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DEMANDE D'INFORMATION AUX AUTORITÉS FRANÇAISES

Objet: Food contact materials containing Bisphenol A

The attention of DG Enterprise and Industry has been drawn to some alleged obstacles to the free movement of goods related to the adoption of French Law n° 2012-1442 of 24 December 2012, which bans the manufacture, import, export and placing on the market of all packaging, containers and utensils intended to come into contact with food, that contain Bisphenol A (“BPA”), (“the BPA Law”).¹ Under the BPA law, as from 1 January 2013, all BPA-based packaging, containers and utensils which are intended to come into contact with food for babies and infants up to 3 years of age are banned. All other BPA-based packaging, containers and utensils, will be banned from 1 January 2015.

National provisions governing the placing on the market of a product not covered by technical specifications harmonised or recognised at European Union level must comply with obligations under the Treaty, in particular with the principle of the free movement of goods, as set out in Articles 34 and 36 TFEU (see, to that effect, judgment of 13 March 2008 in Case C-227/06 *Commission v Belgium*, paragraph 34).

The Commission considers that the French BPA ban risks distorting the functioning of the internal market and, as a consequence, France may become a separate market as regards plastic food contact materials and coatings (as well as pacifiers, teats and teething rings for babies and infants), creating major obstacles for traders from other Member States, as well as non-EU countries, wishing to market their goods in France.

Regulation (EC) N° 1935/2004² on materials and articles intended to come into contact with food and Regulation (EU) N° 10/2011³ on plastic material and articles harmonize national laws on the content requirements of plastic food contact materials. In particular, Regulation

¹ Loi n° 2012-1442 du 24 décembre 2012 visant à la suspension de la fabrication, de l'importation, de l'exportation et de la mise sur le marché de tout conditionnement à vocation alimentaire contenant du bisphénol A; JORF n°0300 du 26 décembre 2012 page 20395.

² Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC; OJ L 338, 13.11.2004, p. 4–17.

³ Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food; OJ L 12, 15.1.2011, p. 1-89.

(EU) N° 10/211 authorises the use of BPA as monomer in the manufacturing of plastic materials and articles with a specific migration limit of 0,6 mg/kg. The only exception to this use is polycarbonate infant feeding bottles, where the European Commission has banned the use of BPA. Member States may not enforce a wider ban than provided for under Regulation (EU) N° 10/2011, except as a temporary ‘safeguard’ measure under Article 18 of Regulation (EC) No 1935/2004 on the basis that the material or article could endanger human health.

However, according to the complainant, the French BPA Law does not seem to meet the conditions for applying the Article 18 safeguard mechanism: notably, it appears that France has not adduced any ‘detailed grounds’ for concluding that BPA in plastic food contact materials endangers human health, other than the two reports of the French Agency for Food, Environmental and Occupational Health & Safety, “ANSES”⁴, which were, at the time of the adoption of the legislation, preliminary.

On 13 October 2011, the European Commission asked the European Food Safety Agency (“EFSA”) to analyse whether the two ANSES reports contain any elements that would require a revision of EFSA’s previous opinions.

In 2006, EFSA had set the tolerable daily intake (“**TDI**”) of 0.05 mg/kg body weight/day for BPA and reconfirmed this TDI in 2008. In 2010, EFSA carried out a detailed and comprehensive review of recent scientific literature and studies on the toxicity of BPA at low doses, and concluded, in its opinion of 27 September 2010, that it could not identify any new evidence which would lead it to revise the TDI for BPA. EFSA’s Scientific Panel also stated that the data currently available did not provide convincing evidence of neurobehavioural toxicity of BPA.

On 24 November 2011, EFSA’s Scientific Panel adopted its Statement on the ANSES reports on BPA which France used to justify its October 2011 proposal (the “EFSA 2011 Statement”). Having assessed the preliminary report on BPA prepared by ANSES, EFSA’s Scientific Panel did not find any new evidence in the report which would lead to a revision of the current TDI for BPA. It concluded that “the Panel overall considers that the information in the ANSES report does not change the views that the Panel expressed in 2010.” In its 2011 Statement, EFSA also committed to reconsider its opinion following further evaluations of new studies and of new data from ongoing low dose studies. This opinion is scheduled for completion by end of May 2014.

On 9 April 2013, ANSES published a complete risk assessment report⁵ in which it concluded⁶, that some situations of exposure of pregnant women to BPA pose a risk to the mammary gland of the unborn child. The confidence level associated with these results was described as “moderate” by the majority of the experts. Some experts of the working group regarded this confidence level as “limited”, mainly due to the model’s sensitivity to the bioavailability factor.

An obstacle to trade may be justified under Article 36 TFEU or on the basis of one of the overriding requirements in the public interest recognized by the Court of Justice of the European Union. It is for the national authorities to demonstrate that the restriction on the free movement of goods is justified on one of these grounds.⁷ Furthermore, the Member State must demonstrate that its legislation is necessary to effectively protect the public

⁴ <http://www.anses.fr/en/documents/CHIM2009sa0331Ra-0EN.PDF>

⁵ <http://www.anses.fr/en/documents/CHIM2009sa0331Ra-0EN.PDF>

⁶ The ANSES report took into account all exposure media: air, settled dust and food (including water intended for human consumption), and excluded certain specific exposure situations (cash register receipts, water from refillable polycarbonate containers).

⁷ See Case C-192/01, *Commission v Denmark* [2003] I-09693.

interests invoked.⁸ Thus, the French authorities must demonstrate that such legislation is necessary to effectively protect the public interests invoked.

It is settled case law that the national provision must be appropriate for securing the attainment of the objective pursued and must not go beyond what is necessary in order to attain it and that it is for the competent national authorities to show that their legislation complies with those criteria.⁹

In consequence, the Commission services would like to receive more information from the French authorities on the above mentioned BPA Law, especially as regards its adequacy to the aims sought, its justification and proportionality. They would appreciate the view of the French authorities on the information presented above and notably on the following:

- *According to our information France is the only country in the world to ban the use of BPA in the manufacture of all packaging, containers and utensils food contact materials intended for food contact. If this is true, on what scientific basis?*
- *The Commission would like to receive clarifications on the treatment that the French authorities propose as regards for traders from other EU Member States, as well as non-EU countries, who wish to place their goods on the French market.*
- *The Commission would like to receive clarification if the French BPA law applies to all food contact materials such as pipes, machineries, silos coated with epoxy resins. Does it apply to empty packaging as well as filled packaging and what are the transitional provisions for the respective packaging?*
- *Would the French BPA law apply to products in transit through France from another country and destined to another country?*
- *The French BPA Law will have far-reaching repercussions on industry as it will affect all of the companies in the industrial supply chain engaged in the manufacture and sale of BPA-based packaging, containers and utensils. The Commission will thank being presented with any impact assessment studies by the French authorities on the economic consequences of switching to an alternative packaging system.*
- *Did the French authorities consider other measures less restrictive to trade to manage the risk posed by BPA? If yes, were these measures dismissed as not adequate and if yes on which grounds?*
- *Did the French authorities assess the economic impact of all measures identified as adequate?*
- *In view of the ANSES full risk assessment report published in April 2013 did the French Authorities review the adequacy and proportionality of the measure?*
- *The reasons why France has enacted a measure which goes far beyond the requirements posed by Regulation (EU) N° 10/2011 on plastic food contact materials.*

⁸ See, to that effect, case C-333/08 *Commission v France*, para. 87 [2010] I-00757.

⁹ See paragraphs 53 and 54 of Case C-150/11, *Commission v Belgium*, not yet published.

- *Finally, could France explain the reasons for adopting the BPA Law before the comprehensive EFSA re-evaluation of the science on BPA is available?*

Nous vous remercions de l'attention que vous porterez à la présente.

[Redacted]

[Redacted]