

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

CONSULTATION SUMMARY PAGE

Date launched:	09 APRIL 2018	Closing date:	04 JUNE 2018
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Who will this consultation be of most interest to?
 Businesses that manufacture, import, wholesale and/or retail plastic; recycled plastic materials and articles intended to come into contact with food; and varnishes and coatings. Port health authorities; 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 (England) (Amendment) Regulations 2018 will provide for the execution and enforcement, in England, of:

- [Commission Regulation \(EC\) No. 282/2008](#) on recycled plastic materials intended to come into contact with food (“the Recycling Regulation”).
- [Commission Regulation \(EU\) No. 2016/1416](#) (“the revised Plastics Regulation”) amending [Commission Regulation \(EU\) No. 10/2011](#) (“the Plastics Regulation”) on plastic materials and articles intended to come into contact with food
- [Commission Regulation \(EU\) No. 2018/213](#) on the use of bisphenol A in varnishes and coatings intended to come into contact with food (“the BPA Regulation”)

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 (England) (Amendment) Regulations 2018, and on the associated Impact Assessment.

Responses to this consultation should be sent to:

<p>Tim Chandler Food Contact Materials</p> <p>FOOD STANDARDS AGENCY</p> <p>Tel: +44 (0)20 7276 8127</p>	<p>Postal address: Food Standards Agency Clive House, 6th floor, 70 Petty France, London, SW1H 9EX</p> <p>Email: foodcontact2018@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 Materials and Articles in Contact with Food (England) (Amendment) Regulations 2018

Detail of Consultation

1. We welcome your comments on:
 - the proposed Materials and Articles in Contact with Food (England) (Amendment) Regulations 2018 (“the proposed Regulations”) (Annex B), providing enforcement authorities with the necessary powers, for the execution and enforcement of the Recycling Regulation, the revised Plastics Regulation and BPA Regulation
 - any cost implications (with supporting evidence) that come from changes derived from the Recycling Regulation, the revised Plastics Regulation and BPA Regulation and as indicated in the Impact Assessment at Annex C
 - any costs associated with the proposed testing of food contact plastics for new migration limits for aluminium and zinc
 - the Food Standards Agency’s (FSA) proposal on introducing compliance notices to act as a first intervention, rather than starting with criminal sanctions
2. The FSA in Wales and Northern Ireland will be carrying out similar consultations relating to their regions. Food Standards Scotland will be carrying out their own consultation.
3. The proposed Regulations will amend the existing [Materials and Articles in Contact with Food \(England\) Regulations 2012](#).

Background

4. 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.

The Recycling Regulation

5. Commission Regulation (EC) No. 282/2008 (“the Recycling Regulation”) establishes the specific rules for food contact recycled plastic materials and articles². It came into force on 17 April 2008, and is directly applicable throughout the EU. Food contact materials made from recycled plastics can only be placed on the market if they are manufactured from plastic, obtained from an authorised recycling process. Under Article 5 of the recycling regulations, the European Food Safety Authority (EFSA) is responsible for carrying out a safety assessment and publishing an Opinion on each recycling processes. This is to determine whether a process reduces potential contamination to a level which will not pose a health risk.
6. The European Commission (the Commission) will make a risk management decision to grant or refuse authorisation for individual recycling processes and publish Decisions on each EFSA Opinion. This will contain a set of criteria and the critical steps associated with the recycling process which need to be adhered to by the recycler. Authorised processes must be managed by a quality assurance system that

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

² OJ Ref L86, 20.03.2008, pg. 9-18 Available to download from the Eur-Lex website.

guarantees the reproducible quality of the recycled plastics. Until the Commission publishes Authorisation Decisions, the provisions given in Article 3, 9, 10 and 12 of the Recycling Regulation do not apply.

7. Commission Decisions are expected to be published at the end of 2018. Trade in and use of recycled plastic from a recycling process already in place on the date of entry into force of the Recycling Regulation, for which authorisation is refused, or no application was submitted in accordance with Article 13, shall be permitted until six months after the date of adoption of the Decisions. Trade in and use of recycled plastic materials and articles containing recycled plastic from a recycling process already in place on the date of entry into force of the Recycling Regulation, for which authorisation is refused or no valid application has been submitted in accordance with Article 13, shall be permitted until exhaustion of stocks.
8. To ensure that recycling processes once authorised are being operated in accordance with the relevant Commission Decision under Article 10, Member State competent authorities are required to undertake official controls in the form of audits. The FSA is preparing to implement the requirements of Article 10, the aim being to ensure that for each audit there is the minimum of administrative and economic burdens placed upon industry and the authorities.

The revised Plastics Regulation

9. Commission Regulation (EU) No. 10/2011³ (“the Plastics Regulation”) establishes the specific rules for plastic materials and articles. It is regularly amended to improve clarity and to keep up with advances in technology. New substances may also be added to authorise use in the manufacture of food contact plastics. The EFSA evaluates new and re-evaluates existing substances for risks to public health arising from the migration of chemicals from food contact plastics into food.
10. Commission Regulation (EU) No. 2016/1416⁴ (“the revised Plastics Regulation”) came into force on 14 September 2016, and is directly applicable throughout the EU. Materials and articles compliant prior to 14 September 2016 are subject to a one-year transitional period. Migration limits for aluminium and zinc, in point 2(a), and the assignments of food simulants in point 3(c) of the Annex, apply from 14 September 2018.
11. The revised Plastics Regulation amends Articles 3, 6, 11, 13, 17 and 18 of the Plastics Regulation. It redefines ‘fatty foods’ and assigns a food simulant category for peeled fresh fruit and vegetables for migration testing of plastics not yet in contact with food.
12. The revised Plastics Regulation removes the generic specific migration limit, an unnecessarily burdensome testing requirement for approximately 400 substances used in plastic food contact materials for which migration limits have not been specified.
13. The Authorised Union list is amended to include new substances and change entries for existing ones following risk assessments by the EFSA. The revised Plastics Regulation amends Annexes I, II, III IV and V for certain substances on the basis of new information becoming available.

³ OJ Ref L12, 15.01.2011, pg. 1-89 Available to download from the Eur-Lex website.

⁴ OJ Ref L230, 25.8.2016, pg. 22-42 Available to download from the Eur-Lex website.

The BPA Regulation

14. Commission Regulation (EU) No. 2018/213⁵ on the use of bisphenol A in varnishes and coatings intended to come into contact with food (“the BPA Regulation”) will be directly applicable as from 6 September 2018. The BPA Regulation sets a lower specific migration limit (SML) for the use of BPA in plastics as currently given in the Plastics Regulation, 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 and in polycarbonate drinking cups which, due to their spill proof characteristics, are intended for infants and young children.
15. 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.

Changes to the offences and penalties in the proposed Regulations

16. The current 2012 Regulations contain criminal offences for failing to comply with certain provisions of the European legislation they enforce and implement. The penalties for each of the offences includes failure to comply with:
 1. requirements for a DoC
 - on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both; or on summary of conviction to a fine not exceeding the statutory minimum
 2. supporting documentation
 - on summary conviction a fine not exceeding level 5 on the standard scale of fines for summary offences.
17. The proposed Regulations introduce the use of compliance notices to act as a first intervention for the offences listed above. The compliance notice must state:
 - the reason for the serving of the notice;
 - the steps the person on whom the notice has been served must take;
 - what actions are required by a specific date;
 - that failure to comply with the notice is an offence; and
 - provide details on the right to appeal against the notice

A ‘backstop’ criminal offence will apply if a business fails to comply with a compliance notice, with a penalty on summary conviction of a fine.
18. For food safety offences, existing criminal sanctions will continue to apply; these include the use of unauthorised substances or exceeding specified permitted limits of authorised

⁵ OJ Ref L41, 14.02.2018, pg. 6 Available to download from the Eur-Lex website.

substances. This is to ensure that consumers are not exposed to migration from materials and articles not manufactured in accordance with good manufacturing practice which could pose a risk to consumer health.

19. For the Recycling Regulation and the BPA Regulation, two new criminal offences will be created:
 - Failure to comply with the safety requirements for recycled plastics
 - Failure to comply with the migration limit for varnishes and coatings applied to materials and articles
20. In addition, two types of compliance notices will be created for failure to comply with the DoC requirements for these Regulations. As with the other changes to the DoC, a backstop criminal offence with the relevant penalties would apply upon failure to abide with a compliance notice.

Impact on Industry and Enforcement Authorities

21. As highlighted in the Impact Assessment, there will be one-off familiarisation costs for industries associated with the proposed Regulations and the three European Regulations. There may also be some additional costs associated with testing to new migration limits for aluminium and zinc; revised simulant testing; and/or to demonstrate compliance with the migration limits for BPA from coatings and varnishes.
22. Other than the familiarisation costs mentioned in the Impact Assessment, additional burden on enforcement authorities is likely to be minimal, if not negligible.

The Consultation Process

23. Numerous consultations on harmonising food contact materials have been carried out/conducted since 2002. The FSA carried out two informal consultations in 2004 and 2008, which enabled the FSA to acquire useful information on the practicalities of setting out of detailed auditing provisions within the Recycling Regulation. The 2008 consultation involved comments from enforcement bodies, allowing the FSA to consider frequency of auditing and other factors.
24. 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. The latest comments form the basis of on-going consideration of the auditing provisions of the Recycling Regulation.

Purpose of this Consultation

25. This eight-week consultation is to provide interested parties with the opportunity to give their comments and opinions on the content of the draft Statutory Instrument at Annex B, and to comment and express their opinion on the proposed evidence in respect of any cost implications that may arise from these proposals, as indicated in the Impact Assessment at Annex C.

Consultation Questions

26. We particularly welcome responses and general feedback to the following questions. **For each question please explain your response and provide evidence (where possible) to support your views.**

Questions asked in this consultation:

1(a) We invite stakeholders to comment on the introduction of compliance notices to act as a first intervention for the offences listed above.

1(b) Will the introduction of compliance notices provide adequate protection for consumers?

1(c) We invite stakeholders to comment on the proposal to use 'backstop' criminal offences for failure to comply with a compliance notice. A criminal offence would apply, with a penalty on summary conviction of a fine.

2) We welcome stakeholders' comments on whether the new migration limit for aluminium from plastics; the lower migration limit for zinc from plastics; and simulant testing for unpeeled fruit and vegetables, is likely to lead to significant costs and whether any other costs are expected as a result of the EU Regulation.

3) 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.

4) We invite stakeholders to comment on whether we have adequately captured the nature of England, Wales and Northern Ireland markets 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.

5) We welcome stakeholders' comments on whether our estimates of familiarisation costs to industry (outlined in Tables 4, 6 and 8) and our assumption that it will take businesses up to one hour to familiarise themselves with the requirements of the EU Regulations (plus half an hour for the Recycled Plastics requirements where pertinent) and one hour to disseminate to other members of staff (two or two-and-a-half hours in total) is reasonable.

6) We invite stakeholders' comments on whether our estimates of familiarisation costs to enforcement bodies and official control laboratories (outlined in Table 10) and our assumption that it will take enforcement bodies and official control laboratories one hour to familiarise themselves with the requirements of the EU Regulations, and one hour to disseminate to other members of staff (two hours in total) is reasonable.

7) We welcome stakeholders' comments on our assessment that there may be benefits to industry for using new substances in the manufacture of plastic materials and articles, and benefits from the removal of the Generic Specific Migration Limit.

8) 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.

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

Responding to the Consultation

27. Responses are required by close of business 4 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.

Other Comments

28. In addition to answering the consultation questions, please do not feel restricted in giving additional feedback as any comments that interested parties can provide in relation to the proposed Regulations would be gratefully received. We are particularly interested to hear from small and micro sized enterprises on the likely impact of the Regulations and will particularly appreciate their comment on all aspects of this proposal. 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 the FSA's website within three months following the end of the consultation period.

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

Yours,

Tim Chandler
Food Contact Materials
Food Policy

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Statutory Instrument – The Proposed Materials and Articles in Contact with Food (England) (Amendment) Regulations 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.

FOOD, ENGLAND

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

Made - - - - - ***
Laid before Parliament ***
Coming into force - - - - - *date 2018*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), 2(a) and (3), 31 and 48(1) of the Food Safety Act 1990⁽⁶⁾, and now vested in him⁽⁷⁾, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972⁽⁸⁾.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for certain references to any Annex to the EU instruments specified in regulation 2(3) to be construed as references to that Annex as amended from time to time.

In accordance with section 48(4A) of the 1990 Act the Secretary of State 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⁽⁹⁾, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

⁽⁶⁾ 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.

⁽⁷⁾ Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, 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 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

⁽⁸⁾ 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c.51) and amended by Part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (2008 c.7).

⁽⁹⁾ OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

Title and commencement

1. These Regulations may be cited as the Materials and Articles in Contact with Food (England) (Amendment) Regulations 2018 and come into force on [xxxxx] 2018.

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

2. The Materials and Articles in Contact with Food (England) Regulations 2012⁽¹⁰⁾ are amended in accordance with regulations 3 to 17.

3. In regulation 2 (interpretation) —

(a) in paragraph (1) —

(i) after the definition of “Regulation 2023/2006” insert the following definition —

““Regulation 282/2008” means Commission Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006;”;

(ii) for the definition of “Regulation 10/2011” substitute the following definition —

““Regulation 10/2011” means Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food;”⁽¹¹⁾;

(iii) after the definition of “Regulation 10/2011” insert the following definition —

“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) No. 10/2011 as regards the use of that substance in plastic food contact materials;”⁽¹²⁾; and

(b) for paragraph (2), substitute—

“Expressions used in these Regulations and in Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213 bear the same meaning in these Regulations as they bear in those Regulations.”

4. In regulation 7 (offences of contravening specified provisions of Regulation 450/2009), omit paragraph (2).

5. In regulation 12(8) (controls and limits), for “paragraphs (5), (6) or (7)” substitute “paragraphs (5) or (7)”.

6. In regulation 14 (offences of contravening specified provisions of Regulation 10/2011), omit paragraph (2).

7. For regulation 15 (competent authorities for the purposes of Regulation 10/2011), substitute the following —

“15. The competent authorities for the purposes of Articles 8 and 16(1) of Regulation 10/2011 are the Food Standards Agency, each food authority in its area and each port health authority in its district.”.

8. After regulation 15 insert the following —

“PART 6A

Requirements for Recycled Plastic Materials and Articles

Interpretation of this Part

15A. In this Part any reference to a numbered Article is a reference to that Article of Regulation 282/2008.

Offences of contravening specified provisions of Regulation 282/2008

15B. Subject to the transitional provisions contained in Article 14, any person who places on the market a material or article that fails to comply with Article 3(1) (requirements for plastic materials and articles) is guilty of an offence.

⁽¹⁰⁾ S.I. 2012/2619.

⁽¹¹⁾ This Regulation was last amended by Commission Regulation (EU) 2016/1416 amending and correcting Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (OJ No. L230, 25.8.2016, p.22).

⁽¹²⁾ OJ No. L 41, 14.2.2018, p. 6.

Competent authorities for the purposes of Regulation 282/2008

15C. The competent authorities for the purposes of Article 10 are the Food Standards Agency and each food authority in its area.”.

9. In regulation 16 (restrictions on the use of certain epoxy derivatives (BADGE, BFDGE and NOGE)) —

- (a) in paragraph (1)(b), for “paragraphs (2) and (3) are” substitute “paragraph (2) is”;
- (b) omit paragraph (3), and
- (c) in paragraph (4), for “paragraph (2) or (3)” substitute “paragraph (2)”.

10. After regulation 17 insert the following —

“PART 7A

Requirements for bisphenol A

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. ”.

11. For regulation 19 (offences and penalties) substitute the following —

“**19.**—(1) Any person who contravenes regulation 10(3), 12(8) or 18(2) is guilty of an offence.

(2) Any person who fails to comply with a compliance notice served on them under regulation 19A is guilty of an offence.

(3) Any person who intentionally obstructs a person acting in the execution of Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011, Regulation 2018/213 or these Regulations is guilty of an offence.

(4) Any person who, without reasonable excuse, fails to provide any assistance or information a person may reasonably require for the performance of their functions under the Regulations mentioned in paragraph (3) is guilty of an offence.

(5) Any person who, in purported compliance with any requirement under paragraph (4), knowingly or recklessly supplies information that is false or misleading in any material particular is guilty of an offence.

(6) A person guilty of an offence is liable —

(a) in the case of an offence created by paragraph (1) or (5) or by regulation 4(3), 5, 7(1), 14(1), 15B, 16(4) or 17B —

(i) on conviction on indictment to a fine or to a term of imprisonment not exceeding two years or both, or

(ii) on summary conviction to a fine; and

(b) in the case of an offence created by paragraph (2), (3) or (4), on summary conviction to a fine.

(7) Nothing in paragraph (3) or (4) is to be construed as requiring a person to answer any question or give any information if to do so might incriminate that person.”.

12. After regulation 19 insert the following —

“Compliance notices

19A.—(1) If an authorised officer has reasonable grounds for believing that any person has not complied with, is not complying with or is not likely to comply with a provision specified in regulation 19B (which concerns declarations of compliance with legislative requirements or supporting documentation), the officer may serve a compliance notice on that person.

(2) A compliance notice must state —

- (a) the reason for the service of the notice and the steps the person on whom the notice has been served must take;
- (b) the date and, if appropriate the time, by which each step must be taken;
- (d) that a failure to comply with the notice is an offence; and
- (e) the details of the right to appeal against the notice under regulation 19C.

(3) An authorised officer may serve a notice on a person withdrawing, varying or suspending a compliance notice.

19B. The provisions are —

- (a) paragraphs (4) and (6) of regulation 10;
- (b) paragraph (6) of regulation 12;
- (c) Article 16 of Regulation 1935/2004;
- (d) Article 5 of Regulation 1895/2005;
- (e) Article 10(3) and Article 12 of Regulation 282/2008;
- (f) Article 12 and Article 13 of Regulation 450/2009;
- (g) the second sentence of Article 8, Article 15 as read with Annex IV and Article 16 of Regulation 10/2011;
- (h) Article 4 of Regulation 2018/213.

Appeal against a compliance notice

19C.—(1) Any person served with a compliance notice may appeal against that notice to a magistrates’ court.

(2) The procedure on appeal to a magistrates’ court shall be by way of complaint for an order, and the Magistrates’ Courts Act 1980 shall apply to the proceedings.

(3) The period within which an appeal may be brought shall be one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint for an order shall be deemed for the purposes of this paragraph to be the making of the appeal.

(4) A compliance notice is not suspended pending an appeal unless —

- (a) an authorised officer suspends it under regulation 19A(3); or
- (b) the court directs that it be suspended.

(5) The court may —

- (a) confirm the notice or any requirement contained in it;
- (b) vary the notice or any requirement contained in it; or
- (c) revoke the notice or any requirement contained in it.”.

13. For regulation 20 (execution and enforcement), substitute the following —

“**20.**—(1) Each food authority in its area and each port health authority in its district shall execute and enforce Regulation 1935/2004, Regulation 1895/2005, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 and these Regulations, but a port health authority shall not execute and enforce these Regulations as they relate to Article 10 of Regulation 282/2010 or to Article 4 of Regulation 2023/2006.

(2) Each food authority in its area shall execute and enforce the provisions of Article 4 of Regulation 2023/2006.

(3) The Food Standards Agency may also execute and enforce the provisions of —

- (a) Articles 16(1) and 17(2) of Regulation 1935/2004;
- (b) Article 10(3) of Regulation 282/2008;
- (c) Article 13 of Regulation 450/2009; and
- (d) Article 16(1) of Regulation 10/2011.”.

14. In regulation 23(2) (time limit for prosecutions), for “7(2), 14(2) or 19(2) or (3)” substitute “19(3) or (4)”.

15. In regulation 24(2) (general defences), after “14(1),” insert “15B”, and after “16(4)” insert “17B”..

16. In paragraphs (2) and (3) of regulation 27 (application of various provisions of the Act), in each case after “Regulation 2023/2006,” insert “Regulation 282/2008, Regulation 2018/213,”.

17. In the Schedule (specified provisions of Regulation 10/2011) —

- (a) for the text in the first column of the seventh row (which relates to Article 11) of the table, substitute “Article 11(1) and Annex I, as read with Article 11(3) and (4)”;
- (b) omit the entries in the final row of the table.

Statutory Review

18.—(1) The Food Standards Agency, on behalf of the Secretary of State, must from time to time —

- (a) carry out a review of the operation and effect of regulations 2 to 17;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Food Standards Agency must, so far as is reasonable, have regard to how Regulation 282/2008 and Regulation 2018/213 are executed and enforced in other Member States.

(3) The report must in particular —

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if they do, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Signed by authority of the Secretary of State for Health and Social Care

Minister's name

Parliamentary Under-Secretary of State
Department of Health and Social Care

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations principally provide for the enforcement of Commission Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with food and amending Regulation (EC) No 2023/2006 (OJ No. L86, 28.3.2008, p.9) and 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) No 10/2011 as regards the use of that substance in plastic food contact materials (OJ No. L 41, 14.2.2018, p. 6.).

2. DN: to be completed when draft SI finalised.

3. A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Food Safety Group of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on www.legislation.gov.uk.

Annex C: Impact Assessment

Title: THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) (AMENDMENT) REGULATIONS 2018 IA No: FOOD0160 RPC Reference No: FOOD0160 Lead department or agency: FOOD STANDARDS AGENCY Other departments or agencies: N/A	Impact Assessment (IA)			
	Date: April 2018			
	Stage: Consultation			
	Source of intervention: EU			
	Type of measure: Secondary legislation			
Contact for enquiries: Tim Chandler +44 (0) 20 7276 8127				
Summary: Intervention and Options				RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANDCB in 2014 prices)	One-In, Three-Out	Business Impact Target Status
£-0.10m	£-0.10m	£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 detrimentally affect consumer health, which could potentially create a negative cost to others such as the National Health Service. 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 is necessary to reduce 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 England of Commission Regulation (EC) No. 282/2008 on recycled plastic materials intended to come into contact with foods, Commission Regulation (EU) No. 2016/1416 amending and correcting Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, and Commission Regulation (EU) No. 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food.
- To update the existing offences and penalties in the Materials and Articles in Contact with Food (England) Regulations 2012.

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 (EC) No. 282/2008, nor Commission Regulation (EU) No. 2016/1416 nor Commission Regulation (EU) No. 2018/213. The UK's obligation (under the Treaty on the Functioning of the European Union) to put in place provisions for their enforcement would not be fulfilled which would place the UK at risk of being subject to infraction proceedings.

Option 2 – Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EC) No. 282/2008, Commission Regulation (EU) No. 2016/1416 and Commission Regulation (EU) No. 2018/213.

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

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 10/2023 (subject to laying 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	

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

Signed by the responsible SELECT SIGNATORY: _____ **Date:**

Summary: Analysis & Evidence

Policy Option 1

Description: Option 1: Do Nothing – Do not provide for the enforcement and execution of Commission Regulation (EC) No. 282/2008, nor Commission Regulation (EU) No. 2016/1416 nor 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 non-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 non-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 implement the enforcement provisions of the Commission Regulations.					

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			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 (EC) No. 282/2008, Commission Regulation (EU) No. 2016/1416 and 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: -0.10
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	0.10		0.0		0.10
Description and scale of key monetised costs by 'main affected groups'					
Industry and Enforcement Authorities will face one-off familiarisation costs with the three EU Regulations and the amendment to the 2012 England Regulations. For England only, these amount to Industry costs of £88,128 (an Annual Equivalent Cost of £10,238.29) and Public-sector costs of £16,485.56 (an Annual Equivalent Cost of £1,915.21).					
Other key non-monetised costs by 'main affected groups'					
Some industry sectors may face costs of assessing compliance with the new migration limits for aluminium and zinc from plastics, new migration testing requirements for fresh unpeeled fruit and vegetables, and the migration limit for bisphenol A from varnishes or coatings applied to food contact materials.					
Recyclers may face costs associated with the auditing of recycling processes by competent authorities and as a result of restrictions and specifications that may be set in the Commission Decisions.					
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'					
The deletion of the generic specific migration limit in Commission Regulation (EU) No. 2016/1416 removes an unnecessarily burdensome testing requirement for approximately 400 substances used in plastic food contact materials for which migration limits have not been specified. The Regulation adds ten new substances that can be used in the manufacture of food contact materials. This Regulation also provides some greater flexibility for business operators when testing plastic materials and articles.					
Key assumptions/sensitivities/risks					Discount rate (%)
Proportion of micro, small, medium and large firms in England, Wales and Northern Ireland (E,W&NI) is assumed the same, for each country.					3.5
All recycling firms are assumed to be large.					
80% of plastic manufacturing firms are assumed to be involved with food products.					

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			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 detrimentally affect consumer health, which could potentially create a negative cost to others such as the National Health Service. 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 (England) (Amendment) Regulations 2018 (“the proposed Regulations”) will amend the Materials and Articles in Contact with Food (England) Regulations 2012 (“the 2012 Regulations”) to provide enforcement authorities with the necessary powers for the execution and enforcement of the provisions of the three European Regulations 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 (EC) No. 282/2008 on recycled plastic materials intended to come into contact with foods (“the Recycling Regulation”) was published in the Official Journal of the European Union (OJ) on 28 March 2008¹³ and is directly applicable throughout the EU. Although the Recycling Regulation has been in force since 17 April 2008, several important provisions will only apply from the date of adoption of authorisation decisions on recycling processes. Therefore, the enforcement of the Recycling Regulation in the UK is deferred until the adoption of these decisions which are expected by the end of 2018 (discussed further in this Impact Assessment in paragraph 19).
4. Commission Regulation (EU) No. 2016/1416 (“the revised Plastics Regulation”) amending and correcting Regulation (EU) No. 10/2011¹⁴ (“the Plastics Regulation”) on plastic materials and articles intended to come into contact with food, was published in the OJ on 25 August 2016¹⁵. The revised Plastics Regulation came into force on 14 September 2016, and is directly applicable throughout the EU. There is a transition period of one year allowing materials and articles that were compliant before entry into force of this Regulation to remain on the market, whilst the new migration limits for aluminium and zinc, set out in point 2(a) of the Annex and the assignments of food simulants in point 3(c) of the Annex, will apply from 14 September 2018.
5. Commission Regulation (EU) No. 2018/213¹⁶ 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 plastics as currently given in the Plastics Regulation, 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 and in polycarbonate drinking cups which, due to their spill proof characteristics, are intended for infants and young children.

¹³ OJ Ref L86, 28.03.2008, pg. 9-18 Available to download from the Eur-Lex website.

¹⁴ OJ Ref L12, 15.01.2011, pg. 1-89 Available to download from the Eur-Lex website.

¹⁵ OJ Ref L 230, 25.08.2016, pg. 22-42 Available to download from the Eur-Lex website.

¹⁶ OJ Ref L41, 14.02.2018, pg. 6 Available to download from the Eur-Lex website.

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

Policy objective

7. The proposed Regulations will amend the 2012 Regulations. The purpose of this proposal is to meet several policy objectives:
 - to provide for the execution and enforcement in England of Commission Regulation (EC) No. 282/2008 on recycled plastics, Commission Regulation (EU) No. 2016/1416 on plastics and Commission Regulation (EU) No. 2018/213 on bisphenol A
 - provide for offences of contravening certain provisions of the three European Regulations
 - specify the penalties that the Courts may impose upon conviction for an offence
 - make changes to the existing offences and penalties in the 2012 Regulations so that these are more appropriate and proportionate

Changes to the offences and penalties in the proposed Regulations

8. The 2012 Regulations contain criminal offences for failing to comply with certain provisions of the European legislation they enforce and implement. Currently, the penalties for each of the offences includes failure to comply with:
 1. requirements for a DoC¹⁷
 - 'on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both; or on summary of conviction to a fine not exceeding the statutory minimum'
 2. supporting documentation
 - 'on summary conviction to a fine not exceeding level 5 on the standard scale'
9. The proposed Regulations introduce the use of compliance notices to act as a first intervention for the offences listed above. The compliance notice must state:
 - the reason for the serving of the notice;
 - the steps the person on whom the notice has been served must take;
 - what actions are required by a specific date;
 - that failure to comply with the notice is an offence; and
 - provide details on the right to appeal against the notice

¹⁷ Declaration of Compliance (DoC) requirements are applicable for food contact materials made from plastic, ceramic, regenerated cellulose film and active, intelligent materials and articles and recycled plastics and for materials containing the substance BADGE and its derivatives.

10. The aim of these changes is to ensure that sanctions are appropriate and proportionate, as the absence of a DoC or supporting documentation does not necessarily mean that the food contact material is a risk to health. Compliance notices are therefore considered a more appropriate first intervention in these instances.
11. A 'backstop' criminal offence will apply if a business fails to comply with a compliance notice, with a penalty on summary conviction of a fine. Without a 'backstop' criminal offence, there would not be a sufficient deterrent for manufacturers of food contact materials who fail to provide a DoC and this could ultimately lead to food contact materials being used inappropriately by the end user. This could result in increased risks for consumer health as the required safety information would not have been passed down the supply chain.
12. For food safety offences, existing criminal sanctions will continue to apply; these include the use of unauthorised substances or exceeding specified permitted limits of authorised substances. This is to ensure consumers are not exposed to migration from materials and articles not manufactured in accordance with good manufacturing practice, which could pose a risk to consumer health.
13. For the Recycling Regulation and the BPA Regulation, two new criminal offences will be created:
 - Failure to comply with the safety requirements for recycled plastic
 - Failure to comply with the migration limit for varnishes and coatings applied to materials and articles
14. In addition, two compliance notices will be created for failure to comply with the DoC requirements for these Regulations. As with the other changes to the DoC, a backstop criminal offence with the relevant penalties would apply upon failure to abide with a compliance notice.
15. The FSA is reviewing the approach taken to sanctions in food law to ensure these remain effective, dissuasive and proportionate in line with UK Government advice on the use of criminal sanctions. This could potentially lead to changes in the sanctions in the proposed Regulations in the future.

We particularly welcome responses and general feedback to the questions throughout the Impact Assessment. **For each question please explain your response and provide evidence (where possible) to support your views.**

1(a) We invite stakeholders to comment on the introduction of compliance notices to act as a first intervention for the offences listed above.

1(b) Will the introduction of compliance notices provide adequate protection for consumers?

1(c) We invite stakeholders to comment on the proposal to use 'backstop' criminal offences for failure to comply with a compliance notice. A criminal offence would apply, with a penalty on summary conviction of a fine.

Background

16. The general principles governing the safety of all materials and articles intended to come into contact with food are established in Regulation (EC) No. 1935/2004¹⁸ of the European Parliament and of the Council (“the Framework Regulation”). The Plastics Regulation is a specific measure within the meaning of Article 5(1) of the Framework Regulation and establishes the specific rules for plastic materials and articles intended to come into contact with food.

Requirements for recycled food contact materials and articles

17. Commission Regulation (EC) No. 282/2008 (“the Recycling Regulation”) establishes the specific rules for food contact recycled plastic materials and articles¹⁹. It came into force on 17 April 2008, and is directly applicable throughout the EU. Food contact materials made from recycled plastics can only be placed on the market if they are manufactured from plastic, obtained from an authorised recycling process. Under Article 5 of the Recycling Regulation, the European Food Safety Authority (EFSA) is responsible for carrying out a safety assessment and publishing an Opinion on each recycling processes. This is to determine whether a process reduces potential contamination to a level which will not pose a health risk.
18. The Commission will publish Decisions on each EFSA Opinion to grant or refuse authorisation for individual recycling processes. This will contain a set of criteria and the critical steps associated with the recycling process which need to be adhered to by the recycler. Authorised processes must be managed by a quality assurance system that guarantees the reproducible quality of the recycled plastics.
19. Although the Recycling Regulation has been in force since 17 April 2008, the provisions of Article 3 (requirements for plastic materials and articles), Article 9 (community Register of authorised recycling processes), Article 10 (official control of recycling plants) and Article 12 (DoC and record keeping) will only apply to businesses when the Commission adopts authorisation Decisions on individual recycling processes. These are expected at the end of 2018. These decisions will consider risk assessments from the EFSA on each recycling process.
20. Trade in and use of recycled plastic from a recycling process already in place on the date of entry into force of the Recycling Regulation, for which authorisation is refused or no valid application has been submitted in accordance with Article 13, shall be permitted until six months after the date of the adoption of the Decisions.
21. Trade in and use of recycled plastic materials and articles containing recycled plastic from a recycling process already in place on the date of entry into force of the Recycling Regulation, for which authorisation is refused or no valid application has been submitted in accordance with Article 13, shall be permitted until exhaustion of stocks.

Auditing of the authorisation process for recycled plastics

22. Under Article 10 of the Recycling Regulation, Member State competent authorities are required to undertake official controls in the form of audits on the authorised recycling processes. These controls are to ensure that a given recycling process is operating in accordance with the relevant Commission Decision and that an effective quality assurance

¹⁸ OJ Ref L338, 13.11.2004, pg. 4-17 Available to download from the Eur-Lex website.

¹⁹ OJ Ref L86, 20.03.2008, pg. 9-18 Available to download from the Eur-Lex website.

system is in place, in accordance with [Commission Regulation \(EC\) No. 2023/2006](#) on good manufacturing practice for materials and articles intended to come into contact with food²⁰.

23. The Food Standards Agency (FSA) is preparing for the implementation of this auditing requirement after 2018. The aim is to ensure that these audits produce the minimum administrative and economic burden to industry and competent authorities, whilst ensuring consumer protection. The frequency of auditing is not likely to be specified in the Commission Decisions, but left to individual Member States to decide upon on a risk basis. Proportionate to the potential risks to public health, the likely frequency of auditing is expected to be around every three to five years. The FSA is currently exploring options for the provision of audit functions. A recommendation paper has been written on the auditing options and is under consideration. It is likely that the cost of carrying out the auditing would be passed onto recyclers, in line with European Regulations on Official Controls and the FSA's future regulatory strategy which says that businesses should meet the cost of regulation²¹.

The Plastics Regulation

24. The Plastics Regulation is routinely amended to improve the clarity of the rules and to keep up with technological innovation. Applicants apply to the EFSA for evaluation of new substances that they wish to use in food contact plastics. The EFSA evaluates the risk to public health arising from the migration of these substances into food. If these substances are considered safe by the EFSA, the Commission amends the Plastics Regulation to include these substances.

Changes made by the revised Plastics Regulation to the Annexes of the Plastics Regulation

25. The changes to the Annexes to the Plastics Regulation do not require any changes to be made to the enforcement provisions in the 2018 Regulations as a result of the existing ambulatory reference in the 2012 Regulations. Ten new substances that can be used in the manufacture of food contact plastics and amendments to six existing substances have been introduced by ambulatory references. The other main amendments to the Annexes include:
- the introduction of a migration limit of 1mg/kg for aluminium from plastics (Annex II point 1)
 - a reduction in the existing migration limit for zinc from plastics from 25mg/kg to 5mg/kg (Annex II point 1)
 - allowing the testing in only one food simulant if appropriate scientific evidence is documented showing that that food simulant is the most severe (Annex III point 5)
 - allowing the use of processing conditions used by business operators in food processing (such as pasteurisation or sterilisation) as testing conditions for migration testing (Annex V section 2.1.3 of chapter 2)
 - allowing the use of a single screening test to screen compliance with the Regulation if the migration behaviour of a material or article is well established (Annex III point 5)
 - the introduction of specific migration testing methods for fruits and vegetables (Annex III table 2)

²⁰ OJ Ref L384, 29.12.2006, pg. 75-78 Available to download from the Eur-Lex website.

²¹ Developing the FSA's new approach to regulating food businesses <https://www.food.gov.uk/sites/default/files/fsa160506.pdf>

26. Several other minor clarifications and corrections have been made to the Annexes to remove any doubt about the application of the Plastics Regulation.

2) We welcome stakeholders' comments on whether the new migration limit for aluminium from plastics; the lower migration limit for zinc from plastics; and simulant testing for unpeeled fruit and vegetables, is likely to lead to significant costs and whether any other costs are expected as a result of the EU Regulation.

Please explain your response and provide evidence (where possible) to support your views.

Changes made by the revised Plastics Regulation to the Articles in the Plastics Regulation (not covered by ambulatory references)

27. Very minor changes are required to Schedule 1 to the 2012 Regulations to take account of changes made to the Articles in the Plastics Regulation by the revised Plastics Regulation.
28. The revised Plastics Regulation amends Articles 3, 6, 11, 13, 17 and 18 of the Plastics Regulation. The specific changes include:
- Article 3 was amended to revise the definitions for 'non-fatty food' and introduce a definition of 'hot fill'
 - Article 6 (3) was replaced to clarify that the derogation for specified metal salts of authorised acids, alcohols and phenols applies to multiple salts and not just double salts
 - Article 11 (2) was deleted to remove the requirement to test plastic materials that are not subject to specific migration limits with the generic specific migration limit of 60mg/kg
 - a new point 4 was added in Article 11 to clarify that where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No. 882/2004 that can confirm the absence of migration above a specified limit of detection
 - Article 13 (3) was amended to clarify that substances not listed in the Union list, nor the provisional list, should not migrate through a functional barrier in accordance with the newly amended Article 11 (4)
 - Article 17 3(a) was amended to clarify how migration limits should be specified for caps, gaskets and stoppers and similar sealing articles
 - Article 18 (4) was amended to clarify that the whole of chapter 3 of Annex V is relevant for the verification of compliance with the overall migration limit for materials and articles not yet in contact with food
 - Article 18 (7) was amended to clarify that the correction factors in point 3 of Annex III and Chapter 4 of Annex V should be applied before comparing specific and overall migration test results with the migration limits

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

29. 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.
30. 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.
31. 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 the EFSA set for BPA in 2015²². 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.
32. The 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 the Plastics Regulation, reducing the existing SML for BPA so it is in line with the BPA Regulation.
33. 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, 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.

3) 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 explain your response and provide evidence (where possible) to support your views.

Sectors affected

34. We have used the Interdepartmental Business Register (IDBR) to identify which sectors and industries in England, Wales and Northern Ireland (E,W&NI) may be affected by the policy. The IDBR is a comprehensive register of businesses, which covers 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

²² A tolerable intake is the amount of a substance that can be consumed over a lifetime without presenting an appreciable risk to health.

businesses affected) than the number affected by the policy. For example: “manufacture of plastic packing goods” SIC-2222 refers to all plastic packaging manufacturers 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 2. The central estimate of 80% (which remains conservative) is used to calculate the best estimate of the costs and benefits.

Industry

The Recycling Regulation

35. This Regulation will affect:

- the eight recycling businesses in England producing recycled material for food contact use (assuming their processes are authorised by Commission Decisions)
- businesses using the recycled material produced from these recycling processes to make new materials and articles for food contact
- businesses using recycled material produced from other authorised EU recycling processes

36. The FSA does not envisage that the adoption of the authorisation decisions on recycling processes will lead to additional costs for recyclers. Some of the authorisation decisions may set restrictions on the amount of recycled material that can be incorporated into finished products as a result of the safety assessments carried out by the EFSA. The eight businesses in England who have pending applications for authorisation of their recycling processes may therefore already be complying with any restrictions as the decisions are likely to closely follow the EFSA opinions. As mentioned in paragraph 23 it is likely that there will be a small cost to recyclers associated with the auditing provisions required by the Recycling Regulation. Conversely, there may also be a benefit for recyclers, as the authorisation decisions may open new markets for the recycled plastic produced under EU-authorised recycling processes.

The revised Plastics Regulation

37. Any costs to industry associated with the revised Plastics Regulation relate to businesses involved in the manufacture of plastic materials and articles intended to come into contact with food (including articles such as food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment), not the whole packaging industry. This will apply equally to all businesses in this sector regardless of size.

The BPA Regulation

38. 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 (EC) No. 1935/2004.

39. This Impact Assessment is based on England and all costs and benefits are provided for England only. However, as changes to the legislation in England will require similar changes

to be enacted in each of the devolved administrations we have provided analysis for E,W&NI; Tables 1 and 2 summarise the distribution across E,W&NI of the sectors that are affected by the proposed Regulations. A more detailed description of the SIC codes is provided in Annex 3. There remains uncertainty as to the number of affected businesses using IDBR SIC classification. As a result, the number of businesses set out in Tables 1 and 2 represents 80% of the maximum number of potentially affected businesses (full sensitivity analysis can be found in Annex 2).

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

Sectors	England	Wales	Northern Ireland	Total
Plastics manufacturer (2222)	316	20	12	348
Recyclers producing material for food contact	8	0	0	8
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 E,W&NI

Firm Size	Micro	Small	Medium	Large	Total
Plastics manufacturer (2222)	138	119	80	11	348
Recyclers producing material for food contact	0	0	0	8	8
Food canners/coatings manufacturers (2529, 2592, 2561)	847	456	108	14	1425

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

4) We invite stakeholders to comment on whether we have adequately captured the nature of the England, Wales and Northern Ireland markets 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

40. Enforcement authorities will also be affected by the proposed Regulations as they will be responsible for providing for the enforcement of the Recycling Regulation, the changes to the Plastics Regulation made by the revised Plastics Regulation and the BPA Regulation. There will also be one-off costs to enforcement bodies for familiarisation with the proposed Regulations and the three EU Regulations. Table 3 shows the number of enforcement authorities that are affected by the proposed Regulations. 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

Enforcement Body	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 (EC) No. 282/2008, nor Commission Regulation (EU) No. 2016/1416, nor Commission Regulation (EU) No. 2018/213.

41. Under this option, the three directly applicable European Regulations would still be applicable in England and the rest of the UK. However, enforcement authorities in England 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 their enforcement would not be fulfilled which would place the UK at risk of being subject to infraction proceedings.

Option 2: Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EC) No. 282/2008, and Commission Regulation (EU) No. 2016/1416 and Commission Regulation (EU) No. 2018/213.

42. This option will provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the three EU Regulations in England. 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 (EC) No. 282/2008, nor Commission Regulation (EU) No. 2016/1416, nor Commission Regulation (EU) No. 2018/213.

43. 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 Regulations.

Option 2: Make appropriate domestic Regulations for the execution and enforcement of Commission Regulation (EC) No. 282/2008, and Commission Regulation (EU) No. 2016/1416 and Commission Regulation (EU) No. 2018/213.

44. This is the preferred option as it will enable the execution and enforcement of the three European Regulations in England.

Costs - Option 2

Industry Familiarisation (one-off costs)

45. Under Option 2, there will be a one-off cost to industry for reading and familiarising themselves with the Recycling Regulation, the revised Plastics Regulation and the new BPA Regulation.
46. Familiarisation costs are quantified by multiplying the time it will take for a manager to familiarise themselves with the Regulations, by the median hourly wage rate of that manager, uplifted by 20% to allow for overheads. Total costs in England are calculated by multiplying total business cost by the number of businesses within that industry. We have assumed that for industry it will be one or more of either the regulatory, technical or production manager that will be responsible for familiarisation with the three EU Regulations. The median hourly wage rate for a production manager in the Annual Survey

of Hours and Earnings (ASHE) is £21.25, which uplifted for overheads is £25.50²³. There is no median hourly wage posted for regulatory or technical managers within the ASHE. Therefore, the assumption has been made that their median hourly wage rate will be similar to that of a production manager, which will be taken as representative of the costs incurred for each role. The businesses affected under this Option are:

A] recyclers of plastic materials and articles producing material for food contact (there are 8 recyclers in England)

B] manufacturers of plastic packaging goods and other plastic products that are intended to come into contact with food, including businesses that use recycled plastic to produce these goods

C] coatings manufacturers, can makers and food canners.

A] Familiarisation costs for plastic recyclers producing material for food contact

47. We have assumed that one production manager at a recycling plant will be responsible for familiarisation with the Regulations. As they will already be familiar with the requirements of the Recycling Regulation through making an application for authorisation under the Regulation, we have assumed that costs will only result from familiarising themselves with the requirements of the authorisation Decision.
48. We estimate that 2 hours are required for familiarisation; one hour for the authorisation Decision and another hour to disseminate the information within the organisation. This results in a familiarisation cost per business of £51.00, giving a total familiarisation cost to plastic recyclers in England of £408.00. Table 4 presents total familiarisation costs by firm size and country and Table 5 presents familiarisation costs as annual equivalent costs:

Table 4: Familiarisation costs for plastic recyclers producing material for food contact

	Micro	Small	Medium	Large	Total
England	£0.00	£0.00	£0.00	£408.00	£408.00
Wales	£0.00	£0.00	£0.00	£0.00	£0.00
N. Ireland	£0.00	£0.00	£0.00	£0.00	£0.00

Table 5: Annual Equivalent Costs (AEC) for plastic recyclers producing material for food contact

	England	Wales	Northern Ireland	Total
AEC (£)	£47.40	£0.00	£0.00	£47.40

B] Familiarisation costs for plastic manufacturing industry (includes users of recycled material)

49. The revised Plastics Regulation is specific to food contact materials and articles manufactured from plastic. We have assumed that one production manager will be responsible for familiarisation.
50. We estimate that two and a half hours are required for familiarisation; one hour for the revised Plastics Regulation, half an hour for the requirements for recycled plastic used to make plastic materials and articles and another hour to disseminate the information within the organisation. This results in a familiarisation cost per business of £63.75, giving a total

²³ <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>
Includes an overhead of 20% (21.25*1.2=25.50)

familiarisation cost to the plastic manufacturing industry in England of £20,145.00. Table 6 presents total familiarisation costs by firm size and country and Table 7 presents familiarisation costs as annual equivalent costs:

Table 6: Familiarisation costs for the plastic manufacturing industry (includes users of recycled material)

	Micro	Small	Medium	Large	Total
England	£7,969.45	£6,862.58	£4,648.85	£664.12	£20,145.00
Wales	£504.40	£434.34	£294.23	£42.03	£1,275.00
NI	£302.64	£260.60	£176.54	£25.22	£765.00

Table 7: Annual Equivalent Costs (AEC) to the Plastic Manufacturing Industry (includes users of recycled material), by Country

	England	Wales	Northern Ireland	Total
AEC (£)	£2,340.35	£148.12	£88.87	£2,577.34

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

51. We have assumed that one production manager will be responsible for familiarisation with the BPA Regulation.
52. We estimate that two hours are required for familiarisation, one hour for the amendments and another hour to disseminate the information within the organisation. This results in a familiarisation cost per business of £51.00, giving a total familiarisation cost for coatings manufacturers, can makers and food canners of £67,575.00. Table 8 presents total familiarisation costs by firm size and country and Table 9 presents familiarisation costs as annual equivalent costs:

Table 8: 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 9: 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.

5) We welcome stakeholders' comments on whether our estimates of familiarisation costs to industry (outlined in Tables 4, 6 and 8) and our assumption that it will take businesses up to one hour to familiarise themselves with the requirements of the EU Regulations (plus half an hour for the Recycled Plastics requirements where pertinent) and one hour to disseminate to other members of staff (two or two-and-a-half hours in total) is reasonable.

If you agree or disagree with our assumptions, please explain your response and provide evidence (where possible) to support your views/comments.

Other Costs

Recyclers

53. As discussed in paragraphs 22 and 23, recycling processes that are authorised by Commission Decisions will have to undergo auditing by Member States.

Plastic manufacturers

54. The revised Plastics Regulation introduces a limit on the migration of aluminium from plastic food contact materials of 1mg/kg. This is derived from the tolerable weekly intake for aluminium of 1mg of aluminium per kilogram of bodyweight per week, as a significant part of the population exceeds this level. Assessing compliance with this migration limit will only affect those manufacturers that use aluminium in their processes. Similarly, the revised Plastics Regulation reduces the existing migration limit of zinc from plastic food contact materials.
55. The revised Plastics Regulation also introduces specific migration testing provisions for plastic materials and articles in contact with fresh unpeeled fruits and vegetables. This will offer improved consumer protection from substances that could migrate from such plastics. It is a requirement that a food simulant should be assigned to certain products for the purposes of testing but this may result in overestimation (depending on size and shape of the fruits and vegetables, and whether fruits and vegetables are peeled or not). The overestimation should be addressed with a correction factor. Depending on the circumstances (type of food simulant required), additional costs may be incurred.

BPA

56. 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.
57. Despite the costs of compliance, the industry was 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)

58. 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.

59. Familiarisation costs are quantified by multiplying the time it will take for an official to familiarise themselves with the Regulations, by the median hourly wage rate of the official, uplifted by 20% to allow for overheads, and the number of enforcement authorities or laboratories affected. A two-hour familiarisation time for all enforcement authorities and OCLs was used as per the original impact assessment.
60. 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 authorities²⁴, 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 uplifted, median hourly wage of a TSO (£17.83²⁵) and as the upper bound the uplifted, median hourly wage rate of a EEO (£22.76²⁶). This gives a central estimate of £20.30. (For full sensitivity analysis, see Annex 1).
61. For OCLs we have used an ASHE median hourly wage estimate for a science and technology professional of £20.18 which increases to £24.22 when adjusted for overheads.
62. 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 E,W&NI enforcement of £18,245.45. Table 10 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 converted 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 England affected by this proposal is estimated to be £16,485.56 which yields an annual equivalent cost of £1,915.21 for a period of 10 years. Table 11 presents familiarisation costs as annual equivalent costs.

Table 10: 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

Table Notes:

1. Totals may not sum due to rounding.

²⁴ Note that TSOs or EEOs may be responsible for enforcing this legislation depending on resource in each local authority

²⁵ <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>
Includes an overhead of 20% (14.86*1.2=17.83)

²⁶ <https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>
Includes an overhead of 20% (18.97*1.2=22.76)

2. 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.

Table 11: Annual Equivalent Costs (AEC) for enforcement authorities by country

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

6) We invite stakeholders' comments on whether our estimates of familiarisation costs to enforcement bodies and official control laboratories (outlined in Table 10) and our assumption that it will take enforcement bodies and official control laboratories one hour to familiarise themselves with the requirements of the EU Regulations, 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 explain your response and provide evidence to support your views / comments.

Benefits - Option 2

Industry

63. A benefit of the revised Plastics Regulation is that it allows industry to use new substances in the manufacture of plastic materials and articles to keep up with innovation. The requirement to test for compliance with the generic specific migration limit for substances for which no specific migration limit has been set has been removed as the migration levels from all substances are already subject to compliance with an overall migration limit. The removal of this overly burdensome testing requirement will be a benefit to businesses. Another benefit of the revised Plastics Regulation is that it provides more flexibility in compliance testing.
64. Having all the legislation in one place is helpful for smaller businesses if they are given confidence there is only one main regulation they need to reference to ensure compliance. Without this reassurance there will be concern that a regulation amendment such as this may be missed.

7) We welcome stakeholders' comments on our assessment that there may be benefits to industry for using new substances in the manufacture of plastic materials and articles, and benefits from the removal of the generic specific migration limit.

If you agree or disagree with this assessment, please explain your response and provide evidence (where possible) to support your views / comments.

Enforcement authorities

65. The amendment will provide for the execution and enforcement in England of Commission Regulation (EC) No. 282/2008 on recycled plastics, Commission Regulation (EU) No. 2016/1416 on plastics and Commission Regulation (EU) No. 2018/213 on bisphenol A; and provide for offences of contravening certain provisions of the three European Regulations,

provide for the provision of Compliance Notices, together with specifying the penalties that the Courts may impose upon conviction for an offence.

66. 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 legislations.

Consultation

67. During the course of negotiations with the Commission, FSA officials have frequently consulted 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.
68. Numerous consultations on harmonising food contact materials have been carried out/conducted since 2002. The FSA carried out two informal consultations in 2004 and 2008, which enabled the FSA to acquire useful information on the practicalities of setting out auditing provisions within the recycling Regulation. The 2008 consultation involved comments from enforcement bodies, allowing the FSA to consider frequency of auditing and other factors.
69. 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. The latest comments form the basis of on-going consideration of the auditing provisions of the Recycling Regulation.
70. In 2017, the Commission and the EFSA welcomed comments via a public consultation on the draft BPA Regulation and the hazard assessment protocol respectively. The FSA actively encouraged stakeholder participation for both consultations. 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 inform the UK on its negotiation position on BPA.
71. A total of 151 comments from European stakeholders were received via the public consultation on the hazard assessment protocol, which was held between 30 June to 3 September 2017. The 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

72. The FSA will conduct a formal public consultation from 9 April 2018 on this Impact Assessment and draft Statutory Instrument. This will be of interest to businesses that manufacture, import, wholesale and/or retail plastic and recycled plastic materials and articles intended to come into contact with food, PHAs, Local Enforcement Authorities, consumers and other parties that deal with policy and legislation on food contact materials.

Small and Micro Businesses Assessment

73. As the E,W&NI food and drink packaging industry sector is comprised of mainly small and micro businesses, these will be impacted the most by changes in the new EU Regulations. For this reason, the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.
74. The food and drink packaging industry is highly fragmented and diverse and is served by many suppliers. In 2001, the packaging industry employed approximately 100,000 people in around 2,700 companies – 85% of which are described as small-to micro-sized companies. In 2003²⁷, a study of the UK's entire packaging industry identified 13,000 packaging companies which combined, 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.
75. The potential commercial impact of the proposals applies equally to all businesses involved, small or large. 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 E,W&NI, which was highlighted within this Impact Assessment, it is often not feasible to exempt smaller businesses from new food measures. This is because it 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.

8) 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 explain your response and provide evidence (where possible) to support your response.

Statutory Post-Implementation Review

76. The FSA is required by the UK Government to carry out a review every five years on the way in which EU legislation is implemented and enforced by the relevant domestic legislation and, to the extent that it is reasonably practicable, to compare that with how the same EU measures are implemented or enforced in other Member States. The FSA will carry out a review in October 2023 (or earlier) to assess whether the Regulations are achieving their intended objectives.

Race/Gender/Disability Equality Issues

77. 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.

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

Please explain your response and provide evidence (where possible) to support your response.

²⁷ 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 2 Sensitivities of One-off Familiarisation Costs under percentages of plastics manufacturers involved in food contact materials (Central, Low or High)

Cost	Description	0	1	2	3	4	5	6	7	8	9	Total	Average/AEC	Present Value
80% of businesses	Familiarisation costs	£22,185.00	0	0	0	0	0	0	0	0	0	£22,185.00	£2,577.35	£22,185.00
100% of businesses	Familiarisation costs	£27,731.25	0	0	0	0	0	0	0	0	0	£27,731.25	£3,221.68	£27,731.25
50% of businesses	Familiarisation costs	£13,865.62	0	0	0	0	0	0	0	0	0	£13,865.63	£1,610.84	£13,865.63

Annex 3 Description of the SIC codes

Industry	SIC Code
Manufacturing: Food Contact Plastics	
Manufacturer of plastic packaging goods	2222
Manufacture of other plastic products	2229
Manufacturing	
Manufacture of other tanks, reservoirs and containers of metal	2529
Treatment and coating of metals	2561
Manufacture of light metal packaging	2592

Annex D – List of Interested Parties

Aim to Recycle
ALS Global
Ampcor
Association of Consumer Research
Association of Port Health Authorities
Ball Europe
Bettys and Taylors Group
Biffa
Biopac UK Ltd
Boots UK Limited
Brakes
Breast Cancer UK
British Bottlers' Institute
British Ceramic Confederation
British Coatings Federation
British Plastics Federation
British Retail Consortium
British Rubber & Polyurethane Products Association
British Soft Drinks Association
British Standards Committee
Campden BRI
Catering Equipment Suppliers Association
Centre for Process Innovation
Chem Trust
Chemical Industries Association
Chilled Food Association
Choice Waste Management Limited
Clean-Tech
Coca Cola European Partners
Confederation of Paper Industries
Coveris Rigid
Crown Packaging UK PLC
Department for Business, Energy and Industrial Strategy
Department for Environment, Food and Rural Affairs
Enviropack Ltd
Expopet Ltd
Federation of Small Businesses
Food and Drink Federation
Food Service Packaging Association
Futamura UK
Graphic Packaging
Green Ant Plastic Recycling
H J Heinz
Huhtamaki
Innovia Films
Jayplas
JEFAC Limited
LGC

Lewis Moberly
LINPAC Packaging Limited
Local Government Association
Marks and Spencer PLC
Metal Packaging Manufacturers Association
Morrisons PLC
Nampak
Nestle UK
Ostle and Maillard
Oxo-biodegradable Plastics Association
Packaging and Films Association
Parkside Flex
Pepsico
Plastics Europe
Polymer Extrusion Technologies (UK) Ltd
PPG
Rexam Plastic Packaging
RPC Llantrisant
Sainsburys Supermarkets Limited
Schoeller Allibert
Smithers Pira
Smithers Rapra
TDX-TSS Ltd
Tesco
The Co-operative Retail group (CWS) Ltd
The Food and Environment Research Association
The Pack Hub
The Packaging Federation
Trading Standards Institute
Tyler Packaging
Ultimet Films
Valspar
Veolia
Vision Packaging Ltd
Vow pack
Waitrose
WRAP