5.6.2013

NOTIFICATION 2013/230/F **BY FRANCE CONCERNING THE PROPOSED DECREE ON LABELLING OF FOOD CONTACT MATERIALS CONTAINING BISPHENOL A (BPA)**

On 2 May 2013, France notified the European Commission of its intention to adopt a decree laying out the conditions for a health warning to be added to all BPA-based food packaging and objects coming into contact with food and marketed to the final consumer. The label would caution against consumption by breastfeeding and pregnant women, and children up to the age of 3 years. The standstill period, as per the notification procedure laid out in Directive 98/34/EC, ends on 5 August 2013.

FoodDrinkEurope, the food packaging value chain (EMPAC) and the raw material producers (PC/BPA Group and Epoxy Resin Committee of PlasticsEurope) make the following comments about the proposal to label BPA-based food packaging: **The labelling**

- **will create a distortion of the free movement of goods in the European Single market as well as in the global food market**
- **will cause disproportionate costs for businesses, in particular SMEs, not only in France, but in all EU Member States and countries globally importing food to the EU**
- **will create unjustified concern and add little to no choice for consumers rather than enhance their protection**
- **is not justified nor proportionate based on existing safety assessment of BPA-based food contact, including the most recent one from the European Food Safety Authority (EFSA, 2011)**
- **undermines the existing EU food contact regulation and its institutions.**

The European joint value chain industries affected by this proposed French measure therefore strongly call on the European Commission and the Member States to submit reasoned objections to the proposed French measure by filing a “detailed opinion”, as per European Union Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

Detailed comments about the proposal to label BPA-based food packaging

A. The proposed labelling will create a distortion of the free movement of goods in the European Single market as well as for the global food market

The notified decree defines the implementation conditions of a national law which can only apply to its territory. Therefore, "market" can only be understood as applying to the French market. The obligation to apply a label on BPA-based food contact materials marketed in France imposes a specific additional requirement on products that are legal in all other Member States. Producers and manufacturers based outside France will not be allowed to sell their products on the French market due to such a requirement from the date the proposed national law would become enforced. This would seriously affect the functioning of the EU Single market. Similarly, producers and manufacturers outside the EU would encounter barriers to the import of their products to France which would translate in a disruption of the international market.

The labelling decree exempts from labeling products which have been put on the French market before the enforcement date. This means that a can which was produced in, or was imported to France before the enforcement date is exempted from labeling, while if the can was produced outside France, put on the European market but not on the French market and is only imported after the enforcement date, it is not exempted.

Products intended to be put on the market around 1.10.2013 are already produced and ready for shipment to their destinations since several months. Imported fruit and vegetables, for example, are largely delivered to the EU via the ports in Rotterdam and Antwerp. These products have already entered the EU, but not yet their destination countries.

In practice, for a can imported to France, this means: The food or beverage can which is legal for sale in France if crossing the French border on the 30th of September will become illegal if entering France on the 1st of October, while still continuing to be legal in all other EU countries. Products are thus not equally treated in the EU, which is a clear distortion of the Single EU Market.

B. Labelling would cause disproportionate costs for businesses, in particular SMEs, not only in France, but in all EU Member States and countries globally importing food to the EU

The labelling of BPA-based food contact materials is intended to be a short term measure in France, to be applied until the entry into force of a total restriction on BPA in food contact materials starting on 1 January 2015. Requiring a label will incur significant additional costs for producers and manufacturers and in particular SMEs. **Business and economic impact of labelling is disproportionate given the short time spam of application, i.e. potentially 14 months.**

In many cases, food packaging manufacturers have already produced packaging which will be sold on the EU market after October 2013, the enforcement date currently foreseen by France. In addition, since the draft decree on labelling is not finalised and may be adopted potentially only in early August 2013, manufacturers would only have two months to adapt their packaging and add the label. **It is impossible for manufacturers and importers of food products to change the packaging/add a French market labelling to their products within such a short timeframe.** Realistically, such a transition requires a minimum of 6 months, but generally it is at least 12 months.

For a business outside France that has a proportion of output from a given production site which is exported to France, the practical choices are to either stop exporting and loose that volume, or move the whole production to comply with French law at an additional cost across that entire volume. Separate stocks of packaging articles in the same production location would add complexity and costs due to specific line switching to produce for France.

In practice, this means for example: canned tomatoes from Italy, or canned Spanish fish, if they are already produced, may not be delivered to France after 1.10.2013, and for several further months. Because of their seasonality, this may result in a shortage of supply for French consumers. SME´s will lose considerable business.

C. The proposed measure would create unjustified concern and add little to no choice for consumers rather than enhance their protection

BPA-based materials in food contact comply with strict EU safety rules. There is no validated evidence that the exposure of consumers food packaging made from materials based on BPA could cause a safety risk to human health. The proposed labelling of BPA-based food packaging would only cause unjustified concern for consumers.

Furthermore, to date, for a number of BPA-based food contact materials such as cans, there are no equally proven alternatives. The French measure requires ANSES to report to Parliament on the safety of alternatives and to-date industry does not know the criteria which will be used to make that assessment.

Moreover, for some segments of packed food, there are currently no options for packages without intentionally added BPA. Therefore, labelling of these products would not encourage an informed consumer choice and would only entail avoidance of the products by consumers.

For a range of products the mandatory labelling will be inappropriate since they are not intended to be consumed by children, pregnant or breastfeeding women, anyway (i.e alcoholic beverages)[i].

In addition, for certain packaging, suppliers have noted that technically unavoidable trace amounts of BPA can be detected even though BPA is not intentionally used in the packaging. Therefore there may be packaging which could contain trace amounts of BPA but which are not be labelled as they are not BPA-based. The French labelling requirement is not – and far from it – a guarantee that there is no BPA present in the product, and therefore the claim is misleading, regardless of wording, because the presence of BPA in the final product is not only from packaging. The consequent assumption by consumers that the absence of a label implies that the packaging is BPA-free would actually be misleading.

D. The proposed labelling is not justified nor proportionate based on existing safety assessments of BPA-based food contact materials, including the most recent one from the European Food Safety Authority (EFSA, 2011).

There is no evidence that the exposure to food contact products made from BPA-based materials causes a risk to human health, including for newborns, children, breastfeeding or pregnant women.

EU and authorities around the Globe repeatedly risk assessed the use of BPA in such applications and confirmed its safety. Since 2006 the European Food Safety Authority (EFSA) alone has undertaken four thorough assessments of BPA; these assessments corroborated that BPA is safe for use in products coming in contact with food. After review of the 2011 French Food Safety Agency (ANSES) report on BPA, EFSA and the European Commission concluded there was no need for any risk reduction measures further to those already in place.

In April 2013, the US Food and Drug Administration (FDA) published an interim update of an ongoing evaluation of the most recent science on BPA[1]. The FDA reconfirmed the safety of the substance: "FDA's current assessment is that BPA is safe at the very low levels that occur in some foods. This assessment is based on review by FDA scientists of hundreds of studies including the latest findings from new studies initiated by the agency."

Already in April, the Government of Canada released the results of the second Canadian Health Measures Survey (CHMS) covering the period 2009-2011[2]. These results showed that typical BPA intake is more than 1,000 times below safe intake level and they reconfirmed Health Canada´s statement from 2012 "that current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population".

Most importantly, EFSA is performing a new assessment on BPA to be released in early 2014[3]. The Authority is reviewing a new report[4] on BPA released by ANSES on 9 April 2013 and new data from low-dose studies ongoing in the United States of America. EFSA will particularly focus on exposure of vulnerable groups, including children, assessing dietary exposure but also the contribution of non-dietary sources.

The labelling proposed by France is unjustified as the studies upon which the proposed measure is based have either been dismissed or will be further assessed in reasonable delays, i.e. in early 2014.

In addition, as EU and other authorities (US FDA, Health Canada, FSANZ) repeatedly risk assessed the use of BPA in food contact applications and confirmed its safety for consumer in its current uses, a labelling obligation would be disproportionate.

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[i] The mandatory mention will be misleading for alcoholic beverages which are not intended for any of the target consumers (children, breastfeeding and pregnant women). Such mention will also be disproportionate and superfluous with current law already prohibiting distribution of alcoholic beverages to minors and a health warning for pregnant women affixed on them.

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[1] US Food and Drug Administration http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm
[2] Government of Canada http://www.statcan.gc.ca/pub/82-625-x/82-625-x2013001-eng.htm
[3] European Food Safety Agency (EFSA) update, http://www.efsa.europa.eu/en/press/news/120424.htm?WT.mc_id=EFSAHL01&emt=1
[4] Anses, http://www.anses.fr/sites/default/files/documents/CHIM2009sa0331Ra-0.pdf