

BISPHENOL A: TOWARDS AN INCREASING REGULATORY FRAMEWORK

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On the 13th December 2012, the French Senate definitively adopted a law aiming to remove bisphenol A from all food containers.

By 1st January 2013, all containers destined for children under the age of 3 should be free from this substance. This ban will cover all food containers by 1st July 2015 (extended deadline from the first text approved by the National Assembly in October 2011 which set the ban for January 2014).

Bisphenol A (BPA), a synthetic chemical that has been used for more than half a century in the industry, has been suspected since the 1990s of being harmful. For many years, suspicions have been multiplying in the scientific community and **there are many voices in favour of denouncing a 'worldwide health scandal', often compared to that of asbestos.** These suspicions are accompanied by a strong tendency, in various parts of the world, to reinforce regulations on the matter as a precautionary measure.

‘ **Bisphenol A (BPA), found in a wide variety of products, is a controversial chemical substance that is suspected of being an endocrine disruptor.**

What is bisphenol A? Where is it used?

Bisphenol A is a synthetic chemical used mainly in the manufacturing of:

- **plastics such as polycarbonate** (2/3 of world production)
- **epoxy resins** (1/3 of world production).¹

A wide variety of industrial sectors use this substance, which is found in numerous products.

- **Polycarbonate** is a rigid and transparent plastic that is both heat and shock resistant, and is used in a wide range of products such as DVDs, computers, household appliances, spectacles, contact lenses, reusable water bottles and medical equipment.
- **Epoxy resins** are mainly used as a covering for industrial and consumer applications, such as food, canned drinks, and protective layers for electronic, marine and medical usages, etc.²

Why is there concern over this substance? Where is the evidence?

BPA is strongly suspected of being an endocrine disruptor, partially responsible for the large, and as yet unexplained, increase in illnesses linked to the hormonal system, such as some forms of cancer, as well as fertility and obesity problems.

The whole of the population is heavily exposed to this substance; according to a study published in 2005 in the Environmental Health Perspectives Journal, BPA is present in the urine of 95% of the Western population.

(1) Information provided by PlasticsEurope's PC/BPA-group, www.bisphenol-a-europe.org. • (2) For a more complete list: http://www.bisphenol-a-europe.org/uploads/BPA_applications.pdf.

Today, oral exposure to BPA is predominant and is considered the greatest cause for concern (skin exposure, particularly with regard to thermal papers used for receipts, was also identified to a lesser extent).

Amongst the most sensitive to BPA are pregnant women, new-born babies and young children. BPA tends to transfer in small quantities into food and drink which is stored in materials containing this substance; such a transfer is increased under the influence of heat or acidity. This is why, apart from toys and childcare articles, food containers are the most affected by this issue, despite only representing less than 5% of BPA applications.

Public health agencies throughout the world have already fixed tolerable daily intakes (TDI) at 0.05 mg/kg of body weight. However, an increasing number of studies have shown health issues in animals and strong suspicions in humans too, even at low levels of exposure.

What regulations are in place?

Today, due to lack of unanimity within the scientific community, none of the public health agencies (WHO,³ EFSA⁴ in Europe or the FDA⁵ in the United States) have reviewed their BPA evaluation. It should also be highlighted that the European Chemicals Agency (ECHA),⁶ under the REACH Regulation framework, does not at the moment include bisphenol A in its list of substances of concern.

However, many countries have already introduced bans regarding this substance, as a precautionary matter.

Canada was the first to ban the use of BPA in baby bottles; since 2010, the substance has been classed as 'potentially harmful to human health and the environment'. Several countries have followed suit by implementing partial or total bans on food containers aimed at children (some states and counties in the **United States, Costa Rica, Brazil, Malaysia**, etc.).

In the United States, the FDA continues to carry out complementary evaluations of the substance. Despite their position

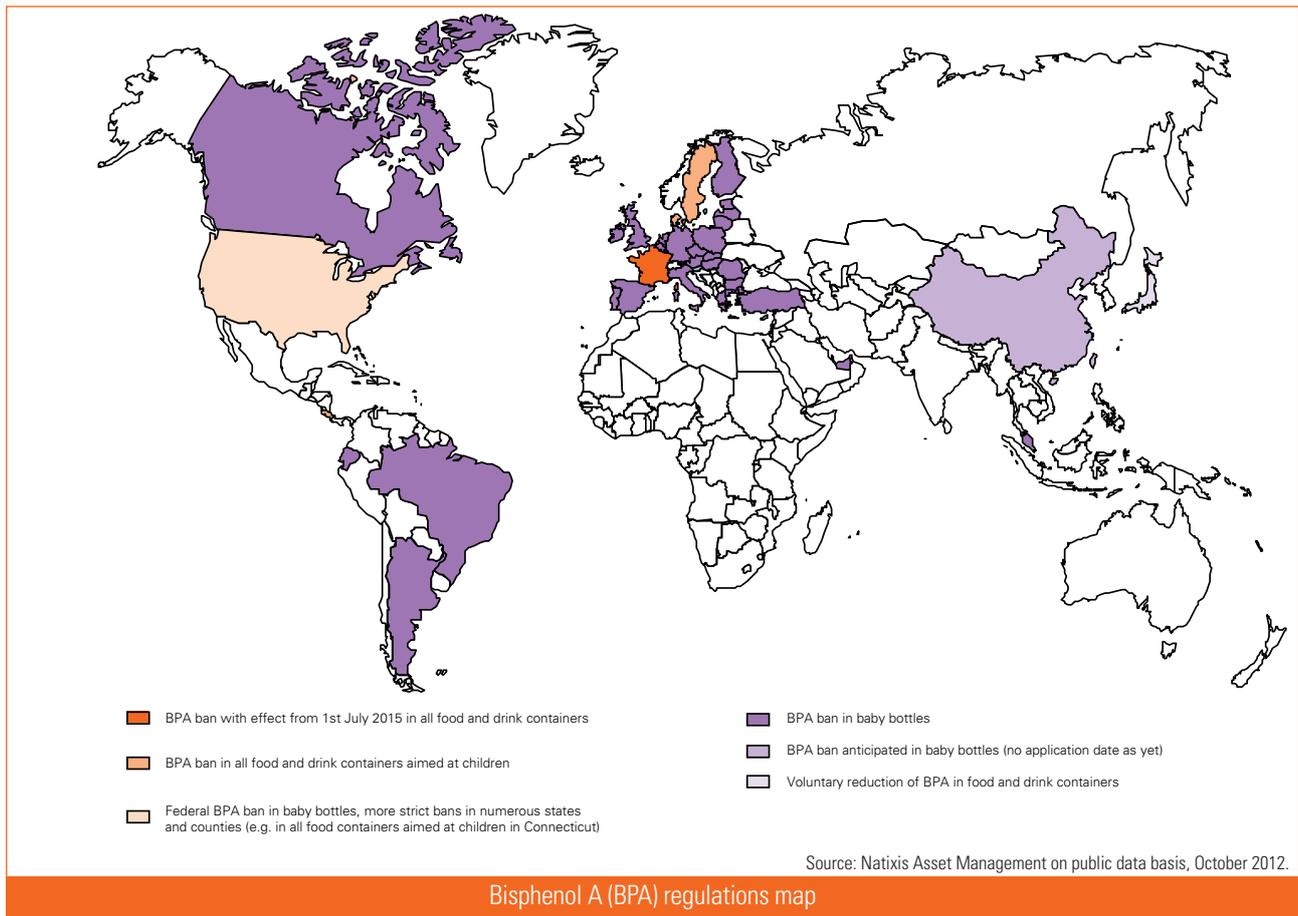
on the substance remaining unchanged, in July 2012, the agency announced the immediate removal of BPA in baby bottles. They also declared that they were reacting to the demands of the industry that, due to consumer demand, had already eliminated the substance from its products.

In **France**, the use of BPA in baby bottles has been banned since 2010. In October of 2011, the French Agency for Food, Environmental and Occupational Health Safety (ANSES) published two reports relating to the health effects and the usage of bisphenol A, confirming strong scientific concerns about BPA. Following the publication, the Senate definitively voted a law in December 2012 aiming to ban the manufacture, import, export and placing of food products on the market for all packaging, containers or utensils containing BPA as of January 2014 (date postponed to July 2015 by the Senate in first reading). This ban is set to be applied as soon as 2013 for containers aimed at children under the age of 3 years.

With regard to the **European Union**, despite the absence of sufficient scientific proof from the EFSA, the Agency has expressed some reservations about the effects of BPA on new-borns. The regulatory procedure was therefore begun with the adoption (effective since March 2011) of the ban of BPA in baby bottles. The European Commission has in addition asked the EFSA to review its BPA evaluation (an opinion on this is expected in spring 2013). Likewise, the ANSES has asked the ECHA for a more strict classification of bisphenol A as being toxic to reproduction (response expected early 2013).

‘ **Despite the absence of scientific proof of the harmfulness of BPA, we are seeing a progressive reinforcement of regulations through the application of the precautionary principle.**

(3) WHO: World Health Organisation. More info at www.who.int • (4) EFSA: European Food Safety Authority. More info at www.efsa.europa.eu • (5) FDA: Food and Drug Administration. More info at www.fda.gov • (6) ECHA: European Chemicals Agency. More info at www.echa.europa.eu.



BPA alternatives: risks and opportunities for key players in the food and chemical industries

As previously mentioned, the main sources of bisphenol A exposure are found in food packaging and containers, and mainly coatings in metal-based tins and drinks cans, as well as jar lids. If responsibility for the production of this substance is mainly down to the chemical industry (Dow Chemical and Bayer being the main producers), the players most exposed to the risk of controversy are the users, i.e. businesses in the food sectors.

‘ Though there are a few alternatives to BPA in polycarbonates, substitution is much more difficult in epoxy resins.

Given the progress of debates, even if the health risk is not recognised, BPA still constitutes an increasing regulatory risk for food producers, first and foremost for the manufacturers of preserved products, canned drinks and products for children. Banning the use of bisphenol A in food containers raises the question of the existence of substitutes proven to be harmless. Bisphenol A substitutes are specific to material, use, industrial procedure, etc.

Polycarbonate substitutes are not major causes for concern. Numerous alternative materials exist (more than 21 substitutes were identified by ANSES)⁽⁷⁾ including glass, stainless steel and ceramic, as well as other older and more widely used plastic materials such as polyethylene or polypropylene which are used in the manufacturing of baby bottles. PET is also a substitute, though its harmlessness has not yet been completely proven. More innovative materials have also been developed by American and Korean companies, for example, Tritan Copolyester™ developed by Eastman Chemical Company or Ecozen® by SK Chemicals.

(7) ANSES, September 2011, Note on the results of the call for contributions following publication of the reports on the health effects and uses of bisphenol A (BPA) and list of BPA alternatives and/or substitutes, June 2012, <http://www.anses.fr/Documents/CHIM2009sa0331.pdf>. (in French only)



In contrast, the search for epoxy resin substitutes seems more difficult.

Used as a protective layer between food and its metallic container, BPA-based resins have certain safety advantages in terms of food security and conservation length (flexibility, adherence, fight against corrosion, etc.), which justify their general use. For example, 95% of metallic food containers have traces of BPA in the United States.⁸ Different preserved food properties imply adapted substitutes for each product (acidity, fat content, etc.).

Despite these difficulties, many companies, particularly American ones, are either already using BPA-free packaging or have announced BPA elimination objectives (Heinz, Tupperware, Eden Foods, etc.). Some alternative materials exist or have been developed (18 substances identified by ANSES).

Other than materials such as glass, many substitutes are already in use:

- some American companies specialising in organic food, such as Eden Foods, use oleoresins (already used before the 1960s)
- several Japanese companies choose to insert a PET film to reduce BPA transfer
- other companies create product ranges where the BPA transfer from packaging to food is limited (for example, Bonduelle's vapour range that contains zero juice).

Innovative materials have already been developed, such as isosorbide diglycidil ether from Archer Daniels Midland. While we have 50 years' experience in using BPA, we need to confirm that the existing substitutes have no long-term undesired health effects.

In addition, there are still numerous substitutes to be found, as well as proving their harmlessness. In general, the development of this type of coating requires 1–3 years of work, followed by a toxicity test period of 2–3 years before receiving approval for commercialisation.⁹

Conclusion

In summary, the substitution challenge remains in the use of materials offering the same benefits as those of bisphenol A, whilst offering satisfactory long-term health guarantees.

It is important to note that the question of bisphenol A relates to a wider issue for the food industry linked to the transfer of chemical substances into food. Other substances have also been identified by scientists as presenting risks to consumer health, such as phthalates. **It is estimated that around 100,000 substances present in packaging can transfer into food, and scientific knowledge on these substances is currently limited.** The topic remains an important point of vigilance for the food industry and an important source of innovation for new materials.

We can expect a reinforced public debate and regulations on health-related topics, as with bisphenol A. The most proactive groups on health-related issues will be amongst those best positioned to address sustainable development issues.

‘ BPA equates to a major problem for the food industry, linked to the migration of chemical substances in food.

(8) Judy Lakind, 2012, 'Can coatings for foods and beverages: issues and options', *International Journal of Technology, Policy and Management*, http://www.inderscience.com/www/pdf/2012ijtpm_lakind_openaccess.pdf. • (9) Lakind, 2012, *Op. cit.*

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