PlasticsEurope
Association of Plastics Manufacturers

COMPLAINT

to the European Commission

Concerning the failure by France to comply with its obligations under EU law

by adopting a Law banning, *inter alia*, the manufacture, import, export and placing on the market of food contact materials containing Bisphenol A

25 March 2013

ASSOCIATION OF PLASTICS MANUFACTURERS IN EUROPE AISBL
Avenue E. Van Nieuwenhuyse 4/3 - B -1160 Brussels - Belgium
Tel (32-2) 675 32 97 - Fax (32-2) 675 39 35
VAT BE 416 155 338 - WWW.PLASTICSEUROPE.ORG

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I. Executive Summary

The present complaint, brought by PlasticsEurope, concerns French Law n° 2012-1442 of 24 December 2012, banning 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 French BPA Law**"). Under the 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, will be banned from 1 January 2015.

The French BPA ban will seriously distort the internal market. France will become a wholly 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 put their goods on the French market. The fact that the law runs contrary to specific EU legislation and the opinion of the European Food Safety Agency (EFSA) creates considerable legal uncertainty for economic operators. As well as undermining the integrity and credibility of EFSA and the body of EU law governing the internal market and regulating food contact materials, this uncertainty will stifle innovation and economic enterprise in Europe. Rather than protecting the health of consumers, the French ban could in fact be detrimental, given the lack of any single, safe substitute for BPA. The ban will also adversely affect consumer welfare in terms of both choice and prices.

The complaint argues that the French law infringes the following provisions of EU law:

1. The principle of the free movement of goods. The French BPA law is an unjustified and disproportionate restriction on the free movement of goods, breaching Articles 34 and 35 TFEU. France cannot invoke the protection of public health to justify the law, since this objective is already addressed at EU level (notably in Regulation 1935/2004 on food contact materials, Commission Regulation 10/2011 on plastic food contact materials and Commission Regulation 1895/2005 on epoxy derivatives in food contact materials). These provisions already reconcile the objectives of protecting public health with the smooth functioning of the internal market. In any event, a justification on grounds of public health is unfounded since the French ban is not based on a *"seriously considered health policy"*. It is based on a preliminary report by the French food safety agency (ANSES), which suffers from serious deficiencies and is contradicted by the findings of EFSA and several food safety agencies across the world which have reviewed the science and have concluded that BPA is safe in food contact materials. Critically, EFSA considered that the ANSES report does not change the view of the EFSA Panel in 2010, and does not justify a change in the current European approach to the risk management of BPA.

2. Regulation 1935/2004 on food contact materials and Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food. These regulations, which harmonize national laws on the content requirements of plastic food contact materials, allow the presence of BPA with a specific migration limit of 0,6 mg/kg. The only exception 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 these regulations, except as a temporary 'safeguard' measure under Article 18 based on strictly precautionary measures. However, the French BPA Law does not meet the conditions for applying the Article 18 safeguard mechanism: notably, France has not

adduced any 'detailed grounds' for concluding that BPA in plastic food contact materials endangers human health, other than in the reports of ANSES, which are acknowledged to be preliminary. EFSA's Scientific Panel has since reviewed these preliminary reports and concluded that they do not justify revising the tolerable daily intake for BPA.

3. Commission Regulation 1895/2005 on epoxy derivatives in food contact materials. The French BPA ban is contrary to this regulation which lays down specific migration limits for 'BADGE', an epoxy resin used in coatings in, for example, metal cans.

4. The precautionary principle. France has misapplied the precautionary principle, which presupposes a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent result of international research. As explained below, the ANSES reports are not comprehensive risk assessments and EFSA's multiple comprehensive risk assessments of BPA confirm that BPA does not pose a risk to health.

5. The Technical Standards Directive 98/34. France's failure to re-notify the French Law, which is substantially altered from the draft law notified in 2011 (on which a number of Member States raised substantive concerns), constitutes a breach of its obligations under that directive.

6. WTO law. Finally, the French BPA law raises technical barriers to trade that might contravene WTO law.

The Complainant therefore asks that the Commission take the necessary steps to bring these infringements to an end. Specifically, the Commission is invited to:

a. initiate infringement proceedings against France under Article 258 TFEU;

b. as regards France's pending notification under Article 18 of Regulation 1935/2004, formally decline to adopt amendments to Commission Regulation 10/2011 on plastic food contact materials;

c. take the necessary steps to ensure that France complies with its obligations under the TRIS Directive; and

d. request France to delay the implementation of the French BPA Law until EFSA publishes its scientific opinion on the human health risks associated with BPA, expected in May 2013, and to make a formal, public, declaration to this effect.

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II. Details of the Complainant

7. PlasticsEurope ("**the Complainant**") is a trade association which represents the plastics manufacturers of Europe. It has more than 100 member companies, located across the 27 Member States. The member companies produce over 90% of all polymers in the EU plus Norway, Switzerland, Croatia and Turkey. More information on PlasticsEurope and its members is available at http://www.plasticseurope.org.

8. The registered office of PlasticsEurope is at:

Association of Plastics Manufacturers in Europe AISBL
Avenue E. Van Nieuwenhuyse 4, Box 3
Auderghem, B - 1160 Brussels
Belgium
Tel: +32 (2) 675 32 97
Fax: +32 (2) 675 39 35

III. Representation

9 [redacted] and [redacted]

White & Case LLP
62 Rue de la Loi
1040 Brussels
Belgium

Email: [redacted] and [redacted]
Tel [redacted]

IV. Member State or public body alleged to have infringed EU law

10. The French Republic.

V. Description of facts giving rise to complaint

a. The draft law of 2011

11. On 12 October 2011, the French *Assemblée Nationale* adopted a draft legislative proposal, seeking a ban of the manufacture, import, export and placing on the market of all food packaging containing Bisphenol A ("**BPA**"). The draft proposal provided for the following:

a. A temporary ban, to take effect from 1 January 2013, of all BPA-based packaging, containers and utensils which are intended to come into contact with food for babies and children up to the age of 3 years.

b. A temporary ban of all other BPA-based packaging, containers and utensils, to take effect from 1 January 2014.

c. A health warning to be affixed to all BPA-based food packaging, cautioning against its use by pregnant women, breastfeeding women and children up to the age of 3 years.

d. The French government is to submit a progress report drawn up by the French National Agency for Food Safety and Occupational and Environmental Health ("**ANSES**") to the French parliament on substitutes for BPA, as well as their safety and suitability for use in the manufacture of plastics and resins for food use by 31 October 2012.

b. The TRIS notification

12. The draft proposal of 12 October 2011 was notified to the European Commission and the Member States insofar as it related to non-plastic materials on 19 October 2011[1] under the Technical Regulations Information System under Directive 98/34 ("**the TRIS Directive**").[2] France sought to justify the proposal on the basis of two reports published on 27 September 2011 by ANSES on the health effects of BPA[3] and on the uses of BPA[4].

13. The French authorities invoked the emergency procedure, which enables Member States to bypass the standstill period provided for in the TRIS Directive[5]. This was rejected by the European Commission ("**the Commission**").

14. In response to the TRIS notification, the Czech Republic, the Netherlands, Spain and the United Kingdom issued detailed opinions and the Commission, Italy and Slovenia issued comments. The effect of these detailed opinions was to prolong the standstill period for the adoption of the French law by an additional 3 months, to 20 April 2012.

15. In spite of receiving detailed opinions indicating that the draft proposal would create obstacles to the free movement of goods in the EU, France did not amend its proposal, but instead extended its scope of the law by adding a ban on pacifiers, teats and teething rings containing BPA and the use of tubes containing DEHP in pediatric, neonatal and maternity services to the law. To the Complainant's knowledge, France has not formally replied to these detailed opinions, nor has it re-notified the Law under TRIS.[6]

c. The EFSA Opinion

16. The day after the adoption of the French draft proposal, 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 necessitate a revision of EFSA's previous opinions.

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[1] Notification number 2011/529/F.
[2] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).
[3] ANSES, "Effets sanitaires du bisphénol A", rapport d'expertise collective, 2011.
[4] ANSES, "Connaissances relatives aux usages du bisphénol A", rapport d'étude, 2011.
[5] Article 9(7), Directive 98/34/EC.
[6] According to Article 8 of the TRIS Directive, Member States are obliged to re-notify a draft law under TRIS if *"they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive."*

17. In 2006, EFSA had set the tolerable daily intake ("**TDI**") of 0.05 mg/kg body weight/day for BPA.[7] It confirmed this in 2008.[8] 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,[9] that it could not identify any new evidence which would lead it to revise the tolerable daily intake for BPA. EFSA's Scientific Panel also stated that the data currently available did not provide convincing evidence of neurobehavioural toxicity of BPA.

18. 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**").[10] 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 tolerable daily intake 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. The opinion is scheduled for completion in May 2013.[11]

d. The French BPA Law

19. On 24 December 2012, the French President approved the draft proposal of 12 October 2011, with amendments, in the form of Law n° 2012-1442, banning the manufacture, import, export and placing on the market of all packaging, containers and utensils intended to come into contact with food, if they contain BPA.[12] This law is attached at Annex 1.

20. The French BPA law is comprised of 4 Articles.

21. Article 1 of the French law takes effect by way of amendment to law 2010-729 on infant feeding bottles.[13] It provides for the following:

    a. A 'temporary' ban, which took effect from 1 January 2013, of all BPA-based packaging, containers and utensils which are intended to come into contact with food for babies and children up to the age of 3 years.

    b. A 'temporary' ban of all other BPA-based food packaging, containers and utensils, due to take effect from 1 January 2015.

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[7] Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to 2,2-BIS(4-HYDROXYPHENYL)PROPANE, EFSA Journal 2006, 428.
[8] "Toxicokinetics of Bisphenol A – Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food", EFSA Journal 2008, 838.
[9] Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A, EFSA Journal 2010; 8(9):1829.
[10] EFSA Journal 2011;9(12):2475.
[11] *See* EFSA press release of 29 October 2012: http://www.efsa.europa.eu/en/events/event/121029 htm.
[12] 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.
[13] Loi no 2010-729 du 30 juin 2010 tendant à suspendre la commercialization de biberons produits à base de bisphénol A.

c. A health warning must be affixed to all BPA-based food packaging, cautioning against its use by pregnant women, breastfeeding women and children up to the age of 3 years. The conditions of the warning are to be established by a separate decree.

d. The French government is to submit a report to the French parliament evaluating the toxicity of potential substitutes for industrial applications of BPA by 1 July 2014.

22. Article 2 takes effect by way of inserting the following text into the French Consumer Code[14] and Public Health Code[15], respectively:

    a. Agencies referred to in Article L 2-15-1 are empowered to enforce breaches of the French BPA law.

    b. It is forbidden to produce, sell, market, export and import pacifiers, teats and teething rings containing BPA.

23. Article 3 on medical devices takes effect by way of amendment to the French Public Health Code[16] as follows:

    a. From 1 July 2015, the use of tubes containing di(2-ethylhexyl) ("**DEHP**") phthalate is banned in pediatric, neonatal and maternity services.

    b. Infant feeding bottles containing BPA and fulfilling the definition of medical devices in Article L. 5211-1 are banned.

24. Article 4 contains a provision for the French Government to present a report to the French Parliament on endocrine disruptors.

25. The bans are "temporary" in the sense they will remain in force until the measures are revoked by the French government after having consulted ANSES.[17]

26. The French law, insofar as it relates to BPA, is extremely broad in scope. Article 1 extends to all packaging, containers and utensils which are intended to come into direct contact with food. The law does not provide further instruction concerning the precise time that such packaging, containers or utensils will be deemed to enter into direct contact with food. As a result, the law is understood to cover all packaging, containers and utensils which are intended to come into direct contact with food, *no matter when* they are in contact with food. This is very far-reaching; it includes not only packaging used during the sale and commercialisation of food, such as storage containers, can linings, jar lids and bottles, but also applications at factories used during the preparation of food, such as industrial storage containers and pipes.

[14] La Section 1 du chapitre V du titre Ier du livre II du code de la consommation.
[15] 1º de l'article L.5231-2 du code de la santé publique.
[16] Le titre Ier du livre II de la cinquième partie du code de la santé publique.
[17] 2º of Article 1, Loi no 2010-729 which specifies that the ban remains in force *« jusqu'à ce que le Gouvernement, après avis de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, autorise la reprise de ces opérations. »*

e. The Article 18 safeguard notification

27. According to Article 18 of Regulation 1935/2004 on food contact materials,[18] France was required to '*immediately inform the other Member States and the Commission and give reasons for the suspension or restriction*' upon adoption of a law which restricts a material, such as BPA, which is otherwise expressly authorized under EU law.[19] France notified the French BPA law to the European Commission under Article 18 insofar as it related to plastic food contact materials on 7 January 2013.[20]

VI. Practical implications of the French BPA law

28. The main commercial applications for BPA. BPA is the basic building block for certain plastic materials. The two main applications for BPA (which together account for 96% of BPA-based applications in Europe) are polycarbonate plastics and epoxy resins (BPA diglycidylether). BPA is also used as an additive in a resin to coat thermal printing papers, such as receipts from cash registers.

- Polycarbonate plastic is shatter proof and can be sterilized at high temperatures without deforming or damaging the container. This ensures that packaging is unbreakable, capable of being properly cleaned and therefore hygienic.

- Epoxy resin is used to coat the interior of metal cans and components such as caps and closures on glass jars. Epoxy resins are used to guarantee the safe conservation of the packaged product, which may otherwise be infected by bacteria or other external agents.

For the majority of products, there is currently no accepted, suitable alternative substances or materials available. The alternatives which are available are either significantly inferior to the existing products or themselves pose an uncertain level of risk to human health or to the environment.

29. The French BPA Law will seriously distort the internal market. As is expressly recognized by EU legislation in this area, "*differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of substances used in the manufacture of materials and articles intended to come into contact with food may hinder the free movement of those materials and articles, creating conditions of unequal and unfair competition.*"[21] To the Complainant's knowledge, France is the only country in the world to ban BPA in all food contact materials. Manufacturers which produce and sell goods which are legal in all other EU Member States will be prevented from selling them on the French market. Effectively France will become a wholly separate market as regards plastic food contact materials and coatings, (as well as pacifiers, teats and teething rings for babies and infants). This will create

[18] 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). *See also* Recital I, Commission Regulation 10/2011.
[19] Article 18, Regulation 1935/2004 (ibid.).
[20] The French notification is attached at Annex 2.
[21] Recital 13 of Regulation 1935/2004 (ibid.).

major obstacles for traders from other Member States, as well as non-EU countries, who wish to put their goods on the French market. For example, instead of having one type of metal can with BPA-based resin liners for all food products sold in the EU, manufacturers of cans and food processors will have to produce, distribute and stock many different varieties of cans with different BPA-free resin liners depending on the food product they will contain. As a result of the French law, food producers will be forced to dedicate entire production lines to products intended for the French market. This will significantly raise production costs for producers wishing to sell to France, distorting competition in the internal market. If producers choose not to produce these new varieties of cans, they will be barred altogether from putting their products on the French market.

30. The uncertainty created by the French BPA Law concerning the regulation of food and food contact materials in Europe will stifle innovation and economic enterprise in Europe. France's implementation of the French BPA law contravenes the well-established primacy of EU law over national law,[22] creating an uncertain situation where business and industry no longer know the rules and therefore cannot plan for today or invest for the future. Specifically, with the exception of baby bottles, EU law expressly permits the sale of BPA-based plastic food contact and sets a total specific migration limit of 0,6 mg/kg.[23] Yet rather than following the EU's science and risk based regulation of BPA in food contact materials,[24] France, with full knowledge of the EU law, is enacting a broad ban on BPA that is neither science nor risk-based. With such a unilateral, and apparently politically-driven ban in one Member State, business and industry have no legal certainty as to what BPA-based products can be legally marketed in the EU. This uncertainty is especially difficult for companies to deal with given the current difficult economic climate. More troubling is the total as to whether unilateral, non-science based action will be condoned by the EU in future on as yet unknown products. Industry needs certainty that the requirements for food contact materials are regulated by science-based, EU-wide regulation to have the confidence to continue to invest in Europe.

31. The French BPA Law severely undermines the integrity and credibility of the European food safety agency, EFSA. France has contradicted EFSA advice which expressly recommends retaining the current permitted level for BPA in plastic food contact materials in Europe. It has refused to wait for the outcome of the comprehensive EFSA re-evaluation of the science on BPA, due in May 2013, before taking unilateral action.

32. The French BPA Law undermines the integrity and credibility of EU law regulating the internal market and food contact materials. France has enacted a unilateral measure which goes far beyond the scope of Regulation 10/2011 on plastic food contact materials and Regulation 1935/2004 on food contact materials. The effect of this is to suggest that the current European regulation of food contact materials is unreliable and fails to adequately protect European consumers. The Complainant believes that the absence of an EU-level reaction will set a precedent for further unfounded unilateral action by other Member States, further jeopardising the internal market.

[22] Case 6/64, *Falminio Costa v. ENEL* [1964] ECR 585, 593.
[23] Commission Regulation 10/2011, Annex I, Substance No. 151 *(2,2-bis(4-hydroxyphenyl)propane)*. See also Commission Implementing Regulation 321/2011 of 1 April 2011 amending Regulation 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (OJ L 87, 2.4.2011, p.1).
[24] Specific measures regulating food contact materials, being liable to affect public health, may only be adopted after consulting EFSA: Recital 11 of Regulation 1935/2004 (ibid.).

33. Substitute materials may put consumer health in danger. It is inaccurate for France to imply that a single, safe substitute for BPA exists. For example, within the metal packaging industry alone, several hundred types of coating are currently used for a large variety of different foods, heat processing conditions, can types and manufacturing technologies. The substitute materials for BPA are in fact much less-tested and less is known about the newly developed replacement chemistries, which have far less performance history than BPA. Replacements have shown performance or operational weaknesses and for several applications, substitutes are not yet available which can guarantee the same level of safety and functionality as BPA. In general, all substitutes show higher rates of flavour absorption, which makes it difficult to maintain the organoleptic properties of food and drinks over time in storage. Substituting BPA in epoxy coatings for metal containers is particularly challenging for products with acidic or fatty contents, such as colas, ciders, tomatoes, mustard, gherkins, duck and pork meat. As regards these products, the potential for food borne illness is a substantial health issue. The use of polycarbonate in consumer products is a niche-application, which is more expensive than commodity plastics and is only selected when other materials do not fulfill the specific requirements, particularly high temperature and unbreakability/mechanical strength, such as large (5 gallon) water containers and other reusable containers. The Complainant considers that it is misleading and unrealistic for France to assume that safe substitutes will be available by 1 January 2015 when the BPA ban becomes fully applicable.[25]

34. The French BPA Law will have far-reaching repercussions on industry. The French law 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 European market for the use of BPA in food packaging materials is significant. The plastics market generates a turnover of around 300 million euros per year and the industrial supply chain employs more than 1,6 million people in around 50,000 companies, particularly in small and medium-sized enterprises in the plastic transformation sector. These include the raw material suppliers who supply BPA, plastic producers, epoxy producers, plastic compounders who prepare plastic formulations, machinery manufacturers, food manufacturers and product distributors. All of these companies which are based in France or exporting to France will need to adapt their processes at substantial cost, to ensure that their products are compliant with the French BPA law.

35. The French BPA Law will have a considerable socio-economic impact in Europe and impact on market prices. Forcing industry to switch to alternative packaging will involve a huge capital write-off and investment in researching packaging alternatives, and providing alternative machinery and production equipment. Small volume producers, predominantly SMEs active in the food industry, will be disproportionately affected by these costs. Consumers will suffer at the end, as cost increases are passed on. For many segments and applications there is no thoroughly tested alternative to BPA, so there is potential for certain packaged foods to be withdrawn from sale entirely in France. Consumers in France will lose products which are considered to be safe by the EU's food safety agency and all other Member States.

36. To give a concrete example, Dijon mustard has especially designed lids that are coated with epoxy resins made with BPA. These epoxy resins protect the lid from the acidity of

[25] See paper of J. LaKind, "*Can coatings for foods and beverages: issues and options*", Int. J. Technology, Policy and Management, available at http://www.inderscience.com/www/pdf/2012ijtpm_lakind_openaccess.pdf.

the mustard and are essential to preserve the shelf life of Dijon mustard, providing airtight, anti-bacterial seals to ensure that it does not spoil. When these lids are produced, a layer of epoxy resins is first applied to the lid, followed by another layer of varnish. If the French law is implemented, in 2015, Dijon mustard producers will no longer be allowed to use these types of lids. However, there are no equivalent alternatives or substitutes available that are as high-performing, or as safe, as epoxy resins made with BPA. In 2015, producers may no longer be able to guarantee the quality and taste that people have come to expect from Dijon mustard.[26]

37. A further example is the market for large '5 gallon' water bottles, used for water dispensers. As regards to these specific products alone, the Complainant understands that the French BPA ban will affect approximately 2000 companies, with a turnover of approximately EUR 1.180 million, employing approximately 50.000 employees in Europe. The Complainant estimates that the cost of changing labeling in the 5 gallon water bottle market as a result of the French BPA law will be approximately EUR 59 million and will take between two and three years.

38. There will be a similar socioeconomic impact on the markets for epoxy resins used for cans. In Europe, approximately 33 000 tons per year of bare epoxy resin are used in the cans industry. This corresponds to roughly 97,000 tons per years of can coating formulations used in the European market, which accounts for approximately EUR 380 million. In France, the epoxy resin market is estimated at 9000 tons per year and the formulations market is estimated at 28,500 tons per year, which accounts for roughly EUR 111.5 million.

39. <u>The French BPA Law will have negative implications for the environment</u>. The Complainant believes that forcing a switch in packaging, which has been developed and streamlined over many years, will have the effect of increasing the volume of packaging required, as well as its weight. This will result in a corresponding increase in transport, storage and logistical costs. Moreover, alternative packaging is likely to have an impact on the current recycling mechanisms in place, and reduce rates of recycling.

VII. <u>Provisions of EU law which have been infringed</u>

40. It is the Complainant's view that the French law infringes:

    a. The principle of the free movement of goods. In particular, Article 34 of the Treaty on the Functioning of the European Union ("**TFEU**") which prohibits quantitative restrictions on imports between Member States and measures having equivalent effect and Article 35 TFEU which prohibits quantitative restrictions on exports between Member States and measures having equivalent effect;

    b. Regulation 1935/2004 on food contact materials;

[26] See further the article published on 12/10/2012 on <u>http://www.bfmtv.com/societe/video-moutarde-dijon-menacee-linterdiction-bpa-357094 html</u>

c. Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food;[27]

d. Commission Regulation 1895/2005 on epoxy derivatives in materials and articles intended to come into contact with food;[28]

e. The precautionary principle; and

f. Directive 98/34 establishing TRIS.[29]

41. The Complainant therefore respectfully requests that the Commission, pursuant to its obligation under Article 17 TEU to oversee the application of EU law and to ensure the correct application of the Treaties and EU legislation, take the necessary steps to bring these infringements to an end. Specifically, the Commission is invited to:

a. initiate infringement proceedings against France under Article 258 TFEU;

b. as regards France's pending notification under Article 18 of Regulation 1935/2004, formally decline to adopt amendments to Commission Regulation 10/2011 on plastic food contact materials;

c. take the necessary steps to ensure that France complies with its obligations under the TRIS Directive; and

d. request France to delay the implementation of the French BPA Law until EFSA publishes its scientific opinion on the human health risks associated with BPA, expected in May 2013, and to make a formal, public, declaration to this effect.

42. The facts and arguments to support this view are set out in more detail below. We would be pleased to develop any of these. Please do not hesitate to contact us should you require further information or clarification on any of these points.

VIII. Analysis under EU law

a. Breach of the Treaty principle of the free movement of goods

43. It is the Complainant's view that the French BPA law is an unjustified and disproportionate restriction on the free movement of goods, breaching Articles 34 and 35 TFEU. The Court of Justice of the EU ("**ECJ**") has consistently confirmed that any

[27] Commission Regulation 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ L 12, 15.1.2011, p.1, as amended by Commission Implementing Regulation 321/2011 of 1 April 2011, OJ L 87, 2.4.2011, p.1.
[28] Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food, OJ L 302 , 19/11/2005, p.28.
[29] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, OJ L 204, 21.7.1998, p. 37.

national measure which is potentially capable of directly or indirectly hindering trade between EU Member States is prohibited, unless it is both justified and proportionate.[30]

44. In relation to both plastic and non-plastic materials, the French BPA law hinders free trade between EU Member States, because it restricts both imports and exports of BPA-based food packaging, containers and utensils. The restriction applies to both French and foreign business. The ECJ has previously found that a ban is clearly a quantitative restriction.[31]

45. The Complainant is not alone in its conviction that the French BPA law restricts the free movement of goods. In the context of the TRIS notification of October 2011, the Czech Republic, the Netherlands, Spain and the United Kingdom all issued detailed opinions. While the Complainant has not had access to these documents, it assumes that these all raise concerns that the proposed measure may create obstacles to the free movement of goods since, according to Article 9(2) of the TRIS Directive, detailed opinions are only to be issued where it is considered that "*the measure envisaged may create obstacles to the free movement of goods within the internal market*". The Complainant understands that the Italian and Slovenian comments also indicated concern about the impact of the French law on the free movement of goods. France has evidently ignored these comments and detailed opinions.

Public health protection is already comprehensively addressed at the EU level

46. The French BPA Law is apparently based on the objective of protecting public health.[32] However, the Complainant considers that France may not, as a matter of EU law, invoke the grounds of the '*protection of life and health of humans*' under Article 36 TFEU to justify the French law.

47. The European Court has confirmed that a Member State cannot invoke a public policy objective to justify a restriction on trade if this public policy objective is already addressed at EU level.[33] The Court has confirmed this in its judgment on the UK ban on the export of veal calves:

> "*While Article 36 of the Treaty* [now Article 36 TFEU] *allows the maintenance of restrictions on the free movement of goods, justified on grounds of public morality, public policy or the protection of the health and life of animals, which constitute fundamental requirements recognised by Community law, recourse to Article 36 is nevertheless no longer possible where Community directives provide for hamonisation of the measures necessary to achieve the specific objective which would be furthered by reliance on this provision.*"[34]

48. In that case, the Court considered the Community legislature had already sought to reconcile the interests of animal protection and of the smooth functioning of the organization of the common market in calves and derived products, so the UK could not

[30] Case 8/74 *Procureur du Roi v Benoît and Gustave Dassonville* ECR [1974] 00837.
[31] Case 7/61 *Commission v Italy* [1961] ECR 317 and Case 34/79 *R v Henn and Darby* [1979] ECR 3795.
[32] See Report No 201 of Senator Schillinger on the draft law, registered with the French Senate on 11 December 2012, which states that the purpose of the law is to protect the population from the suspected toxicity of BPA.
[33] Case C-1/96 *R v Maff, ex p Compassion in World Farming Ltd* [1998] ECR I-1281.
[34] Case C-1/96 *R v Maff, ex p Compassion in World Farming Ltd* [1998] ECR I-1281, paragraph 47.

rely on Article 36 to justify further national restrictions. The Court held that this principle applies *"even if the matter in question has not been exhaustively regulated"* at EU level.[35]

49. It is clear that the EU has already sought to reconcile the interests of health protection and the smooth functioning of the internal market for food contact materials. To the extent that BPA poses a risk to health, this has already been dealt with extensively by the EU legislation. The Complainant refers to the following pieces of EU legislation:

    a. Regulation 1935/2004 ("**the Framework Regulation**") on food contact materials, which aims to "*ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers*".[36]

    b. Regulation 10/2011, a specific measure adopted under the Framework Regulation, which sets a specific migration limit for BPA in plastic food contact materials, aiming to "*ensure that the food contact material does not pose a risk to health*".[37]

    c. Regulation 1895/2005, which regulates BPA in epoxy derivatives and aims to *"avoid risks to human health and barriers to the free movement of goods."*[38]

50. Based on this, as a matter of EU law, the French BPA ban cannot be justified by recourse to Article 36 TFEU. To the extent that France invokes health risks posed by BPA as a justification for the new law, these are already addressed by the EU legislation in the field.

The French law is not justified on grounds of public health protection

51. Even if France could rely on Article 36 TFEU to justify the new law, the Complainant submits that a justification on grounds of public health protection is unfounded.

52. The ECJ has held that, in order to justify a measure on grounds of health protection, the Member State must prove the existence of a "*seriously considered health policy*".[39] To do so, it must be shown that the restriction is consistent and clearly related to the goal of health protection. Justification of a total ban additionally requires the Member State to show that the marketing of the product poses a "*serious risk to public health*".[40]

53. The Complainant does not consider the French law to be based on a "*seriously considered health policy*". The only scientific basis for the French Law is a preliminary report published on 27 September 2011 by ANSES on the health effects of BPA (the "**ANSES Report**"). In both the TRIS notification of the original legislative proposal and the Article 18 notification of the new BPA law, France has invoked this preliminary report to justify the ban. Since the ANSES Report, France has not adduced any new

[35] Case C-1/96 *R v Maff, ex p Compassion in World Farming Ltd* [1998] ECR I-1281, paragraph 41.
[36] Article 1, Regulation 1935/2004.
[37] Recital 35. Regulation 10/2011.
[38] Recital 1, Regulation 1895/2005.
[39] Case 40/82 *Commission v UK* [1982] ECR 2793.
[40] Case C-270/02 *Commission v Italy* [2004] ECR I-1559, paragraph 22.

evidence to justify the need to ban BPA. However, the ANSES Report cannot be said to support any *"seriously considered health policy"*.

54. First, this report is preliminary in nature.[41] Any policy based on a mere preliminary study cannot be said to be "seriously considered".

55. Second, EFSA has expressly cast doubt on the conclusions of the ANSES Report. In 2011, the EFSA Scientific Panel concluded that the information contained in the ANSES Report did not change the views expressed by the EFSA Panel in 2010, and did not justify a change in the current European approach to the risk management of BPA. The EFSA panel found that the ANSES report was based on studies which had serious shortcomings. In particular, its results could not be reproduced and therefore confirmed. Furthermore, ANSES used unrepresentative routes of exposure, testing the effects of BPA when it is directly injected into the body, rather than when trace quantities are ingested orally.[42] The Complainant does not consider that France has shown that BPA poses a *"serious risk to public health"*. To prove this, the Member State must provide the relevant evidence, such as technical, scientific, statistical and nutritional data, and all other relevant information. The ANSES Report is insufficient for these purposes – it does not disprove the extensive testing that has already been done on BPA. EFSA has performed four thorough assessments of BPA in the last five years, including after the ANSES Report was issued. As set out in paragraphs 16-18 above, these assessments consistently find that BPA is safe for use in food contact materials. Most recently, in November 2011, EFSA held that the ANSES Report on BPA did not reveal any new evidence which would lead to a revision of the current TDI for BPA.[43]

56. Third, the methodology and conclusions of the ANSES Report contradict the findings of several food safety agencies across the globe, which have reviewed the science and have concluded that BPA is safe in food contact materials. These include the EU Risk Assessment Report[44], the FDA[45] and the WHO report[46]. These reviews largely investigated the same scientific database as ANSES and concluded that exposure to BPA from food contact materials is very low and poses no risk to human health. Recent reviews on BPA conducted by the Advisory Committee of the German Society of Toxicology and the Japanese National Institute of Advanced Industrial Science and Technology similarly indicate that risk of BPA with regard to human health is not noteworthy.[47] Since 2008, numerous papers of US Federal Government research on BPA

[41] Section 1, ANSES (Agence National de Sécurité sanitaire, de l'alimentation, de l'environnement et du travail), "Effets sanitaires du bisphénol A", rapport d'expertise collective, 2011.
[42] For example, BPA was injected into the body of animals, which is irrelevant for human BPA risk assessment where the main source of exposure is oral at trace levels.
[43] "Statement on the ANSES reports on bisphenol A - EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids" EFSA Journal 2011, 9(12): 2475.
[44] "EU Risk Assessment Report on Bisphenol A", 2008, CAS: 80-05-7, EINECS No: 201-245-8.
[45] "Update on Bisphenol A for Use in Food Contact Applications", U.S. Food and Drug Administration, January 2010, Updated on March 30 2013.
[46] "Toxicological and Health Aspects of Bisphenol A", Joint FAO/WHO expert meeting to review toxicological and health aspects of bisphenol A: final report, including report of stakeholder meeting on bisphenol A, 1-5 November 2010, Ottawa, Canada, NLM classification: QV 223.
[47] April 2011 review of BPA conducted by the Advisory Committee of the German Society of Toxicology, Publikation der Beratungskommission der Gesellschaft für Toxikologie: Hengstler JG, Foth H, Gebel T, Kramer PJ, Lilienblum W, Schweinfurth H, Völkel W, Wollin K-M, Gundert-Remy U. Critical evaluation of key evidence on the human health hazards of exposure to bisphenol A. Crit Rev Toxicol. 2011 Apr;41(4):263-91;

have been published in peer-reviewed scientific literature.[48] Reference is also made to the peer-reviewed study by Pacific Northwest National Laboratory, the US Centers for Disease Control and the US Food and Drug Administration, which found no unmetabolised BPA in human blood, demonstrating that BPA is unlikely to affect human health.[49] The principal author of this study, [redacted], has most recently performed a meta-analysis of 150 studies which confirmed that BPA is not found in human blood. This analysis was presented on 16 February 2013 at the American Association for the Advancement of Science (AAAS).[50] Taken together, these studies provide strong support for the safety of BPA, showing that it is efficiently metabolized and eliminated in adult humans and efficiently metabolized at all ages.

57. Fourth, the ANSES Report suffers from serious deficiencies, which explain the contradictions between this and the other studies cited above:

- ANSES' conclusions are not based on a comprehensive 'weight of evidence' approach: The ANSES Report does not define or apply consistent quality criteria for specific studies used as a basis for its conclusions. The entire database of science on BPA was not taken into account to form a holistic view based on the quality and weight of all the available science. This differs from the accepted norms for panel reviews of other independent global authorities.

- ANSES' conclusions are based on routes of exposure that are not reflective of any potential human exposure to BPA from food packaging: The ANSES Report is largely based on the conclusions of studies where animals are exposed to BPA via non-oral routes, namely subcutaneous injection. Since exposure to trace amounts of BPA by humans would primarily arise from oral exposure from food, to is not appropriate to draw conclusions from studies on non-oral exposure. Unless the underlying research can demonstrate a relationship between dose and response, and a clear mode of action, the door opens for arbitrary legislation to protect against any kind of effect, without any objective basis. Numerous peer review studies including recent US government funded studies[51] have proved that trace amounts of BPA which are ingested orally are rapidly secreted by non-human primates and humans and constitute no risk to human health.

- ANSES' conclusions do not take into account existing studies consistently identified as the 'Gold Standard' by other review panels: Certain studies

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and August 2011 study by the Japanese National Institute of Advanced Industrial Science and Technology on Bisphenol A, AIST Risk Assessment Document Series No. 4.

[48] See the summary dated February 2013 of the recent US Federal Government Research on BPA, containing references to the studies, attached as Annex 6.

[49] Research conducted at Pacific Northwest National Laboratory (Richland, WA) with Participation from CDC (Atlanta, GA) and FDA (Jefferson, AR) Laboratories; Funded by EPA Grant by Teeguarden, J. G., Calafat, A. M., Ye, X., Doerge, D. R., Churchwell, M. I., Gunawan, R., and Graham, M. 2011, "24-Hour human urine and serum profiles of bisphenol A during high dietary exposure", Toxicological Sciences 123(1):48-57.

[50] [redacted] meta-analysis is expected to be published in the near future.

[51] For example, the research conducted at FDA Laboratory in Jefferson Doerge, D. R., by Twaddle, N. C., Woodling, K. A., and Fisher, J. W. 2010. Pharmacokinetics of bisphenol A in neonatal and adult rhesus monkeys. Toxicology and Applied Pharmacology. 248(1):1-11. See also the research conducted at EPA Laboratory in Research Triangle Park, NC by Ryan, B. C., Hotchkiss, A. K., Crofton, K. M., and Gray Jr., L. E. 2010. In utero and lactational exposure to bisphenol A, in contrast to ethinyl estradiol, does not alter sexually dimorphic behavior, puberty, fertility and anatomy of female LE rats. Toxicological Sciences. 114(1):133-148

which have been recognised as key studies by other review panels have not been properly taken account of in the ANSES Report.[52] These studies conclude that BPA does not pose a risk to human health.

- The ANSES Report explicitly states that it is based on 'hazard identification' and not 'risk assessment': This approach goes against the obligations set out in the General Food Law[53], which states that *"In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure."*[54] The EFSA evaluations are compatible with the principles of general food law and should remain the basis for EU risk management. The ANSES report merely identifies hazard, without properly considering the level of risk which will result from that hazard. ANSES' approach devalues the current criteria and processes for EU risk assessment, without providing any credible alternative assessment criteria. At the same time France calls for alternative substances which must be proved to be safe. This creates considerable uncertainty: should the substitutes be proved safe by reference to the same criteria which France has rejected for the purpose of BPA?

58. Reference is also made to the detailed comments of PlasticsEurope on the ANSES Report of 27 September 2011.[55]

59. In addition to the lack of evidence showing the health risk posed by BPA, France has not proposed any viable substitutes for BPA. The Article 18 safeguard notification is extremely vague about the possibility of substitutes, simply stating that a consultation with undefined 'professionals' revealed that there are alternative solutions for certain applications.[56] In the Complainant's view, it is wholly unrealistic to believe that viable substitutes for BPA will be available by the time the ban enters into force on 1 January 2015. The identification of potential substitutes for BPA and the testing of these for safety and technical viability requires several years of further work, which cannot be achieved before 1 January 2015. This further demonstrates that the French Law is not based on a seriously considered health policy.

60. The credibility of the French public health justification is further reduced by the fact that no other Member State has deemed it necessary to introduce such a general ban. Nor have the French authorities indicated why French consumers should be more at risk from exposure to BPA in food contact materials than consumers elsewhere in the EU. The lack of any "problem specific to that Member State" – which is a precondition to the application of the environmental safeguard measure in Article 114(5) TFEU[57] – is relevant when considering an attempt by a Member State to invoke the public policy derogations to the free movement rules.

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[52] For example, the multi-generational studies reported by Ema et al. (2001) and Tyl et al. (2002 and 2008).
[53] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, p.1.
[54] Article 6, Regulation (EC) No 178/2002.
[55] See Annexes 3 and 4.
[56] See Annex 2.
[57] Discussed in Joined Cases C‑439/05 P and C‑454/05 P *Land Oberösterreich v Commission* [2007] ECR I‑7141, paragraphs 66 et seq.

The French law is disproportionate

61. Even if France did have grounds to restrict BPA on the basis of public health protection, the national measure must also be proportionate to that objective in order to comply with EU law. The ECJ has held that the principle of proportionality requires that the national measure must be both suitable and necessary to protect public health.[58] The Complainant considers that the French law is not necessary and is disproportionately burdensome relative to the objective of ensuring public health protection.

62. The Complainant considers that the French law banning BPA is not necessary to protect public health. BPA is currently permitted in the EU at controlled levels and is regularly subject to scientific testing. The existing EU legislation on BPA is sufficient to protect human health. EFSA has held that banning BPA in food contact materials would bring no demonstrable benefit to the health and safety of consumers. Indeed, banning BPA could even prove counter-productive since is plays a critical role in ensuring the hygiene and safety of foodstuffs, for example, in linings for metal cans.

63. The available substitutes to BPA are less known and less tested. France has not confirmed an alternative as being safer. The Complainant considers that the list of substitutes to BPA put forward by ANSES is misleading and dangerous in its potential misinterpretation by recipients. For the majority of products, there are currently no adequate alternative substances or materials available. The alternatives which are available are either significantly inferior to the existing products or pose an uncertain level of risk to human health or to the environment. The replacement of BPA with a less-tested alternative is not a suitable means to protect human health.

64. According to the ECJ, for a measure to be 'necessary', no less onerous measure should be capable of achieving the same results.[59] The French BPA Law is extremely onerous, due to its wide scope. The Court has confirmed that a total prohibition on the marketing of a substance which can be lawfully manufactured and marketed in other Member States is the most restrictive measure that a Member State could adopt from a free movement of goods perspective.[60] The French BPA Law is far more wide-reaching than the current EU legislation, since it applies to all packaging, containers and utensils which are intended to in direct contact with food, no matter when they are in contact with food. The French BPA law does not delimit its scope in any further detail. By contrast, Regulation 1935/2004 (and the specific measures on plastic food contact materials and epoxy resins adopted thereunder) have a carefully defined scope as follows[61]:

> *"2. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:*
>
> *(a) are intended to be brought into contact with food; or*
>
> *(b) are already in contact with food and were intended for that purpose; or*

[58] Case C-302/87 *Commission v Denmark* [1988] ECR 4607.
[59] Case C-343/09 *Afton Chemical Ltd v Secretary of State for Transport*, judgment of 8 July 2010, para 45.
[60] Case C-192/01 *Commission v Denmark* [2003] ECR I-9693, para 48.
[61] Article 1, Regulation 1935/2004.

(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

3. This Regulation shall not apply to:

(a) materials and articles which are supplied as antiques;

(b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food;

(c) fixed public or private water supply equipment."

65. According to the ECJ, the Member State bears the burden of proving that its stated aim cannot be achieved by any other means which would be less restrictive on intra-EU trade between the Member States.[62] The Complainant considers that France has not discharged its burden of proof. The EFSA Statement of November 2011, finding that the ANSES report failed to provide sufficient evidence to support reviewing the current tolerable daily intake of BPA in plastics, supports this view. If France considers it necessary to introduce unilateral measures, a less onerous approach would be to impose a labelling requirements, or to obtain a commitment from ANSES to review the science within a set timeframe or when new scientific evidence emerges, and then consider whether legislation would be justified by such studies.

b. <u>Incompatibility with Regulation 1935/2004 and Commission Regulation 10/2011</u>

66. The French BPA law is also incompatible with harmonized EU legislation, contained in the Framework Regulation 1935/2004 on food contact materials and Commission Regulation 10/2011 on plastic food contact materials.

67. The Framework Regulation 1935/2004 on food contact materials provides for the adoption of specific measures on groups of materials and articles intended to come into contact with food. Its purpose, as set out in Article 1, is "*to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers."*

68. Regulation 10/2011 is a 'specific measure', adopted under Article 5 of the Framework Regulation, which seeks both to ensure public safety[63] and to eliminate the differences between the laws of the Member States, which could create barriers to trade within the EU and conditions of unfair competition as regards food contact materials.[64] Regulation 10/2011 provides that the use of BPA is permitted in the manufacture of plastic materials and articles intended to come into contact with food, with a total specific migration limit of 0,6 mg/kg.[65] The sole exception to this is the use of BPA in polycarbonate infant

[62] Case 104/75 *De Peijper* [1976] ECR 613.
[63] *See* Recital 2 of Commission Regulation 10/2011.
[64] *See* Recital 1 Commission Regulation 10/2011.
[65] Substance No. 151 2,*2-bis(4-hydroxyphenyl)propane,* Annex I, Commission Regulation 10/2011.

feeding bottles, which has been banned in the EU as from 1 June 2011.[66] The broad scope of the French law evidently goes further than Commission Regulation 10/2011, since it would implement a total restriction on BPA-based food contact materials.

69. The legal basis of the Framework Regulation and the specific measures adopted thereunder is Article 114 TFEU – the establishment and functioning of the internal market. The internal market legal basis is shared competence, pursuant to Article 4 TFEU. This means that the Member States can enact national legislation in the field only if the EU has chosen not to. Conversely, where exhaustive harmonisation exists at EU level, Member States are not generally entitled to adopt stricter national provisions.[67] As regards plastic food contact materials, the EU has chosen to "exhaustively" harmonise the field.[68]

70. According to the Framework Regulation, Member States are not legally entitled to enforce a wider ban on a substance regulated by a specific measure – such as BPA - unless they apply to the Commission for a temporary 'safeguard' measure under Article 18. The Article 18 derogation may only be invoked when a Member State has *"detailed grounds for concluding that the use of a material or article endangers human health"*. Those grounds must arise *"as a result of new information of a reassessment of existing information"*.

71. France has notified the BPA law to DG Sanco insofar as it relates to plastic food contact materials on 7 January 2013 as a 'safeguard measure' pursuant to Article 18.[69] However, it is the Complainant's view that the French BPA Law does not meet the conditions for applying the Article 18 safeguard mechanism.

    a. First, as a general point, the EU Courts have repeatedly confirmed that all derogations and exemptions from EU legislation must be applied restrictively and in exceptional cases only, in order to uphold the purpose and effect of the legislation.[70] The Complainant does not consider this to be an exceptional case.

    b. Second, France has failed to adduce any 'detailed grounds' for concluding that BPA in plastic materials endangers human health. The Article 18 notification simply indicates that BPA is 'suspected' of having health effects in humans. It is based on the preliminary ANSES Report, which, as EFSA has confirmed, does not reveal any new information to suggest that levels of BPA in compliance with the specific migration limit of 0,6 mg/kg would endanger human health. The ANSES Report does not provide adequate grounds to justify any derogation from the EU limit.

    c. Third, the purpose of the temporary safeguard mechanism is to prevent danger to human health in circumstances where there is clear evidence that a substance

[66] Commission Implementing Regulation (EU) No. 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, OJ L 87, 2.4.2011, p.1.
[67] Regulation 1935/2004, Article 6 provides that it is only in the absence of specific measures that Members States may maintain or adopt national provisions.
[68] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004, on materials intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EC, OJ L 338/4, 13.11.2004, Article 5 provides for the adoption of specific measures for groups of materials and articles. Commission Directive 2002/72, to be repealed by Commission Regulation 10/201, is such a specific measure.
[69] See Annex 2.
[70] Case 113/80 *Commission v Ireland* [1981] ECR 1625.

poses a serious risk to human health.[71] The French BPA law was not adopted in these circumstances. Finally, there is no new, local, risk posed by BPA that goes above and beyond the general health risk that was already considered by the EU legislators during the negotiations for the Regulation 10/2011 and, more recently, Regulation 321/2011 which introduced amendments to Regulation 10/2011 as regards polycarbonate infant feeding bottles. In so doing, the EU institutions are obliged, under Article 114(3) TFEU, to *"take as a base a high level of protection, taking account in particular of any new development based on scientific facts"*. The Commission continues to scrutinize new developments on BPA based on scientific facts, as is evidenced by regular opinions by EFSA on BPA. By failing to wait for the adoption of the EFSA report, expected for May 2013, the French BPA law frustrates this process and undermines the harmonized EU legislation on plastic food contact materials.

72. As such, the French Ban is incompatible with Commission Regulation 10/2011 on plastic food contact materials and the Framework Regulation 1935/2004 on food contact materials.

c. Incompatibility with Commission Regulation 1895/2005

73. The French ban is also incompatible with Regulation 1895/2005 on epoxy derivatives in materials and articles intended to come into contact with food. Regulation 1895/2005 is also a specific measure which was adopted within the framework of Regulation 1935/2004, which has as its object the establishment and functioning of the internal market in food contact materials.

74. Regulation 1895/2005 lays down specific migration limits for bisphenol-A diglycidyl ether ("**BADGE**"), an epoxy resin used to make food contact potable water coatings. Epoxy can coatings are most often produced by using a high molecular weight epoxy resin formulation. This is produced by either the reaction of epichlorohydrin with BPA, or by the reaction of BADGE with BPA to give the polymer. The French ban, which would effectively ban BPA in epoxy resins used in food-contact materials, is thus also incompatible with this EU Regulation because it prohibits the use of an approved, regulated chemical.

d. Breach of the precautionary principle

75. The Complainant considers that the French law represents a misapplication of the precautionary principle. Where there is not already exhaustive harmonisation at the EU level, the precautionary principle allows Member States to take certain protective measures, where there is scientific uncertainty regarding the risks.[72]

76. The Complainant considers that in this case, there has been exhaustive harmonisation by the EU, but for the sake for completeness, this section will also address the precautionary principle. According to EU law, there are limits to the application of the precautionary principle; it cannot be blindly invoked by Member States to justify measures which are otherwise incompatible with the common market. The ECJ has held that a correct application of the precautionary principle presupposes a comprehensive assessment of the

[71] *See* Article 18 and Recital 20, Framework Regulation.
[72] Case C-192.01 *Commission v Denmark* [2003] ECR I-9693.

risk to health based on the most reliable scientific data available and the most recent result of international research.[73] In this case, the French law is not based on the most recent results of scientific research. The EFSA Statement of November 2011, which post-dates the French ANSES Report, found that there was no need to revise the status quo in relation to BPA.

77. The ECJ has also held that protective measures *"founded on mere suppositions which are not yet scientifically verified"* cannot justify Member State action on the basis of the precautionary principle.[74] The ANSES Report on health effects of BPA concluded that health effects had only been 'suspected' in humans. The Article 18 safeguard notification made by France, supposedly to justify the need for urgent unilateral action, repeats that *"le bisphénol A est ainsi suspecté d'être responsable de perturbations endocriniennes et de troubles de la reproduction chez l'homme."* [75] These suspicions have not been scientifically verified.

78. The Complainant thus considers that a precautionary approach is unwarranted in this case. EFSA has repeatedly and thoroughly assessed studies pointing at alleged toxicity of BPA and has concluded that these studies have serious shortcomings which do not justify a change in the current level of restriction of BPA. The unnecessary adoption of a ban on BPA pre-empts – wrongly in the Complainant's view - the outcome of EFSA's scientific assessment of BPA. It contradicts the existing safety assessments of BPA-based food contact materials.

e. Breach of the TRIS Directive

79. France notified the 2011 draft law under the TRIS system on 19 October 2011[76], but has failed to re-notify the BPA law before it was enacted. The Complainant considers this to represent a procedural breach of Article 8(1) of the TRIS Directive, which requires Member States to re-notify a law if *"they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive."*

80. The scope of the BPA law as adopted is significantly broader than the draft law which was notified under TRIS. In addition to packaging, containers and utensils containing BPA, the French BPA law also now bans pacifiers, teats and teething rings containing BPA (new Article 2) and the use of tubulars containing DEHP in pediatric, neonatal and maternity services (new Article 3). These were not referenced in the original TRIS notification regarding non-plastic materials.

81. The Commission seems to agree that these additional bans represent a significant alteration in the scope of the law from the draft which was originally notified. In a letter dated 29 October 2012[77], the Commission made the following statement:

> *"After having carefully examined the draft bill as amended by the Senate, I would like to inform you that it appears that the changes made in the draft*

[73] Case C-333/08 *Commission v. France* [2010] ECR I-00757, para 92.
[74] Case C-236/01 *Monsanto Agricoltura Italia* [2003] ECR I-8105, para 106.
[75] See Annex 2.
[76] Notification number 2011/529/F.
[77] See Annex 9.

> *have the effect of significantly altering its scope in the meaning of Article 8(1), paragraph 3 of the Directive. In particular, the draft contains additional restrictions concerning medical devices containing certain substances (new Article 1(4)) and prohibition of the use of certain materials containing the following phthlalates: DEHP, DBP and BBP (new Article 3). Consequently, the changes made to the draft bill notified under reference 2011/529/F should be notified to the Commission."* (emphasis added)

82. France's failure to notify the new law under the TRIS system frustrates the object and purpose of the TRIS Directive, which was specifically enacted by the EU to ensure transparency as regards national initiatives for the establishment of technical standards or regulations.[78] It deprives both Member States and the Commission of the opportunity to comment on the new aspects of the French law, which in themselves may create a substantial obstacle to the free movement of goods in the internal market. The ECJ has previously ruled that if a Member State fails to notify a technical regulation under TRIS, the national law should be seen as unenforceable.[79]

83. In addition, the Commission has recognized in a letter dated 7 February 2013 that the decree which will set out the design and contents of the health warning required by the French legislation[80] will most likely constitute a further technical regulation under EU law, which will require notification under the TRIS Directive before France can bring it into force. The Commission has made the following statement in this regard:

> *"It seems that the decree in question laying down the conditions under which the health warning shall be presented could contain technical regulations in the meaning of Directive 98/34/EC. To the extent that the future decree contains such technical regulations it should be notified to the Commission in the framework of Directive 98/34/EC at draft stage."*[81] (emphasis added)

84. To the Complainant's knowledge, France has, to date, not made any TRIS notification for the labelling decree. Of course, there is still time for France to comply with its obligations under the TRIS Directive, but if the decree enters into force without the requisite prior TRIS notification, this will represent a further procedural breach of Article 8 of the TRIS Directive.

f. Request for the Commission to take the necessary measures

85. In light of the facts and law set out above, the Complainant respectfully requests that the Commission, pursuant to its obligation under Article 17 TEU to oversee the application of EU law and to ensure the correct application of the Treaties and EU legislation, takes the necessary steps to bring these infringements to an end. Specifically, the Commission is invited to:

    a. initiate infringement proceedings against France under Article 258 TFEU;

[78] Recital 3, Directive 98/34/EC.
[79] Case C-194/94 *CIA Security International SA v Signalson SA and Securitel SPRL* [1996] ECR I-2201.
[80] As provided for in Article 1 of the French BPA law.
[81] Letter from [redacted] to [redacted] dated 7 February 2013, annexed at Annex 8.

b. as regards France's pending notification under Article 18 of Regulation 1935/2004, formally decline to adopt amendments to Commission Regulation 10/2011 on plastic food contact materials;

c. take the necessary steps to ensure that France complies with its obligations under the TRIS Directive; and

d. request France to delay the implementation of the BPA Law until EFSA publishes its scientific opinion on the human health risks associated with BPA, expected in May 2013, and to make a formal, public, declaration to this effect.

IX. Legal implications under WTO law

86. Finally, we note that the French law will give rise to technical barriers to trade that may contravene WTO law. The Complainant refers to the statement of the US Foreign Agricultural Service on the French BPA Ban,[82] which concluded that, while it was difficult to assess precisely the impact of the France law on US exports to France, there was a significant trade in canned food and drink from the US to Europe (beer, soft drinks, seafood, fruits and vegetables, food preparations and ingredients), which could be in jeopardy to the extent that these goods' packaging contains BPA.

87. The legal aspects under the WTO are not dealt with in this Complaint. However, it is noted that these should not be ignored, since, in the event of a challenge to the French BPA Law in the context of the WTO, it would fall on the Commission to defend the French position.

X. Details of any approaches already made to EU institutions

88. The Complainant has been involved in ongoing discussions about the regulation of BPA, and attempts by individual Member States to ban it, with the European Commission, in particular DG Sanco and DG Enterprise. Examples of recent correspondence with the Commission's services are attached to this Complaint at Annexes 10 to 15. The Complainant would be pleased to provide more details if necessary.

89. Generally, in these discussions the Complainant has acted in an alliance with the other industry associations FoodDrinkEurope[83] and Empac.[84] Both associations, which together represent a significant section of European industry, are supportive of the position set out in the present complaint.

[82] See Annex 8.
[83] FoodDrinkEurope represents the food and drink industries of the EU at the level of European and international institutions. Its membership is made up of 26 national federations, including 3 observers, 26 European sector associations and 19 major food and drink companies. See www fooddrinkeurope.eu
[84] Empac (European Metal Packaging) brings together more than 200 manufacturers, suppliers and their national associations, to promote the benefits of rigid metal packaging. See www.empac.eu

90. The Complainant would very much welcome the opportunity to meet with the Commission's services and provide further details on the effects of the French law for European companies, and its incompatibility with EU law.

91. The Complainant has also made a number of submissions to EFSA in the context of its scientific review of BPA and attended stakeholder meetings. Examples of recent submissions include the reports on 'Dietary Exposure to Bisphenol A from Chocolate Moulds in Europe' and 'Dietary Exposure to Bisphenol A in Water from Polycarbonate in Europe' of February 2013, attached to this Complaint at Annexes 18 and 19.

92. To date, the Complainant has not made any approaches to other EU bodies.

XI. Approaches made to national authorities, whether central, regional or local

93. The Complainant is engaged in ongoing discussions with the French authorities, including the *Direction Générale de la Santé*, the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*, the *Direction Générale de la Compétitivité, de l'Industrie et des Services*, the *Ministère de l'Ecologie, du Développement durable et de l'Energie* and the *Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt*. Examples of submissions made are the position papers of the "Filière Plastique" sent to the French authorities during the debate on the French BPA Law, attached as Annexes 16 - 17.

94. To date, the Complainant has not had any recourse to national courts or other procedures such as arbitration or conciliation.

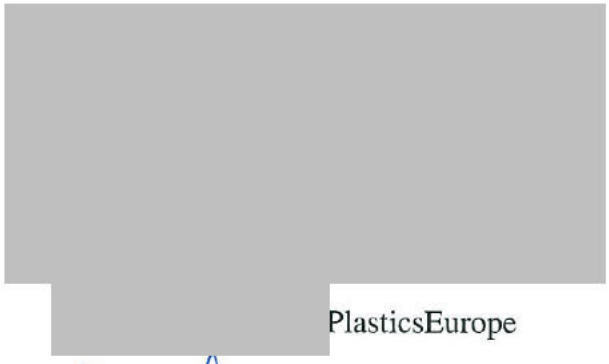
XII. List of supporting documents

Annex 1	The French BPA Law (*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*)
Annex 2	French notification of 7 January 2013 under the safeguard mechanism of Article 18 of Regulation 1935/2004 on food contact materials (Ref. Ares(2013)27833).
Annex 3	Plastics Europe comments of 30 November 2011 on the ANSES Report of 27 September 2011 (FR)
Annex 4	Plastics Europe comments of 18 November 2011 on the ANSES Report of 27 September 2011 (EN)
Annex 5	Plastics Europe Press release of 18 February 2013 on new US research on BPA.
Annex 6	Summary dated February 2013 of the recent US Federal Government Research on BPA, containing references to the studies.
Annex 7	Letter dated 29 October 2012 from DG Enterprise [redacted] concerning TRIS (Ref. Ares(2012)1282348).
Annex 8	Letter dated 7 February 2013 from DG Enterprise [redacted] (Ref. Ares(2013)166284).
Annex 9	Statement of 6 February 2013 of the US Foreign Agricultural Service on the French BPA Ban.
Annex 10	Letter of 10 November 2011 to DG SANCO on FR TRIS notification
Annex 11	Letter dated 22 December 2011 to DG SANCO opposing FR TRIS notification
Annex 12	Letter dated 19 September 2012 to DG SANCO
Annex 13	Letters dated 9 November 2012 from FoodDrinkEurope, PlasticsEurope and Empac to the Directors-General of DG Sanco, DG Enterprise and DG Trade.
Annex 14	Letter dated 21 December 2012 from the Directors-General of DG Sanco (P. Testori Coggi) and DG Enterprise (D. Calleja Crespo) (Ref. Ares(2012)1538678).
Annex 15	Letter dated 24 January 2013 to the Directors-General of DG Sanco (P. Testori Coggi) and DG Enterprise (D. Calleja Crespo)
Annex 16	Position paper of the « Filière plastique » of September 2012 on the draft French law
Annex 17	Position paper of the « Filière plastique » on BPA of 30 September 2011
Annex 18	Report of 11 February 2013 on “Dietary Exposure to Bisphenol A from Chocolate Moulds in Europe”, Crème Global for Plastics Europe
Annex 19	Report of 11 February 2013 on “Dietary Exposure to Bisphenol A in Water from Polycarbonate in Europe”, Crème Global for Plastics Europe

XIII. Confidentiality statement

95. PlasticsEurope authorises the European Commission to disclose its identity in its contacts with the French authorities.

XIV. Place, date and signature of complainant

Signature: 

PlasticsEurope

Place: Brussels

Date: 25/03/2013