

Title: THE PROPOSED MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2018

CONSULTATION SUMMARY PAGE

Date launched:	23 April 2018	Closing date:	18 June 2018
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Who will this consultation be of most interest to?
 Businesses that manufacture, import, wholesale and/or retail plastic; intended to come into contact with food; and varnishes and coatings. Local enforcement authorities; consumers and other interested stakeholders, who may have an interest in the policy and legislation on food contact materials.

What is the subject of this consultation?
 The proposed Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2018 will amend the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012 to provide for the execution and enforcement, of [Commission Regulation \(EU\) No. 2018/213](#) which regulates the use of Bisphenol A (BPA) in varnishes and coatings intended to 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, consumers and other interested stakeholders on the proposed Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2018 and the related Impact Assessment.

Responses to this consultation should be sent to:

Executive Support Unit FOOD STANDARDS AGENCY Tel: +44 (0)28 90417700	Postal address: Food Standards Agency 10a-10c Clarendon Road, Belfast BT1 3BG Email: executive.support@food.gov.uk
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Impact Assessment included?	Yes X	No
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The Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2018

Detail of Consultation

1. We welcome your comments on the proposed Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2018 (“the proposed Regulations”) (Annex B).
2. The purpose of the proposed Regulations is to provide for the enforcement in Northern Ireland of [Regulation \(EU\) 2018/213](#) in relation to the use of Bisphenol A (BPA) in varnishes and coatings that are in contact with food and in plastic food contact materials.
3. The proposed Regulations will amend the existing [Materials and Articles in Contact with Food Regulations \(Northern Ireland\) 2012 \(“the 2012 Regulations”\)](#)
4. The FSA in England and Wales and Food Standards Scotland will be carrying out similar consultations relating to their regions.

Proposals

5. The options being considered are:

Option 1 – Do 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 Northern Ireland 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.

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

6. Regulation (EC) No. 1935/2004¹ of the European Parliament and of the Council (“the Framework Regulation”) lays down the general safety rules for all materials and articles intended to come into contact with food. Article 5(1) of the Framework Regulation allows for specific measures for groups of materials and articles.

7. 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

¹ OJ Ref L338, 13.11.2004, pg. 4-17 Available to download from the Eur-Lex website.

food and beverage cans to act as a barrier to protect the surface of the packaging material from damage from certain foods.

8. 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.

The BPA Regulation

BPA in varnishes and coatings

9. On the basis of European Food Safety Authority (“EFSA”) advice, Commission Regulation (EU) 2018/213 has been adopted to set a specific migration limit (SML) 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.

10. The Regulation also specifies that, as a derogation from the above, from 6 September 2018 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, 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.

11. The 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 DoC is a document that provides assurance to customers that the material or article complies with the legislation.

12. 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.

13. 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

14. 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.

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

16. 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.

17. 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.

18. 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.

19. The 2012 Regulations do not require an amendment to provide for the enforcement of these substantive amendments; they will be captured by the existing ambulatory reference in those Regulations.

20. 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.

The Consultation Process

21. An 8-week public consultation is being launched to provide interested parties in Northern Ireland with an opportunity to comment on the proposals and its associated impacts. The FSA anticipate that the proposed Regulations will cause minimal impact to industry and enforcement. The main costs arising are likely to be one-off familiarisation costs and possible costs associated with testing to demonstrate compliance with the new migration limits for BPA from coatings and varnishes. Further details can be found in our Impact Assessment at Annex C.

22. Any comments that you can provide in relation to the proposed Regulations would be gratefully received. We are particularly interested to hear from small and medium sized enterprises on the likely impact of the Regulations and will particularly appreciate your comment on all aspects of this proposal.

23. Following the consultation, we will review the responses received and consider what impact the proposed Regulations will have. A summary of all comments received will be published on our website within three months of the end of the consultation.

Consultation Questions

24. We particularly welcome responses to the following questions, along with any evidence that you can provide to support your views:

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 agree with 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

Responding to the Consultation

25. Responses are required by close of business 18 June 2018. Please state in your response whether you are responding as a private individual, or on behalf of an organisation (including details of any stakeholders your organisation represents) or company.

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

Annie Chambers
Standards and Dietary Health

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Statutory Rule – The Proposed Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2018

Annex C: Impact Assessment

Annex D: List of interested parties

Annex A - Publication of personal data and confidentiality of responses

1. The European General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC and was developed to harmonize data privacy laws across Europe. In accordance with the GDPR, we are required to provide a privacy notice in relation to this public consultation. The Food Standards Agency will be known as the “Controller” of the personal data provided to us. We need to collect this information to allow us to effectively carry out our official duties of policy development and for the purposes of record keeping. In responding to this consultation, you have consented to provide this information to us but are able to withdraw your consent at any time by getting in touch with us.
2. Personal information is stored on servers within the European Union and cloud based services have been procured and assessed against the national cyber security centre cloud security principles. Personal information will not be used for any purpose other than in relation to this consultation. Personal information will be stored for as long as necessary to carry out the above functions and for five years from receipt in accordance with our retention policy. No third parties have access to your personal data unless the law allows them to do so.
3. You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner’s Office (ICO). Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address: informationmanagement@food.gov.uk
4. In accordance with the FSA principle of openness, the FSA shall keep a table of comments received during the consultation along with our response to be made available to the public on receipt of a request to the [FSA Consultation Coordinator](#) (020 7276 8308). The published table of comments 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](#). Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex D. 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 contact us if you require this consultation in an alternative format such as Braille or large print.
7. **This consultation has been prepared in accordance with [HM Government Consultation Principles](#).**

2018 No. 0000

FOOD

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

Made - - - - *0th Month 2018*

Coming into operation - *0th Month 2018*

The Department of Health(a), in exercise of the powers conferred by Articles 15(2), 16(1) and (2), 25(1)(a), (2)(a) and (3), and 47(2) of the Food Safety (Northern Ireland) Order 1991(b) makes the following Regulations.

In accordance with Article 47(3A) of that order, it 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), as last amended by Regulation (EC) No 652/2014 of the European Parliament and of the Council(d), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Citation and commencement

1. These Regulations may be cited as the Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2018 and come into operation on 0th Month 2018.

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

2. The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012(e) are amended in accordance with regulations 3 to 12.

3. In regulation 2 (interpretation)—

- (a) in the definition of “Directive 84/500/EEC” after “foodstuffs” insert “as last amended by Commission Directive 2005/31/EC”(f);

(a) Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.), section 1
(b) S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I. 12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R. 2004 Nos 482 and 505
(c) OJ No. L 31, 1.2.2002, p.1
(d) OJ No L 189, 27.6.2014, p 1
(e) S.R. 2012 No.384 as amended by S.R. 2017 No. 157
(f) OJ No. L110, 30.4.2005, p.36

- (b) in the definition of “Regulation 1935/2004” after “89/109/EEC” insert “as last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council”(a);
- (c) in the definition of “Regulation 2023/2006” after “food” insert “as last amended by Commission Regulation (EC) No 282/2008”(b);
- (d) in the definition of “Regulation 10/2011” for “Commission Regulation (EU) No. 2017/752” substitute “Commission Regulation (EU) 2018/79”(c)
- (e) after the definition of “Regulation 10/2011” insert—
 - ““Regulation 2018/213” means Commission Regulation (EU) No. 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) 10/2011; as regards the use of that substance in plastic food contact materials;”(d);
- (f) in paragraph (2), for “Regulation 450/2009 or Regulation 10/2011” substitute “Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213”.

4. In regulation 13(1), for “In this Part and in the Schedule any reference” substitute “Except in regulation 14(1), any reference in this Part and in Schedule 1”.

5. In regulation 14(1), for “Article 22(4) and (5) and Article 23,” substitute “Article 2 of Commission Regulation (EU) No 1282/2011, Article 2 of Commission Regulation (EU) No 1183/2012, Article 2 of Commission Regulation (EU) No 202/2014, Article 2 of Commission Regulation (EU) 2015/174, Article 2 of Commission Regulation (EU) 2016/1416, Article 2 of Commission Regulation (EU) 2017/752 and Article 2 of Regulation (EU) 2018/79,”.

6. In regulation 16(2), for “Subject to Article 6(1), (2) and (4) (transitional provisions) a” substitute “A”.

7. 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 authority for the purposes of Article 4(3) are the Food Standards Agency and each district council in its district.”

8. In regulation 19 (offences and penalties)—

- (a) in paragraph (2), after “Regulation 10/2011” insert “Regulation 2018/213”;

(a) OJ No. 188, 18.1.2009, p.14
 (b) OJ No. L86, 28.3.2008, p9
 (c) OJ No. L14, 19.1.2018, p31
 (d) OJ No L 41 14.2.2018 p.6-12

(b) in paragraph (5)(a), for “or 16(4)” substitute “, 16(4) or 17B”.

9. In regulation 23(2) (general defences), after “16(4)” insert “17B”.

10. In regulation 26(1)(a) (application of various provisions of the Order)—

(a) at the end of sub-paragraph (iv), delete “and”; and

(b) after paragraph (v) insert “(vi) Article 4 of Regulation 2018/213; and”.

11. Omit regulations 27 and 28.

12. In Schedule 2, Part 1 (modification of Article 9(1)), paragraph 1, after Article 9(1A)(e) as applied, after paragraph (e) insert “(f) Article 4 of Regulation 2018/213”.

Sealed with the official seal of the Department of Health on 0th Month 2018.

A circular stamp with the initials "L.S." inside.

A Name
A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

To be completed after consultation

Annex C

Title: THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2018 IA No:	Impact Assessment (IA)
	Date: March 2018
	Stage: Consultation
	Source of intervention: EU
	Type of measure: Secondary legislation
Contact for enquiries:	
<u>Summary: Intervention and Options</u>	
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 Northern Ireland 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 in Northern Ireland.

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

Summary: Analysis & Evidence

Policy Option 1 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			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0.0	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	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: - 0.00
2017	2017	10			

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 Northern Ireland Regulations. For Northern Ireland only, these amount to Industry costs of £2,040 (an Annual Equivalent Cost of £237) and Public-sector costs of £494.99 (an Annual Equivalent Cost of £57.51).

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 (Amendment) Regulations (Northern Ireland) 2018 (“the proposed Regulations”) will amend the Materials and Articles in Contact with Food Regulations (Northern Ireland) 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”) 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 Northern Ireland 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,

⁸OJ Ref L338, 13.11.2004, pg. 4-17

⁹A 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 based on Northern Ireland only and all costs and benefits are provided for Northern Ireland. However, as changes to the legislation in Northern Ireland 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 Northern Ireland and the rest of the UK. However, enforcement authorities in Northern Ireland 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 Northern Ireland. 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 Northern Ireland.

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 Northern Ireland results in a total familiarisation cost for the BPA Regulation of £2,040. 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

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<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14> Includes an overhead of 20% (21.25*1.2=25.50)

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

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

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 Northern Ireland affected by this proposal is estimated to be £494.99 which yields an annual equivalent cost of £57.51 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/occupation4digitsoc2010ashtable14> Includes an overhead of 20% (14.86*1.2=17.83)

¹³

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14> 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.

Benefit - 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 Northern Ireland of Commission Regulation (EU) No. 2018/213 on bisphenol A;
30. As with business, Local Authorities have expressed 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

31. During the course of negotiations with the Commission, FSA officials have 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.
32. 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.
33. 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 the inform the UK on its negotiation position on BPA.
34. 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

35. The FSA will conduct a formal public consultation from 18 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

36. 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.
37. 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.
38. 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.
39. 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

40. 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

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

IP List

Northern Ireland district council Environmental Health Officers

Northern Ireland Food Advisory Committee

Northern Ireland Food and Drink Federation

Invest NI

Canyon

Cirrus Plastics

PrimePac Ltd

Valpar Industrial Ltd

Greiner Packaging Ltd

JK McKenna Ltd

Distrupol Ireland Ltd

Northern Ireland Plastics Ltd

Springvale EPS Ltd

Beverage Plastics

McShane Manufacturing

Active Packaging

Jordan Plastics

MSO Cleland

Quinn Glass

Quinn Packaging

Delta Packaging

Smurfit

Saica

Huhtamaki

Boxmore

CAFRE