



Internal Market, Industry, Entrepreneurship and SMEs DG

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Member of Cabinet Bienkowska

Meeting with PlasticsEurope on BPA **(17/04/2015 11:00)**

BRIEFING NOTE

Scene setter: You are meeting a delegation from PlasticEurope, the trade association representing the polymer producers in Europe. The meeting will focus on the policy concerning Bisphenol A (BPA) and in particular the measures taken by France in this regard. In 2013, PlasticsEurope filed a complaint with the Commission against this measure. Recently EFSA issued a scientific opinion, concluding there is no consumer health risk from BPA exposure.

Table of contents

1. CONTEXT	2
2. KEY MESSAGES.....	2
3. BACKGROUND INFORMATION	3
a. French measures on BPA.....	3
b. EFSA Opinion on BPA.....	4
c. About PlasticsEurope	5

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DG GROW.C.2

1. CONTEXT

- *French Law n° 2012-1442 of 24 December 2012 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 (“the BPA law”). 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 3 years of age are banned. **All other BPA-based packaging, containers and utensils, are banned from 1 January 2015.***
- *France is the **sole country** not only in the EU, but in the world, having adopted such a measure.*
- *EFSA's **Scientific Opinion**, published on 21 January 2015, concluded that there is **no consumer health risk from BPA exposure.***
- *France is now considering adopting soon **further restrictions** – even full bans – on the use of other products covered by EU harmonised legislation, like toys.*
- ***PlasticsEurope filed a complaint** on 3 April 2013. **Plastics Europe** is one of the leading European trade associations, representing more than 100 member companies, producing over 90% of all polymers across the EU28 member states plus Norway, Switzerland and Turkey.*
- *The detrimental impact of the measure is estimated as amounting to losses estimated to **€1.5 billion/year** by the complainants. If the restrictions/bans go further, this figure will be substantially increased.*

2. KEY MESSAGES

- We are currently in discussion with the French authorities on the compatibility of a full ban on BPA with Articles 34-36 TFEU.
- EFSA's Scientific Opinion, published on 21 January 2015, concluded that there is no consumer health risk from BPA exposure. The competent Commission services (in particular DG SANTE, but also DG GROW) are currently assessing EFSA's opinion.
- The Commission will remain in dialogue with France and conclude on the complaint against the French ban once it has assessed in full the EFSA Opinion.

Contact: 

3. BACKGROUND INFORMATION

a. French measures on BPA

NB: The complaint by PlasticsEurope is being treated now under reference NIF 2015/4010. No formal infringements procedure launched yet.

- An initial request for information concerning the consequences of the national legislation was sent to the French authorities via EU PILOT 5815/13/ENTR (Ref.: Ares(2013)3800684) as well as an additional request for information (Ares(2014)2134764 - 27/06/2014, with supplementary information being requested by the Commission on 18/08/2014). The French authorities replied respectively on 22/04/2014, 16/07/2014, 13/10/2014 and 18/11/2014.
- Additionally, the Commission services addressed administrative letters to the French authorities on 23/10/2014 and 22/12/2014 (Ref.: Ares(2014)3518848 and Ares(2014)4654485) strongly suggesting that the effective entering into force of the measure is postponed while awaiting for EFSA's final opinion. The French authorities replied on 26/12/2014 that the measures will enter into force as foreseen on 1 January 2015.
- The case was moved into the infringements database/NIF, an inter-service consultation was launched for a draft Letter of Formal Notice. LS issued a positive opinion and SANTE a negative one. Consequently it was decided to put the case on hold for the moment, until EFSA's final opinion is fully assessed.

Notification under Directive 98/34

- The draft measure was notified by France under **Directive 98/34/EC procedure** (ref.: 2011/529/F). When assessing the draft legislation the Commission services suggested issuing a detailed opinion on the basis of Article 34 TFEU. However, the responsible Cabinet at the time decided to only issue **strong comments**, given the fact that there was no clear evidence that BPA would not be dangerous for human health.

Legal assessment

- The French measure has been adopted unilaterally and, in the absence of an EFSA opinion, without adequate scientific grounds. The measure raises numerous objections as regards its compatibility with the Treaty rules on free movement of goods, and especially as regards its **justification and proportionality**.
- The French BPA law provides for the suspension of the manufacturing, import, export and placing on the market of any packaging, container or utensil involving BPA and intended to come into direct contact with food or after 1 January 2015. It is safe to assume that the functioning of the internal market will be strongly affected (esp. importations of fruit/vegetables/fish into France – but exportations of French products will also be affected, as some companies in other MS will not accept products using BPA substitutes).
- The application of the principle of **mutual recognition** as regards products using BPA that have been lawfully marketed in other MS, where they are not considered a particular risk, is not taken into consideration.

- The measure has been adopted in the absence of adequate dialogue with interested parties: questionnaires were addressed only to French representative organizations.
- The legislation at issue goes beyond what is necessary in order to attain the objective pursued – no other MS, or any other third country, has adopted a full ban on the use of BPA apart from products aimed at infants and young children.
- No other measures less-detrimental to the free movement of goods appear to have been considered.
- **Furthermore, measures adopted are not coherent with the objective sought**, in as much as the legislation at issue provides for exceptions with regard to the so-called "industrial applications": The measure does not apply to industrial materials and equipment used in the production, processing, storage or transportation of foodstuffs (fixed tanks, boat or truck vats, reservoirs, tanks, silos, piping, pipes ...). This inconsistent regulatory approach has been explained by concerned parties as a way to not affecting national producers (especially wine producers) which extensively rely on this kind of installations.
- The measure creates a **great degree of legal uncertainty** as regards the use of BPA, imported products, the control and enforcement system and the non-covered areas. No guidelines have been issued.

In the light of the current state of EU law, the French measure is **fully disproportionate and creates considerable legal uncertainty, both within the internal market and as regards the EU commercial relations with third countries**. Its economic impact is also significant for the European industry, which is the polycarbonate, metal packaging and food industry, and whose foremost representative is **PlasticsEurope**.

b. EFSA Opinion on BPA

- EFSA's final Opinion on BPA issued on 21 January 2015 differs from that of the French risk assessment body (ANSES), published in 2013. The main differences arise from expert judgement on whether a conclusion can be drawn from specific studies to derive a safe level (Tolerable Daily Intake or TDI). ANSES determined that some situations of exposure of pregnant women to BPA pose a risk to the mammary gland of the unborn child. Although EFSA has not come to the same conclusion, it has taken the same studies into account and additional studies since ANSES published its report, in coming to a final conclusion on the risk from BPA to public health.
- EFSA used a more refined methodology than they had previously, considered the widest possible range of studies and integrated all possible uncertainties into its risk assessment which led to a lowering of the safe level (temporary Tolerable Daily Intake).
- Divergence of opinion between scientists is to be expected as it reflects the scientific process. The agreed EU procedure was followed by the EFSA and the French Agency and the basis of the divergence explained. It is unhelpful to question the reputation of EFSA for something which is quite reasonable and will undoubtedly arise again.
- DG SANTE is currently assessing EFSA's opinion. Even if EFSA's opinions are merely advisory and are perhaps not always reflected in Community's legislation, they do undeniably have normative effects. For one thing, the Commission cannot simply disregard the agency's advice. In accordance with legislation laying down the

authorization procedures, for instance in the area of GM food and feed, it has to find equivalent scientific evidence and give reasons justifying its reliance thereon.

- The Risk Assessment Committee of the European Chemical Agency (ECHA) published on 14 March 2014 an opinion¹ proposing a more severe hazard classification for BPA (Toxic for reproduction category 1B “May damage fertility” compared to the current Category 2 “Suspected of damaging fertility”). The Commission is considering its inclusion in the harmonized classification contained in the CLP Regulation (EC No 1272/2008). However, this opinion considers only the intrinsic hazards and does not reflect the risks due to the exposure of the substance as carried out in the EFSA opinion.

c. About PlasticsEurope

From the PlasticsEurope website:

- PlasticsEurope is one of the leading European trade associations with centres in Brussels, Frankfurt, London, Madrid, Milan and Paris. They are networking with European and national plastics associations and have more than 100 member companies, producing over 90% of all polymers across the EU28 member states plus Norway, Switzerland and Turkey.
- The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection.
- More than 1.4 million people are working in about 62,000 companies (mainly small and medium sized companies in the converting sector) to create a turnover in excess of 300 billion EUR per year.
- The plastics industry includes polymer producers - represented by PlasticsEurope, converters - represented by EuPC and machine manufacturers - represented by EUROMAP.
- PlasticsEurope promotes the positive contributions of plastics by:
 - Highlighting the material’s beneficial properties and its positive contributions to society throughout its life cycle;
 - Providing society with educational information to help raise awareness and correct misconceptions;
 - Liaising with European and national institutions in policy matters to secure decisions based on accurate information;
 - Communicating plastics contribution to sustainable development, innovation and quality of life;
 - Initiating in depth studies and sharing experiences.

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¹ <http://echa.europa.eu/documents/10162/777918ff-33b5-46ff-be89-2bdc406d34fa>