Explanatory Memorandum to the Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Member's Declaration

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011. I am satisfied that the benefits outweigh any costs.

Gwenda Thomas AM
Deputy Minister for Social Services
Assembly Minister in Charge of the Proposed Measure

February 2011

Explanatory Memorandum for the Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011

1. Description

This Statutory Instrument will provide for the enforcement in Wales of Commission Directive 2011/8/EU, which introduces the most recent amendments restricting the use of Bisphenol A in infant feeding bottles.

2. Matters of Special Interest to the Constitutional Affairs Committee

None

3 Legislative Background

Welsh Ministers have the powers to make these Regulations under sections 16(2), 17(2), 26(1) and (2)(A) and 48(1) of the Food Safety Act 1990.

This instrument is subject to the negative procedure.

4 Purpose and Intended Effect of the Legislation

Harmonised European Union (EU) rules on plastic materials and articles are laid down by Commission Directive 2002/72/EC as amended, relating to plastic materials and articles intended to come into contact with food stuffs. This principal Directive is implemented in Wales by the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009[1]. The principal Directive includes lists of substances that can be used in the manufacture of food contact plastics and any restrictions on the use necessary to safeguard both human health and the nature and quality of foodstuffs.

The Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011 implement the transitional arrangements of Commission Directive 2011/8/EU so as to introduce the most recent amendment to the principal Directive restricting the use of Bisphenol A (BPA) in infant feeding bottles. The new Directive prohibits from 1st March 2011 the manufacture and from 1st June 2011 prohibits the placing on the market and import of infant feeding bottles manufactured using BPA.

BPA is an industrial chemical that is mainly used in combination with other chemicals to manufacture plastics and resins. BPA is used in polycarbonate, a type of transparent, rigid plastic, used, amongst other things, to make infant (baby) bottles and has been used in their manufacture for many years.

It is known that small amounts of BPA can migrate into foods from polycarbonate plastics if the plastic or resin, when heated, is damaged or breaks down into foodstuffs and beverages and therefore ingested. The principal Directive sets limits for this. A specific migration limit (SML) for BPA is set down in that Directive that is

[1] SI 2009 No. 481(W.49)

based on a temporary Tolerable Daily Intake (TDI) of 0.01 mg/kg bodyweight which assumes that a person with a bodyweight of 60kg consumes 1kg of food every day packaged in plastic that contains BPA.

In its 2006 opinion, the European Food Safety Authority (EFSA) established a higher TDI of 0.05 mg/kg bodyweight: the SML remained at 0.06 mg/kg, maintaining an additional safety factor.

In spring 2010, two EU Member States presented to the Commission scientific studies on which they had respectively based national restrictions on BPA. The Commission asked EFSA for an updated opinion on the safety of BPA, taking into account 800 scientific studies that had been carried out on the substance.

EFSA's opinion was published on 30 September 2010 and concluded that TDI for BPA 0.05 mg/kg bodyweight per day did not require adjustment in light of the studies. A minority opinion of one, however, was that the TDI should become a temporary TDI to reflect remaining uncertainties.

At a Commission Working Group Meeting on food contact materials held on 8 October 2010, the Commission indicated that in light of the uncertainty noted by EFSA it intended to adopt a precautionary approach and presented two options aimed at minimising infants' exposure to BPA. The options were to either prohibit the use of BPA in polycarbonate baby bottles or prohibit the use of BPA in all plastic materials and articles intended to come into contact with infant formula and follow on formula.

On 25 November 2010, the Commission presented a draft proposal to the Standing Committee on the Food Chain and Animal Health (SCoFCAH); a Commission Directive to introduce a phased ban on polycarbonate infant feeding bottles intended for infants of up to 12 months of age manufactured using BPA, which was adopted by a Quality Majority.

The new Directive amends the principal Directive as follows: in Annex II, Section A, the text column 4 under the reference number 134860 as regards the monomer 2,2-bis(4-hydroxyphenyl)propane will be replaced by the following:

> "SML(T) = 0,6 mg/kg. Not to be used for the manufacture of polycarbonate infant feeding bottles"

1. Consultation

The FSA carried out an informal consultation with other Government Departments which have a wider interest in BPA such as the Department for Business Innovation and Skills (BIS), the Department of Environment, Food and Rural Affairs (Defra), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health and Safety Executive (HSE) whilst discussions with the Commission were ongoing.

The FSA held a scoping meeting with industry and consumer groups on 18 October 2010 to get an indication of the impact of the Commission's earlier proposed options.

The Food Standards Agency held a public consultation from 22 December 2010 to 14 January 2011. Forty-nine stakeholders in Wales were consulted. One hundred and seventy two responses were received UK-wide, with no responses received in Wales. In their response, industry generally reiterated what it had told the FSA when initially consulted in October 2010. The retail sector confirmed that it had already moved away from infant formula bottles manufactured using BPA and the manufacturing sector expressed concern that the prohibition is not supported by scientific evidence, and about the potential for wider prohibitions. No responses were received from consumer groups. However, one hundred and sixty identical emails were received in support of the prohibitions from individuals mainly resident in the USA via a petition hosted by the US website 'change.org' that facilitates social action campaigns.

6. Regulatory Impact Assessment

6.1 Options

Do nothing would allow the continued use of BPA in the manufacture of feeding bottles intended for infants up to 12 months of age and the placing on the market and import of such products manufactured using BPA in Wales. Do nothing would be a breach of the UK's obligations as an EU Member State, and could give rise to infraction proceedings against the UK by the Commission in the European Court of Justice under Article 258 of the Treaty on the Functioning of the EU.

National Regulations to implement the Commission Directive would minimise the exposure of infants of up to 12 months of age in Wales to BPA. Making these Regulations will also be commensurate with the UK's obligations as a Member State under the Treaty of Functioning of the EU.

6.2 Costs and Benefits

Various costs to business would arise from the introduction of a legislative ban of polycarbonate infant feeding bottles. These include a 'one-off' familiarisation cost, production and testing costs associated with the use of other materials, and costs of 'write-off'.

It is estimated that these costs will be minimal, as anecdotal evidence suggested that there are a limited number of baby bottles manufactured in the UK and any costs that do rise will be mitigated by the evidence that suggests manufacturers of infant feeding bottles are already moving away from the use of BPA.

Introducing new legislative requirements for businesses and local authorities as the result of a BPA ban would mean they would have to read and familiarise themselves with the legislation pertaining to what is and isn't permitted for use. The FSA estimates that it will take the relevant manufacturing businesses and local authority officers approximately 1 hour to read and become familiar with the new legislation.

With the introduction of a ban on the use of BPA, there is the potential that costs to manufacturing industry may be incurred in times of increased production costs. Where suitable materials are available, they may be more expensive (consultation responses indicated that the increase is likely to be between 5% and 10%), which will either increase costs to businesses reducing the profit margins, or increased

costs to consumers if the market structure is such that costs be passed on through price increases.

In addition, although evidence suggests that 'tried and tested' alternative products are available, responses from the initial consultation with industry have voiced concerns that there is a potential risk that the ban on BPA may result in some market players using less familiar substances and materials in the manufacture of infant feeding bottles; this could be a problem if outcomes on health are more uncertain than the risk associated with BPA. However, strict safety guidelines currently in place on manufacturers already producing BPA free bottle feeding products will limit impact/risk of this occurring.

As businesses currently manufacture infant feeding bottles containing BPA, introducing a ban without an adequate 'phase-in' period will result in businesses facing costs associated with writing off excess BPA stock. Evidence from the earlier informal consultation however indicates that the majority of infant feeding bottles are imported from outside the UK and so the costs to UK manufacturers are likely to be limited. Costs of write-off could still be incurred by UK retailers on any existing and advance purchase stock. Depending on the magnitude of stock holdings per affected UK businesses, this cost could be substantial.

Despite the potential for such costs to be incurred, responses from informal consultation have suggested that this option would be 'least impactful' on the retail sector because BPA bottles are being phased out, or have already been phased out, by most retailers as a result of consumer preferences. It was further suggested that an additional 6 months to one year on top of the June 2011 deadline would be required for all BPA stock to be exhausted. However, as the ban on sales will be in place as of June 2011, there may be some costs of write-off to retailers, particularly for small and medium UK retailers. Stock turnover for these businesses is likely to be much slower than with large retailers and they may be less likely to stock BPA free products as standard.

Results from informal consultation have indicated that industry fears that if a ban on BPA in infant feeding bottles is implemented, this could potentially lead to a ban in the use of BPA in other food related products. Evidence suggests that the use of polycarbonate across Europe is extensive; the industry employs some 550,000 workers with a total gross salary and wage cost of €18bn (2007 prices) which contributes €6bn in labour taxes; and in 2007 €37bn of value added in the EU depended on polycarbonates. Of the total EU polycarbonate market 12% is consumed by the UK.

Some Member States have already imposed a ban on the use of BPA in infant feeding bottles. Therefore, an EU wide ban may put UK manufacturers at a competitive disadvantage as firms operating in Member States with a ban currently in place will already have the technical 'know how' and processes to capture additional market share.

Given the magnitude and scope of the market any impact on the use of BPA in other technologies could have significant economic impacts; quantification of these would require a large number of non-evidence based assumptions so it has not been possible to provide an estimate.

A related issue, identified as part of the informal consultation, was the negative impact that a ban on BPA could have on consumer safety perception; a ban on the use of BPA in infant feed bottles may send a signal to consumers that BPA is an unsafe product, which is contrary to EFSA's most recent findings.

In September 2010 the EU food safety advisory board, EFSA, published an opinion that found no evidence to suggest toxicity or harmful results from the use of BPA in baby feeding bottles. A such, the FSA estimates that there will be no beneficial public health impacts as a result of introducing the BPA ban. The ban would be introduced under the 'precautionary principle'. There is no incremental benefit to businesses as a result of this option.

6. Competition Assessment

The Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011 will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

7. Small Firms Impact Test

There is some potential risk that small and medium sized enterprises will be disproportionately affected by this option although we are not aware of any impact on Welsh businesses. Write-off costs of these retailers may be greater than other retailers as turnover of stock may be slower and not adequately accounted for in the given transition period.

8. Post Implementation Review

An FSA review will take place in June 2012, one year after the prohibition on the placing on the market and import of relevant products comes into force. Its objective will be to assess the extent to which the prohibition on polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using BPA has been (a) met by manufacturers, importers, wholesalers, retailers and other industry partners and (b) enforced by enforcement authorities.