EXPLANATORY MEMORANDUM TO

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

2011 No. 231

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument implements 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")[1].

2.2 The new Directive introduces an EU-wide prohibition on the use of Bisphenol A[2] (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.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 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 England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009[3].

4.2 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.

5. Territorial Extent and Application

5.1 This instrument applies to England only.

5.2 Separate but parallel legislation is being made for Scotland, Wales and Northern Ireland.

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[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF
[2] 2,2-bis(4-hydroxyphenyl)propane
[3] SI 2009 No. 205

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 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.

7.2 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[4], 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.

7.3 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[5] 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.

7.4 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.

7.5 The Commission presented its formal proposal for a vote in the Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 25 November 2010 which was adopted by 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 2011.

[4] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620772817.htm
[5] http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm

8. Consultation outcome

Informal Consultation

8.1 Whilst discussions 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 and held a meeting with a consumer group in mid-November 2010.

Formal Public Consultation

8.2 The FSA conducted a formal public consultation from 20 December 2010 to 14 January 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 Impact Assessment that accompanies this Explanatory Memorandum were included in the consultation.

8.3 The FSA received 172 responses to the consultation. 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.

8.4 A full summary of comments received in response to the consultation will be published on the FSA's website.

9. Guidance

9.1 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.

10. Impact

10.1 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.

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

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The instrument will apply to all businesses small and large.

12. Monitoring & review

12.1 Central and local authorities in England 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/

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

13. Contact

13.1 Colin Clifford at the Food Standards Agency, Tel: 020 7276 8538, Email: colin.clifford@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

Title:	Impact Assessment (IA)
Bisphenol A: The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011 **(To implement, in England, a phased EU-wide Prohibition on Polycarbonate Infant Feeding Bottles manufactured using Bisphenol A)**	**IA No:** FOOD0058
	Date: 03/02/2011
Lead department or agency: **Food Standards Agency**	**Stage:** Final
	Source of intervention: EU
Other departments or agencies:	**Type of measure:** Secondary legislation

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

A measure proposed by the European Commission under the precautionary principle that was adopted on 25 November 2010 was published as Commission Directive 2011/8/EU and came into force on 1 February 2011. It amends existing European Union (EU) legislation on plastic food contact materials to introduce, in the EU, a phased prohibition on polycarbonate feeding bottles manufactured using the chemical Bisphenol A (BPA) that are intended for infants of up to 12 months of age. Government intervention is required to implement the Commission Directive into national law.

What are the policy objectives and the intended effects?

The policy objective is to implement the Commission Directive and in so doing prohibit, in England, (a) the manufacture of polycarbonate feeding bottles intended for infants of up to 12 months of age using BPA from 1 March 2011 and (b) the placing on the market and import of polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using BPA from 1 June 2011. The intended effect is to minimise the exposure of infants of up to 12 months of age to BPA.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

Option 1: Do Nothing. Allow the continued use of BPA in the manufacture of feeding bottles intended for infants of up to 12 months of age in England and the placing on the market in, and import into, England of plastic feeding bottles intended for infants of up to 12 months of age manufactured using BPA.

Option 2: National regulations relating to England to implement the Commission Directive and minimise the exposure of infants of up to 12 months of age to BPA. This is the preferred option.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	The policy will be reviewed in June 2012
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For Implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible: Minister:***Anne Milton*** ..... Date:***14th February 2011***.....

Summary: Analysis and Evidence

Policy Option 1

Description:

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, England of plastic feeding bottles intended for infants of up to 12 months of age manufactured using BPA).

Price Base Year 2009	PV Base Year N/A	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: £0m**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£0m		£0m	**£0m**

Description and scale of key monetised costs by 'main affected groups'

There are no incremental monetised costs associated with this option. Current scientific evidence suggests that BPA in the quantities ingested from infant feeding bottles, would not be sufficient to cause any harm.

Other key non-monetised costs by 'main affected groups'

There are no incremental non monetised costs associated with this option

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£0m		£0m	**£0m**

Description and scale of key monetised benefits by 'main affected groups'

There are no incremental monetised benefits associated with this option.

Other key non-monetised benefits by 'main affected groups'

There are no incremental benefits associated with this option; this is the baseline against which the other options will be assessed. .

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Costs of infraction may result from failure to implement the Commission Directive.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			1st March 2011		
Which organisation(s) will enforce the policy?			LAs and PHAs		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** £0m	**Benefits:** £0m	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro** £0m	**< 20** £0m	**Small** £0m	**Medium** £0m	**Large** £0m
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	15
Small firms Small Firms Impact Test guidance	No	15
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	15

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

National regulations to implement the Commission Directive and minimise the exposure of infants of up to 12 months of age in England to BPA.

Price Base Year 2009	PV Base Year N/A	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: -£0.07m**

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	£0.07m	£0m	**£0.07**

Description and scale of key monetised costs by 'main affected groups'

There will be a one off familiarisation cost to business of no more than £61,977 (England only). This represents an 'equivalent annual net cost' to business of approximately £7450 over 10 years.
There will also be a 'one off' cost of familiarisation to enforcement authorities of £8,076.

Other key non-monetised costs by 'main affected groups'

The infant feeding bottle and baby formula manufacturing industries may face costs associated with production and testing of BPA alternatives and without an adequate 'phase-in' period affected manufacturers and some retail businesses will also incur costs of 'write-off'. Indirect secondary costs may also be borne by industries in the wider BPA market through spillovers association with an increase in negative consumer perceptions.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	£0m	£0m	**£0m**

Description and scale of key monetised benefits by 'main affected groups'

There are no monetised incremental benefits associated with this option.
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 'precautionary principle'.

Other key non-monetised benefits by 'main affected groups'

There are no non-monetised benefits associated with this option.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

IDBR data has been used to estimate the number of manufacturing and retail businesses affected by this option. However due to the narrow scope of the policy, the sectors identified (and thus costs associated with familiarisation) will be an overestimate.
There are policy risks associated with unintended consequences of negative spillovers to the wider BPA industry.
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.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB: N/A	**AB savings:** N/A	**Net:** N/A	**Policy cost savings:**	

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			1st March 2011		
Which organisation(s) will enforce the policy?			LA's and PHA's		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** £0m	**Benefits:** £0m	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[2] Statutory Equality Duties Impact Test guidance	No	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	15
Small firms Small Firms Impact Test guidance	No	15
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	15

[2] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties, part of the Equality Bill, apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

References

No.	Legislation or publication
1	**Commission Directive 2002/72/EC, as amended** http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm
2	**The Plastic Materials and Articles in Contact with Food (England) Regulations 2009** http://www.legislation.gov.uk/uksi/2009/205/contents/made
3	**European Food Safety Authority Scientific Opinion on Bisphenol A** http://www.efsa.europa.eu/en/scdocs/scdoc/1829.htm
4	**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** http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF
5	**Commission Directive 2006/141/EC on infant formulae and follow-on formulae** http://ec.europa.eu/food/food/labellingnutrition/children/formulae_en.htm

Evidence Base

Annual profile of monetised costs and benefits* - (£m) constant prices

See Spreadsheet below for all options	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	£0.07									
Annual recurring cost										
Total annual costs	£0.07									
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Transition costs detailed in the spreadsheet show Equivalent Annual Net costs to Business and are for England Only

Evidence Base (for summary sheets)

Problem under Consideration

1. A measure proposed by the European Commission under the precautionary principle and adopted on 25 November 2010 was published formally in the Official Journal (OJ) of the European Union as 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") and came into force on 1 February 2011.

2. The new Directive introduces, in the EU, a phased prohibition on polycarbonate feeding bottles intended for infants of up to 12 months of age that contain the chemical Bisphenol A (BPA), which is used in plastic materials to provide rigidity.

3. Government intervention is required to implement the Commission Directive into national law.

Policy Objective / Intended Effect

4. The policy objective is to implement the new Directive 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 England from 1 March 2011, and;

   - Prohibit the placing on the market in, and import into, England 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[3] in England of up to 12 months of age to BPA.

Plastic Food Contact Materials Legislation

5. 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 England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009[4].

6. 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.

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

Bisphenol A

8. 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 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

[3] 'infant' as defined in Directive 2006/141/EC (OJ L 401, 30.12.2006, p1)
[4] SI 2009 No. 205

9. 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 0.01 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.

10. In its 2006 opinion, the European Food Safety Authority (EFSA) established a higher TDI of 0.05 mg/kg bodyweight; the SML remained at 0.6mg/kg, maintaining an additional safety factor.

    http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620772817.htm

Background to Commission Directive 2011/8/EU

11. 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.

12. EFSA's opinion was published on 30 September 2010 and concluded that the TDI for BPA 0.05 mg/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)

13. 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.

14. 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.

15. 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 ll, 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 1st 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 1st 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.

16. 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.

17. 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

18. Recital 16 of the Directive indicates that the 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.

Sectors Affected

19. 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.

20. 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[5]) data as a guide).

21. 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[6] 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)

22. 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.

OPTIONS CONSIDERED

Policy 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, England of plastic feeding bottles intended for infants of up to 12 months of age manufactured using BPA).

Costs

23. There are no incremental 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

[5] http://www.statistics.gov.uk/idbr/idbr.asp
[6] Standard Industrial Classification http://www.statistics.gov.uk/methods_quality/sic/downloads/sic2007explanatorynotes.pdf

infant feeding bottles, would not be sufficient to cause any harm; the policy would therefore be adopted under the precautionary principle.

Benefits

24. There are no incremental benefits associated with this option; this is the baseline against which the other options will be assessed.

Policy Option 2: National regulations to implement the Commission Directive and minimise the exposure of infants of up to 12 months of age in England to BPA. This is the preferred option.

Costs

25. 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'.

26. 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

27. Introducing new legislative requirements for businesses as a result of the BPA ban, would mean that businesses have to read and familiarise themselves with new legislation pertaining to what is and isn't permitted use.

28. 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)[7] 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 stakeholders suggest 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.

Table 2: Number of affected manufactuers by location

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

Source: IDBR (see footnote 1)

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 footnote 1)

29. 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)[8], hourly wage rate of a production manager £19.38[9], which is then uprated by 30% to account for overheads in line with SCM methodology (£25.19 inclusive)[10], yields a total cost to business of approximately £70,000.

[7] http://www.statistics.gov.uk/idbr/idbr.asp
[8] http://www.statistics.gov.uk/statbase/product.asp?vlnk=13101
[9] £19.38*1.3=£25.19
[10] SCM methodology http://www.berr.gov.uk/files/file44503.pdf

Table 4: Familiarisation costs by location

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 approximate 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 approximate to 2 d.p. and when grossed may result in rounding error.

30. 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, though 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

31. 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.

32. 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[11] already producing BPA free bottle feeding products will limit the impact/risk of this occurring.

Costs of 'write-off'

33. 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 still be incurred by UK retailers on any existing and advance purchase stock. Depending on the magnitude of stock holdings per affected UK business this cost could be substantial.

34. 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.

[11] BornFree, Mothercare, Tommee Tippee

Negative Spillovers

35. 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[12] 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.

36. 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.

37. 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.

38. 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.[13]

COSTS TO ENFORCEMENT AUTHORITIES

'One off' Familiarisation Costs

39. 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

	England	Scotland	Wales	Northern Ireland	UK
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 2 d.p. and when grossed may result in rounding error.

BENEFITS

40. In September 2010 the EU food safety advisory body, EFSA[14], 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. The ban would be introduced under the 'precautionary principle'.

41. There are no incremental benefits to businesses as a result of this option.

[12] 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
[13] (http://www.foodproductiondaily.com/Quality-Safety/No-plans-to-extend-bisphenol-A-ban-says-European-Commission
[14] http://www.efsa.europa.eu/

DIRECT COSTS AND BENEFITS TO BUSINESSES: EQUIVALENT ANNUAL NET COST (EANC)

42. In order for 'one-off' transition and ongoing costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula[15]. Under Standard HMT Green book guidance[16] a discount rate of 3.5% is used.

43. Total one-off costs for Industry across the UK have been estimated at approximately £70,543. As there are no benefits to business as a result of this policy these costs are net. This yields an EANC of approximately £8,500[17]over 10 years. For England only this represents a one off cost of approximately £61,977 and an EANC of £7,500[18] over 10 years.

Consultation

Informal Consultation

44. Whilst discussions 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. As BPA has wider applications and is an environmental contaminant to which an EU Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is also relevant, the FSA also consulted informally at this time with other Government Departments and Agencies with an interest in these wider aspects. These included 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). The FSA also held a meeting with a consumer group in mid-November 2010 which was in support of the Commission's proposals.

45. During this informal consultation activity, the retail sector advised the FSA that it was already moving away from infant feeding bottles manufactured using BPA. The key concerns of industry and other Government Departments were that the Commission's proposals were not based on scientific evidence and about the possibility of the Commission extending any ban to the use of BPA in applications wider than its use in food contact materials such as its use in can coatings, toys for infants, medical devices and other packaging applications. Industry and consumer interests also voiced concerns that a ban on BPA would result in the use of substances less studied and well understood as BPA in the manufacture of infant feeding bottles.

46. As regards the potential for a wider ban, the Commission has since confirmed, as reported in the trade press, that it has no plans to extend the prohibition to other applications of BPA:

    http://www.foodproductiondaily.com/Quality-Safety/No-plans-to-extend-bisphenol-A-ban-says-European-Commission

Formal Public Consultation

47. A formal public consultation relating to England was launched by the FSA in England 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/consulteng/2010/bisphenolapmacfregs2011eng

48. In addition to publishing the consultation on its website, the FSA also sent the consultation direct to 132 consultees. These included food industry organisations; sector-specific organisations such as those representing manufacturers of plastic food contact materials, metal and coated cans and multi-layered bonded packaging; those with a general interest in food contact materials; consumer organisations; Government Departments including the Department for Business Innovation and

[15] The equivalent annual cost formula is as follows: EAC=PVC/A, where A =[1-1/(1+r)^t]/r, PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.
[16] http://www.hm-treasury.gov.uk/data_greenbook_index.htm
[17] Please note these figures have been rounded to the nearest £100
[18] See footnote 15

49. The consultation sought comments on two options; a 'Do nothing' option and the preferred option of national regulations to implement the Commission Directive in order to minimise the exposure of infants of up to 12 months of age in England to BPA. Comments were invited on draft national Regulations, the draft Commission Directive, and an earlier draft of this impact assessment all of which were included in the consultation package. Consultees were also asked to consider, and where possible provide answers to, a number of specific questions set out in both the consultation letter and draft Impact Assessment. These included questions about the costs associated with using alternative substances to BPA in the manufacture of infant feeding bottles, potential write-off costs on existing stocks of infant feeding bottles containing BPA, potential costs of removing such products from the market and familiarisation costs associated with the proposed Regulations to prohibit infant feeding bottles manufactured using BPA.

50. The FSA received 172 responses to the consultation. 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. However, 160 identical e-mails were received in support of the prohibition from individuals mainly resident in the USA via a petition hosted by the US website 'change.org' that provides tools to facilitate social action campaigns.

51. A full summary of comments received in response to the consultation will be published on the FSA website at the same location as the consultation, as detailed at paragraph 47 above.

RISKS AND ASSUMPTIONS

52. For Policy 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.

53. For Policy 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.

54. 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 IA options.

55. 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.

SPECIFIC IMPACT TESTS

COMPETITION

56. Using the OFT competition assessment framework[19], it has been established that the preferred policy option is unlikely to have any material negative impact on competition. We assert that this

[19] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf

SMALL FIRMS

57. 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.

SUSTAINABILITY

58. Impacts under the three pillars of sustainable development (environmental, economic and social) have been, and continue to be, considered in the preparation of this Impact Assessment. 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.

RACE EQUALITY ISSUES

59. There is no evidence to suggest at this time of a differential health impact of this policy on any ethnic groups.

GENDER EQUALITY ISSUES

60. There is no evidence at this time that indicates a significant differential health impact of this policy on different genders.

DISABILITY EQUALITY ISSUES

61. There is no evidence to suggest any differential impacts of this policy for disabled people.

Basis of the review: A policy review undertaken by the Food Standards Agency.
Review objective: The 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.
Review approach and rationale: The Food Standards Agency will collate and analyse feedback received from industry and enforcement authorities.
Baseline: The Baseline is the summary of analysis and evidence relating to Option 1 ('Do nothing') set out in this Impact Assessment.
Success criteria: Industry and enforcement authorities working to ensure that polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using BPA are no longer available on the market in England.
Monitoring information arrangements: The Food Standards Agency will collate feedback it receives from industry and enforcement authorities and work with these interests where problems or suspected infringements of the Regulations arise.
Reasons for not planning a PIR: N/A