toxicity of bisphenol A,
- the safety of materials currently used or that may be used to replace plastics and resins containing bisphenol A.

3. EXPERT ASSESSMENT METHOD

The request was assessed internally by the Physico-chemical risk assessment unit (UERPC) based on the report by the "Bisphenol A" working group (WG), currently being finalised in response to Request no. 2009-SA-0270, and after consulting the "Chemical and physical contaminants and residues" scientific panel which met on 22 February 2010.

4. DISCUSSION

1. Regarding the critical period of exposure to bisphenol A

AFSSA's reasoning is based on the report by the "Bisphenol A" WG and the consultation with the "Chemical and physical residues and contaminants" CES, details from which are presented below:

Based on the toxicological studies analysed by the "Bisphenol A" WG (Murray *et al.* 2007, Howdeshell *et al.* 2008, Palanza *et al.* 2008, Fernandez *et al.* 2009, Monje *et al.* 2009, Nakagami *et al.* 2009, Ryan *et al.* 2009, Salian *et al.* 2009a, b, c, Somm *et al.* 2009, Bosquiazzo *et al.* 2010, Braniste *et al.* 2010), the conclusions of the reports by the NTP-CERHR[1] (September 2008) and

[1] NTP-CERHR: National Toxicology Program - Center for the Evaluation of Risks to Human Reproduction (American scientific panel).

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the OEHHA[2] (October 2009), the critical period of exposure to bisphenol A is during the development of the nervous system and reproductive system which extends from *in utero* exposure (through pregnancy) until the age of 3 years.

However, AFSSA stresses that other stages of development, such as puberty (and even pre-puberty), are also sensitive to endocrine disruptors, but that to our knowledge no study on the toxicity of bisphenol A has specifically investigated these periods of exposure.

AFSSA reiterates that the toxicity studies in which bisphenol A was administered during the perinatal period in rodents (during gestation and lactation until weaning) and which were conducted according to international standards, have not so far characterised health risks at current human levels of exposure.

As stated in its Opinion of 29 January 2010, AFSSA is continuing its expert assessment work, in collaboration with the international network of health agencies, to establish the significance to human health of the effects observed at doses below that used to derive the tolerable daily intake.

Regarding sources of dietary exposure to bisphenol A, it will be possible to identify the major contributors following studies to assess the exposure of the French population, which will be detailed in a forthcoming AFSSA Opinion (in response to Request no. 2010-SA-0041). In particular, it will be possible to determine the contribution, both for infants (from polycarbonate feeding bottles, infant formulas, jars of baby food and breast milk) and pregnant or lactating women (from canned foods, canned drinks, etc.).
Ultimately, with regard to the exposure of infants, it will be possible to determine the respective roles of the mothers (during pregnancy and lactation) and feeding bottles, infant formula and jars of baby food (during the perinatal period).

2. Regarding European and international studies on the toxicity of bisphenol A

To identify European and international studies on the toxicity of bisphenol A, five initiatives have been undertaken:

a) In June 2009, AFSSA launched a European consultation through the national focal points for EFSA. The results of this consultation can be made available to the departments of the DGS.
b) In October 2009, EFSA began a similar review and updated the information received by AFSSA.
c) EFSA's information exchange platform (IEP) is regularly consulted by the AFSSA focal point (access is limited to national focal points).
d) AFSSA is working with an international liaison group called the International Food Chemical Safety Liaison Group (IFCSLG) which brings together the following bodies:
    - Canada (Health Canada)
    - USA (FDA)
    - Australia and New Zealand (FSANZ)
    - EU (EFSA)
    - European Commission (DG Sanco)
    - France (AFSSA)
    - Japan (Food Safety Committee)
    - United Kingdom (UK-FSA)

    AFSSA took part in the meeting held in Parma on 4-5 November 2009 (whose agenda included a review of bisphenol A) as well as the telephone conference of 9 February 2010. This last discussion was on bisphenol A and the organisation of the joint FAO/WHO Expert Meeting on bisphenol A that will be taking place in Canada in October 2010. Studies of interest as well as current or projected management measures were discussed (the meeting report is available to the departments of the DGS). AFSSA is continuing to actively monitor

[2] OEHHA: Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Reproductive and Cancer Hazard Assessment Branch (Californian branch of the US-EPA).

this group's work. In addition, the English version of the AFSSA Opinion of 29 January 2010 was sent to the WHO on 10 February.

e) As part of a cooperation agreement between the German Federal Institute for Risk Assessment (BfR) and AFSSA, a French delegation recently presented the conclusions of the recent AFSSA Opinion on bisphenol A and the questions raised by this Opinion to the BfR (1-2 February 2010). It was agreed to strengthen bilateral collaboration on this topic. This will initially result in the joint organisation of two events on the theme of endocrine disruptors (19-20 April 2010 in Germany, end of 2010 in France).

3. Regarding the safety of materials currently used or that may be used to replace plastics and resins containing bisphenol A.

Concerning the safety of the materials currently used or that may be used to replace plastics and resins containing bisphenol A, it should be noted that these are covered by the European regulations on materials and articles intended to come into contact with food (Regulation (EC) no. 1935/2004) and more specifically those applicable to plastic materials (Directive 2002/72/EC as amended).

It can therefore be reiterated that only monomers authorised at the European level following a risk assessment conducted by EFSA (or previously by the SCF) may be used in plastics or resins. In these regulations, the finished materials are not subject to prior evaluation by the European agency but are marketed under the responsibility of manufacturers.

Using the example of bisphenol S (a polyethersulfone monomer used instead of polycarbonate in feeding bottles), which was assessed in 2000 by the SCF based on only four toxicity studies, AFSSA considers it important that the relevance of reassessing the alternative products currently on the market be discussed rapidly at Community level.

5. CONCLUSION

In order to reduce, through the use of substitute products, human exposure to bisphenol A, particularly for pregnant women and newborns, AFSSA stresses the importance of a rigorous risk assessment process for any products being considered as substitutes for bisphenol A. This assessment process is included in the European regulation, for which a reassessment of the previously approved monomers in light of current scientific knowledge would be relevant.

These are the data that AFSSA is able to provide in response to the request from the DGS for an Opinion regarding clarification of the AFSSA Opinion on bisphenol A issued on 29 January 1010.

The Director General

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KEYWORDS

Bisphenol A, critical exposure

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