

## EXECUTIVE NOTE

### THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) AMENDMENT REGULATIONS 2011

SSI 2011/100

#### Description

The above instrument was made in exercise of the powers conferred by sections 16(2), 17(1), 26(1)(a) and 2(a) and 48(1) of the Food Safety Act 1990.

#### Policy Objective

This instrument implements transitional arrangements set out in Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (OJ No. L26, 29.1.2011, p.11) (“the new Directive”)<sup>1</sup>.

The new Directive introduces an EU-wide prohibition on the use of Bisphenol A<sup>2</sup> (BPA) in the manufacture of polycarbonate feeding bottles intended for infants up to 12 months of age from 1 March 2011 and a prohibition on the placing on the market in, and import into the EU of, polycarbonate feeding bottles manufactured using BPA intended for infants up to 12 months of age from 1 June 2011.

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 foodstuffs (“the principal Directive”) which is implemented in Scotland by the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009<sup>3</sup>.

The principal Directive includes lists of substances that can be used in the manufacture of food contact plastics and any restrictions on that use necessary to safeguard both human health and the nature and quality of foodstuffs. Changes to these lists are transposed by an ambulatory reference in the 2009 Regulations and now include those made by the new Directive to prohibit the use of BPA in infant feeding bottles. This instrument implements the transitional arrangements set out in the new Directive.

#### Policy background

##### What is being done and why

BPA is an industrial chemical that is mainly used in combination with other chemicals to manufacture plastics and resins. It is used in polycarbonate, a type of transparent, rigid plastic, used, amongst other things, to make infant (baby) feeding bottles and has been used in their manufacture for many years. BPA is one of a large number of substances that may have the potential to interact with the body’s hormone systems.

---

<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

<sup>2</sup> 2,2-bis(4-hydroxyphenyl)propane

<sup>3</sup> SSI 2009 No. 426

It is known that small amounts of BPA can migrate into foods from polycarbonate plastics if the plastic or resin is damaged or breaks down and the principal Directive sets limits for this. The specific migration limit (SML) for BPA is 0.6mg/kg and is based on a Tolerable Daily Intake (TDI) of 0.01 mg/kg bodyweight which assumes that a person with a bodyweight of 60kg consumes 1 kg of food every day packaged in plastic that contains BPA. Whilst in its 2006 opinion<sup>4</sup>, the European Food Safety Authority (EFSA) established a higher TDI of 0.05 mg/kg bodyweight, the SML remained at 0.6mg/kg, maintaining an additional safety factor.

In Spring 2010, two EU Member States presented scientific studies on which they had respectively based national restrictions on BPA to the European Commission. The Commission asked the European Food Safety Authority (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<sup>5</sup> and concluded that the TDI for BPA did not require adjustment in the 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 in EFSA's opinion it intended to adopt a precautionary approach and suggested two approaches for minimising infants' exposure to BPA from plastic food contact materials. At a further Working Group meeting on 8 November 2010 the Commission indicated its favoured approach, this being a phased prohibition on polycarbonate feeding bottles manufactured using BPA intended for infants of up to 12 months of age.

The Commission presented its formal proposal for a vote in Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 25 November 2010 which was adopted by a Qualified Majority. This was published formally in the Official Journal (OJ) of the European Union (OJ No.L26, 29.1.2011, p.11) as Commission Directive 2011/8/EU and came into force on 1 February.

## **Consultation**

Whilst discussion with the Commission were ongoing, the Food Standards Agency (FSA) held a scoping meeting with industry in mid-October 2010 to get an indication of the impact of the initial options presented by the Commission. The FSA also consulted informally at this time with other Government Departments and Agencies that have an interest in wider applications of BPA such as Scottish Government Health and Rural and Enterprise Directorate and Scottish Environmental Protection Agency (SEPA), along with officials within the Better Regulation and Industry Executive.

The FSA conducted a formal public consultation from 20 December 2010 to 14 February 2011, seeking comments on two options; a 'Do nothing' option and the preferred option of national Regulations to implement the Commission Directive. The draft Commission Directive, a draft of this instrument and an earlier draft of the Business and Regulatory Impact Assessment that accompanies this Executive Note were included in the consultation.

---

<sup>4</sup> [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620772817.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620772817.htm)

<sup>5</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm>

Two hundred and nine stakeholders were consulted on these proposals. These ranged from sector specific organisations, such as those representing industry sectors, to those with a wider interest in food contact plastics. We also consulted enforcement authorities, public analysts, Scottish Federation of Small Businesses, consumer organisations and various non-governmental organisations.

2 responses were received in Scotland, one from a Local Authority and the other from Scottish Plastics and Rubber Association. 172 responses were received in England. In its responses, industry generally reiterated what it had told the FSA when informally consulted in October 2010. The retail sector confirmed that it is already moving away from infant feeding 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, but 160 identical e-mails were received in support of the prohibition from individuals mainly resident in the USA via a petition hosted by a US website that provides tools to facilitate social action campaigns. A full summary of comments received in response to the consultation will be published on the FSA's website.

### **Other Administrations**

This instrument applies in relation to Scotland only. Separate but parallel legislation is being made for England, Wales and Northern Ireland.

### **Guidance**

It is not intended to issue guidance as the European measure this instrument implements is relatively straightforward. The FSA will, however, be writing to external partners to alert them to the legislative changes.

### **Impact**

Manufacturers of polycarbonate infant feeding bottles will face costs associated with reading and familiarising themselves with the new legislation. Manufacturers may further incur costs in respect of production and testing of new products and write-off of existing stock. Retailers (particularly SMEs) may also face costs of write-off if they hold a stock of BPA feeding bottles. There is no particular impact on charities or voluntary bodies, rural areas or on members of the ethnic communities of any particular racial group.

Costs to the public sector are minimal. Some familiarisation costs will be incurred but there are no identifiable costs over and above this.

A Business Regulatory Impact Assessment has been prepared and will be published alongside the Executive Note on [www.legislation.gov.uk](http://www.legislation.gov.uk).

### **Regulating small business**

The instrument will apply to all businesses small and large. The Scottish Federation of Small Business were included in the consultation process and did not raise any concerns.

## **Monitoring & review**

The authorities in Scotland routinely monitor foodstuffs on sale to the public to ensure compliance with relevant legislation. Food contact materials on the market are surveyed routinely and the results published on the FSA website at <http://www.food.gov.uk/science/surveillance/>

The Agency will work with enforcement authorities where problems arise or suspected infringements of the instrument arise. The effectiveness of the instrument will also be monitored via feedback from industry and enforcement authorities, and the policy will be reviewed by the Food Standards Agency in June 2012.

## **Contact**

**Fiona Bruce,  
Food Standards Agency Scotland,  
6<sup>th</sup> Floor St. Magnus House,  
25 Guild Street,  
Aberdeen AB11 6NJ.**

**Tel: 01224 285170**

**Email: [fiona.bruce@foodstandards.gsi.gov.uk](mailto:fiona.bruce@foodstandards.gsi.gov.uk)**

**9th February 2011**

[www.food.gov.uk](http://www.food.gov.uk)



## FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

### THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) AMENDMENT REGULATIONS 2011

<b>File No:</b>	CHA091
<b>Date:</b>	February 2010
<b>Stage:</b>	Final
<b>Source of intervention:</b>	EU
<b>Contact for enquiries:</b>	Fiona Bruce
<b>Phone no.</b>	01224 285170
<b><u>email</u></b>	<a href="mailto:Fiona.bruce@foodstandards.gsi.gov.uk">Fiona.bruce@foodstandards.gsi.gov.uk</a>

## **Title of Proposal**

1.1 The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011 implements, in Scotland, a phased EU-wide prohibition on polycarbonate infant feeding bottles intended for infants of up to 12 months of age that contain the chemical Bisphenol A (BPA).

### **1. Purpose and intended effect**

#### **• Objectives**

2.1 The policy objective is to implement Commission Directive 2011/8/EU by means of national legislation that will:

- Prohibit the use of BPA in the manufacture of polycarbonate feeding bottles intended for infants of up to 12 months of age in Scotland from 1 March 2011, and;
- Prohibit the placing on the market in, and import into, Scotland of polycarbonate feeding bottles manufactured using BPA intended for infants of up to 12 months of age from 1 June 2011.

The intended effect is to:

- Minimise the exposure of infants<sup>1</sup> in Scotland of up to 12 months of age to BPA.

#### **• Legislative Background**

2.2 Harmonised EU rules on plastic food contact materials are laid down by Commission Directive 2002/72/EC relating to plastic material and articles intended to come into contact with foodstuffs ("the principal Directive"). The principal Directive is implemented in Scotland by The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009<sup>2</sup>.

2.3 The principal Directive includes lists of substances that can be used in the manufacture of food contact plastics and any restrictions on that use necessary to safeguard both human health and the nature and quality of foodstuffs. Changes to these lists are transposed by an ambulatory reference in the 2009 Regulations and now include those made by the new Directive to prohibit the use of BPA in infant feeding bottles.

2.4 The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011 will implement the transitional arrangements set out in the new Directive.

### **Bisphenol A**

2.5 BPA (*2,2-bis(4-hydroxyphenyl)propane*) 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 feeding (baby) bottles and has been used

---

<sup>1</sup> 'infant' as defined in Directive 2006/141/EC (OJ L 401, 30.12.2006, p1)

<sup>2</sup> SSI 2009 30

in their manufacture for many years. BPA is one of a large number of substances that may have the potential to interact with the body's hormone systems.

- 2.6 It is known that small amounts of BPA can migrate into foods from polycarbonate plastics if the plastic or resin when heated, damaged or breaks down into foodstuffs and beverages and can therefore be ingested. The principal Directive sets limits for this. A specific migration limit (SML) for BPA is set down in that Directive that is based on a temporary Tolerable Daily Intake (TDI) of 0.01mg/kg bodyweight which assumes that a person with a bodyweight of 60kg consumes 1kg of food every day packaged in plastic that contains BPA.
- 2.7 In its 2006 opinion, the European Food Safety Authority (EFSA) established a higher TDI of 0.05mg/kg bodyweight; the SML remained at 0.6mg/kg, maintaining an additional safety factor.

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620772817.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620772817.htm)

### **Background to Commission Directive 2011/8/EU**

- 2.8 In Spring 2010, two EU Member States presented to the European Commission scientific studies on which they had respectively based national restrictions on BPA. The Commission asked the European Food Safety Authority (EFSA) for an updated opinion on the safety of BPA, taking into account 800 scientific studies that had been carried out on the substance.
- 2.9 EFSA's opinion was published on 30 September 2010 and concluded that the TDI for BPA 0.05mg/kg bodyweight per day did not require adjustment in the light of the studies. A minority opinion of one, however, was that this TDI should become a temporary TDI to reflect remaining uncertainties.

<http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm>

- 2.10 At a Working Group meeting on food contact materials held on 8 October 2010, the Commission indicated that in the 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. At a further Working Group meeting on 8 November 2010 the Commission indicated its favoured approach, this being a phased prohibition on polycarbonate feeding bottles manufactured using BPA intended for infants of up to 12 months of age.
- 2.11 On 25 November 2010, the Commission presented its formal proposal for a vote in the Standing Committee on the Food Chain and Animal Health (SCoFCAH) which was adopted by Qualified Majority.
- 2.12 The Commission's proposal was published formally as Commission Directive 2011/8/EU on 1 February 2011 in the Official Journal of the European Communities dated 29 January 2011 and came into force on 1 February 2011. The main provisions of the Directive are as below:

- **Article 1** amends the principal Directive as follows:  
In Annex II, Section A, the text in column 4 under the reference number 134860 as regards the monomer 2,2-bis(4-hydroxyphenyl)propane will be replaced by the following:

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

(\*) infant as defined in Directive 2006/141/EC, OJ L 401, 30.12.2006, p1.

- **Article 2(1)** requires Member States to adopt the Directive by 15 February 2011.
- **Article 2(3)** requires Member States to:
  - Prohibit from 1<sup>st</sup> March 2011, the manufacture of plastic materials and articles intended to come into contact with food which do not comply with the principal Directive as amended
  - prohibit from 1<sup>st</sup> June 2011, the placing on the market and import of plastic materials and articles intended to come into contact with food which do not comply with the principal Directive as amended.

2.13 The Recitals to the Directive explain the Commission's rationale. Recital 20 indicates that the use of BPA in the manufacture of and placing on the market of polycarbonate infant feeding bottles should be banned.

2.14 The Directive is available to download free of charge from the following website address at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

### **Commission Market Evaluation**

2.15 Recital 16 of the Directive indicates that Commission had evaluated the infant feeding bottle market and had been advised by industry that they were voluntarily moving away from the use of BPA and thus the economic impact of the proposed measure is likely to be limited. The recital goes on to explain the Commission therefore concluded that infant feeding bottles on the EU market should be replaced by mid-2011. This fact has been confirmed by a major manufacturer of infant feeding bottles.

### **Rationale for Government intervention**

2.16 Government intervention is necessary to implement the Directive into national law to restrict the use of BAP in polycarbonate infant feeding bottles. These proposals fulfil the Government's policy objectives of meeting its EU obligations; of keeping food safe by reducing the risks to consumers from chemical migration; of meeting the Lisbon agenda to improve the competitiveness of businesses in Europe by providing harmonised rules within which business compete; and, of simplifying the laws in Scotland.

2.17 The Food Standards Agency in Scotland (FSAS) believes that the adoption of these proposals provides a precautionary measure to ensure consumer protection in relation to food safety.

2.18 Do nothing would mean that the Government would have failed to implement these policies. It would also create potential for the UK to become liable for infraction proceedings and it would not be possible to implement only parts of

this proposal. Businesses in Scotland would have to comply with the proposals being made here if their goods were legally compliant elsewhere in the EU.

## **2. Consultation**

### **• Within Government**

3.1 Scottish Government Health and Rural Directorates, Scottish Enterprise, Scottish Environment Protection Agency and Enterprise Directorate in BIS have been informed of the new proposals whilst discussions with the Commission were ongoing. No comments were received.

### **• Public Consultation**

3.2 A formal public consultation relating to Scotland was launched in the FSA in Scotland on 20 December 2010 and closed on 14 January 2011. The consultation documents can be viewed on the Agency's website at: <http://www.food.gov.uk/consultations/consultscot/2010/bisphenolapmacfregs2011scot>

3.3 In addition to publishing the consultation on its website, FSA in Scotland also sent the consultation direct to 209 consultees. These included food industry organisations; sector-specific organisations; those with a general interest in food contact materials and consumer organisations.

### **• Business**

3.3 In Scotland, the Scottish Rubber and Plastics Association were contacted who suggested various manufacturers to contact. After contacting these businesses it became apparent that they were not directly affected by the Commission's proposals but indicated that there may be a knock on effect for their industries. From these enquiries it appears that there are no Scottish manufacturers directly affected by the new proposals. The Scotch Whisky Association have also been contacted as they had previously asked to be kept informed as they have an interest with respect to bottle caps. We also contacted retailers but again were unable to find any involved in the sale of infant feeding bottles containing BPA.

3.4 At a UK level the Agency held a scoping meeting with industry and consumer groups to get an indication of the impact of the Commission's earlier proposed options. Comments received from industry on the Commission's initial proposals are summarised below:

3.5 The Trade Association representing the various retail sectors commented that the majority of their members had either phased out the use of BPA in infant feeding bottles or were in the process of doing so. The proposed ban on the use of BPA in infant feeding bottles would have the least impact on the retail sector of the Commission's proposals. In terms of timings, they said that their members would require an additional six months to a year on top of any Commission deadlines, to ensure completely that all BPA stock would be sold.

3.6 The Trade Association representing the metal packaging industry that produces internally coated and uncoated cans, ends and closures for food and drink commented that whilst a ban on BPA in polycarbonate infant feeding bottles

would not impact directly on metal packaging, it would however raise doubts on the safety of BPA in the manufacture of food contact materials in general. They acknowledged that the indication that the ban would only apply to plastic materials and articles within the scope of the principal Directive and not specifically cover coatings on metals, hence, this would not directly impact on metal packaging manufacturers.

- 3.7 Comments received from the Trade Association representing specialist infant nutrition largely concentrated on the manufacture of infant formula and follow-on-formula, which is mainly manufactured outside the UK. They commented that BPA is used as a sealant or interface in infant and follow-on formula packaging, which is estimated at 30% of that market. They also added that the likely financial costs of using alternatives to BPA in packaging for infant and follow-on formula would be high; however their comments did not indicate any likely impact specific to the ban on BPA in infant feed bottles.
- 3.8 The Trade Association representing the UK plastic packaging industry, which includes raw materials producers, additive suppliers and manufacturers of semi-finished plastic products, again, their comments were largely based on the Commission's initial two options in relation to BPA, which included the current option adopted by the Commission of restricting the use of BPA in infant feeding bottles.
- 3.9 They indicated that any legislative restrictions on the use of BPA in polycarbonate would be unacceptable to its members. They emphasised that they firmly believed in a science based risk assessment and risk management process for all food contact materials and based on the current EFSA opinion there was no basis for reducing the TDI for BPA and saw no justification for any change. They also acknowledged that there were very few polycarbonate baby bottles left on the European market, as alternative materials were being used to produce baby bottles and these alternatives were mainly produced in non-EU countries.
- 3.10 The association also commented that a ban on polycarbonate infant feeding bottles could result in the ban being extended to other BPA applications, such as can coatings, toys for the age group 0-3 years, medical devices, other packaging applications, e.g. water containers etc. The Commission has confirmed that the ban is specific to the use of BPA infant feeding bottles and is unlikely to extend to other applications of BPA, as reported in various trade press articles (<http://www.foodproductiondaily.com/Quality-Safety/No-plans-to-extend-bisphenol-A-ban-says-European-Commission>).

### **3. Options**

- Option 1 – Do Nothing. (Allow the continued use of BPA in the manufacture of feeding bottles intended for infants of up to 12 months in age and the placing on the market in, and import into, Scotland of plastic feeding bottles intended for infants of up to 12 months of age manufactured using BPA.)
  - Option 2 – National regulations to implement the Commission Directive and minimise the exposure of infants of up to 12 months of age in Scotland to BPA.
- 
- **Sectors and groups affected**

- 4.1 Firms in the UK plastics manufacturing sector and UK retailers that currently sell infant feeding bottles containing BPA could be affected by this policy. However, because the scope of the policy (in terms of businesses affected) is narrow, it is difficult to provide accurate estimates of the precise number of retailers and manufacturers that will face any impact.
- 4.2 Where appropriate, an attempt has been made to estimate the number of manufacturers potentially affected in each of the option sections (using the interdepartmental business register (IDBR<sup>3</sup>) data as a guide).
- 4.3 As this option may also affect retailers, assumptions have been made about the types of retailers likely to sell affected products; these are outlined in table 1 below. However, because of the nature of IDBR SIC<sup>4</sup> code classifications it has not been possible to identify the exact number of retailers that sell infant feeding bottles.

**Table 1: Number of affected retailers by location**

	England	Scotland	Wales	N. Ireland	UK
Supermarkets	23,965	2,980	1,525	1,035	29,505
Department Stores	5,705	555	430	110	6,800
Chemists	3,690	370	205	245	4,510
Total	33,360	3,905	2,160	1,390	40,815

Source: IDBR (see footnote 1)

- 4.4 The impacts on these businesses are likely to be an overestimate for two key reasons: 1) IDBR data is not sufficiently narrow in identification scope for our purposes and 2) it is understood that UK industry is already voluntarily moving away from the use of BPA in polycarbonate baby bottles.

### Benefits

- 4.5 Option 1 – Industry may benefit from not having to find a replacement for BPA and indirectly from unnecessary costs being imposed on them if any of the other options are implemented.
- 4.6 Option 2 - In September 2010 the EU food safety advisory body, EFSA<sup>5</sup>, published an opinion that found no evidence to suggest toxicity or harmful results from use of BPA in baby feeding bottles. As such, the Agency estimates that there will be no beneficial public health impacts as a result of introducing the BPA ban. This ban would be introduced under the ‘precautionary principle’.
- 4.7 There are no benefits to businesses as a result of this option.

### Costs

- 4.8 **Option 1** – There are no public health costs or costs to business associated with the ‘do nothing’ option. Current scientific evidence (EFSA study) suggests that BPA in the quantities ingested from infant feeding bottles, would not be sufficient to cause any harm; the policy would therefore be adopted under the precautionary principle.

<sup>3</sup> <http://www.statistics.gov.uk/idbr/idbr.asp>

<sup>4</sup> Standard Industrial Classification

[http://www.statistics.gov.uk/methods\\_quality/sic/downloads/sic2007explanatorynotes.pdf](http://www.statistics.gov.uk/methods_quality/sic/downloads/sic2007explanatorynotes.pdf)

<sup>5</sup> <http://www.efsa.europa.eu/>

- 4.9 **Option 2** –Various costs to business would arise with the introduction of a legislative ban of polycarbonate infant feeding bottles these include ‘one-off’ familiarisation costs, production and testing costs associated with use of other materials, and costs of ‘write-off’.
- 4.10 We estimate these costs will be minimal because anecdotal evidence suggests there are a limited number of baby bottle manufacturers in the UK and any costs that do arise will be mitigated by the evidence that suggests manufacturers of infant feeding bottles are already moving away from the use of BPA.

**One-off’ familiarisation costs to Industry**

- 4.11 Introducing new legislative requirements for businesses as the result of a BPA ban, would mean that businesses have to read and familiarise themselves with new legislation pertaining to what is and isn’t permitted use.
- 4.12 As the sector affected is narrow in scope it is difficult to provide accurate estimates of the number of businesses affected. Using 2009 SIC code data and the Inter-departmental Business Register (IDBR)<sup>6</sup> it has been possible to isolate the sector likely to encompass production of baby bottles (manufacture of other plastic products SIC code 22.29) but it has not been possible to identify the exact subset. Further to this, information from consultation with suggested that a large proportion of infant feeding equipment is manufactured outside the UK. As such, the number of businesses affected is likely to be an overestimate.

\*SIC Code 22.29 covers ‘Manufacture of other plastic products’ which is very wide ranging and to date we have not found any manufacturers of infant feeding bottles in Scotland.

**Table 2: Number of affected manufacturers by location**

SIC code	England	Scotland	Wales	N. Ireland	UK
2229*	2,460	*115	135	90	2,800

Source: IDBR (see footnote1)

**Table 3: Number of affected manufacturers by size**

SIC Code	Micro	<20	Small	Medium	Large	Total
2229	1,965	370	280	165	20	2,800

Source: IDBR (see footnote1)

- 4.13 The Agency estimates that it will take the relevant manufacturing businesses approximately 1 hour to read and become familiar with the new legislation. Multiplying this time by the ASHE (Annual Survey of Hours and Earnings)<sup>7</sup>, hourly wage rate of a production manager £19.38<sup>8</sup>, which is then uprated by 30% to account for overheads in line with SCM methodology (£25.19 inclusive)<sup>9</sup>, yields a total cost to business of approximately £70,000.

**Table 4: Familiarisation costs by location**

<sup>6</sup> <http://www.statistics.gov.uk/idbr/idbr.asp>  
<sup>7</sup> <http://www.statistics.gov.uk/statbase/product.asp?vlnk=13101>  
<sup>8</sup> £19.38\*1.3=£25.19  
<sup>9</sup> SCM methodology <http://www.berr.gov.uk/files/file44503.pdf>

SIC Code	England	Scotland	Wales	N. Ireland	UK
2229	£61,977	2,897	£3,401	£2,267	£70,543

*Note: Totals may not sum due to rounding*

*Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximately to 2 d.p. and when grossed may result in rounding error.*

**Table 5: Familiarisation costs by business size**

SIC Code	Micro	<20	Small	Medium	Large	Total
2229	£49,506	£9,322	£7,054	£4,157	£504	£70,543

*Note: Totals may not sum due to rounding*

*Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximately to 2 d.p. and when grossed may result in rounding error.*

- 4.14 Note that this is very likely to be an overestimate of the costs of familiarisation as the sector definition is larger than ‘infant bottle manufacturers’. In addition, anecdotal evidence suggests that there are only a small number of infant bottle manufacturers in the UK, through at present we have been unable to ascertain exactly how many. The estimate should therefore be treated with caution and considered an upper limit.

### **Production and Testing Costs**

- 4.12 With the introduction of a ban on the use of BPA, there is the potential that costs to manufacturing industry may be incurred in terms of increased production costs. Where substitute materials are available, they may be more expensive (consultation responses indicate the increase is likely to be between 5% and 10%), which will either increase costs to businesses (if increased costs are absorbed) reducing profit margins, or will increase costs to consumers if the market structure is such that costs may be passed on through price increases.
- 4.13 In addition, although evidence suggests that ‘tried and tested’ alternative products are available, industry have voiced concerns that there is a potential risk that a ban on BPA may result in some market players using less well understood substances and materials in the manufacture of infant feeding bottles; this could be a problem if outcomes on health are more uncertain than the risks associated with BPA. However, strict safety guidelines currently in place on manufacturers<sup>10</sup> already producing BPA free bottle feeding products will limit the impact/risk of this occurring.

### **Costs of ‘write-off’**

- 4.15 As businesses currently manufacture infant feeding bottles containing BPA, introducing a ban without an adequate ‘phase-in’ period (currently to be implemented March 2011) will result in businesses facing costs associated with writing-off excess BPA stock. Evidence from consultation however, indicates that the majority of infant feeding bottles are imported from outside of the UK and so the costs to UK manufacturers are likely to be limited. Costs of write-off could be incurred by UK retailers on any existing and advance purchase stock.

<sup>10</sup> BornFree, Mothercare, Tommee Tippee

Depending on the magnitude of stock holdings per affected UK business this cost could be substantial.

- 4.16 Despite the potential for such costs to be incurred, responses from 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 sold through. 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. Due to the inherent uncertainties surrounding the potential for costs in this area, it has not been possible for the Agency to monetise the associated costs.

### **Negative Spillovers**

- 4.17 Results from 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<sup>11</sup> suggests that the use of polycarbonates 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 €6 billion 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.
- 4.18 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.
- 4.19 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.
- 4.20 A related issue, identified as a result of the consultation process, is the negative impact that a ban on BPA could have on consumer safety perceptions; a ban on the use of BPA in infant feeding bottles may send a signal to consumers that BPA is an unsafe product, which is contrary to EFSA's most recent findings. It is however worth noting that the EU has sought to minimise any issues associated with public perception by publicly confirming that it will not seek to extend the prohibition of the use of BPA to other products.<sup>12</sup>

### **Costs to Enforcement Authorities**

---

<sup>11</sup> Fact Sheet Socio Economic Contribution 0909, Polycarbonate: a major contributor to Europe's Economy and quality of life – Plastics Europe. [http://www.bisphenol-a-europe.org/uploads/Lay\\_Socio-economic%20contribution\\_09092009.pdf](http://www.bisphenol-a-europe.org/uploads/Lay_Socio-economic%20contribution_09092009.pdf)

<sup>12</sup> (<http://www.foodproductiondaily.com/Quality-Safety/No-plans-to-extend-bisphenol-A-ban-says-European-Commission>)

### **'One-off' familiarisation costs**

- 4.21 With the introduction of new legislation, enforcement officers will also have to read and familiarise themselves with relevant documentation. The Agency estimates that it will take approximately 1 hour to do this at the ASHE reported wage rate of £15.97 for a public service professional. To account for overheads, as per SCM methodology, this wage rate has been uprated by 30%; this yields a total cost to local authorities of approximately £9,700 (see table 6).

**Table 6: Costs of enforcement by location**

	<b>England</b>	<b>Scotland</b>	<b>Wales</b>	<b>Northern Ireland</b>	<b>UK</b>
Number of Local Authorities	389	32	22	26	469
Enforcement Cost	£8,076	£664	£457	£540	£9,737

*Note: Totals may not sum due to rounding*

*Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2d.p. and when grossed may result in rounding error.*

### **Risks and Assumptions**

- 4.22 For option 1, 'Do nothing' financial penalties may result from failure to respond to the Commission Directive. This would contradict the UK Government's commitment to meeting EU obligations (with the intent of fulfilling policy on consumer protection). There would be potential for the UK to become liable to infraction proceedings. It would leave the regulation of food contact materials in the UK deficient in comparison with the rest of the EU.
- 4.23 For option 2, the scope in terms of sectors affected by this policy, is very narrow and not clearly defined by existing data. As such it has been necessary to use SIC code data with a broader scope which will result in an overestimation of the likely costs involved. Unfortunately at this stage no better data is available.
- 4.24 There are risks associated with unintended consequences of negative spillovers to industries in the wider BPA market associated with negative consumer perceptions, which are important to note; these are described in detail in the unintended consequences section of each of the BRIA options.
- 4.25 There is also a potential risk that SMEs will be disproportionately affected by this option. Write-off costs of SME retailers may be greater than other retailers as turnover of stock may be slower and not adequately accounted for in the given transition period. Given the inherent uncertainties about the degree of impact in this area we have not been able to provide robust quantification.

### **4. Scottish Firms Impact Test**

- 5.1 Stakeholders, including the Scottish Federation of Small Businesses and trade associations, have been consulted throughout the negotiations on the legislation. We have been unable to identify any Scottish manufacturers of infant feeding bottles and any retailers that have been contacted to date do not stock infant feeding bottles containing BPA. Therefore no face-to-face discussion has taken place to date. It was confirmed during consultation with a

trade association that there were no business directly involve in the manufacture of infant feeding bottles. Retailers also confirmed that they did not have feeding bottles containing BPA on sale.

- 5.2 There is some potential risk that SMEs will be disproportionately affected by this option. Write-off costs of SME retailers may be greater than other retailers as turnover of stock may be slower and not adequately accounted for in the given transition period.
- 5.3 Small and Medium sized businesses are encouraged to respond to issues which they feel may have an impact. None responded.

#### **Competition Assessment**

- 5.4 Using the Office of Fair Trading competition assessment framework<sup>13</sup>, it has been established that the preferred policy option (option 2) is unlikely to have any material negative impact on competition. We assert that this policy 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.

#### **Test run of business forms**

- 5.5 No new or additional forms will be introduced by this proposal therefore no test run need be completed.

### **5. Legal Aid Impact Test**

- 6.1 The Legal Aid Team have been informed of the proposal and confirm that the proposal will not introduce new criminal sanctions or civil penalties therefore there are no legal aid implications.

### **6. Enforcement, sanctions and monitoring**

#### **• Enforcement**

- 7.1 Enforcement of any new Regulation in Scotland is primarily the responsibility of the 32 LA's in Scotland as defined by the Food Safety Act 1990.

#### **• Sanctions**

- 7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

#### **• Monitoring**

- 7.3 The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

---

<sup>13</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf)

## 7. Implementation and delivery plan

The new Directive requires Member States to adopt and publish national legislation to implement its requirements by 15 February. However, during discussions, the Commission indicated that it understood the difficulties that some Member States may have in transposing a Directive to that timescale, therefore the instrument will now come into force on 1 March 2011.

The publication of the Plastic Materials and Articles in Contact with Food (Scotland) Amendments Regulations 2011 will be communicated to stakeholders by email, letter and monthly Enforcement Report. This will be done shortly after publication on legislation.gov.uk website.

The Agency will work with enforcement authorities where problems arise or suspected infringements of the instrument arise.

### Post-implementation review

The effectiveness of the instrument will also be monitored via feedback from industry and enforcement authorities, and the policy will be reviewed by the Food Standards Agency in June 2012.

## 8. Summary and recommendation

The Agency recommends Option 2, to implement national regulations (the Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011) to implement the Commission Directive and minimise the exposure of infants of up to 12 months of age in Scotland to BPA. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law. Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

## 9. Summary costs and benefits table

<b>Option</b>	<b>Total benefit per annum: economic, environmental, social</b>	<b>Total cost per annum: economic, environmental social policy and administrative</b>
<b>1 Do Nothing</b>	Not having to find a replacement for BPA and indirectly from unnecessary costs being imposed on them.	No public health costs or costs to business associated with this option. Cost to the UK Government of infractions proceedings if they do not implement the Directive.
<b>2 implement national regulations to implement the Commission Directive</b>	In September 2010 the EU food safety advisory body, EFSA, published an opinion that found no evidence to suggest toxicity or harm results from use of BPA in baby feeding bottles. As such, the Agency is unable to estimate any beneficial public health impacts as a result of introducing the BPA ban. The ban would be introduced under the	One of cost to business of familiarisation of no more than £2,987 (Scotland only).  One of cost to enforcement authorities of familiarisation of no more that £664 (Scotland only)

<p><b>and minimise the exposure of infants of up to 12 months of age in Scotland to BPA.</b></p>	<p>'precautionary principle' Harmonises standards across Member States &amp; removes barriers to trade</p>	
--	--	--

## 11. Declaration and publication

### *Final Stage –*

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Ministers signature .....

Ministers title .....

Date .....

### **Contact point**

Fiona Bruce  
 Safety, Policy & Regulation Development  
 Food Standards Agency Scotland  
 6th floor, St Magnus House  
 25 Guild Street  
 Aberdeen  
 AB11 6NJ  
 Tel: 01224  
 e-mail: [fiona.bruce@foodstandards.gsi.gov.uk](mailto:fiona.bruce@foodstandards.gsi.gov.uk)

**Other Impact Assessments carried out**

**Sustainability**

Impacts under the three pillars of sustainable development (environmental, economic and social) have been, and continue to be, considered in the preparation of this BRIA. Option 2 is the preferred option because it minimises the costs to Industry and the public sector, while achieving desired goals, where no notable benefits are associated with the alternative options.

## TRANSPOSITION NOTE

### THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) AMENDMENT REGULATIONS 2011

Directive 2011/8/EU amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (O.J. L 26, 29.1.2011, p.11)

<b>Articles of Directive 2011/8/EU</b>	<b>Objectives</b>	<b>Implementation</b>	<b>Responsibility</b>
Article 1	This amends Annex II of Directive 2002/72/EC to prohibit the use of BPA in the manufacture and placing on the market of polycarbonate infant feeding bottles.	Regulation 2(5) of the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 provides an ambulatory reference that implements this prohibition.	The Scottish Ministers.
Article 2.1	This requires Member States to implement Directive 2011/8/EU by 15 February 2011, publish and communicate this to the European Commission and provide for the provisions to contain a reference to the Directive.	Implementation will be completed when the Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011 come into force on 1st March 2011.	As above.
Article 2.2	This prohibits, from 1st March 2011 the manufacture of, and from 1st June 2011 the placing on the market and import into the EU of, plastic materials and articles intended to come into contact with food and which do not comply with Directive 2002/72/EC as amended by Directive 2011/8/EU.	Regulation 2(2) of the Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011 gives effect to these transitional arrangements by amending the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009.	As above.