

Title: The proposed Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018

CONSULTATION SUMMARY PAGE

Date launched:	3 April 2018	Closing date:	26 June 2018
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Who will this consultation be of most interest to?
 Businesses that manufacture, import, wholesale and/or retail materials and articles intended to come into contact with food that contain or may contain Bisphenol A, port health authorities, local enforcement authorities, consumers and others who may have in interest in the policy and legislation on food contact materials.

What is the subject of this consultation?
 The drafting of Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 to amend the Materials and Articles in Contact with Food (Wales) Regulations 2012 (“the 2012 Regulations”) to provide for the enforcement in Wales of Commission Regulation (EU) No 2018/213. Regulation 2018/213 regulates the use of Bisphenol A (“BPA”) in varnishes and coatings that come into contact with food and in plastic food contact materials.

What is the purpose of this consultation?
 To seek comments from industry, enforcement authorities, port health authorities, consumers and other interested stakeholders on the proposed Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018.

Responses to this consultation should be sent to:

<p>Andrew Dodd Food Policy Team</p> <p>FOOD STANDARDS AGENCY Tel: 029 2067 8930</p>	<p>11th Floor Southgate House Wood Street Cardiff CF10 1EW Email: Andrew.dodd@food.gov.uk</p>
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Impact Assessment included?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> See Annex A for reason.
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The proposed Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018

DETAIL OF CONSULTATION

Food Standards Agency in Wales (FSA) would welcome your comments on the draft Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (“the proposed Regulations”) (see Annex B)

The proposed Regulations will amend the 2012 Regulations to provide for the enforcement in Wales of Commission Regulation (EU) No 2018/213.

Introduction

The purpose of the proposed Regulations is to –

- Provide for the enforcement of Regulation (EU) 2018/213 in relation to the use of BPA in varnishes and coatings that are in contact with food and in plastic food contact materials.

Proposals

The options being considered are:

Option 1 – To not provide for the enforcement of Regulation (EU) 2018/213 in relation to the use of BPA in varnishes and coatings that are in contact with food and in plastic food contact materials. Not providing for the enforcement of Regulation (EU) 2018/213 in relation to the use of BPA in varnishes and coatings that are in contact with food and in plastic food contact materials would mean that there would not be an enforcement mechanism in Wales in relation to the directly applicable European Regulation on BPA. As an EU Member State, the UK remains obliged to provide for the enforcement of EU legislation. The Welsh Ministers remain under an obligation to comply with EU requirements in relation to Wales.

Option 2 – Provide for the enforcement of Regulation (EU) 2018/213 in relation to the use of BPA in varnishes and coatings that are in contact with food and in plastic food contact materials.

Key proposal(s):

- **Provide for the enforcement of Regulation (EU) 2018/213 in relation to the use of BPA in varnishes and coatings that are in contact with food and in plastic food contact materials.**

Background

Bisphenol A (BPA) is used in the manufacture of certain materials and articles intended to come into contact with food, including polycarbonate, a hard, clear plastic,

which is used in many consumer products and epoxy resins, which act as a protective lining on the inside of some metal-based food and beverage cans.

BPA can migrate into food from the material or article with which it is in contact, resulting in exposure to BPA for consumers of those foods. Some studies suggest that BPA has a range of different possible health effects, including endocrine disrupting properties which are relevant to humans. Endocrine disruptors are chemicals that can interfere with endocrine (or hormone) systems at certain doses.

BPA in varnishes and coatings

On the basis of European Food Safety Authority (“EFSA”) advice, Commission Regulation (EU) 2018/213 has been adopted to set limits for the amount of BPA that may be released from varnishes and coatings used in food contact materials into the food with which they are in contact. As of the Regulation’s application on 6 September 2018, no more than 0.05mg of BPA may be released from varnishes and coatings per kg of food with which they are in contact.

The Regulation further provides that, as a derogation from the above, from 6 September 2018, no migration of BPA shall be permitted from varnishes or coatings specifically intended to come into contact with foods for babies, infants or young children.

Varnished or coated materials that were lawfully placed on the market before 6 September 2018 will be permitted to remain on the market until stocks are exhausted.

The proposed 2018 Regulations will amend the 2012 Regulations to provide for the enforcement of the requirements of Commission Regulation (EU) 2018/213 in relation to BPA in varnishes and coatings.

BPA in plastic food contact materials

Currently, Regulation (EU) No 10/2011 sets out specific requirements for the manufacture and marketing of plastic materials and articles that come into contact with food, including in relation to the use of BPA. Among other things, the Regulation sets a maximum migration limit for BPA of 0.6mg per kg of food with which the plastic is in contact.

Regulation 10/2011 also currently provides that BPA may not be used in the manufacture of polycarbonate infant feeding bottles.

From 6 September 2018, Regulation (EU) No 2018/231 will amend Regulation 10/2011 in relation to BPA use in plastic food contact materials. On the basis of EFSA advice, the BPA migration limit is to be lowered to 0.05mg per kg of food.

The amendments also provide that, in addition to the existing prohibition on the use of BPA in the manufacture of polycarbonate infant feeding bottles, the use of BPA will not be permitted in the manufacture of spill-proof polycarbonate drinking cups or bottles which are intended for infants and young children.

Plastic food contact materials that were lawfully placed on the market before 6 September 2018 will be permitted to remain on the market until stocks are exhausted.

The 2012 Regulations need not be amended to provide for the enforcement of these substantive amendments; they will be captured by the existing ambulatory reference in those Regulations.

The proposed 2018 Regulations will therefore only provide for the enforcement of the transitional provision to ensure that businesses will be permitted to continue marketing plastic food contact materials lawfully placed on the market before 6 September 2018.

Engagement and Consultation Process

Consultation Process

A 12 week public consultation is being launched to provide interested parties with an opportunity to comment on the proposals and its associated impacts. The FSA anticipate that the proposed Regulations will cause minimal impact to a fully compliant society and the main cost arising is likely to be familiarisation costs.

We are particularly keen to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage them to comment on all aspects of the proposal.

Any responses received as part of this consultation will be given careful consideration and a summary of the responses received will be published on our website within three months of publication of the regulation.

Questions asked in this consultation:

Q1: Will implementation of these Regulations affect your business?

If you believe your business or business in your area would be affected by the regulations, please provide us with information on the number of food businesses potentially affected, their location and ideally firm size in terms of the number of employees.

Q2: Do you consider that the policy/proposed Regulations will have an effect on opportunities for use of the Welsh language?

Q3: We would like to know your views on the effects that the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 would have on the Welsh language, specifically on:

- i) opportunities for people to use Welsh and**
- ii) on treating the Welsh language no less favourably than English.**

Q4: What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Other relevant documents

The Materials and Articles in Contact with Food (Wales) Regulations 2012 are available to download free of charge from the legislation.gov.uk website at:

<http://www.legislation.gov.uk/wsi/2012/2705/contents/made>

Commission Regulation (EU) 2018/213 is available to download free of charge from the EURlex website at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018R0213&from=EN>

Responses

1. **Responses are required by close 26 June 2018**. 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).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Andrew Dodd
Food Policy Team
Food Standards Agency Wales

Enclosed

Annex A: Standard Consultation Information

Annex B: Statutory Instrument

Annex C: Impact Assessment

Annex D: List of interested parties

Annex A

Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the [FSA Consultation Coordinator](#) (020 7276 8308). The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. 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 <http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc> 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 C. 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. A Welsh version of the consultation package can be found at www.food.gov.uk
7. Please contact us if you require this consultation in an alternative format such as Braille or large print.
8. This consultation has been prepared in accordance with HM Government consultation principles¹.

¹ <http://www.bis.gov.uk/policies/bre/consultation-guidance>

Annex B

W E L S H S T A T U T O R Y I N S T R U M E N T S

2018 No. (W.)

FOOD, WALES

The Materials and Articles in Contact with Food (Wales) (Amendment)
Regulations 2018

EXPLANATORY NOTE

(This note is not part of the Regulations)

2018 No. (W.)

FOOD, WALES

**The Materials and Articles in Contact with Food (Wales) (Amendment)
Regulations 2018**

Made ***

*Laid before the National Assembly for Wales****

Coming into force ***

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), 2(a) and (3) and 48(1) of the Food Safety Act 1990⁽²⁾.

In accordance with section 48(4A)⁽³⁾ of the Food Safety Act 1990, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency before making these Regulations.

There has been open and transparent public consultation during the preparation and evaluation of these Regulations 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⁽⁴⁾.

Title, application and commencement

1.—(1) The title of these Regulations is the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018.

(2) These Regulations apply in relation to Wales.

(3) These Regulations come into force on XX.

Amendment of the Materials and Articles in Contact with Food (Wales) Regulations 2012

2. The Materials and Articles in Contact with Food (Wales) Regulations 2012⁽⁵⁾ are amended in accordance with regulations 3 to 8.

3. In regulation 2 (interpretation)—

(a) in paragraph (1), after the definition of “Regulation 10/2011” insert the following definition—

““Regulation 2018/213” (“*Rheoliad 2018/213*”) means Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and

⁽²⁾ 1990 c. 16. Section 16(2) was amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”). Section 17(1) and (2) was amended by paragraphs 8 and 12(a) of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 48 was amended by paragraph 8 of Schedule 5 to the 1999 Act. Functions formerly exercisable by the “the Ministers” so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by 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 (c. 32).

⁽³⁾ Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.

⁽⁴⁾ OJ No L 31, 1.2.2002, p 1, as last amended by Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ No L 117, 5.5.2017, p 1).

⁽⁵⁾ S.I. 2012/2705 (W. 291), amended by S.I. 2017/832 (W. 202).

amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials⁽⁶⁾;

- (b) in paragraph (2), for “Regulation 450/2009 or Regulation 10/2011” insert “Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213”.

4. After regulation 17 (competent authorities for the purposes of Regulation 1895/2005) insert—

“PART 7A

Requirements for bisphenol A in varnishes and coatings intended to come into contact with food

Interpretation of Part 7A

17A. In this Part any reference to a numbered Article is a reference to the Article so numbered in Regulation 2018/213.

Offences of contravening specified provisions of Regulation 2018/213

17B. Subject to the transitional provisions contained in Article 6, any person who places on the market a material or article that fails to comply with Article 2 is guilty of an offence.

Competent authorities for the purposes of Regulation 2018/213

17C. The competent authorities for the purposes of Article 4(3) are the Food Standards Agency and each food authority in its area.”

5. In regulation 19 (offences and penalties)—

- (a) in paragraph (2), for “Regulation 10/2011” substitute “Regulation 10/2011, Regulation 2018/213”;
- (b) in paragraph (5)(a), for “or 16(4)” substitute “, 16(4) or 17B”.

6. In regulation 24(2) (general defences), for “16(4)” substitute “16(4), 17B”.

7. In regulation 27(1)(a) (application of various provisions of the Act), after sub-paragraph (v), insert—

“(vi) Article 4 of Regulation 2018/213; and”.

8. In Schedule 2, in Part 1 (modification of section 10), in section 10(1A) as applied, after paragraph (e) insert—

“(f) Article 4 of Regulation 2018/213”.

Name

Title of Minister, one of the Welsh Ministers

Date

⁽⁶⁾ OJ No L 41, 14.2.2018, p 6.

Annex C

Title: THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (WALES) (AMENDMENT) REGULATIONS 2018 IA No:	Impact Assessment (IA)
	Date: March 2018
	Stage: Consultation
	Source of intervention: EU
	Type of measure: Secondary legislation
Contact for enquiries:	
Summary: Intervention and Options	
RPC Opinion: RPC Opinion Status	

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present	Net cost to business per year	One-In, Three-Out	Business Impact Target Status
£-0.00m	£-0.00m	£0.0m	Not in scope	Qualifying provision

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

Unregulated transfer of chemicals from materials and articles intended to come into contact with food may potentially create a negative cost to others such as the National Health Service, through detrimentally affecting consumer health. Consumers are unable to assess the risks involved when consuming a product that has been in contact with food contact materials because they cannot observe the level of chemical migration and do not have the full information to make informed choices about such risk. Government intervention to regulate reduces the chronic and acute health risks to consumers arising from chemical migration from food contact materials into the food they eat.

What are the policy objectives and the intended effects?

To provide for the execution and enforcement by enforcement authorities in Wales of Commission Regulation (EU) No. 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do Nothing – Do not provide for the enforcement and execution of Commission Regulation (EU) No. 2018/213. This option could lead to the UK being liable to infraction proceedings by the European Commission.

Option 2 – Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EU) No. 2018/213.

Option 2 is the preferred option as it meets all the policy objectives.

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Will the policy be reviewed? The policy will be reviewed on an ongoing basis. There is no specific review period. If applicable, set review date:				
Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	Micro Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: N/A		Non-traded: N/A

DRAFT

Description: Option 1: Do Nothing – Do not provide for the enforcement and execution of Commission Regulation (EU) No. 2018/213.

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate					
Description and scale of key monetised costs by ‘main affected groups’					
There are no monetised incremental costs associated with this option. This is the baseline against which other options are assessed.					
Other key non-monetised costs by ‘main affected groups’					
There are no monetised incremental costs associated with this option. This is the baseline against which other options are assessed.					
BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Benefit (Present Value)
Low	Optional		Optional		Optional
High	Optional		Optional		Optional
Best Estimate					
Description and scale of key monetised benefits by ‘main affected groups’					
There are no monetised incremental benefits associated with this option. This is the baseline against which other options are assessed.					
Other key non-monetised benefits by ‘main affected groups’					
There are no monetised incremental benefits associated with this option. This is the baseline against which other options are assessed.					
Key assumptions/sensitivities/risks					
Costs of infraction may result from failure to provide for the enforcement of the Commission Regulation.					

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Costs: 0.0			Score for Business Impact Target (qualifying provisions only) £m:
Benefits: 0.0	Net: 0.0		
			0.0

Summary: Analysis & Evidence Policy Option 2

Description: Option 2 – Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EU) No. 2018/213.

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -0.00

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.00	0.0	0.00

Description and scale of key monetised costs by ‘main affected groups’

Industry and Enforcement Authorities will face one-off familiarisation costs with the one EU Regulation and the amendment to the 2012 Wales Regulations. For Wales only, these amount to Industry costs of £3,060 (an Annual Equivalent Cost of £355.50) and Public-sector costs of £1,264.90 (an Annual Equivalent Cost of £146.95).

Other key non-monetised costs by ‘main affected groups’

Some industry sectors may face costs of assessing compliance with the migration limit for bisphenol A from varnishes or coatings applied to food contact materials.

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

Description and scale of key monetised benefits by ‘main affected groups’

No monetised benefits have been identified.

Other key non-monetised benefits by ‘main affected groups’

Key assumptions/sensitivities/risks

Proportion of micro, small, medium and large firms in the UK is assumed the same for each country.

3.5

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0.0	Benefits: 0.0	Net: 0.0	
			0.0

Evidence Base (for summary sheets)

Problem under consideration and rationale for intervention

1. The unregulated migration of chemicals from materials and articles intended to come into contact with food may potentially create a negative cost to others such as the National Health Service, through detrimentally affecting consumer health. Consumers are unable to assess the risks involved when consuming a product that has been in contact with food contact materials because they cannot observe the level of chemical migration and do not have the information to make informed choices about such risks.
2. Government intervention to regulate such products reduces the chronic and acute health risks to consumers arising from chemical migration from food contact materials into the food they eat. The proposed Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (“the proposed Regulations”) will amend the Materials and Articles in Contact with Food (Wales) Regulations 2012 (“the 2012 Regulations”) to provide enforcement authorities with the necessary powers for the execution and enforcement of the provisions of the European Regulation mentioned below. This provides for the continuation of consumer protection against migration of chemicals from food contact materials that could carry an unacceptable long-term risk to consumer health.
3. Commission Regulation (EU) No. 2018/213⁷ on the use of bisphenol A (BPA) in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No. 10/2011 (“the BPA Regulation”) entered into force on the twentieth day following that of its publication in the OJ and will be applicable from 6 September 2018. The BPA Regulation sets a lower specific migration limit (SML) for the use of BPA in plastic food contact materials than is currently provided for in Regulation (EU) 10/2011 and extends this to BPA use in varnishes and coatings applied to materials and articles intended to come into contact with food. It also bans the use of BPA in varnishes and coatings for food contact materials intended to come into contact with food for babies/infants/young children and in polycarbonate drinking cups which due to their spill proof characteristics are intended for infants and young children.
4. The BPA Regulation requires that varnished or coated materials and articles containing BPA should be accompanied with a Declaration of Compliance (DoC), which should be renewed to reflect any changes in the migration levels from the varnish or coating that has been applied to materials and articles. A “Declaration of Compliance” is a document that provides assurance to a customer that the material or article complies with the legislation.

Policy objective

5. The proposed Regulations will amend the 2012 Regulations. The purpose of this proposal is to meet several policy objectives:

⁷ OJ Ref L41, 14.02.2018, pg. 6: full title: Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No. 10/2011 as regards the use of that substance in plastic food contact materials

- to provide for the execution and enforcement in Wales of Commission Regulation (EU) No. 2018/213 on bisphenol A
 - provide for offences of contravening certain provisions of the European Regulation
 - specify the penalties that the Courts may impose upon conviction for an offence
6. For the BPA Regulation, one new criminal offence will be created:
- Failure to comply with migration limit for varnishes and coatings applied to materials and articles

Background

7. The general principles governing the safety of all materials and articles intended to come into contact with food are established in Regulation (EC) No. 1935/2004⁸ of the European Parliament and of the Council (“the Framework Regulation”).

Requirements for bisphenol A (BPA) in varnishes and coatings intended to come into contact with food

8. BPA is a chemical substance used in the manufacture of certain food contact materials such as plastic (polycarbonates) and coatings (epoxy resins). Polycarbonate is mainly used in food contact applications such as water cooler bottles based on the properties that it provides compared to other plastics. BPA-based epoxy resin is used to make the coatings applied to the inside of metal food and beverage cans to act as a barrier to protect the surface of the packaging material from damage from certain foods.
9. In accordance with Article 6 of the Framework Regulation, some member states have adopted national provisions in those areas for which specific measures have not been established at European level.
10. Due to these divergent rules in some Member States, the Commission felt it necessary to introduce a specific measure on the use of BPA in coatings and varnishes applied to food contact materials. This Regulation sets a Specific Migration Limit (SML) of 0.05mg/kg for the migration of BPA from varnishes and coatings applied to food contact materials. This SML is derived from the temporary tolerable daily intake (t-TDI) that EFSA set for BPA in 2015.⁹ The t-TDI takes account of some remaining uncertainties in relation to potential health effects and exposure estimates and therefore the precautionary principle is applied. It is expected that on-going long-term research will help to reduce these uncertainties.
11. EFSA concluded that the dietary exposure to BPA for the highest exposed groups, which includes infants, children and adolescents, is below the t-TDI, indicating that there is no health concern at the estimated levels of exposure. The BPA Regulation amends Regulation (EU) 10/2011, which sets migration limits for plastic food contact materials, reducing the existing SML for BPA from plastic food contact materials and articles so it is in line with the SML for BPA from varnishes and coatings.
12. The BPA Regulation also specifies that there shall be no permitted migration of BPA from varnishes or coatings applied to materials and articles specifically intended to come into contact with either infant formula, follow-on formula,

⁸ OJ Ref L338, 13.11.2004, pg. 4-17

⁹ A tolerable intake is the amount of a substance that can be consumed over a lifetime without presenting an appreciable risk to health.

processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, or milk-based drinks and similar products specifically intended for young children.

1) We invite stakeholders to comment on our assessment that there may be costs associated with testing to demonstrate compliance with the new migration limits for BPA from coatings and varnishes. If you agree or disagree with this assessment, please provide evidence to support your views.

Sectors affected

13. We have used the Interdepartmental Business Register (IDBR) to identify which sectors and industries may be affected by the policy. The IDBR is a comprehensive register of UK businesses, covering 99% of UK economic activity. The data in the register is structured by the UK Standard Industrial Classification of Economic Activities (SIC 2007). Given the aggregate nature of the IDBR, it has been difficult to identify precise subsectors that will be affected by the proposed Regulations. This means that the sectors identified and used in the analysis will be larger (in terms of number of businesses affected) than number affected by the policy. For example: “manufacture of plastic packing goods” SIC 22.22 refers to all plastic packaging manufacture not exclusively those in contact with food. To minimise the impact of these uncertainties we have provided sensitivity analysis around the final costings (sector size of 50% and 80%, respectively, of the actual sector size in the available data), see Annex Table 2. The central estimate of 80% (which remains conservative) is used to calculate the best estimate of the costs and benefits.

Industry

The BPA Regulation

14. The FSA does not envisage that a reduction in the specific migration limit for BPA from plastics will change the existing cost of compliance for plastic manufacturers. There will be a cost for businesses associated with testing for compliance with the new SML for BPA from varnishes and coatings applied to food contact materials and articles. However, at present businesses are still required to demonstrate compliance with the Framework Regulation on food contact materials, Regulation No.1935/2004.

This Impact Assessment is for businesses in Wales only and all costs and benefits are provided for Wales. However, as changes to the legislation in Wales will require similar changes to be enacted in each administration we have provided analysis for England, Wales and Northern Ireland; Tables 1 and 2 summarise the distribution of the sectors that are affected by the proposed Regulation.

Table 1: Option 2 - Sectors affected by the Regulation by Country

	England	Wales	Northern Ireland	Total
Food canners/coatings manufacturers (2529, 2592, 2561)	1325	60	40	1425

Source IDBR 2016. For details and SIC codes see Annex 3

Table 2: Option 2 - Sectors affected by firm size for UK

Firm Size	Micro	Small	Medium	Large	Total
Food canners/coatings manufacturers (2529, 2592, 2561)	847	456	108	14	1425

2) We invite stakeholders to comment on whether we have adequately captured the nature of the UK market or not. If not, please provide us with an approximation of the number of firms affected and their size in terms of number of employees.

Enforcement bodies

15. Enforcement authorities will also be affected by the proposed Regulations as they will be responsible for providing for the enforcement of the BPA Regulation. There will also be one-off costs to enforcement bodies for familiarisation with the proposed domestic Regulations and the EU Regulation. Table 3 shows the number of enforcement authorities that are affected by the Regulation. This includes Local Authorities (LAs), Port Health Authorities (PHAs) and Official Control Laboratories (OCLs).

Table 3: Number of LAs, PHAs and public OCLs in each country

	England	Wales	Northern Ireland
LA	353	22	11
PHA	34	2	0
OCL	16	6	1

Source: FSA internal data

Options Considered

Option 1: Do not provide for the enforcement and execution of Commission Regulation (EU) No. 2018/213.

16. Under this option, the directly applicable European Regulation would still be applicable in Wales and the rest of the UK. However, enforcement authorities in Wales would not have the necessary powers to enforce certain provisions, which could consequently have adverse impacts on public health. Non-compliance with these legal requirements could not be prevented and penalties could not be imposed on those in breach of the requirements. The UK's obligation (under the Treaty on the Functioning of the European Union) to put in place provisions for its enforcement would not be fulfilled which could lead to the UK being subject to infraction proceedings.

Option 2: Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EU) No. 2018/213.

17. This option will provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the EU Regulation in Wales. This ensures that enforcement authorities fulfil the requirement placed upon them and that the Courts can impose the associated penalties.

Options Appraisal

Costs and Benefits

Option 1: Do not provide for the enforcement and execution of Commission Regulation (EU) No. 2018/213.

18. There are no relatable costs or benefits associated with this option to the main affected groups. This is the baseline against which the other policy option is appraised. There is however the risk of costs as a result of infraction proceedings as a failure to implement the enforcement provisions of the Commission Regulation.

Option 2: Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EU) No. 2018/213.

19. This is the preferred option as it will enable the execution and enforcement of the European Regulation in Wales.

Costs - Option 2

Industry

Familiarisation (one-off costs)

20. Under Option 2, there will be a one-off cost to industry for reading and familiarising themselves with the new BPA Regulation and the proposed Regulations. The businesses affected under this Option are:

A] coatings manufacturers, can makers and food canners.

A] Familiarisation costs for coatings manufacturers, can makers and food canners

We have assumed that it is the production manager that will be responsible for familiarisation. The median hourly wage rate of a production manager is £25.50¹⁰. We assume that one production manager per business will be required for familiarisation. We estimate that familiarisation will take in total two hours, one hour for familiarisation with the amendments and another hour to disseminate the information within the organisation. This results in a total familiarisation cost per business of £51.00. Multiplying this by the total number of businesses in Wales results in a total familiarisation cost for the BPA Regulation of £3,060. Table 4 presents total familiarisation costs by firm size and UK country and Table 5 presents familiarisation costs as annual equivalent costs:

Table 4: Familiarisation costs for coatings manufacturers, can makers and food canners

	Micro	Small	Medium	Large	Total
England	£40,143.56	£21,632.92	£5,129.46	£669.06	£67,575
Wales	£1,817.82	£979.60	£232.28	£30.30	£3,060
NI	£1,211.88	£653.07	£154.85	£20.20	£2,040

Table 5: Annual Equivalent Costs (AEC) for coatings manufacturers, can makers and food canners

	England	Wales	Northern Ireland	Total
AEC (£)	£7,850.54	£355.50	£237.00	£8443.04

Table Notes:

1. Totals may not sum due to rounding.
2. Due to the aggregated nature of IDBR, some subsectors covered by the analysis will be larger than the actual subsection covered by the policy. The IDBR does not disaggregate data by sector, business size and country simultaneously. These categorisations are therefore estimated based on the proportion of businesses in each country, for each size of business.
3. Costs are estimated by uplifting wage rates by 20% to account for overheads; this means the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in rounding error.

3) We welcome stakeholders' comments on whether our estimates of familiarisation costs to industry (outlined in Tables 1, 2 and 3) and our assumption that it will take businesses up to one hour to familiarise themselves with the requirements of the EU Regulation and one hour to disseminate to other members of staff (two hours in total) is reasonable.

If you agree or disagree with our assumptions, please provide evidence to support your view.

Other Costs

BPA

21. The introduction of a SML for migration of BPA from coatings and varnishes applied to food contact materials has cost implications with regards to migration testing and possibly the frequency of such tests. The coatings industry has said that they will no longer be able to use total extraction to measure the migration of BPA.
22. Despite the costs of compliance, the industry is very keen to see this measure adopted as it will lead to harmonisation of the internal market, which is expected to outweigh their costs.

Enforcement authorities

Familiarisation (one-off costs)

23. There will be a one-off cost to Enforcement Authorities (EAs) for reading and familiarising themselves with the new Regulations. Local Authorities (LAs) and Port Health Authorities (PHAs) are responsible for enforcing food safety and food hygiene legislation in their respective areas and as such, will need to be aware of the legislative changes. In addition, there will also be a one-off cost to Official Control Laboratories (OCLs) for reading and familiarising themselves with the changes to testing requirements.
24. Familiarisation costs are quantified by multiplying the time it will take for an official to familiarise themselves with the Regulations by the wage rate of the official and the number of enforcement authorities or laboratories affected. A two-hour familiarisation time for all enforcement authorities and OCLs was used.

25. For LAs and PHAs, either an Environmental Enforcement Officer (EEO) or a Trading Standards Officer (TSO) will be required to familiarise themselves with the new enforcement provisions. To account for the differences across enforcement authorities¹¹, wage rates for both TSOs and EEOs are used to produce a range of values for hourly pay. As the lower bound we have used the median hourly wage of a TSO (£17.83¹²) and as the upper bound the median hourly wage rate of a EEO (£22.76¹³). This gives us a central estimate of £20.30. For all sensitivity analysis, see Annex 1.
26. For OCLs we have used an Annual Survey of Hours and Earnings (ASHE) median wage estimate for a science and technology professional of £20.18 which increases to £24.22 when adjusted for overheads.
27. We have estimated that that one enforcement officer per EA and one science professional per OCL is required for familiarisation.

For LAs and PHAs, this results in a lower bound familiarisation cost of £35.66 and an upper bound familiarisation cost of £45.53 and a central (mid-point) estimate of £40.60 per authority. For OCLs the familiarisation cost per authority is £48.43. Multiplying the cost per authority by the number of authorities, taking into account the wage differences between PHAs/LAs and OCLs, results in a total familiarisation cost to UK enforcement of £18,245.45. Table 6 presents the familiarisation costs by country.

For one-off costs to be compared with annual costs on an equivalent basis across the entire time span of the policy, one-off costs are transformed into Annual Equivalent Costs (AEC) by dividing the one-off cost by an annuity factor.

The total one-off cost to enforcement authorities and OCLs in Wales affected by this proposal is estimated to be £1,264.90 which yields an annual equivalent cost of £146.95 for a period of 10 years. Table 6 presents familiarisation costs as annual equivalent costs.

Table 6: Table summarising the familiarisation costs by country

	England	Wales	Northern Ireland	Total
LA	£14,330.39	£893.11	£446.56	£15,670.06
PHA	£1,380.26	£81.19	£0.00	£1,461.45
OCL	£774.91	£290.59	£48.43	£1,113.93
Total	£16,485.56	£1,264.90	£494.99	£18,245.45

¹¹ Note that TSOs or EEOs may be responsible for enforcing this legislation depending on resource in each local authority

¹²

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010asetable14> Includes an overhead of 20% (14.86*1.2=17.83)

¹³

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010asetable14> Includes an overhead of 20% (18.97*1.2=22.76)

Table Notes:

1. Totals may not sum due to rounding.
2. Costs are estimated by uplifting wage rates by 30% to account for overheads; this means the wage rates reported in the text are approximate to 2 decimal places and when grossed may result in rounding error.

Table 7. Annual Equivalent Costs (AEC) for enforcement authorities by UK country

	England	Wales	Northern Ireland	Total
AEC (£)	£1,915.21	£146.95	£57.51	£2,119.67

4) We invite stakeholders' comments on whether our estimates of familiarisation costs to enforcement bodies and official control laboratories (outlined in Table 6) and our assumption that it will take enforcement bodies and official control laboratories one hour to familiarise themselves with the requirements of the EU Regulation, and one hour to disseminate to other members of staff (two hours in total) is reasonable.

If you agree or disagree with our assumptions, please provide evidence to support your views.

Benefits - Option 2

Industry

28. Having all the legislation in one place is helpful for smaller businesses as long as they are given confidence there is only one overarching piece of legislation they need to reference to ensure compliance. Without this reassurance there will be concern that an amendment such as this may be missed.

Enforcement authorities

29. The amendment will provide for the execution and enforcement in Wales of Commission Regulation (EU) No. 2018/213 on bisphenol A;
30. As with business, Local Authorities have expressed the attitude that a single consolidated piece of legislation is a benefit as it provides clarity on the EU Regulations they provide enforcement for. They are unlikely to miss the new requirements due to fragmentation of the legislation and will provide the clarity as to their powers to enforce the new European legislation.

Consultation

Within Government

31. Agreement was sought on the negotiating position on key issues throughout EU negotiations relating the BPA Regulation from the relevant government departments:

1. Department of Health and Social Care (formally Department of Health)
2. Department for Business Energy and Industrial Strategy (formally Department for Business, Innovation and Skills)
3. Foreign and Commonwealth Office
4. Cabinet Office
5. Department for Exiting the European Union
6. Department for Environment, Food and Rural Affairs

Each department was updated with progress reports with no adverse comments received to date.

57. During the course of negotiations with the Commission, FSA officials have frequently conveyed information to interested organisations, including industry, research institutes, consumer groups, enforcement bodies, public analysts and others with an interest in policy issues related to food contact materials.
58. The FSA continued to hold informal discussions with stakeholders whilst keeping in touch with developments at the EU level. In 2014, the FSA wrote to local authorities and other government departments to help identify who would be best placed to perform the official controls.
59. In 2017, the Commission and EFSA welcomed comments via a public consultation on the draft BPA Regulation. The FSA actively encouraged stakeholder participation in the consultation. For the BPA Regulation, there was the option for stakeholders to share their views via the FSA rather than responding directly to the consultation platform. This helped to inform the UK on its negotiation position on BPA.
60. EFSA had also carried out separate public consultations on BPA in 2013 and 2014, which focussed specifically on general BPA human exposure and BPA toxicology, respectively. Almost 500 comments from European stakeholders were received from these earlier consultations.

Formal Consultation

61. The FSA will conduct a formal public consultation from 3 April 2018. Businesses that manufacture, import, wholesale and/or retail materials and articles intended to come into contact with food, PHAs, Local Enforcement Authorities, consumers and others who may have an interest in the policy and legislation on food contact materials will be asked a number of questions.

Wider Impacts

Small & micro business assessment

62. The UK food and drink packaging industry sector is comprised of mainly small and micro businesses and therefore the greatest impact from changes in from the new EU Regulation introduced in the UK will, in the clear majority of cases, be on small and micro businesses. For this reason, the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

63. The food and drink packaging industry is highly fragmented and diverse and is served by many suppliers. In 2003¹⁴, a study of the UK's packaging industry identified 13,000 packaging companies in the UK, combined they employ 250,000 people. The study also revealed that half of all packaging companies have a turnover less than £10 million, and that 85% are small to medium size enterprises. It should be noted however, that not all the packaging would be destined as food packaging.
64. In 2001, the industry employed approximately 100,000 people in around 2,700 companies – 85% of which are described as small-to micro-sized companies. The potential commercial impact of the proposals applies equally to all businesses involved small or large.
65. EU legislation generally applies to food businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. Due to the high ratio of small and micro food businesses in the UK it is often not feasible to exempt smaller businesses from new food measures as this would fail to achieve the intended effect of reducing risks to consumer health. That said, the FSA makes every effort to minimise burdens on small and micro businesses and pays particular attention to impacts on them.

5) We invite stakeholders' comments on whether or not you agree with our assumption that there will not be a significant impact on small or microbusinesses as a result of this legislation.

If you agree or disagree with this assessment, please provide evidence to support your response.

Race/Gender/Disability Equality Issues

66. There will be no impacts on existing health, wellbeing or other social inequalities, on human rights, on levels of crime or crime prevention, or on skills and education. There will be no differential impact on rural or urban areas, nor are there any specific local or regional effects.

6) We welcome stakeholder's comments on whether you are aware of any other impacts as a result of the EU Regulation and national Regulations?

Please provide evidence to support your response.

¹⁴ Mintel, March 2003

Annex 1

Sensitivities of One-off Familiarisation Costs under Different Wage Rates (Central, Low or High) per LA, PHA and OCL by Country

	England	Wales	Northern Ireland
LA	353	22	11
PHA	34	2	0
OCL	16	6	1
Familiarisation Cost LA			
Low	£12,589.39	£784.61	£392.30
Central	£14,330.39	£893.11	£446.56
High	£16,071.38	£1,001.62	£500.81
Familiarisation Cost PHA			
Low	£1,212.58	£71.33	£0.00
Central	£1,380.26	£81.19	£0.00
High	£1,547.95	£91.06	£0.00
Familiarisation Cost OCL			
Central	£774.91	£290.59	£48.43
Total (Low)	£14,576.88	£1,146.53	£440.74
Total (Central)	£16,485.56	£1,264.90	£494.99
Total (High)	£18,394.25	£1,383.26	£549.24

Annex D

Welsh Government
Ty Nant Spring Water Limited
Cardiff Metropolitan University
Minton, Treharne & Davies Limited
The Patchwork Traditional Food Company
Welsh Hills Bakery
Castell Howell Foods Ltd
Gwaun Valley Meats
OP Chocolate Ltd
Lewis Fine Foods Ltd
GRH Food Company Ltd
Menter a Busnes
Food Centre Wales
Uren Food Group Ltd
Dailycer Ltd
Drink Pac UK Ltd
Tate and Lyle Food Systems
Otley Brewing Company Ltd
One Stop Stores Limited
Abergavenny Fine Foods Ltd
Prince's Gate Spring Water
Rhydwen Bakery
Mark Hunter Ltd
Cranberry Foods Limited
Zero2Five
Coleg Menai
Welsh Local Government Association (WLGA)