

# FOOD STANDARDS AGENCY CONSULTATION

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)

# **CONSULTATION SUMMARY PAGE**

| Date consultation launched: | Closing date for responses: |
|-----------------------------|-----------------------------|
| 20 December 2010            | 14 January 2011             |

# Who will this consultation be of most interest to?

Manufacturers, importers and retailers of polycarbonate feeding bottles intended for infants of up to 12 months in age manufactured using the chemical Bisphenol A and consumers who use such products. The consultation will also be of interest to consumer groups and enforcement authorities.

# What is the subject of this consultation?

The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011. These regulations would implement the provisions of a Commission Directive adopted on 25 November 2010 that will introduce a phased European Unionwide prohibition on polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using Bisphenol A. The regulations would achieve this by making amendments to The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 (SI 2009 No. 205).

# What is the purpose of this consultation?

To provide interested parties with the opportunity to comment on the proposed Regulations that would implement the Commission Directive and the evidence used to assess the impact.

| Responses to this consultation should be sent to: |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|
| Name: Nasreen Shah                                | Postal address: Room 4B,                       |  |  |  |  |  |  |
| <b>Division/Branch: Chemical Safety Division</b>  | Aviation House,                                |  |  |  |  |  |  |
| FOOD STANDARDS AGENCY                             | 125 Kingsway,                                  |  |  |  |  |  |  |
| Tel: 020 7276 8553                                | London, WC2B 6NH.                              |  |  |  |  |  |  |
| Fax: 020 7276 8446                                | Email: Nasreen.a.shah@foodstandards.gsi.gov.uk |  |  |  |  |  |  |
|   |  |  |  |  |  |  |  |

| Is an Impact Assessment included with this consultation? | Yes |  | No See Annex A for reason. |
|--|-----|--|----------------------------|
|--|-----|--|----------------------------|





# 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)

# **DETAIL OF CONSULTATION**

- We would welcome your comments on the proposed Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011, enclosed as **Annex B**.
- 2. These proposed Regulations would implement the provisions of a European Commission Directive which was adopted at the Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 25 November 2010 as enclosed as **Annex C**. The Directive will introduce a phased European Union-wide prohibition on polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using Bisphenol A (BPA).
- 3. The Directive, which will be published formally in due course, will require EU Member States to implement its provisions into national law so as to prohibit the manufacture of polycarbonate feeding bottles intended for infants of up to 12 months of age using BPA from March 2011 and the placing on the market and import of such products manufactured using BPA from 1 June 2011.
- 4. Comments are also requested on the Impact Assessment (IA), enclosed at **Annex D** and we would particularly welcome comments on any cost implications that may arise from this proposal.
- 5. The Food Standards Agency in Scotland, Wales and Northern Ireland will each consult on parallel but separate Regulations.

# **Background**

# Bisphenol A

- 6. 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. It 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.
- 7. It is known that small amounts of BPA can migrate into foods from polycarbonate plastics if the plastic or resin is heated, damaged or breaks down into foodstuffs and beverages and therefore be ingested. Commission Directive 2002/72/EC ("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.

8. 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

# EU Legislation on Plastic Food Contact Materials

9. Harmonised EU rules on plastic food contact materials as a whole are laid down by this Directive is implemented in England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009<sup>1</sup>.

# The European Food Safety Authority's opinion on BPA

In Spring 2010, two EU Member States presented to the European Commission scientific studies on which they had each 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. The EFSA opinion was published on 30 September 2010, and concluded that the TDI for BPA 0.05 mg/kg bodyweight did not require adjustment in the light of these scientific 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

- 11. 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. The options were to either prohibit the use of BPA in polycarbonate baby bottles or prohibit the use of BPA in all plastic materials and articles intended to come into contact with infant formula and follow on formula.
- 12. On 25 November 2010, the Commission presented a draft proposal to the Standing Committee on the Food Chain and Animal Health (SCoFCAH); a Commission Directive to introduce a phased ban on polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using BPA, which was adopted by Qualified Majority.
- 13. The Directive will be published formally in the Official Journal of the European Union in due course and will come into force 20 days after its publication. Pending official publication of the Directive, we expect that its main provisions will be as below:
  - > Article 1 will amend 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:

<sup>&</sup>lt;sup>1</sup> SI 2009 No. 205

- 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) will require Member States to adopt the Directive by 15 February 2011.
- > Article 2(3) will require Member States to:
  - Prohibit from 1 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 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.
- 14. 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.
- 15. The Directive, when published, will be available to download free of charge from the following website address at: <a href="http://europa/eu/int/eur-lex/en/index.htm">http://europa/eu/int/eur-lex/en/index.htm</a>. If, contrary to current expectations, the published version should differ in any significant respect from the draft text on which the summary at paragraph 13 is based on; we will issue a further communication to interested parties.

# **This Consultation**

# Purpose of the Consultation

- 16. The Food Standards Agency is conducting this consultation to seek comments from interested parties and obtain their views on the proposal to implement the provisions of the new Directive via the proposed Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011.
- 17. The key proposal on which this consultation seeks comments is as follows:

# Key proposal:

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

# **Consultation Process**

- 18. The Agency has carried out early, informal, consultation with interested parties which amongst other things has facilitated the development of the draft Impact Assessment that forms part of this consultation. These informal consultation activities included:
  - Contact with industry groups and trade associations, followed by a scoping meeting held on 18 October 2010.

- Contact with consumer groups.
- Contact and meetings with other government departments which have a
  wider interest in BPA such as the Department of Environment, Food and
  Rural Affairs (DEFRA), Department of Business Innovation and Skills
  (BIS), the Medicines and Healthcare products Regulatory Agency (MHRA)
  and the Health and Safety Executive (HSE).
- 19. Comments received from interested parties including those from other Government Departments so far, have been reflected in the draft IA. However, we would now welcome comments on any additional costs likely to arise from the implementation of the new Commission Directive.
- 20. We would be particularly keen to hear from SMEs on any likely impact and would encourage them to comment on all aspects of the proposal and its intended effect.

# Questions asked in the draft Impact Assessment at Annex C to this consultation:

- Q1. Is the number of businesses affected reflective of infant feeding bottle manufacturers in the UK? We would be grateful for any available evidence on this sector.
- Q2. Is the time estimate a reasonable reflection of the time that would be spent by manufacturing firms in familiarisation? If you disagree, please provide evidence to support your views.
- Q3. What is the proportion of BPA free bottles currently manufactured in the UK? We would be grateful for any available evidence.
- Q4. If alternatives to BPA are already being used in the manufacture of infant feeding bottles, what are the costs for doing this? Please provide any available evidence.
- Q5. What is the quantity and value of stock that would likely face write-off if any immediate ban were introduced? Please provide evidence to support your views.
- Q6. Is 1 hour an accurate representation of the familiarisation time required to ensure enforcement of this option? If you disagree with this assessment, please provide evidence to support your views.
- Q7. Are Small and medium enterprises (SME's) potentially affected? Please provide evidence to support you views.

# Other relevant documents

21. As indicated in paragraph 8, above, a copy of the EFSA opinion on BPA published on 30 September 2010 is available at:

http://www.efsa.europa.eu/en/scdocs/doc/1829.pdf.

22. The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 are available from Stationery Office book shops or the Stationery Office PO Box 29, Norwich, NR3 IGN, Tel: 0870 600 5522, fax: 0870 600 5533. Statutory Instruments issued since 1997 are also published, free-of-charge, on the website of the Office of Public Sector Information, address <a href="http://www.opsi.gov.uk">http://www.opsi.gov.uk</a>. Copies can also be purchased via that website.

# Responses

- 23. Responses are required by close of business on Friday 14 January 2011. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).
- 24. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

Nasreen Shah Regulatory Officer Chemical Safety Division

# **Enclosed**

**Annex A: Standard Consultation Information** 

Annex B: The Draft Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011

Annex C: C(2010) final Draft Commission Directive amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles

**Annex D: Draft Impact Assessment** 

Annex E: List of interested parties

# Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

# Publication of personal data and confidentiality of responses

- 2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <a href="http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc">http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc</a> Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
- 3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
- 4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

# **Further information**

- 5. A list of interested parties to whom this letter is being sent appears in Annex E. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
- 6. Please let us know if you need paper copies of the consultation documents or of anything specified under 'Other relevant documents'.
- 7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: <a href="http://www.berr.gov.uk/files/file47158.pdf">http://www.berr.gov.uk/files/file47158.pdf</a> The Consultation Criteria from that Code should be included in each consultation and they are listed below:

# The Seven Consultation Criteria

#### Criterion 1 — When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

# Criterion 2 — Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

# Criterion 3 — Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

# Criterion 4 — Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

#### Criterion 5 - The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

# Criterion 6 - Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

# Criterion 7 - Capacity to consult

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

- 8. Criterion 2 states that Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible. This consultation is not being held for a full 12 weeks because please see the third paragraph in the 'detail of the consultation' page 2.
- 9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex C.
- 10. For details about the consultation process (<u>not</u> about the content of this consultation) please contact: <u>Food Standards Agency Consultation Co-ordinator</u>, Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

# Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at:

# http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at:

# http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

The questionnaire can also be used to update us about your existing contact details.

#### STATUTORY INSTRUMENTS

# 2011 No.

# FOOD, ENGLAND

# The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011

Made - - - - \*\*\*

Laid before Parliament \*\*\*

Coming into force - - Month 2011

The Secretary of State makes the following Regulations 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  $1990(\mathbf{a})$ , and now vested in him( $\mathbf{b}$ ).

In accordance with section 48(4A) of the Food Safety Act 1990 he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

#### Title and commencement

**1.** These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011 and come into force on [xxxxx] 2011.

<sup>(</sup>a) 1990 c.16, section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999Act". Section 48 was also amended by S.I. 2004/2990. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.

<sup>(</sup>b) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scotlish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

<sup>(</sup>c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468 with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

# Amendment to the Plastic Materials and Articles in Contact with Food (England) Regulations 2009

- **2.**—(1) The Plastic Materials and Articles in Contact with Food (England) Regulations 2009(**a**) are amended in accordance with paragraph (2).
- (2) After regulation 21 (transitional defence relating to PVC gaskets containing epoxidised soy bean oil) insert the following as regulation 21A —

# "Transitional defences relating to infant feeding bottles containing Bisphenol A

- **21A.**—(1) In any proceedings for an offence under regulation 3 in connection with the sale or import into the EU of a polycarbonate infant feeding bottle which fails to meet the required standard it shall be a defence to prove that the plastic material or article
  - (a) was placed on the market or as the case may be imported in to the EU before 1st June 2011; and
  - (b) complied with these Regulations as they stood immediately before the amendment made to Annex II to the Directive by Commission Directive [2010/XX/EU].
- (2) In any proceedings for an offence under regulation 4 in connection with the use of Bisphenol A in the manufacture of a polycarbonate infant feeding bottle it shall be a defence to prove that the plastic material or article
  - (a) was manufactured before 1st March 2011; and
  - (b) complied with these Regulations as they stood immediately before the amendment made to Annex II to the Directive by Commission Directive [2010/XX/EU].
- (3) In this regulation Commission Directive [2010/XX/EU] means Commission Directive [2010/XX/EU] amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles.".

Signed by authority of the Secretary of State for Health

Minister's name
Parliamentary Under Secretary of State,
Department of Health

Date

 $<sup>\</sup>mbox{(a)} \quad \mbox{S.I. } 2009/205, \mbox{ amended by S.I. } 2010/2225.$ 

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

- 1. These Regulations amend the Plastic Materials and Articles in Contact with Food (England) Regulations 2009 (S.I. 2009/205 as previously amended by S.I. 2010/2225) ("the principal Regulations") in order to provide for the implementation in England of transitional arrangements contained in Commission Directive [2010/XX/EU] amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles ("the new Commission Directive").
- **2.** The new Commission Directive contains a prohibition on the manufacture, sale and import of plastic feeding bottles for infants that are manufactured using Bisphenol A, together with transitional provisions for phasing in this prohibition. The principal Regulations contain (at regulation 2(5)) an ambulatory reference which has the effect of implementing the prohibition.
- **3.** These Regulations amend the principal Regulations to provide for the implementation of the transitional arrangements in the new Commission Directive (regulation 2(2)).
- **4.** A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Food Safety Group of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

# **SANCO**/2010/12642

EN EN

# **EUROPEAN COMMISSION**



Brussels, C(2010) final

Draft

# **COMMISSION DIRECTIVE ../.../EU**

of [...]

amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles

(Text with EEA relevance)

EN EN

#### Draft

# **COMMISSION DIRECTIVE ../.../EU**

of [...]

# amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles

(Text with EEA relevance)

#### THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC<sup>1</sup>, and in particular Article 18 (3) thereof,

After consulting the European Food Safety Authority,

# Whereas:

(1) Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs<sup>2</sup> authorises the use of 2,2-bis(4-hydroxyphenyl)propane, commonly known as Bisphenol A (hereinafter "BPA"), as monomer for the manufacture of plastic materials and articles intended to come into contact with foodstuffs in accordance with the opinions of the Scientific Committee on Food(hereinafter "SCF")<sup>3</sup> and the European Food Safety Authority (hereinafter "the EFSA")<sup>4</sup>.

(2) BPA is used as monomer in the manufacture of polycarbonate plastics. Polycarbonate plastics are used amongst others in the manufacture of infant feeding bottles. When heated under certain conditions small amounts of BPA can potentially leach out from food containers into foods and beverages and be ingested.

OJ L 338, 13.11.2004, p. 4.

OJ L 220, 15.8.2002, p.18.

Opinion of the Scientific Committee on Food on Bisphenol A, expressed on 17 April 2002. SCF/CS/PM/3936 Final 3 May 2002. http://ec.europa.eu/food/fs/sc/scf/out128\_en.pdf

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-BIS(4-HYDROXYPHENYL)PROPANE (Bisphenol A) Question number EFSA-Q-2005-100, Adopted on 29 November 2006, The EFSA Journal (2006) 428, p. 1. and Toxicokinetics of Bisphenol A, Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) (Question No EFSA-Q-2008-382) Adopted on 9 July 2008, The EFSA Journal (2008) 759, p. 1.

- (3) On 29 March 2010 the Danish Government informed the Commission and the Member States that it has decided to apply the safeguard measures provided for in Article 18 of Regulation (EC) No 1935/2004 and to temporarily ban the use of BPA for the manufacture of plastic materials in contact with food intended for children aged 0-3.<sup>5</sup>
- (4) The Danish Government substantiated its safeguard measure with a risk assessment provided on 22 March 2010 by the National Food Institute at the Technical University of Denmark (hereinafter "DTU Food"). The risk assessment covers the evaluation of a comprehensive study carried out on animals exposed to BPA in low doses monitoring the development of the nervous system and the behaviour in new-born rats. DTU Food has also evaluated whether the new data changes its previous evaluation of the toxic effects on the development of the nervous system and behaviour possibly caused by BPA.
- (5) In accordance with the procedure provided for in Article 18 of Regulation (EC) No 1935/2004 on 30 March 2010 the Commission asked the EFSA to give its opinion on the grounds adduced by Denmark for concluding that the use of the material endangers human health, although it complies with the relevant specific measures.
- (6) On 6 July 2010 the French Government informed the Commission and on 9 July 2010 the Member States that it has decided to apply the safeguard measures provided for in Article 18 of Regulation (EC) No 1935/2004 and to temporarily ban the manufacture, import, export and placing on the market of feeding bottles containing BPA<sup>6</sup>
- (7) The French Government substantiated its safeguard measure with two opinions issued by the French Food Safety Authority (AFSSA) on 29 January 2010 and 7 June 2010 and the report published on 3 June 2010 by the National Institute of Health and Medical Research (INSERM).
- (8) On 23 September 2010 the EFSA adopted the opinion of its Panel on food contact materials, enzymes, flavourings and processing aids (hereinafter "the Panel") on BPA responding to the Commission's request of 30 March 2010 as well as covering the evaluation of the specific neurobehavioural study evaluated in the Danish risk assessment and the review and evaluation of other recently published studies on BPA<sup>7</sup>.
- (9) In its opinion the Panel concludes that based on the comprehensive evaluation of recent human and animal toxicity data, no new study could be identified, which would call for a revision of the current tolerable daily intake (hereinafter "TDI") of 0.05 mg/kg bodyweight per day. This TDI is based on the no adverse effect level of 5 mg/kg bodyweight per day from a multi-generation reproductive toxicity study in rats, and the application of an uncertainty factor of 100, which is considered as

Bekendtgørelse om ændring af bekendtgørelse om materialer og genstande bestemt til kontakt med fødevarer, Lovtidende A, Nr.286, 27.3.2010.

LOI n° 2010-729 du 30 juin 2010 tendant à suspendre la commercialisation de biberons produits à base de bisphénol A, JORF n°0150 du 1 juillet 2010, page 11857.

Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF) (Question Nos: EFSA-Q-2009-00864, EFSA-Q-2010-01023 and EFSA-Q-2010-00709) adopted on 23 September 2010, EFSA Journal 2010; 8(9):1829.

conservative based on all information on BPA toxicokinetics. However, in a minority opinion one Member of the Panel concluded that the effects observed in certain studies raised uncertainties which may not be covered by the current TDI which should therefore be considered temporary until more robust data becomes available in the areas of uncertainty.

- (10) The Panel noted that some animal studies conducted on developing animals have suggested other BPA-related effects of possible toxicological relevance, in particular biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours. These studies have many shortcomings. The relevance of these findings in relation to human health cannot be assessed at present. In case any new relevant data becomes available in the future, the Panel will reconsider its opinion.
- (11) Infant formula or breast milk is the only source of nutrition for infants up to the age of 4 months, and it remains the major source of nutrition for some additional months. In its opinion of 2006 the EFSA concluded that infants aged 3 and 6 months fed using polycarbonate infant feeding bottles have the highest exposure to BPA, though below the TDI. For this group of infants the level of exposure to BPA decreases once feeding from polycarbonate bottles is phased out and other sources of nutrition become dominant.
- (12) Even if the infant has sufficient capacity to eliminate BPA at worst case exposure the EFSA opinion pointed out that an infant's system to eliminate BPA is not as developed as that of an adult and it only gradually reaches the adult capacity during the first 6 months.
- The potential toxicological effects may have a higher impact in the developing (13)organism. According to the opinions of the Scientific Committee on Food of 1997<sup>8</sup> and 1998 certain effects, in particular endocrine and reproductive effects, effects on the immune system and the neurodevelopement are of particular relevance to infants. Reproductive effects and neurodevelopmental effects of BPA have been studied extensively in standard multigeneration toxicological tests and in other studies, which took account of the developing organism and did not reveal effects in doses below the TDI. However, studies which could not be taken into account for setting the TDI due to many shortcomings showed BPA related effects of possible toxicological relevance. These effects in particular those on the biochemical changes in the brain, which may affect neurodevelopment and on immune modulation are reflecting the area of particular concern for infants highlighted in the SCF opinions of 1997 and 1998. In addition, the EFSA opinion of 2010 mentions the enhancing effect of an early exposure to BPA on tumour formation later on in life when exposed to a carcinogen. Also in this case the sensitive stage is the developing organism. Thus the infant can be identified as the particular vulnerable part of the population as regards those findings for which the relevance for human health could not yet be fully assessed.

Opinion of the Scientific Committee for Food on: A maximum residue limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children (expressed on the 19th September 1997).

Further advice on the opinion of the Scientific Committee for Food expressed on the 19 September 1997 on a Maximum Residue Limit (MRL) of 0.01 mg/kg for pesticides in foods intended for infants and young children (adopted by the SCF on 4 June 1998).

- (14) According to the EFSA opinion of 2006 polycarbonate feeding bottles is the main source of exposure to BPA for infants. Alternative materials to polycarbonate that do not contain BPA exist on the EU market, in particular glass and other plastic infant feeding bottles. These alternative materials have to comply with the strict safety requirements set out for food contact materials. Therefore, it is not necessary to continue the use of BPA containing polycarbonate for infant feeding bottles.
- (15) Given that there exists a possible particular vulnerability of infants to potential effects of BPA although also the infant is deemed to be able to eliminate BPA and even where the risk, notably to human health, has not yet been fully demonstrated, it is appropriate to reduce their exposure to BPA as much as reasonably achievable, until further scientific data is available to clarify the toxicological relevance of some observed effects of BPA, in particular as regards biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours.
- (16) The Commission evaluated the infant feeding bottle market and received an indication by the relevant producers that voluntary action by the industry for replacements on the market are ongoing and the economic impact of the proposed measure is limited. Therefore, all BPA containing infant feeding bottles on the EU market should be replaced by the middle of 2011.
- (17) The precautionary principle referred to in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>10</sup> allows the Union to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.
- (18) Taking into account that there are uncertainties in the present state of scientific research with regard to the harmfulness of BPA exposure to infants<sup>11</sup> through polycarbonate infant feeding bottles that would need to be clarified the Commission is entitled to take a preventive measure regarding the use of BPA in polycarbonate infant feeding bottles on the basis of the precautionary principle which is applicable in a situation in which there is scientific uncertainty, even if where the risk, notably to human health, has not yet been fully demonstrated.
- (19) Thus, it is necessary and appropriate for the achievement of the basic objective of ensuring a high level of human health protection to obviate sources of danger to physical and mental health that may be caused to infants by BPA exposure through feeding bottles.
- (20) Until further scientific data is available to clarify the toxicological relevance of some observed effects of BPA, in particular as regards biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours, the use of BPA in the manufacture and placing on the market of polycarbonate infant feeding bottles should be temporarily banned. Directive 2002/72/EC should therefore be

OJ L 31, 1.2.2002, p.1.

As defined in Commission directive 2006/141/EC, OJ L 401, 30.12.2006, p.1

- amended accordingly. The Authority has a mandate to monitor new studies to clarify these endpoints.
- (21) Following the evaluation of the technical and economic feasibility to implement the proposed measure it is concluded that the measure is no more restrictive of trade than is required to achieve the high level of health protection chosen in the Union.
- (22) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

#### HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Directive 2002/72/EC is amended as follows:

In Annex II, Section A, the text in column 4 under the reference number 13480 as regards the monomer 2,2-bis(4-hydroxyphenyl)propane is replaced by the following:

"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, p.1

# Article 2

- 1. Member States shall adopt and publish, by [15 February 2011] at latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.
  - When Member States adopt the provisions referred to in paragraph 1, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
- 2. Member States shall apply the provisions referred to in paragraph 1 in such a way as to prohibit from [1 March 2011] the manufacture of and from [1 June 2011] the placing on the market and importation into the Union of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive.
- 3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

# Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission José Manuel BARROSO The President Title:

# 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)

Lead department or agency: Food Standards Agency Other departments or agencies:

# Impact Assessment (IA)

IA No: FOOD0058

Date: 16/12/2010
Stage: Consultation

Source of intervention: EU

Type of measure: Secondary legislation

**Contact for enquiries:** 

Nasreen Shah, Tel: 020 7276 8553 Nasreen.A.Shah@foodstandards.gsi.gov.uk

# **Summary: Intervention and Options**

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

A Directive proposed by the European Commission under the precautionary principle was adopted on 25 November 2010 which will introduce, in the European Union (EU); a phased prohibition on polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using the chemical Bisphenol A (BPA), which is used in plastic materials to provide rigidity. Government intervention will be required to implement the Commission Directive into national law once it has been published formally.

# What are the policy objectives and the intended effects?

The policy objective is to introduce a prohibition on 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 the placing on the market in, and import into, England of such products manufactured using BPA from 1 June 2011. The intended effect is to minimise the exposure of infants of up to 12 months of age in England 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 in age and the placing on the market and import of such products manufactured using BPA in England.

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.

| 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 on 1 June 2012 |
|---|--|
| Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review? | Yes  |

#### **SELECT SIGNATORY Sign-off** For consultation 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: | Chief Executive: | Date: |
|----------------------------|------------------|-------|
|                            | =                |       |

**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 and import of such products manufactured using BPA in England).

| Price Base       | PV Bas | se  | Time Period                   | Net Benefit (Present Value (PV)) (£m) |  |                |                                   |  |
|------------------|--------|-----|-------------------------------|---------------------------------------|--|----------------|-----------------------------------|--|
| <b>Year</b> 2009 | Year N | N/A | Years 10                      | Low: C                                | )ptional   | High: Optional | Best Estimate: £0m                |  |
| COSTS (£r        | n)     |     | Total Tra<br>(Constant Price) | nsition<br>Years                      | Average Annual (excl. Transition) (Constant Price) |                | <b>Total Cost</b> (Present Value) |  |
| Low              |        |     | Optional                      |                                       | Optional   |                | Optional                          |  |
| High             |        |     | Optional                      |                                       | Optional   |                | Optional                          |  |
| Best Estimat     | te     |     | £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 Tra<br>(Constant Price) | ansition<br>Years | Average Annual (excl. Transition) (Constant Price) | <b>Total Benefit</b><br>(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 be | urden (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?  |                   |            | 15 <sup>th</sup> February 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 requirem   | nents?            |            | No                             |                      |  |    |
| What is the CO <sub>2</sub> equivalent change in greenhouse gas (Million tonnes CO <sub>2</sub> equivalent) | Traded: Non-trade |            | raded:<br>N/A                  |                      |  |    |
| Does the proposal have an impact on competition?  |                   |            | No                             |                      |  |    |
| What proportion (%) of Total PV costs/benefits is directl primary legislation, if applicable?               | Costs:<br>£0m     |            |                                | <b>efits:</b><br>£0m |  |    |
| Annual cost (£m) per organisation (excl. Transition) (Constant Price)                                       | Small<br>£0m      | Med<br>£0m | dium<br>1                      | <b>Large</b><br>£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<br>within IA |
|--|--------|-----------------------|
| Statutory equality duties <sup>1</sup>                                     | No     | 15                    |
| Statutory Equality Duties Impact Test guidance                             |        |                       |
| 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  | No     | 15                    |
| Sustainable Development Impact Test guidance                               |        |                       |

<sup>-</sup>

<sup>&</sup>lt;sup>1</sup> 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**

**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       | PV Bas | se Time Period              | Net Be             | nefit (Prese                                       |                |                                   |
|------------------|--------|-----------------------------|--------------------|--|----------------|-----------------------------------|
| <b>Year</b> 2009 | Year N | Years 10                    | Low: C             | Optional   | High: Optional | Best Estimate: -£0.07m            |
| COSTS (£1        | n)     | Total T<br>(Constant Price) | ransition<br>Years | Average Annual (excl. Transition) (Constant Price) |                | <b>Total Cost</b> (Present Value) |
| Low              |        | Optional                    |                    | Optional   |                | Optional                          |
| High             |        | Optional                    |                    | Optional   |                | Optional                          |
| Best Estimat     | te     | £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) | <b>Total Tra</b> (Constant Price) | nsition<br>Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit<br>(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 (%)

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 be | 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?   |       |      | 15 <sup>th</sup> Febr       | 15 <sup>th</sup> February 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 <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent) |       |      | Traded: Non-traded: N/A N/A |                                | raded:           |       |  |
| 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:<br>£0m               |                                | Benefits:<br>£0m |       |  |
| Annual cost (£m) per organisation (excl. Transition) (Constant Price)  | Micro | < 20 | Small                       | Med                            | dium             | 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<br>within IA |
|--|--------|-----------------------|
| Statutory equality duties <sup>2</sup>                                     | No     | 15                    |
| Statutory Equality Duties Impact Test guidance                             |        |                       |
| 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  | No     | 15                    |
| Sustainable Development Impact Test guidance                               |        |                       |

<sup>&</sup>lt;sup>2</sup> 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 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 <sub>0</sub> | Y <sub>1</sub> | Y <sub>2</sub> | <b>Y</b> <sub>3</sub> | <b>Y</b> <sub>4</sub> | <b>Y</b> <sub>5</sub> | <b>Y</b> <sub>6</sub> | <b>Y</b> <sub>7</sub> | Y <sub>8</sub> | <b>Y</b> <sub>9</sub> |
|---------------------------------------|----------------|----------------|----------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------|-----------------------|
| Transition costs                      | £0.07          |                |                |                       |                       |                       |                       |                       |                |                       |
| Annual recurring cost                 |                |                |                |                       |                       |                       |                       |                       |                |                       |
| Total annual costs                    | £0.07          |                |                |                       |                       |                       |                       |                       |                |                       |
| Transition benefits                   |                |                |                |                       |                       |                       |                       |                       |                |                       |
| Annual recurring benefits             |                |                |                |                       |                       |                       |                       |                       |                |                       |
| Total annual benefits                 |                |                |                |                       |                       |                       |                       |                       |                |                       |

<sup>\*</sup> 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**

- A Directive proposed by the European Commission under the precautionary principle was adopted on 25 November 2010 and will introduce, in the European Union (EU), a phased prohibition on 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.
- 2. Government intervention will be required to implement the Commission Directive into national law once it has been published formally.

# **Policy Objective / Intended Effect**

- 3. The policy objective is to:
  - ➤ Introduce a prohibition on 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 the placing on the market in, and import into, England of such products manufactured using BPA from 1 June 2011.

The intended effect is to:

Minimise the exposure of infants in England of up to 12 months of age to BPA.

# **EU Legislation on Plastic Food Contact Materials**

4. 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<sup>3</sup>.

# **Bisphenol A**

- 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 in their manufacture for many years.
- 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 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.
- 7. 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 the Commission Directive**

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.

<sup>&</sup>lt;sup>3</sup> SI 2009 No. 205

9. 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)

- 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. The options were to either prohibit the use of BPA in polycarbonate baby bottles or prohibit the use of BPA in all plastic materials and articles intended to come into contact with infant formula and follow on formula.
- 11. On 25 November 2010, the Commission presented a draft proposal to the Standing Committee on the Food Chain and Animal Health (SCoFCAH); a Commission Directive to introduce a phased ban on polycarbonate feeding bottles intended for infants of up to 12 months of age manufactured using BPA, which was adopted by Qualified Majority.
- 12. The Directive will be published in the Official Journal of the European Communities in due course and will come into force 20 days after its publication. Pending official publication of the Directive, we expect that its main provisions will be as below:
  - ➤ Article 1 will amend 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) will require Member States to adopt the Directive by 15 February 2011.
- > Article 2(3) will require 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.
- 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.
- 14. The Directive, when published, will be available to download free of charge from the following website address at: <a href="http://europa/eu/int/eur-lex/en/index.htm">http://europa/eu/int/eur-lex/en/index.htm</a>. If, contrary to current expectations, the published version should differ in any significant respect from the draft text on which the summary at paragraph 11 is based on; we will issue a further communication to interested parties.

# **Commission Market Evaluation**

15. 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.

# **Proposed National Regulations**

16. The proposed Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011 would implement amendments that the Directive will make to the principal Directive, as detailed in paragraph 11 above.

# **Sectors Affected**

- 17. 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.
- 18. 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>4</sup>) data as a guide).
- 19. 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>5</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             | 29,670  | 3,535    | 1,955 | 1,145      | 36,305 |

Source: IDBR (see footnote 1)

20. 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**

<u>Policy Option 1:</u> 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 of the market and import of such products manufactured using BPA in England.

#### Costs

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

# **Benefits**

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

<sup>&</sup>lt;sup>4</sup> http://www.statistics.gov.uk/idbr/idbr.asp

<sup>&</sup>lt;sup>5</sup> Standard Industrial Classification http://www.statistics.gov.uk/methods\_quality/sic/downloads/sic2007explanatorynotes.pdf

<u>Policy Option 2:</u> 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**

- 23. 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'.
- 24. 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**

- 25. 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.
- 26. 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 provided through informal consultation has 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.

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)

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.

27. 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.

<sup>&</sup>lt;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>&</sup>lt;sup>8</sup>£19.38\*1.3=£25.19

<sup>&</sup>lt;sup>9</sup> SCM methodology <a href="http://www.berr.gov.uk/files/file44503.pdf">http://www.berr.gov.uk/files/file44503.pdf</a>

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.

28. 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

# **Consultation questions:**

- 1. Is the number of businesses affected reflective of infant feeding bottle manufacturers in the UK? We would be grateful for any available evidence on this sector.
- 2. Is the time estimate a reasonable reflection of the time that would be spent by manufacturing firms in familiarisation? If you disagree, please provide evidence to support your views.

# **Production and Testing Costs**

- 29. 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.
- 30. In addition, although evidence suggests that 'tried and tested' alternative products are available, responses from the informal consultation with 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.

# **Consultation question:**

- 3. What is the proportion of BPA free bottles currently manufactured in the UK? We would be grateful for any available evidence.
- 4. If alternatives to BPA are already being used in the manufacture of infant feeding bottles, what are the costs for doing this. Please provide any available evidence.

# Costs of 'write-off'

31. 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 for informal 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.

<sup>&</sup>lt;sup>10</sup> BornFree, Mothercare, Tommee Tippee

32. Despite the potential for such costs to be incurred, responses from informal consultation have suggested that this option would be 'least impactful' on the retail sector because BPA bottles are being phased out, or have already been phased out, by most retailers as a result of consumer preferences. It was further suggested that an additional 6 months to one year on top of the June 2011 deadline would be required for all BPA stock to be 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.

# **Consultation question:**

5. What is the quantity and value of stock that would likely face write-off if an immediate ban were introduced? Please provide evidence to support your views.

# **Negative Spillovers**

- 33. Results from informal consultation have indicated that industry fears that if a ban on BPA in infant feeding bottles is implemented, this could potentially lead to a ban in the use of BPA in other food related products. Evidence<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.
- 34. 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.
- 35. 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.
- 36. A related issue, identified as part of informal consultation, was 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.

# **COSTS TO ENFORCEMENT AUTHORITIES**

# 'One off' Familiarisation Costs

37. 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.

<sup>&</sup>lt;sup>11</sup> Fact Sheet Socio Economic Contribution 0909, Polycarbonate: a major contributor to Europe's Economy and quality of life

<sup>-</sup> Plastics Europe. http://www.bisphenol-a-europe.org/uploads/Lay Socio-economic%20contribution 09092009.pdf

#### **Consultation question**

6. Is 1 hour an accurate representation of the familiarisation time required to ensure enforcement of this option? If you disagree with this assessment, please provide evidence to support your views.

# **BENEFITS**

- 38. In September 2010 the EU food safety advisory body, EFSA<sup>12</sup>, 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 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'.
- 39. There are no incremental benefits to businesses as a result of this option.

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

- 40. 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 13. Under Standard HMT Green book guidance 14 a discount rate of 3.5% is used.
- 41. Total one-off costs for Industry across the UK have been estimated at approximately £70,543m. As there are no benefits to business as a result of this policy these costs are net. This yields an EANC of approximately £8500<sup>15</sup> over 10 years. For England only this represents a one off cost of approximately £61,977 and an EANC of £7500<sup>16</sup> over 10 years.

# **Consultation**

# Within Government

- 42. The Agency carried informal consultation with other Government Departments which have a wider interest in BPA such as the Department for Business Innovation and Skills (BiS), the Department of Environment, Food and Rural Affairs (Defra), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health and Safety Executive (HSE) whilst discussions with the Commission were ongoing.
- 43. Following the SCoFCAH meeting, other Government Departments that had expressed concerns about the possible ban extending the ban on the use of BPA in applications other than food contact materials was unlikely. However, 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.

#### **Public Consultation**

- 44. 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:
- 45. 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

<sup>12</sup> http://www.efsa.europa.eu/

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.

<sup>14</sup> http://www.hm-treasury.gov.uk/data\_greenbook\_index.htm

<sup>15</sup> Please note these figures have been rounded to the nearest £100

<sup>&</sup>lt;sup>16</sup> See footnote 15

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.

- 46. 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.
- 47. 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.
- 48. The trade association representing the UK plastics packaging industry, which includes raw materials producers, additive suppliers and manufacturers of semi-finished plastic products, again, their comments were largely focused on the Commissions 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.
- 49. 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.
- 50. 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. However, given the restrictions in the current Commission proposal specifically deals with a ban on the use of BPA in polycarbonate infant feeding bottles, it is unlikely that ban would be extended to other BPA applications. Thus other sectors are unlikely to be affected by the proposals discussed here. This latter point has been confirmed by the Commission, as reported in the trade press.

# **RISKS AND ASSUMPTIONS**

- 51. 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.
- 52. 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.
- 53. 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.

- 54. 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.
- 55. A PIR Plan will be completed and consulted on when a policy option is finally agreed by the EC.

# **SPECIFIC IMPACT TESTS**

# **COMPETITION**

56. Using the OFT competition assessment framework<sup>17</sup>, it has been established that the preferred policy option 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.

# **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.
- 58. Small and Medium sized businesses are encouraged to respond to issues which they feel may have an impact.

#### **SUSTAINABILITY**

59. 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

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

#### **GENDER EQUALITY ISSUES**

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

# **DISABILITY EQUALITY ISSUES**

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

# **Consultation question:**

7. Do you have any comments on the initial results of the specific tests recorded above?

<sup>&</sup>lt;sup>17</sup> http://www.oft.gov.uk/shared oft/reports/comp policy/oft876.pdf

# Annex 1: Post Implementation Review (PIR) Plan

| <b>Basis of the review:</b> [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];  |
|--|
| <b>Review objective:</b> [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] |
| Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]                                  |
| Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]   |
| Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]  |
| Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection of monitoring information for future policy review]  |
| Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]  |

# **Circulation List**

| Company  |
|--|
|  |
| AMDEA  |
| Alba Plastics  |
| Association of Consumer Research                                 |
| Association of Port Health Authorities                           |
| Bird and Bird  |
| Boots UK Limited   |
| Boots PDQ Centre   |
| British Adhesives and Sealants Association                       |
| British Ceramic Confederation                                    |
| British Coatings Federation                                      |
| British Plastics Federation                                      |
| British Retail Consortium  |
| British Soft Drinks Association                                  |
| British Specialist Nutrition Association                         |
| CATRA  |
| Cadbury Schweppes  |
| Campden & Chorleywood Food Research Association                  |
| Campden & Chorleywood Food Research Association                  |
| Catering Equipment Suppliers Association                         |
| Centre for Analytical Research in the Environment                |
| Chemical Industries Association                                  |
| Chilled Food Association   |
| Colormatrix Europe   |
| Crown Corporate Technologies                                     |
| Dairy Industry Federation  |
| Danapak Flexibles Limited  |
| Department for the Environment, Food and Rural Affairs           |
| Business, Innovation and Skills                                  |
| Dexter Packaging Products  |
| Eclipse Scientific Group   |
| Enterprise Directorate   |
| Federation of Small Businesses                                   |
| The Food and Environment Research Association                    |
| Food And Drink Federation  |
| Food Policy Update   |
| H J Heinz  |
| Halton Borough Council   |
| Home Retail Group  |
| Industry Council for Packaging and the Environment Innovia Films |
| JWP Ltd  |
| Kenwood Limited  |
| Kirkstone Plastics Limited                                       |
|  |
| Laboratory of the Government Chemist                             |

| LACORC                                    |
|---|
| LACORS                                    |
| LINPAC Packaging Limited                  |
| London Port Health Authority              |
| Lovell White Durrant                      |
| Marks & Spencer Plc                       |
| Meridian Speciality Packaging             |
| Metal Packaging Manufacturers Association |
| National Consumer Council                 |
| National Consumers' Federation            |
| Nippon Gohsei                             |
| Office of Fair Trading                    |
| Packaging and Films Association           |
| Pillsbury Europe                          |
| Phillips Avent                            |
| PIRA International                        |
| Plastics Europe                           |
| Provision Trade Federation                |
| Pulse Speciality Products                 |
| RAPRA Technology Limited                  |
| RDA Packaging Consultants                 |
| Rexam Plastic Packaging                   |
| Sainsburys Supermarkets Limited           |
| Sinclair International Limited            |
| Technical Indexes                         |
| The Co-operative Retail Group (CWS) Ltd   |
| The Industrial Packaging Association      |
| Toxicology Advice & Consulting Limited    |
| Trading Standards Institute               |
| UNIVAR Limited                            |
| Weetabix Limited                          |
| WHICH                                     |
| Wilsanco Plastics Limited                 |
|   |