

## FOOD STANDARDS AGENCY CONSULTATION

### THE PLASTIC KITCHENWARE (CONDITIONS ON IMPORTS FROM CHINA) (ENGLAND) REGULATIONS 2011

#### CONSULTATION SUMMARY PAGE

<b>Date consultation launched:</b>	<b>Closing date for responses:</b>
28 <sup>th</sup> April 2011	27 <sup>th</sup> May 2011

**Who will this consultation be of most interest to?**  
 Businesses that manufacture, import, wholesale and/or retail polyamide and melamine plastic kitchenware from China and Hong Kong, consumers who use such products, consumer groups, Port Health Authorities, HM Revenue and Customs, UK Border Agency and Local Enforcement Authorities.

**What is the subject of this consultation?**  
 The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011 which would provide for the execution and enforcement, in England, of European Commission Regulation (EU) No. 284/2011 which lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong, Special Administrative Region, China.

**What is the purpose of this consultation?**  
 To seek comments from industry, enforcement and consumer interests on the Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011 and the associated draft Impact Assessment.

**Responses to this consultation should be sent to:**

Name: Nasreen Shah Division/Branch: Chemical Safety Division FOOD STANDARDS AGENCY Tel: 020 7276 8553 Fax: 020 7276 8446	Postal address: Room 3B, Aviation House, 125 Kingsway, London, WC2B 6NH. Email: <a href="mailto:nasreen.a.shah@foodstandards.gsi.gov.uk">nasreen.a.shah@foodstandards.gsi.gov.uk</a>
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<b>Is an Impact Assessment included with this consultation?</b>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> See Annex A for reason.
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# **THE PLASTIC KITCHENWARE (CONDITIONS ON IMPORTS FROM CHINA) (ENGLAND) REGULATIONS 2011**

## **DETAIL OF CONSULTATION**

1. We would welcome your comments on:
  - **The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011 (“the proposed national Regulations”) at Annex B.** These Regulations would provide for the execution and enforcement, in England, of Commission Regulation (EU) No. 284/2011 (“the EU Kitchenware Regulation”) at **Annex C** which lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in, or consigned from, China, including Hong Kong (hereafter referred to together as “China”).
  - **The draft Impact Assessment (IA) at Annex D.** We would particularly welcome comments and supporting evidence in respect of any cost implications that may arise from this proposal.
2. The Food Standards Agency in Scotland, Wales and Northern Ireland will be carrying out consultations on parallel but separate Regulations relating to those parts of the UK and associated draft Impact Assessments.

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

3. Harmonised EU rules on plastic food contact materials are currently laid down by Commission Directive 2002/72/EC (as amended) relating to plastic materials and articles intended to come into contact with foodstuffs (“the principal Directive”). This Directive has been consolidated in the form of a new EU Regulation<sup>1</sup>, which will apply from 1<sup>st</sup> May 2011, with the relevant requirements remaining unaltered. These requirements are implemented in England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009<sup>2</sup>. The legislation requires that PAAs should not be detectable using the detection limit of 0.01 milligram per kilogram of food.

## **Background**

### ***Plastic Food Contact Materials Imported into the EU from China***

4. Several notifications and alerts have been received via the EU Rapid Alert System for Food and Feed (RASFF) in respect of plastic food contact materials imported into the EU from China releasing chemicals into food or food simulant<sup>3</sup> at levels exceeding those laid down in the principal Directive.
5. These notifications and alerts related primarily to polyamide plastic kitchenware releasing primary aromatic amines or melamine kitchenware releasing formaldehyde into food or food simulant at levels exceeding those respectively laid down in Part A of Annex V and Section A of Annex II to the principal Directive.

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<sup>1</sup> Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.

<sup>2</sup> SI 2009 No. 205

<sup>3</sup> Food simulants are materials intended to mimic the migration behavioural properties of foods. They are used in the laboratory to provide a conservative estimate of the amount of individual substances that may migrate from packaging into food.

## **Primary Aromatic Amines (PAAs) and Formaldehyde**

6. PAAs and formaldehyde may respectively occur in polyamide or melamine plastic food contact materials as a result of the presence of impurities or breakdown products. PAAs are a family of compounds, some of which are proven to be carcinogenic, while others are suspected carcinogens and could potentially be a health risk to consumers. Formaldehyde also has the potential to cause adverse health effects.
7. Levels of formaldehyde have been released into foods that are higher than those authorised in EU legislation from melamine plastic kitchenware also originating in or consigned from China.
8. Formaldehyde is produced on a large scale and is used in the production of phenolic, urea, melamine and polyacetal resins. Formaldehyde is also used as an intermediate in the manufacture of industrial chemicals and as an aqueous solution (formalin) as a disinfectant and preservative.
9. In 2007, the European Food Safety Authority's (EFSA) CEF (Food Contact Materials, Enzymes, Flavourings and Processing Aids) Panel concluded that there is no evidence indicating that formaldehyde is carcinogenic by the oral route, on the basis of recent and previous evaluation. There is evidence that formaldehyde can elicit immune effects such as hypersensitivity and contact dermatitis in sensitive individuals. The World Health Organisation (WHO) Concise International Chemical Assessment Document (CICAD, 2002) suggests that "the concentration of formaldehyde likely to elicit contact dermatitis reactions in hypersensitive individuals may be as low as 30 milligrams per litre".

## **European Commission Initiatives and Action**

10. The Commission has taken forward several initiatives with the Chinese control authorities and the industry concerned to increase their knowledge of EU legislation on food contact materials. Despite these initiatives, two missions of the Commission's Food and Veterinary Office (FVO) to China in 2009 identified serious weaknesses in the official control system of plastic food contact materials imported into the EU.
11. Large quantities of polyamide and melamine plastic kitchenware originating in or consigned from China have failed to comply with the requirements of the legislation. The increasing levels of alerts in several Member States subsequent to these visits have resulted in specific control measures being introduced by the Commission in the form of the EU Kitchenware Regulation.

## **The EU Kitchenware Regulation**

12. The EU Kitchenware Regulation was published in the Official Journal (OJ) of the European Union on 23 March 2011<sup>4</sup> and is directly applicable throughout the EU. It came into force on 11 April 2011 and will apply from 1 July 2011. It can be downloaded from the European Union website at:

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2011:077:SOM:EN:HTML>

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<sup>4</sup> Ref OJ, L77, 23.03.2011, pg 25-29

13. The Regulation lays down the specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from China. Its key requirements are as follows:

- Relevant consignments may only be imported into the EU if the importer submits a declaration to the competent authority that the products comply with the requirements in Directive 2002/72/EC on plastic food contact materials concerning the release of PAAs and formaldehyde. A template declaration<sup>5</sup> is annexed to the Regulation. A laboratory report must accompany the declaration.
- Importers or their representatives must provide prior notification of consignments originating in or consigned from China to the competent authority at least two working days before the estimated date and time of their physical arrival.
- Documentary checks (for documents required by the Regulation) must be carried out by competent authorities on all relevant consignments within two working days of their arrival.
- Random identity checks (visual checks to ensure that accompanying documents relate to the contents of a consignment) and physical checks (sampling and laboratory analysis) must be undertaken by competent authorities, on 10% of all relevant consignments.
- The results of physical checks must be made available as soon as technically possible. The competent authority at the first point of entry may authorise the onward transportation of consignments pending the results of the checks whilst ensuring that such consignments remain under continuous competent authority control.
- Competent authorities must keep records of the checks they undertake which must include details of each consignment checked, including (i) the size in terms of numbers and articles; and (ii) the country of origin, the number of consignments subject to sampling and analysis; and the results of the checks.
- Member States must inform the Commission immediately of the non-compliance identified by laboratory analysis through the EU Rapid Alert System for Food and Feed (RASFF) and are required to submit a quarterly report to the Commission by the end of the month following each quarter.
- Competent authorities are required to indicate on declarations whether relevant consignments are acceptable or not for release. Relevant consignments may only be released for free circulation on presentation to Customs authorities of a declaration endorsed by the competent authority confirming that the consignment is acceptable for release.
- Member States may designate<sup>6</sup> specific first points of introduction for relevant consignments. Where they do, they must publish and maintain an up-to-date list

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<sup>5</sup> The declaration required by the EU Kitchenware Regulation is in addition to that required under The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 (SI 2009/205) and Article 16 of Regulation (EC) 1935/2004 on articles and materials intended to come into contact with food.

<sup>6</sup> At present a decision has not been made to designate specific points of introduction in the UK; this issue is currently under consideration. Should the decision be made to designate points of introduction, the Agency will advise stakeholders as appropriate.

of these on the internet and report the link to the Commission which will publish a consolidated list on its own website.

### ***Proposed National Regulations***

14. The proposed Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011 would provide for the execution and enforcement of the EU Kitchenware Regulation. They would:
- Designate Port Health Authorities and Local Authorities at points of entry as having responsibility for the enforcement of the EU Kitchenware Regulation in England;
  - Provide powers for dealing with non-compliant consignments;
  - Provide for the recovery, by enforcement authorities, of the costs of additional official controls arising from the EU Kitchenware Regulation;
  - Create offences for contravening certain provisions of the EU Kitchenware Regulation and for defences against prosecution for committing an offence in particular circumstances;
  - Specify the penalties that the Courts may impose upon conviction for an offence; and
  - Providing for administrative arrangements such as service of notices and rights of appeal.

### ***Recovery of Costs Associated with Enforcing the EU Kitchenware Regulation***

15. The proposed national Regulations would allow all costs arising from the *additional* official controls undertaken by Enforcement Authorities arising from the EU Kitchenware Regulation, including any action taken following non-compliance, to be recovered from importers or their representatives. Articles 27, 28 and 54 of Regulation (EC) No 882/2004, which introduce a voluntary system of fees or charges that Member States may collect when performing particular types of official controls, provide the legal basis for the recovery of these costs
16. Article 4 of the EU Kitchenware Regulation requires importers or their representatives to give notice of the estimated date and time of the arrival of a relevant consignment to Enforcement Authorities of at least 2 working days before its physical arrival. The intention of this provision is to allow Enforcement Authorities to plan and prepare for the checks required by Article 6 of the Regulation. As such, Article 4 has a clear relationship with Article 6 which requires Enforcement Authorities to carry out documentary checks on all consignments within two working days of their arrival. In respect of consignments that arrive without prior notification, it is envisaged that Food Authorities will therefore be permitted, by virtue of the breach of Article 4, to take up to four working days to carry out the checks required by Article 6.
17. In respect of consignments arriving without the required declaration or with a declaration that is not in compliance with Articles 3(1), (2) and (3) of the EU Kitchenware Regulation, under the proposed national Regulations, Enforcement Authorities would have two options. They may choose either to (a) issue a notice

requiring the importer or their representative to submit a compliant declaration within 14 days of the notice or (b) invoke rejection procedures described in paragraph 18, below.

18. In respect of consignments for which a declaration is not provided in compliance with a notice described in paragraph 17 above has been served, not provided within the timescale specified or those found not to be non-compliant following the physical checks and laboratory analysis provided for by Article 6(b) of the EU Kitchenware Regulation, the Enforcement Authority must issue a notice requiring the consignment to be re-dispatched outside the EU or destroyed at the importer's expense within 30 days of the date of the notice.

### ***EU Guidance***

19. The Commission has produced draft Community Guidelines on the EU Kitchenware Regulation and the Commission's Joint Research Centre has produced draft technical Guidelines for laboratories on testing the migration of PAAs from polyamide kitchenware and for formaldehyde from melamine plastic kitchenware. These draft guidelines are currently under discussion with Member States and, once finalised, will be published on the European Union website at:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

### **Consultation**

#### ***Informal Consultation***

20. In Spring/Summer 2010, during the course of European negotiations, the Food Standards Agency (FSA) conducted an informal consultation with trade associations, individual companies, Enforcement Authorities and their representative bodies, the UK Border Agency and HM Revenue and Customs.
21. Comments received by the FSA in response to this informal consultation focused mainly on the cost implications for both industry and enforcement authorities. These comments informed the UK's approach in discussions in EU Working Group meetings, which led to a substantial reduction in the percentage of consignments to be subjected to random physical checks from the 50%, initially proposed by the Commission, down to 10%, as reflected in the published EU Regulation.

#### ***This Consultation***

#### ***Purpose of the Consultation***

22. The FSA is conducting this consultation to seek comments from interested parties and obtain their views on the proposal to make national Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation by enforcement authorities in England.
23. The key proposal on which this consultation seeks comments are as follows:

**Key proposal:**

**To make national Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation by enforcement authorities in England.**

24. Any comments that interested parties are able to provide in relation to the proposed national Regulations would be gratefully received. We would be particularly keen to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage them to comment on all aspects of the proposal and its intended effect.

**Consultation Questions:**

**Q1. Will SMEs be affected and, if so, how many will be affected, and what are the likely financial implications for this sector? Please provide evidence to support your response.**

**Q2. Are the numbers of retailers and wholesalers set out in Table 1 of the draft Impact Assessment an accurate representation of such businesses likely to be affected? Please provide evidence to support your response.**

**Q3. How many importers are likely to be affected? We would be grateful for any available evidence you are able to provide on this sector.**

**Q4. Do you agree with our assumption that charities and voluntary organisations are unaffected? Please provide evidence to support your response.**

**Q5. Do you agree with our estimate of one hour for a TSO or EHO in each enforcement authority to familiarise themselves with the legislation and a further hour for reading and dissemination to key staff? Please provide evidence to support your response.**

**Q6. What new or additional costs over and above those associated with the current relevant enforcement activity are likely to be incurred as a result of the EU Kitchenware Regulation and the national Regulations? Please provide evidence to support your response.**

**Q7. Are the costs of enforcement for a specific Port Health Authority in Table 4 of the draft Impact Assessment typical of those incurred by other Port Health Authorities in respect of similar enforcement activity? Please provide evidence to support your response.**

**Q8. Are the total sampling costs in paragraph 44 of the draft Impact Assessment and the assumptions used to calculate them accurate? Please provide evidence to support your response.**

**Q9. Do Enforcement Authorities have any comments on the proposed national Regulations in so far as they relate to the provisions for enforcement, defences and penalties?**

**Q10. Do you agree with our estimate of one hour for an employee of each business to familiarise themselves with the legislation and a further hour for reading and dissemination to key staff? Please provide evidence to support your response.**

**Q11. What new or additional costs, over and above those associated with current relevant commercial activities would the EU Kitchenware Regulations and the national Regulations cause industry in England to incur? Please provide evidence to support your response.**

**Q12. Are the numbers of consignments used to calculate the cost to businesses (including importers) in paragraph 53 of the draft Impact Assessment an accurate representation? Please provide evidence to support your response.**

**Q13. Do you have any evidence to quantify the daily fee referred to in paragraph 53 of the draft Impact Assessment? (The costs in Table 9 of the draft Impact Assessment are based on a set fee). Please provide evidence to support your response.**

**Q14. Do you agree with our assumption that businesses may incur additional costs for inland storage of consignments pending the release of analytical results? Please provide evidence to support your response.**

**Q15. Are the costs of storing consignments whilst awaiting clearance in Paragraph 55 of the draft Impact Assessment an accurate estimate? Please provide evidence to support your response.**

**Q16. What is the potential loss of earnings (if any) to businesses, while awaiting the release of impounded products? If there is a loss, is this affordable? Please provide evidence to support your response.**

**Q.17 Do you agree that costs recovered by Enforcement Authorities from UK businesses will be passed back by those businesses to the Chinese exporters? Is there any information available to support your response?**

**Q.18 As the additional controls are specific to polyamide and melamine plastic kitchenware originating, in or consigned from, China, what is the likelihood of businesses sourcing such products from elsewhere and, if so, what additional costs, if any, would be incurred? Please provide evidence to support your response.**

**Q.19 Do businesses have any comments on the proposed national Regulations in so far as they relate to the provisions for enforcement, defences and penalties?**

**Q.20 Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Kitchenware Regulation and national Regulation? Please provide evidence to support your response.**

### **Other relevant documents**

25. The Plastic Materials and Articles in Contact with Food (England) Regulations 2009, which are available on the 'legislation.gov.uk' website at:

<http://www.legislation.gov.uk/uksi/2009/205/contents/made>

26. Draft commission services working document in preparation of Community guidelines on conditions and procedures for the import of polyamide and melamine kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China. When published, the guidelines will be available at the following website:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm)

### **Responses**

27. Responses are required by **Friday 27<sup>th</sup> May 2011**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

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

Yours faithfully,

Nasreen Shah  
Regulation and Business Support Team  
Chemical Safety Division

**Enclosed**

**Annex A:** Standard Consultation Information

**Annex B:** The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011

**Annex C:** Commission Regulation (EU) No. 284/2011, laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from China

**Annex D:** Draft Impact Assessment

**Annex E:** List of interested parties

## Queries

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

## Publication of personal data and confidentiality of responses

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

## Further information

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

## The Seven Consultation Criteria

### Criterion 1 — When to consult

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

### Criterion 2 — Duration of consultation exercises

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

**Criterion 3 — Clarity of scope and impact**

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

**Criterion 4 — Accessibility of consultation exercises**

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

**Criterion 5 - The burden of consultation**

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

**Criterion 6 - Responsiveness of consultation exercises**

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

**Criterion 7 - Capacity to consult**

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

8. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.* This consultation is not being held for a full 12 weeks. It is instead being held for a shortened period of 4 weeks given the potential risk to consumer health, the earlier 12-week consultation conducted by the Food Standards Agency in Spring/Summer 2010 and the need for national Regulations to come into force on 1 July 2011 to provide for the enforcement of the EU Regulation from date of its application. This shortened consultation will allow stakeholders the additional opportunity to comment on the proposed national Regulations and associated draft Impact Assessment.
9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex D.
10. For details about the consultation process (not about the content of this consultation) please contact: [Food Standards Agency Consultation Co-ordinator](#), Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

**Comments on the consultation process itself**

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

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

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

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

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

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STATUTORY INSTRUMENTS

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2011 No.

FOOD, ENGLAND

The Plastic Kitchenware (Conditions on Imports from China)  
(England) Regulations 2011

<i>Made</i> - - - -	***
<i>Laid before Parliament</i>	***
<i>Coming into force</i> - -	1st July 2011

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a), and now vested in him(b).

In so far as these Regulations cannot be made under the powers in the Food Safety Act 1990 specified above, the Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(c).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink)(d).

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

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(e), there

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- (a) 1990 c.16, section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.
- (b) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- (c) 1972 c.68.
- (d) S.I. 2003/2901.
- (e) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468 with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

has been open and transparent public consultation during the preparation and evaluation of these Regulations.

### **Title, application and commencement**

1. These Regulations may be cited as the Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011, apply in relation to England only and come into force on 1st July 2011.

### **Interpretation**

2.—(1) In these Regulations —

“the Commission Regulation” means Commission Regulation (EU) No. 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People’s Republic of China and Hong Kong Special Administrative Region, China(a);

“the Act” means the Food Safety Act 1990(b);

“the Agency” means the Food Standards Agency;

“food authority” has the meaning that it bears by virtue of section 5(1) of the Act except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner and Middle Temple);

“relevant product” means polyamide and melamine plastic kitchenware originating in or consigned from People’s Republic of China and Hong Kong Special Administrative Region, China.

(2) Any expression used in these Regulations and the Commission Regulation has the same meaning in these Regulations as it bears in the Commission Regulation and any reference to a numbered Article is a reference to the Article so numbered in the Commission Regulation.

(3) Where any functions under the Food Safety Act 1990 are assigned —

(a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(c), to a port health authority;

(b) by an order under section 6 of the Public Health Act 1936(d), to a joint board for a united district; or

(c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985(e), a single authority for a metropolitan county,

any reference in these Regulations to a food authority shall be construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

### **Breach of conditions on import of plastic kitchenware from China**

3.—(1) No person may place on the market in England any relevant product that has been imported into the European Union other than in compliance with the requirements of Article 3(1),(2) and (3) (import conditions).

(2) No person may place on the market in England any relevant product until —

(a) the checks specified in paragraph 1(a) and, as the case may be, paragraph 1(b) of Article 6 (controls at the first point of introduction) have been completed; and

(b) the food authority has issued a declaration in accordance with Article 3(4) indicating that the relevant product is acceptable for release into free circulation.

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(a) OJ No. L77, 23.3.2011, p.25.

(b) 1990 c.16.

(c) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990.

(d) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

(e) 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

### **Offences and penalties**

4. Any person who fails to comply with paragraph (1) or (2) of regulation 3 is guilty of an offence and liable —

- (a) on conviction on indictment, to a fine; or
- (b) on summary conviction, to a fine not exceeding the statutory maximum.

### **Competent authorities**

5.—(1) The competent authority for the purposes of Articles 3(1) and (4), 4, 6(1), 7 and 9 is each food authority in its area or district.

(2) The competent authority for the purpose of Article 6(2) is the Agency.

### **Execution and enforcement**

6.—(1) It is the duty of each food authority in its area or district to execute and enforce the Commission Regulation and these Regulations.

(2) Each food authority shall —

- (a) immediately inform the Agency of the results of any laboratory analysis which it has caused to be carried out under Article 6(1) if the results of that analysis indicate non-compliance; and
- (b) give the Agency such information and assistance as it may reasonably request in connection with the execution and enforcement of these Regulations.

(3) The Commissioners for Her Majesty's Revenue and Customs shall carry out the functions given to customs authorities under Article 8.

### **Expenses arising from official controls**

7.—(1) Expenses charged pursuant to Article 27(1) of Regulation 882/2004 by a food authority to an importer in connection with the checks mentioned in Article 6(1) shall be payable by the importer on the written demand of the food authority.

(2) Where a food authority identifies non-compliance with the requirements of Article 3(1),(2) or (3) or Article 4, expenses charged pursuant to Article 54(5) of Regulation 882/2004 by a food authority to an importer shall be payable by the importer on the written demand of the food authority.

(3) In paragraph (1) and (2) and in regulation 8(3), Regulation 882/2004 means Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules(a).

### **Notices and actions in the case of non-compliance**

8.—(1) If an importer presents a consignment of relevant product for import into England without submitting a declaration and accompanying laboratory report in accordance with the requirements of Article 3(1),(2) and (3), the food authority may by written notice require the importer to submit such a declaration and laboratory report within 14 days of the date of the notice.

(2) If the documentary checks or the physical checks provided for in Article 6(1)(a) or 6(1)(b) respectively indicate that —

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(a) OJ No. L191, 28.5.2005, p.1. This Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).

- (a) a declaration or a laboratory report as referred to in Article 3(1) and 3(3) respectively has not been provided or, if notice has been served under paragraph (1), has not been provided by the date specified in the notice;
- (b) a declaration or a laboratory report has been provided that does not comply with the requirements of Article 3(1),(2) and (3); or
- (c) the relevant product that is the subject of the checks does not meet the requirements of Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food(a),

the food authority must take the steps set out in paragraph (3).

(3) The food authority must, by written notice —

- (a) require the importer within 30 days of the date of the notice —
  - (i) to re-dispatch the consignment outside the European Union [from the same point of introduction where it was first presented for import into England], or
  - (ii) at the importer's expense to destroy the consignment under official control; and
- (b) inform the importer that if the requirements of sub-paragraph (a) are not complied with the authority may in accordance with Article 54(2)and (5) of Regulation 882/2004 arrange for the destruction of the consignment and recover the costs of storage and destruction from the importer.

(4) Any notice under paragraph (1) or (3) may be served on the importer or the importer's representative.

### **Rights of appeal**

9.—(1) Any person who is aggrieved by a decision of an authorised officer to serve a notice under regulation 8(3) may appeal to a magistrates' court.

(2) The procedure on an appeal to a magistrates' court under paragraph (1) 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 under paragraph (1) may be brought shall be one month from the date on which the notice was served on the person desiring to appeal and the making of a complaint for an order shall be deemed for the purposes of this paragraph to be the bringing of the appeal.

(4) Where on an appeal under paragraph (1) a magistrates' court determines that the decision of the authorised officer is incorrect, the authority shall give effect to the determination of the court.

(5) A person who is aggrieved by the dismissal by a magistrates' court of an appeal to it under paragraph (1) may appeal to the Crown Court.

### **Application of various sections of the Food Safety Act 1990**

10.—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations —

- (a) section 20 (offences due to fault of another person);
- (b) section 21 (defence of due diligence)(b) with the modification that —
  - (i) subsections (2) to (4) shall apply in relation to an offence of contravening regulation 3 as they apply in relation to an offence under section 14 or 15, and
  - (ii) in subsection (4) the references to "sale" are deemed to include references to "placing on the market";
- (c) section 30(8) (which relates to documentary evidence);

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(a) OJ No. L12, 15.1.2011, p.1.

(b) Section 21 was amended by S.I. 2004/3279.

- (d) section 35(1) (punishment of offences)(a), in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);
- (e) section 35(2) and (3)(b), in so far as it relates to offences under section 33(2) as applied by paragraph (3)(c);
- (f) section 36 (offences by bodies corporate); and
- (g) section 36A (offences by Scottish partnerships)(c).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the references in subsection (1) to the Act are to be construed as including references to the Commission Regulation.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act is to be construed as including a reference to the Commission Regulation and these Regulations —

- (a) section 33(1) (obstruction etc. of officers);
- (b) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (a); and
- (c) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under regulation 4 as it applies to offences punishable under section 35(2) of the Act.

#### **Statutory review**

**11.—**(1) Before the end of each review period the Agency must —

- (a) carry out a review of regulations 3 to 10;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review the Agency must, so far as is reasonable, have regard to how the Commission Regulation is 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 so, the extent to which they could be achieved with a system that imposes less regulation.

(4) “Review period” means —

- (a) the period of 5 years beginning with the day on which these Regulations come into force; and
- (b) [subject to paragraph (5),] each successive period of 5 years.

(5) [If the report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.]

Signed by authority of the Secretary of State for Health

*Minister's name*

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- (a) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.
  - (b) Section 35(3) was amended by S.I. 2004/3279.
  - (c) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

**Date**

**Parliamentary Under Secretary of State,  
Department of Health**

## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

**1.** These Regulations.....*(to be completed following consultation)*

**2.** 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 at [www.legislation.gov.uk](http://www.legislation.gov.uk).



**COMMISSION REGULATION (EU) No 284/2011****of 22 March 2011****laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <sup>(1)</sup>, and in particular Article 48(1) thereof,

Whereas:

- (1) Commission Directive 2002/72/EC <sup>(2)</sup> lays down specific provisions relating to plastic materials and articles intended to come into contact with foodstuffs, including compositional requirements, and restrictions and specifications for substances that may be used therein.
- (2) Several notifications and alerts have been received by the Rapid Alert System for Food and Feed pursuant to Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(3)</sup> concerning food contact materials imported into the Union from the People's Republic of China (hereinafter 'China') and Hong Kong Special Administrative Region of the People's Republic of China (hereinafter 'Hong Kong'), releasing into food or food simulant amounts of chemicals that are not in compliance with the Union legislation.
- (3) These notifications and alerts primarily concern polyamide and melamine plastic kitchenware that does not comply with the requirements concerning the release of primary aromatic amines and formaldehyde into food as laid down in Part A of Annex V and Section A of Annex II to Directive 2002/72/EC respectively.
- (4) Primary aromatic amines (hereinafter 'PAA') are a family of compounds, some of which are carcinogenic, while others of these compounds are suspected carcinogens. PAA may arise in materials intended for food contact as a result of the presence of impurities or breakdown products.
- (5) Polyamide kitchenware originating in or consigned from China and Hong Kong has been reported to release high level of PAA into food.
- (6) Directive 2002/72/EC authorises the use of formaldehyde in the manufacture of plastics, provided that these plastics do not release into food more than 15 mg/kg of formaldehyde (specific migration limit (SML) expressed as total formaldehyde and hexamethylenetetramine).
- (7) Melamine kitchenware originating in or consigned from China and Hong Kong has been reported to release into food levels of formaldehyde that are higher than those authorised.
- (8) In the past few years, in order to increase knowledge of the requirements set out in Union legislation concerning food contact materials imported into the Union, the Commission has taken several initiatives, including training sessions for Chinese control authorities and the industry concerned.
- (9) Despite those initiatives, the missions of the Food and Veterinary Office to China and Hong Kong in 2009 identified serious deficiencies in the official control system regarding plastic food contact materials intended for importation into the Union and large quantities of controlled polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong still do not fulfil the requirements of Union legislation.
- (10) Regulation (EC) No 1935/2004 of the European Parliament and of the Council <sup>(4)</sup> lays down specific provisions relating to the materials and articles intended to come into contact directly or indirectly with food, including certain general and specific requirements that these materials and articles should fulfil. Pursuant to Article 24 thereof, Member States shall carry out official controls in order to enforce compliance with that Regulation in accordance with the relevant provisions of Union law relating to official food and feed controls. Those provisions are laid down in Regulation (EC) No 882/2004.
- (11) More specifically, Article 48(1) of Regulation (EC) No 882/2004 provides that in so far as Union legislation does not lay down the conditions and detailed procedures to be respected when importing goods from third countries, they may, if necessary, be laid down by the Commission.

<sup>(1)</sup> OJ L 165, 30.4.2004, p. 1.<sup>(2)</sup> OJ L 220, 15.8.2002, p. 18.<sup>(3)</sup> OJ L 31, 1.2.2002, p. 1.<sup>(4)</sup> OJ L 338, 13.11.2004, p. 4.

- (12) Article 48(2) of Regulation (EC) No 882/2004 provides for the possibility to impose specific import conditions on particular products coming from certain third countries, taking into account the risks associated with these products.
- (13) In order to minimise the health risks that may arise from polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong, each consignment of such products should be accompanied by appropriate documentation, including analytical results showing that it meets the requirements concerning the release of PAA and formaldehyde respectively, as laid down in Directive 2002/72/EC.
- (14) In order to ensure a more efficient organisation of the controls of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong, the importers or their representatives should give prior notification of the arrival and of the nature of the consignments. Likewise, Member States should have the possibility to designate specific first points of introduction through which consignments of these articles may enter the Union. This information should be publicly available.
- (15) In order to ensure a degree of uniformity at the Union level with regard to the controls of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong, the procedure for the official controls, as defined in Article 2 of Regulation (EC) No 882/2004, should be defined in this Regulation. These controls should include documentary, identity and physical checks.
- (16) In the event of non-compliance being identified during the physical checks, Member States should immediately inform the Commission through the Rapid Alert System for Food and Feed.
- (17) Member States should have the possibility, in specific cases, to authorise the onward transportation of consignments of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong from the first point of introduction, provided arrangements are made with the competent authority at the point of destination to ensure the traceability of the consignments pending the results of the physical checks, in order to allow the competent authority to deal with the process of importing such consignments effectively and efficiently.
- (18) The release into free circulation of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong should take place only once all the checks have been completed and the results are known. For that purpose the result of the controls should be made available to the customs authorities before the goods can be released for free circulation.
- (19) A procedure for recording the information obtained from these controls should be established. This information should be submitted regularly to the Commission.
- (20) The provisions of this Regulation should be periodically reviewed, taking into account the information received from the Member States.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### Article 1

##### Subject matter

This Regulation lays down specific conditions and detailed procedures for the import of polyamide and of melamine plastic kitchenware originating in or consigned from the People's Republic of China (hereinafter 'China') and Hong Kong Special Administrative Region of the People's Republic of China (hereinafter 'Hong Kong').

#### Article 2

##### Definitions

For the purpose of this Regulation the following definitions shall apply:

- (a) 'plastic kitchenware' means plastic materials as described in paragraphs 1 and 2 of Article 1 of Directive 2002/72/EC and falling within CN code ex 3924 10 00;
- (b) 'consignment' means a quantity of polyamide or melamine plastic kitchenware, covered by the same document(s), conveyed by the same means of transport and coming from the same third country;
- (c) 'competent authorities' means the competent authorities of the Member States designated in accordance with Article 4 of Regulation (EC) No 882/2004;
- (d) 'first point of introduction' means the point of entry of a consignment into the Union;
- (e) 'documentary check' means the checking of the documents referred to in Article 3 of this Regulation;
- (f) 'identity check' means a visual inspection to ensure that the documents accompanying the consignment tally with the contents of the consignment;
- (g) 'physical check' means the sampling for analysis and laboratory testing and any other check necessary to verify compliance with the requirements concerning the release of PAA and formaldehyde laid down in Directive 2002/72/EC.

*Article 3***Import conditions**

1. Polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong shall be imported into the Member States only if the importer submits to the competent authority for each consignment a declaration, duly completed, confirming that it meets the requirements concerning the release of primary aromatic amines and formaldehyde laid down in Part A of Annex V and in Section A of Annex II to Directive 2002/72/EC respectively.

2. A model of the declaration referred to in paragraph 1 is set out in the Annex to this Regulation. The declaration shall be drawn up in the official language, or in one of the official languages, of the Member State in which the consignment is imported.

3. The declaration referred to in paragraph 1 shall be accompanied by a laboratory report providing:

(a) as regards polyamide kitchenware, analytical results demonstrating that they do not release into foods or food simulants primary aromatic amines in a detectable quantity. The detection limit applies to the sum of primary aromatic amines. For the purpose of the analysis the detection limit for primary aromatic amines is set at 0,01 mg/kg food or food simulants;

(b) as regards melamine kitchenware, analytical results demonstrating that they do not release into foods or food simulants formaldehyde in a quantity exceeding 15 mg/kg food.

4. The competent authority shall indicate in the declaration set out in the Annex to this Regulation, whether the goods are acceptable or not for release into free circulation, depending on whether they fulfil the terms and conditions provided for in Directive 2002/72/EC as set out in paragraph 1.

*Article 4***Prior notification of consignments**

Importers or their representatives shall notify the competent authority at the first point of introduction at least two working days in advance of the estimated date and time of physical arrival of consignments originating in or consigned from China and Hong Kong.

*Article 5***Notification of the first point of introduction**

Where the Member States decide to designate specific first points of introduction for consignments originating in or consigned from China and Hong Kong, they shall publish on the Internet an up-to-date list of these points and communicate the Internet address to the Commission.

The Commission shall display on its website; for information purposes, the links to the national lists of specific first points of introduction.

*Article 6***Controls at the first point of introduction**

1. The competent authority at the first point of introduction shall carry out:

(a) documentary checks on all consignments within two working days from the time of their arrival;

(b) identity and physical checks, including laboratory analysis of 10 % of consignments, and in such a way that it is not possible for the importers or their representatives to predict whether any particular consignment will be subjected to such checks; the results of physical checks must be available as soon as technically possible.

2. If the laboratory analysis referred to in point (b) of paragraph 1 identifies non-compliance, the competent authorities shall immediately inform the Commission of the results through the Rapid Alert System for Food and Feed established by Article 50 of Regulation (EC) No 178/2002.

*Article 7***Onward transportation**

The competent authority at the first point of introduction may authorise the onward transportation of the consignments originating in or consigned from China and Hong Kong, pending the results of the checks referred to in point (b) of Article 6(1).

If the competent authority grants the authorisation referred to in the first paragraph, it shall notify the competent authority at the point of destination and shall supply a copy of the declaration set out in the Annex, duly completed as provided in Article 3 and the results of the checks referred to in point (b) of Article 6(1), as soon as the latter are available.

The Member States shall ensure that appropriate arrangements are put in place to ensure that the consignments remain under the continuous control of the competent authorities and cannot be tampered with in any way pending the results of the checks mentioned in point (b) of Article 6(1).

*Article 8***Release for free circulation**

The release for free circulation of polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong is subject to the presentation to the customs authorities of the declaration set out in the Annex duly completed as provided for in Article 3.

*Article 9***Reporting to the Commission**

1. When checks referred to in Article 6(1) are performed, the competent authorities shall keep records of the following information:

- (a) details of each consignment checked, including:
  - (i) the size in terms of number of articles;
  - (ii) the country of origin;
- (b) the number of consignments subject to sampling and analysis;
- (c) the results of the controls referred to in Article 6.

2. Member States shall submit to the Commission a report including the information referred to in paragraph 1, quarterly by the end of the month following each quarter.

*Article 10***Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall apply from 1 July 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States in accordance with the Treaties.

Done at Brussels, 22 March 2011.

*For the Commission*

*The President*

José Manuel BARROSO

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<b>Title:</b> <b>The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011</b>  <b>Lead department or agency:</b> Food Standards Agency  <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>
	<b>IA No:</b> FOOD0026
	<b>Date:</b> 27 April 2011
	<b>Stage:</b> Consultation
	<b>Source of intervention:</b> EU
	<b>Type of measure:</b> Secondary legislation
<b>Contact for enquiries:</b> Nasreen Shah, Tel: 020 7276 8553 <a href="mailto:Nasreen.a.shah@foodstandards.gsi.gov.uk">Nasreen.a.shah@foodstandards.gsi.gov.uk</a>	

## Summary: Intervention and Options

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

Laboratory analyses on polyamide (nylon) and melamine plastic kitchenware presented for import into the EU from the People's Republic of China and Hong Kong (together referred to as "China" in this document) continue to show the release, into food or food simulant, of primary aromatic amines (PAAs) or formaldehyde respectively, at levels above those permitted by EU legislation. Prolonged exposure to these chemicals may present a risk to consumer health: PAAs are proven to be carcinogenic, whilst excessive levels of formaldehyde can have potential adverse health effects. In order to address the issue of non-compliant product reaching the EU, and the associated risks to consumer health, European Commission Regulation (EU) No. 284/2011 ("the EU Kitchenware Regulation") sets down additional import controls, applicable from 1 July 2011. Government intervention is necessary to provide for the execution and enforcement of the EU Regulation by means of national Regulation.

### What are the policy objectives and the intended effects?

To make national Regulations to provide for the execution and enforcement, in England, of the EU Kitchenware Regulation which aims to reduce the risk of non-compliant plastic kitchenware from China entering the EU, thereby minimising the associated risks to EU consumers.

### 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 execution and enforcement of the EU Kitchenware Regulation in England. This would allow polyamide and melamine plastic kitchenware from China to enter the UK with no additional controls being applied. It would also lead to the UK being liable to infraction proceedings by the European Commission.

**Option 2:** Make national Regulations relating to England to provide for the execution and enforcement of the Commission Regulation.

**Option 3:** Non-regulatory option – European Commission visits to China to encourage the Chinese control authorities to improve the safety standards of kitchenware manufactured there. This option has been tried and tested with the Chinese control authorities without success.

Option 2 is preferred. This option will align the UK with other Member States in the protection of consumer safety.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** July 2016

**What is the basis for this review?** Duty to review. **If applicable, set sunset clause date:** N/A

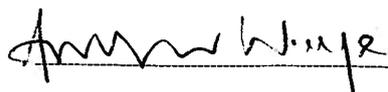
**Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?**

No

### **SELECT SIGNATORY Sign-off** For consultation stage Impact Assessments:

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

Signed by the responsible Chief Executive:

 Date: 27/4/11

PP TIM SMITH

<b>Title:</b> <b>The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011</b>  <b>Lead department or agency:</b> Food Standards Agency  <b>Other departments or agencies:</b>	<b>Impact Assessment (IA)</b>
	<b>IA No:</b> FOOD0026
	<b>Date:</b> 27 April 2011
	<b>Stage:</b> Consultation
	<b>Source of intervention:</b> EU
	<b>Type of measure:</b> Secondary legislation
	<b>Contact for enquiries:</b> Nasreen Shah, Tel: 020 7276 8553 <a href="mailto:Nasreen.a.shah@foodstandards.gsi.gov.uk">Nasreen.a.shah@foodstandards.gsi.gov.uk</a>

## Summary: Intervention and Options

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

Laboratory analyses on polyamide (nylon) and melamine plastic kitchenware presented for import into the EU from the People’s Republic of China and Hong Kong (together referred to as “China” in this document) continue to show the release, into food or food simulant, of primary aromatic amines (PAAs) or formaldehyde respectively, at levels above those permitted by EU legislation. Prolonged exposure to these chemicals may present a risk to consumer health: PAAs are proven to be carcinogenic, whilst excessive levels of formaldehyde can have potential adverse health effects. In order to address the issue of non-compliant product reaching the EU, and the associated risks to consumer health, European Commission Regulation (EU) No. 284/2011 (“the EU Kitchenware Regulation”) sets down additional import controls, applicable from 1 July 2011. Government intervention is necessary to provide for the execution and enforcement of the EU Regulation by means of national Regulation.

### What are the policy objectives and the intended effects?

To make national Regulations to provide for the execution and enforcement, in England, of the EU Kitchenware Regulation which aims to reduce the risk of non-compliant plastic kitchenware from China entering the EU, thereby minimising the associated risks to EU consumers.

### 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 execution and enforcement of the EU Kitchenware Regulation in England. This would allow polyamide and melamine plastic kitchenware from China to enter the UK with no additional controls being applied. It would also lead to the UK being liable to infraction proceedings by the European Commission.

**Option 2:** Make national Regulations relating to England to provide for the execution and enforcement of the Commission Regulation.

**Option 3:** Non-regulatory option – European Commission visits to China to encourage the Chinese control authorities to improve the safety standards of kitchenware manufactured there. This option has been tried and tested with the Chinese control authorities without success.

Option 2 is preferred. This option will align the UK with other Member States in the protection of consumer safety.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** July 2016

**What is the basis for this review?** Duty to review. **If applicable, set sunset clause date:** N/A

<b>Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?</b>	No
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**SELECT SIGNATORY Sign-off** For consultation stage Impact Assessments:

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

Signed by the responsible Chief Executive: \_\_\_\_\_ Date: \_\_\_\_\_

# Summary: Analysis and Evidence

# Policy Option 1

## Description:

**Do Nothing. Do not provide for the execution and enforcement of the EU Kitchenware Regulation in England**

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

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	N/A	N/A	N/A

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

There are no incremental monetisable costs associated with this option.

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

The costs associated with this option are predominantly to public health. Excessive levels of primary aromatic amines (PAAs) are known to be carcinogenic and excessive levels of formaldehyde can have potential adverse health effects. If nothing is done to prevent China from exporting polyamide and melamine plastic kitchenware into England without additional targeted controls, consumers will be exposed to the risk of ingesting PAAs and formaldehyde with potentially serious health impacts.

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	N/A	N/A	N/A

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

There are no incremental benefits associated with this option.

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

There are no incremental benefits associated with this option.

### Key assumptions/sensitivities/risks

Discount rate (%)

Costs of infraction may result from failure to implement the enforcement provisions of the Commission Regulation.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: N/A	Benefits: N/A	Net: N/A	No	IN/OUT

## Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?	England				
From what date will the policy be implemented?	July 2011				
Which organisation(s) will enforce the policy?	LAs & PHAs				
What is the annual change in enforcement cost (£m)?					
Does enforcement comply with Hampton principles?	Yes				
Does implementation go beyond minimum EU requirements?	No				
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)	Traded: N/A		Non-traded: N/A		
Does the proposal have an impact on competition?	No				
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?	Costs:		Benefits:		
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large
Are any of these organisations exempt?	No	No	No	No	No

## Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on...?	<b>Impact</b>	<b>Page ref within IA</b>
<b>Statutory equality duties</b> <sup>1</sup> <a href="#">Statutory Equality Duties Impact Test guidance</a>	No	19

<b>Economic impacts</b>		
Competition <a href="#">Competition Assessment Impact Test guidance</a>	No	19
Small firms <a href="#">Small Firms Impact Test guidance</a>	No	19

<b>Environmental impacts</b>		
Greenhouse gas assessment <a href="#">Greenhouse Gas Assessment Impact Test guidance</a>	No	
Wider environmental issues <a href="#">Wider Environmental Issues Impact Test guidance</a>	No	

<b>Social impacts</b>		
Health and well-being <a href="#">Health and Well-being Impact Test guidance</a>	No	Throughout
Human rights <a href="#">Human Rights Impact Test guidance</a>	No	
Justice system <a href="#">Justice Impact Test guidance</a>	No	
Rural proofing <a href="#">Rural Proofing Impact Test guidance</a>	No	

<b>Sustainable development</b> <a href="#">Sustainable Development Impact Test guidance</a>	No	19
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<sup>1</sup> Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

# Summary: Analysis and Evidence

# Policy Option 2

**Description: Make national Regulations relating to England to provide for the execution and enforcement of the Commission Regulation.**

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -44.94

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A
High	N/A	N/A	N/A
Best Estimate	1.23	5.08	44.94

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

Total cost of £52.01m (constant prices). Total one off costs of £1.23m in England broken down: £1.21m familiarisation cost to industry; £17k familiarisation cost to enforcement authorities; £1.9k familiarisation cost to HMRC and a familiarisation cost to the FSA across the entire UK of £162.

*Please note average annual costs are UK wide costs.* Total average annual costs across the UK of £5.08m broken down: £4.54m in average annual sampling costs to industry; £89k average annual fees to industry for storage; £150k average annual costs to enforcement authorities of reporting to the Commission and £301k average annual charge to the FSA from HMRC to review each consignment arriving in the UK.

Equivalent Annual cost for England totals £148k a year.

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

Potential additional storage costs for business in relation to inland storage of consignments pending the release of analytical results.

Consignments held in Ports may result in loss of earnings for industry.

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

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

No monetisable benefits identified

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

Higher safety standards will reduce consumer exposure to harmful plastics being imported from China which will benefit consumer health and reduce the level of carcinogenic risk.

**Key assumptions/sensitivities/risks**

Discount rate (%) 3.5

The number of affected businesses is likely to be an over estimate which will overestimate the familiarisation costs to industry. The number of plastic imports from China may decrease over time because of increased costs to industry; however we lack the evidence to forecast future levels of imports, and as such we may have overestimated the annual costs.

Costs have been presented as those to England, however annual costs cannot be broken down as they are based on UK imports figures. Costs to the FSA cannot be broken down by location and are UK wide.

<b>Direct impact on business (Equivalent Annual) £m):</b>			<b>In scope of OIOO?</b>	<b>Measure qualifies as</b>
Costs: 4.77	Benefits: N/A	Net: 4.77	No	IN/OUT

## Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?	England				
From what date will the policy be implemented?	July 2011				
Which organisation(s) will enforce the policy?	LAs and PHAs				
What is the annual change in enforcement cost (£m)?	0.15				
Does enforcement comply with Hampton principles?	Yes				
Does implementation go beyond minimum EU requirements?	No				
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)	<b>Traded:</b> N/A		<b>Non-traded:</b> N/A		
Does the proposal have an impact on competition?	No				
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?	<b>Costs:</b>		<b>Benefits:</b>		
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	<b>Micro</b>	<b>&lt; 20</b>	<b>Small</b>	<b>Medium</b>	<b>Large</b>
Are any of these organisations exempt?	No	No	No	No	No

## Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on...?	<b>Impact</b>	<b>Page ref within IA</b>
<b>Statutory equality duties</b> <sup>1</sup> <a href="#">Statutory Equality Duties Impact Test guidance</a>	No	19
<b>Economic impacts</b>		
Competition <a href="#">Competition Assessment Impact Test guidance</a>	No	19
Small firms <a href="#">Small Firms Impact Test guidance</a>	No	19
<b>Environmental impacts</b>		
Greenhouse gas assessment <a href="#">Greenhouse Gas Assessment Impact Test guidance</a>	No	
Wider environmental issues <a href="#">Wider Environmental Issues Impact Test guidance</a>	No	
<b>Social impacts</b>		
Health and well-being <a href="#">Health and Well-being Impact Test guidance</a>	No	Throughout
Human rights <a href="#">Human Rights Impact Test guidance</a>	No	
Justice system <a href="#">Justice Impact Test guidance</a>	No	
Rural proofing <a href="#">Rural Proofing Impact Test guidance</a>	No	
<b>Sustainable development</b> <a href="#">Sustainable Development Impact Test guidance</a>	No	19

<sup>1</sup> Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

# Evidence Base (for summary sheets) – Notes

## References

No.	Legislation or publication
	<b>Commission Directive 2002/72/EC, as amended</b> <a href="http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm">http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm</a>
	<b>Commission Regulation (EU) No. 284/2011</b> <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:077:0025:0029:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:077:0025:0029:EN:PDF</a>

+ Add another row

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

	Y <sub>0</sub>	Y <sub>1</sub>	Y <sub>2</sub>	Y <sub>3</sub>	Y <sub>4</sub>	Y <sub>5</sub>	Y <sub>6</sub>	Y <sub>7</sub>	Y <sub>8</sub>	Y <sub>9</sub>
<b>Transition costs</b>	1.23	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>Annual recurring cost</b>	5.08	5.08	5.08	5.08	5.08	5.08	5.08	5.08	5.08	5.08
<b>Total annual costs</b>	6.31	5.08	5.08	5.08	5.08	5.08	5.08	5.08	5.08	5.08
<b>Transition benefits</b>	N/A									
<b>Annual recurring benefits</b>	N/A									
<b>Total annual benefits</b>	N/A									

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



Microsoft Office  
Excel Worksheet

# Evidence Base (for summary sheets)

## Policy Objective

1. The policy objective is to make national Regulations to provide for the execution and enforcement, in England, of the EU Kitchenware Regulation which aims to reduce the risk of non-compliant plastic kitchenware from China entering the EU, thereby minimising the associated risks to EU consumers. There is enough evidence, by way of notifications and alerts by Member States (85 notifications and alerts between 2009/2010), that polyamide (nylon) and melamine plastic kitchenware imported from China could potentially put consumers at risk due to the excessive levels of primary aromatic amines (PAAs) and formaldehyde that migrate from them into foods that may come into contact with them. This risk can be minimised by targeting and testing imports of such products prior to release for sale on the market.

## Rationale for Intervention

2. Chemical migration from food contact materials and articles can have a negative impact on consumer health. Most consumers are unable to assess the risks involved when consuming a product because they cannot observe or measure the level of chemical migration and do not have full information on the production methods. In this case, unsuspecting consumers could be exposed to potential carcinogenic chemicals through the use of these plastic kitchen utensils from China. Government intervention is, therefore, necessary to minimise these impacts on health.

## EU Legislation on Plastic Food Contact Materials

3. Harmonised EU rules on plastic food contact materials are currently laid down by Commission Directive 2002/72/EC (as amended) relating to plastic materials and articles intended to come into contact with foodstuffs ("the principal Directive"). This Directive has been consolidated in the form of a new EU Regulation<sup>1</sup>, which will apply from 1<sup>st</sup> May 2011, with the relevant requirements remaining unaltered. These requirements are implemented in England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009<sup>2</sup>. The legislation requires that PAAs should not be detectable using the detection limit of 0.01 milligram per kilogram of food.

## Background

4. Significant numbers of notifications and alerts have been received via the Rapid Alert System for Food and Feed (RASFF) pursuant to Article 50 of Regulation 178/2002<sup>3</sup>, concerning food contact materials imported from China into the EU, releasing into food or food simulant<sup>4</sup> amounts of chemicals that are not in compliance with the EU legal limits. Between 2009 and 2010 there were 64 notifications on kitchenware originating from China and 11 from unknown origins. These notifications and alerts primarily concern polyamide and melamine plastic kitchenware, which do not meet the requirements in relation to the release of PAAs and formaldehyde into food, limits are laid down in Part A of Annex V and Section A of Annex II to the principal Directive respectively.
5. PAAs are a family of compounds some of which are proven to be carcinogenic, while others are suspected carcinogens and could potentially pose a health risk to consumers. PAAs in materials and articles intended to come into contact with food may arise as a result of the presence of impurities or breakdown products. High levels of PAAs have been released into food from polyamide kitchenware originating in or consigned from China.
6. Similarly, levels of formaldehyde have been released into foods that are higher than those authorised in EU legislation from melamine plastic kitchenware also originating in or consigned from China.

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<sup>1</sup> Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.

<sup>2</sup> SI 2009 No. 205

<sup>3</sup> 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- OJ L 31, 1.2.2002, p.1

<sup>4</sup> Food simulants are materials intended to mimic the migration behavioural properties of foods. They are used in the laboratory to provide a conservative estimate of the amount of individual substances that may migrate from packaging into food.

7. Formaldehyde is produced on a large scale and is used in the production of phenolic, urea, melamine and polyacetal resins. Formaldehyde is also used as an intermediate in the manufacture of industrial chemicals and as an aqueous solution (formalin) as a disinfectant and preservative.
8. In 2007, the European Food Safety Authority's (EFSA) AFC Panel concluded that there is no evidence indicating that formaldehyde is carcinogenic by the oral route, on the basis of recent and previous evaluation. There is evidence that formaldehyde can elicit immune effects such as hypersensitivity and contact dermatitis in sensitive individuals. The World Health Organisation (WHO) Concise International Chemical Assessment Document (CICAD, 2002) suggests that "the concentration of formaldehyde likely to elicit contact dermatitis reactions in hypersensitive individuals may be as low as 30 milligrams per litre".
9. The Commission has taken several initiatives with the Chinese control authorities and the industry concerned to increase their knowledge of EU legislation on food contact materials. Despite these initiatives, two missions of the Commission's Food and Veterinary Office (FVO) to China (including Hong Kong) in 2009 identified serious weaknesses in the official control systems for plastic food contact materials imported to the EU. Large quantities of polyamide and melamine plastic kitchenware originating in or consigned from China have failed to comply with the requirements of the legislation. The increasing levels of alerts in several Member States subsequent to these visits have resulted in the Commission proposing specific control measures.
10. Commission Regulation (EU) No. 284/2011 ("the EU Kitchenware Regulation") was published in the Official Journal (OJ) of the EU on 23<sup>rd</sup> March 2011 (Ref: OJ, L77, 23.03.2011, pg 25-29), comes into force on 11<sup>th</sup> April 2011 and is directly applicable throughout the EU as of 1<sup>st</sup> July 2011. Its full title is Commission Regulation (EU) No 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China. Copies of the Regulation are available and can be downloaded free of charge from the following website:  
  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:077:0025:0029:EN:PDF>
11. The EU Kitchenware Regulation lays down the specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from China. The requirements of the Regulation are detailed below.

#### **Import Conditions and detailed procedures for the import of melamine plastic kitchenware originating in or consigned from China (including Hong Kong)**

- 12.1 Polyamide and melamine plastic kitchenware can be imported into the Member States only if the importer submits to the competent authority for each consignment a completed declaration, stating that the products comply with the requirements concerning the release of PAAs and formaldehyde as laid down in Part A of Annex V and in Section A of Annex II to the principal Directive. The format for this declaration is set out in the Annex to the EU Kitchenware Regulation.
  - i) The declaration should be drawn up in the official language, or in one of the official languages, of the Member States in which the consignment is imported and must be accompanied by a laboratory report providing:
    - a) As regards polyamide kitchenware, analytical results demonstrating that they do not release into foods or food simulants PAAs in a detectable quantity; that the detection limit applies to the sum of PAAs; and for the purpose of the analysis the detection limit for PAAs is set at 0.01 mg/kg food or food simulants;
    - b) As regards melamine kitchenware, analytical results demonstrating that they do not release into foods or food simulants formaldehyde in a quantity exceeding 15 mg/kg food.

- ii) The competent authority must endorse the declaration to indicate whether the goods are acceptable or not for release into free circulation, depending on whether they fulfil the terms and conditions provided for in the principal Directive as set out in 12.1 above.

### **Prior notification of consignments**

- 12.2 Article 4 requires importers or their representatives to provide prior notification to the competent authority at the first point of introduction into the EU at least two working days in advance of the estimated date and time of physical arrival of consignments originating in or consigned from China.

### **Notification of the first point of introduction**

- 12.3 Where Member States decide to designate specific first points of introduction for consignments from China, they will be required to publish on the internet an up-to-date list of these points and to notify the internet address to the Commission. The Commission will display the links to the national lists of these points of introduction on its website for information purposes.

### **Controls at the first point of introduction**

- 12.4 The competent authority at the first point of entry into the EU must carry out:
  - a) Documentary checks on all consignments within two working days from the time of arrival;
  - b) Random identity and physical checks, including laboratory analysis of 10% of consignments, with the results of physical checks being made available as soon as technically possible.

Competent authorities are required to inform the Commission immediately of the results through the Rapid Alert System for Food and Feed (RASFF) if, by the analysis referred to in (b) above, non-compliance has been identified.

### **Onward transportation**

- 12.5 The competent authority at the first point of entry may authorise the onward transportation of consignments pending the results of the checks as outlined in 12.4 above.

### **Release for free circulation**

- 12.6 Products may only be released for free circulation if a completed declaration, as indicated in Article 3, is presented to the customs authorities by the importer.

### **Reporting to the Commission**

- 12.7 Competent authorities are required to keep records of checks performed including:
  - a) Details of each consignment checked, including (i) the size in terms of numbers and articles; and (ii) the country of origin.
  - b) The number of consignments subject to sampling and analysis; and
  - c) The results of the controls.

Member States are required to submit a quarterly report to the Commission by the end of the month, following each quarter.

- 12.8 In relation to point 12.3 above, at present a decision has not been made to designate specific points of introduction in the UK; this issue is currently under consideration. Should the decision be made to designate points of introduction, the FSA will advise stakeholders as appropriate.

## **Consignments that do not comply with the EU Kitchenware Regulation**

13. Article 4 of the EU Kitchenware Regulation requires importers or their representatives to give notice of the estimated date and time of the arrival of a relevant consignment to Enforcement Authorities at least 2 working days before its physical arrival. The intention of this provision is to allow Enforcement Authorities to plan and prepare for the checks required by Article 6 of the Regulation. As such, Article 4 has a clear relationship with Article 6 which requires Enforcement Authorities to carry out documentary checks on all consignments within two working days of their arrival. In respect of consignments that arrive without prior notification, it is envisaged that Food Authorities will therefore be permitted, by virtue of the breach of Article 4, to take up to four working days to carry out the checks required by Article 6.
14. In respect of consignments arriving without the required declaration or with a declaration that is not in compliance with Articles 3(1), (2) and (3) of the EU Kitchenware Regulation, under the proposed national Regulations, Enforcement Authorities would have two options. They may choose either to (a) issue a notice requiring the importer or their representative to submit a compliant declaration within 14 days of the notice or (b) invoke rejection procedures described in paragraph 15, below.
15. In respect of consignments for which a declaration is not provided or where a notice described in paragraph 14 above has been served, not provided within the timescale specified or for those consignments found not to be non-compliant following the physical checks and laboratory analysis provided for by Article 6(b) of the EU Kitchenware Regulation, the Enforcement Authority must issue a notice requiring the consignment to be re-dispatched outside the EU or destroyed at the importer's expense within 30 days of the date of the notice.
16. This proposal is for a Statutory Instrument (SI) entitled The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011. The objective of the proposed Regulations is to provide enforcement provisions for the EU Kitchenware Regulation, by:
  - designating local authorities and port health authorities as having responsibility for the enforcement of the EU Kitchenware Regulation in England;
  - providing for offences of contravening certain provisions of the EU Kitchenware Regulation and for defences;
  - against prosecution for committing an offence in particular circumstances;
  - specifying the penalties that the Courts may impose upon conviction for an offence;
  - providing for administrative arrangements such as service of notices and rights of appeal;

The proposed national Regulations would allow all costs arising from the additional official controls undertaken by enforcement authorities arising from the EU Kitchenware Regulation, including any action taken following non-compliance, to be recovered from importers or their representatives.

17. The EU Kitchenware Regulation applies to all importers of polyamide and melamine plastic kitchenware originating in or consigned from China. The costs of these controls, we understand, would initially be borne by these importers. However, this financial burden is likely to be passed back to the Chinese exporter. There is a benefit of compliance to businesses in that the additional controls will allow them to place compliant products on the market. There is, however, a remote possibility of businesses seeking alternative producers of these plastic utensils who do not comply with the EU Kitchenware Regulation, if they consider this option economically advantageous.
18. The proposed national Regulations would allow all costs arising from the additional official controls undertaken by enforcement authorities arising from the EU Kitchenware Regulation, including any action taken following non-compliance, to be recovered from importers or their representatives. Articles 27, 28 and 54 of Regulation (EC) No. 882/2004, which makes provision for fees or charges that Member States may or must collect when performing particular types of official controls, provide the legal basis for the recovery of these costs.

## Options Considered

### **Policy Option 1: Do Nothing. Do not provide for the execution and enforcement of the EU Kitchenware Regulation in England**

19. This option would not prevent the EU Kitchenware Regulation from applying in England; it would already be legally binding and applicable throughout the European Union (EU). However, enforcement authorities in the UK would not have the necessary powers to enable them to enforce it. Therefore, the obligation to put in place provisions for its enforcement, for offences to be prosecuted and for penalties for those found to be in breach of the EU Kitchenware Regulation would not be fulfilled. It would also lead to the UK being liable to infraction proceedings.
20. This option would also mean allowing China to continue to export polyamide and melamine plastic kitchenware into England without additional targeted controls, thus exposing consumers to the risk of ingesting primary aromatic amines and formaldehyde with potential adverse health effects.

### **Policy Option 2: National Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation in England**

21. This option provides a significant measure of control that would minimise the potential health risks. The control will, however, place some financial cost on businesses that use, sell and import such products into England. We understand, however, that UK importers and or their representatives will seek to recover these costs from the Chinese exporters. It is our view that large businesses are more likely to be able to achieve cost recovery from the Chinese businesses due to their extensive buying power. However, for SMEs this is less likely to be the case, potentially resulting in them having to bear the costs of the import controls.

#### **Consultation Question**

***(1). Will SMEs be affected and, if so, how many will be affected, and what are the likely financial implications for this sector? Please provide evidence to support your response.***

22. This also ensures that enforcement authorities and port health authorities can fulfil the requirements placed upon them and the Courts can impose penalties that are consistent with those that apply elsewhere in English food law. It also provides for defences to alleged offences in certain specified circumstances.

### **Policy Option 3 – Non-regulatory option - European Commission visits to China to encourage the Chinese control authorities to improve the safety standards of kitchenware manufactured there.**

23. This option has been tried and tested by the European Commission in the shape of two FVO missions with the Chinese control authorities in 2009; however, the initiatives identified serious weaknesses in the Chinese control systems. Thus, this option would fail to deliver the level of protection for consumers agreed as necessary by the EU, as large quantities of polyamide and melamine plastic kitchenware continued to fail to meet the requirements of the principal Directive. This option would not fulfil the requirements of the EU Kitchenware Regulation. The costs and benefits of this option are nil.
24. Thus, option 2 is the preferred option that will achieve the requirements of the EU Kitchenware Regulation.

## Sectors Affected

### Industry

25. This proposal will affect UK retailers, wholesalers and importers of plastic products from China. However, because the scope of the policy (in terms of businesses affected) is narrow and not identified by a standard industrial classification code (SIC), it is difficult to provide accurate estimates of the precise number of businesses that will face any impact.

26. Where appropriate, an attempt has been made to estimate the number of retailers and wholesalers potentially affected (using the Interdepartmental Business Register (IDBR<sup>5</sup>))
27. For retailers, because it is not possible to isolate the precise subsectors affected by this regulation we have made assumptions about the *types* of businesses that may face an impact using SICs that are broader than the limited remit of this policy<sup>6</sup>. As such, the sectors identified below will encompass, but be greater than, all affected businesses. This will inevitably lead to an overestimate of the costs involved but in the absence of any better data, will serve as useful upper bound.
28. The number of wholesalers affected is derived from the IDBR<sup>7</sup> category labelled ‘wholesale of other household goods’; again, because of the wide coverage of this category and the fact that we are dealing with a specific industry in plastics, it is likely that we are overestimating the number of wholesalers affected.
29. The IDBR does not identify importers as a distinct category; attempts have been made to obtain information through informal consultation but, we have been unable, to date, to attain any data on the number of importers. We will endeavour to attain this information through this formal consultation process.
30. Table 1 displays the number of retailers and wholesalers affected by the proposal by country.

**Table 1 – Number of retailers and wholesalers likely to be affected by the Regulations**

	England	Wales	Scotland	NI	UK
Retailers	34,020	2,175	3,835	1,460	41,490
Wholesalers	4,860	140	220	120	5,340
<b>Total</b>	<b>38,880</b>	<b>2,315</b>	<b>4,055</b>	<b>1,580</b>	<b>46,830</b>

Source: IDBR

### **Consultation Questions**

**(2). Are the numbers of retailers and wholesalers set out in Table 1 an accurate representation of such businesses likely to be affected? Please provide evidence to support your response.**

**(3). How many importers are likely to be affected? We would be grateful for any available evidence you are able to provide on this sector.**

31. HM Revenue and Customs (HMRC), Local Authorities and laboratories carrying out the analysis of polyamide and melamine plastic kitchenware will also be affected by these proposals. For these bodies there will be a one-off cost for reading and familiarising themselves with the new Regulations. We believe that charities and voluntary organisations are unaffected by these proposals.
32. The Food Standards Agency (“the FSA”) could also face costs as a result of this proposal. Impacts will be in the form of charges from HMRC as a result of them reading all supporting documents accompany plastic consignments being imported from China.

### **Consultation Question**

**(4). Do you agree with our assumption that charities and voluntary organisations are unaffected? Please provide evidence to support your response.**

<sup>5</sup> <http://statistics.gov.uk/idbr/idbr.asp>

<sup>6</sup> Categories for retailers includes: 47.11 Retail sale in non-specialised stores with food, beverages or tobacco predominating; 47.19 Other retail sale in non-specialised stores and 47.52 Retail sale of hardware, paints and glass in specialised stores

<sup>7</sup> Categories for wholesalers; 46.49 Wholesalers of other household goods.

## Option 1 – Do Nothing

### Costs to the Consumer

33. This is the baseline with which other options are compared. The costs associated with this option are predominantly to public health. Excessive levels of primary aromatic amines (PAAs) are known to be carcinogenic and excessive levels of formaldehyde can have potential adverse health effects. If nothing is done to prevent China from exporting polyamide and melamine plastic kitchenware into England without additional targeted controls, consumers will be exposed to the risk of ingesting primary aromatic amines and formaldehyde with potentially serious health impacts at a huge social cost to the UK.

### Option 2 - Fully implements the necessary requirements and makes appropriate domestic Regulations for the execution and enforcement of the EU Kitchenware Regulation

34. This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the EU Kitchenware Regulation in England, which is binding in its entirety and directly applicable in all EU Member States.

### Costs to Enforcement Authorities

#### One-off Costs

35. There will be a one-off cost to enforcement authorities for reading and familiarising themselves with the new Regulations. Each Local Authority (LA) in its area and each Port Health Authority (PHA) in its district are responsible for enforcing the legislation with respect to food safety and/or food hygiene, and thus will have the responsibility for enforcing the food contact materials legislation. At this stage it is unclear if a Trading Standards Officer (TSO) or an Environmental Health Officer (EHO) would be responsible for enforcing and thus familiarising themselves with these Regulations. To account for the uncertainty, we have used a range for the hourly wage rate using an EHO wage rate of £20.45<sup>8</sup> as the lower bound, and a TSO hourly wage rate of £22.09<sup>9</sup> as the upper bound rate, with the midpoint being £21.27<sup>10</sup>.
36. We have estimated that one enforcement officer per authority will typically invest one hour to read and familiarise themselves with the new Regulations. In addition, we have estimated that each enforcement officer will spend a further hour disseminating key information to staff within the organisation, meaning a total of two hours for familiarisation in each organisation. The familiarisation cost is quantified by multiplying the hourly rate of a TSO/EHO by both the time required to read and disseminate the new Regulations and the total number of enforcement authorities. Using the range of enforcement officers wage rates: £20.45 - £22.09 and a time investment of two hours, results in a familiarisation cost per enforcement authority of between £40.90 and £44.17, with a best estimate of £42.54. Multiplying the familiarisation cost per authority by the 393 enforcement organisations in England comprising 393 LAs and 39 PHAs, results in a total familiarisation cost in England ranging from £16,073 to £17,360, with a best estimate of £16,717. Table 2 displays the familiarisation cost by location using the best estimate.

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<sup>8</sup> Wage rate obtained from the Annual Survey of Household Earnings, 2010. (See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Environmental health officers' £15.73 + 30% to cover overheads = £20.45).

<sup>9</sup> Wage rate obtained from the Annual Survey of Household Earnings, 2010. (See: <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Inspectors of factories, utilities and trading standards' (£16.99 + 30% to cover overheads = £22.09).

<sup>10</sup> (£20.45 + £22.09)/2

**Table 2 - Familiarisation cost to Local Authorities and Port Health Authorities in the UK**

Country	Number of LAs	Best Estimate
England *	393	£16,717
Wales **	23	£978
Scotland	32	£1,361
NI	26	£1,106
UK	474	£20,162

\* includes 39 Port Health Authorities

\*\* includes 1 Port Health Authority

Note: Totals may not sum due to rounding

Wage rates are reported in the text to 2 decimal places and when grossed may result in a rounding error

### Equivalent Annual Net Costs (EANC)

37. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula<sup>11</sup>. Under Standard HMT Green book guidance a discount rate of 3.5% is used.
38. A total one-off cost to enforcement authorities in England affected by this proposal is an estimated £16,717. This yields an EANC of approximately £2,010 in England over 10 years. Table 3 displays the breakdown of the EANC per country.

**Table 3 - Equivalent Annual Net Costs (EANC) to enforcement authorities by location**

Country	EAC
England *	£2,010
Wales **	£118
Scotland	£164
NI	£133
UK	£2,424

\* includes 39 Port Health Authorities

\*\* includes 1 Port Health Authority

Note: Totals may not sum due to rounding

Wage rates are reported in the text to 2 decimal places and when grossed may result in a rounding error

### Consultation questions

**(5). Do you agree with our estimate of one hour for a TSO or EHO in each enforcement authority to familiarise themselves with the legislation and a further hour for reading and dissemination to key staff? Please provide evidence to support your response.**

**(6). What new or additional costs over and above those associated with the current relevant enforcement activity are likely to be incurred as a result of the EU Kitchenware Regulation and the national Regulations? Please provide evidence to support your response.**

### Ongoing Costs

39. In addition to reading and familiarisation costs, it is expected that the procedure for recording information arising from the controls will be established and reports forwarded to the Commission on a quarterly basis. The cost of this administrative work is irrecoverable.
40. In a recent (2010) trial conducted by Suffolk Coastal Port Health Authority in Felixstowe, 1,657 consignments of plastic items were identified on manifests over a 10 week period, most of which will be captured by the EU Kitchenware Regulation.

<sup>11</sup> The equivalent annual cost formula is as follows:  $EAC = PVC/A$ , where  $A = [1 - 1/(1+r)^t]/r$ , where PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

41. Estimates of costs for a typical Port Health enforcement as exemplified by Felixstowe are shown in table 4 below:

**Table 4 – Cost of activities at Felixstowe Port**

	<b>Activity – Document receipt &amp; check</b>	<b>Time Involved</b>	<b>Officer (£50 inc on costs)</b>	<b>Admin (£22 inc on costs)</b>
1	Check ship's manifest and detain consignments	10 mins		£3.67
2	Record receipt of Annex, commercial docs and analytical certificates, Invoice fees.	15 mins		£5.50
3	Conduct documentary check inc analytical cert check, stamp / sign / copy documents & notify HMRC (inc allowance for notifying customs of those consignments captured but not subject to checks)	30 mins	£25.00	
4	Record and submit data for quarterly return	12 mins		£4.40
		<b>Sub total</b>		<b>£38.57</b>
	<b>Activity – Examination sampling &amp; analysis</b>			
1	Determination of correct sampling protocol – exam request information communicated to examination facility	15 mins	£12.50	
2	Examination of consignment including identity check	15 mins	£12.50	
3	Sampling of consignment according to legislation/ guidance Sampling time (assuming simple sampling protocol)	30 mins	£25.00	
4	Prepare sample paperwork and issue detention notice	15 mins	£12.50	
5	Dispatch of samples to laboratory & consumables	Fixed Cost		
6	Analyst fee	Variable	£400.00	
		<b>Sub total</b>		<b>£462.50</b>
	<b>Activity – Charge for Onward transportation arrangements</b>			
1	Arrangement for sampled consignments to move forward to ERTS for detention pending results – dealing with request, completion of additional paperwork.	30 mins	£25.00	
		<b>Sub total</b>		<b>£25.00</b>
		<b>Total</b>		<b>£526.07</b>

ERTS (Enhanced Remote Transit Shed)

42. The evidence from Felixstowe suggests that recording and submitting data to the Commission will take an administrative member of staff 12 minutes to complete per consignment. The cost of reporting each consignment is quantified by multiplying the hourly wage rate of a member of staff carrying out the reporting (£22, as shown in table 4) by the length of time take per consignment (12 minutes) resulting in a cost of reporting each consignment of £4.40. The total cost is quantified by multiplying the cost of reporting each consignment (£4.40) by the total number of consignments entering the UK (approximately 34,000), resulting in an annual reporting cost to enforcement authorities of £149,600.

#### **Consultation Question**

***(7). Are the costs of enforcement for a specific Port Health Authority in Table 4 typical of those incurred by other Port Health Authorities in respect of similar enforcement activity? Please provide evidence to support your response.***

43. Enforcement authorities will also incur sampling and analysis costs as a result of sending consignments sampled for analysis. Initially these costs will be incurred by the enforcement authorities who send the consignments to public analysts; however, enforcement authorities will seek to recover the costs from food importers/or importers of those goods, who then in turn will recover, as we understand it, from the Chinese exporting businesses. SMEs may be adversely affected by this system. Large businesses are more likely to be able to recover costs from Chinese exporters due to their strong buying power whereas SMEs may not be able to claim

<sup>12</sup> ERTS (Enhanced Remote Transit Shed)

back costs in the same way. At present we have no data or information about how this might practically impact SMEs and so we seek stakeholder input via this consultation process.

44. The sampling and analysis cost per consignment comprises of a test for formaldehyde at a cost of £520 and a test for PAAs at a cost of £815, resulting in a total sampling cost of £1,335 per product tested multiplying the total sampling cost by the estimated number of consignments being sent for analysis each year (3,400), results in a total annual sampling cost of £4,539,000, which will be charged back to industry (see industry cost section).

**Table 5 – Ongoing costs to Enforcement Authorities**

On-going Enforcement Costs	Year 0 (m)	Year 1 (m)	Year 2 (m)	Year 3 (m)	Year 4 (m)	Year 5 (m)	Year 6 (m)	Year 7 (m)	Year 8 (m)	Year 9 (m)	Total Cost (m)	Present Value (m)
Reporting costs	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£1.50	£1.29

The present value presents a discounted total cost. Discounting is a technique used to compare future costs (and benefits) that occur in different periods and is based on the principle that, generally, people place a higher value on money today than in the future, which is why future costs are discounted.

### Consultation Questions

**(8). Are the total sampling costs in paragraph 44 of the draft Impact Assessment and the assumptions used to calculate them accurate? Please provide evidence to support your response.**

**(9). Do Enforcement Authorities have any comments on the proposed national Regulations in so far as they relate to the provisions for enforcement, defences and penalties?**

### Costs to HM Revenue and Customs (HMRC)

45. There will be a one-off cost to HMRC for reading and familiarising themselves with the new Regulations. We estimate that one member of HMRC staff per Port Health Authority (PHA) will typically invest one hour to read and familiarise themselves with the new Regulations, plus a further hour to disseminate key information to staff within the organisation, meaning a total of two hours for familiarisation per PHO.
46. The familiarisation cost to HMRC is quantified by multiplying the familiarisation cost per organisation by the time required to read and disseminate the new Regulations. The familiarisation cost per organisation equates to £47.74 based on multiplying the hourly wage rate of a public sector worker (£23.87<sup>13</sup>) by the time taken to become familiar with the regulation (2 hours). Multiplying the familiarisation cost per authority by the 39 PHOs in England generates a one off familiarisation cost to HMRC in England of £1,862.

### Equivalent Annual Net Costs (EANC)

47. It is necessary to equivalently annualise the one off cost to HMRC. The one cost component to HMRC in England totals £1,862, which equates to an equivalent annual cost to HMRC of approximately £224 over 10 years. Table 6 displays the familiarisation cost and EANC by location.

**Table 6 – Familiarisation cost and EANC to HMRC**

Country	Number of PHO's	Total	EANC
England	39	£1,862	£224
Wales	1	£48	£6
Total	40	£1,909	£230

Note: Totals may not sum due to rounding

Wage rates are reported in the text to 2 decimal places and when grossed may result in a rounding error

<sup>13</sup> Wage rate obtained from The Annual Survey of Household Earnings, 2010 (See <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Business and public service associate professionals (£18.36 + 30% to cover overheads = £23.87).

48. The additional controls imposed by the new Regulations are likely to place a significant demand on the enforcement authority's resources. It is estimated from HMRC information that approximately 34,000 (per annum) consignments of plastic kitchenware are imported; it is envisaged that most of these consignment(s) will fall under the scope of the EU Kitchenware Regulation. The Regulation does not allow for the release into free circulation of any consignment(s) until satisfactory completion of checks has been confirmed by HMRC.
49. In accordance with Cabinet Office directives, the HMRC could recover some HMRC costs from the FSA as the lead Agency in the UK. This cost, we understand, is expected to be recovered from the importers. At present we have no detailed information about how this will be done (See FSA costs section for further details).

## Costs to Industry

### One-off Costs

50. Any likely costs to businesses associated with the proposed Regulations relate only to those businesses that import polyamide and melamine plastic kitchenware, this may include wholesalers, supermarkets and other retailers placing such products on the market. For this sector, there will be a one-off cost for reading and familiarising themselves with the Regulations. We have estimated that a business importing polyamide and melamine plastic kitchenware will spend one hour reading and familiarising themselves with the new of Regulations. In addition, we have estimated that each person uses a further hour disseminating key information within the organisation, meaning a total of two hours.
51. It will cost each business £31.15 to become familiar with the new Regulations which is based on an hourly wage rate of £15.57<sup>14</sup> for a manager multiplied by the time taken to read and disseminate the information (2 hours). The total cost is quantified by multiplying the cost per business (£31.15) by the number of retail businesses affected in England (38,880 as shown in table 1) which totals to £1.2m in England. The breakdown of costs is displayed in the table below:

**Table 7 – Familiarisation costs to Industry**

Country	Micro	Small	Medium	Large	Total
<b>England</b>	<b>£1,098,135</b>	<b>£97,822</b>	<b>£11,559</b>	<b>£3,518</b>	<b>£1,211,034</b>
Wales	£65,890	£5,438	£580	£200	£72,108
Scotland	£115,500	£9,459	£997	£349	£126,305
NI	£44,888	£3,774	£413	£138	£49,214
UK	£1,324,413	£116,494	£13,549	£4,205	£1,458,661

*Note: Totals may not sum due to rounding*

*Wage rates are reported in the text to 2 decimal places and when grossed may result in a rounding error*

### Equivalent Annual Net Costs (EANC)

52. As with enforcement authorities above, the one-off cost to industry must also be expressed as equivalent annual costs (EANC). Total one-off costs to industry in England have been estimated at £1.21m. This yields an EANC for industry in England of approximately £146k over 10 years. Table 8 displays the breakdown of the EANC per country.

<sup>14</sup> Wage rate obtained from The Annual Survey of Household Earnings, 2010 (See <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of 'Managers in Distribution, Storage And Retailing' (£11.98 + 30% to cover overheads = £15.57).

**Table 8 - Equivalent Annual Net Costs (EANC) to industry by location**

Country	EAC
<b>England</b>	<b>£145,616</b>
Wales	£8,670
Scotland	£15,187
NI	£5,918
UK	£175,391

*\*includes 39 Port Health Authorities*

*\*\* includes 1 Port Health Authority*

*Note: Totals may not sum due to rounding*

*Wage rates are reported in the text to 2 decimal places and when grossed may result in a rounding error*

### **Consultation Question**

**(10). Do you agree with our estimate of one hour for an employee of each business to familiarise themselves with the legislation and a further hour for reading and dissemination to key staff? Please provide evidence to support your response.**

**(11). What new or additional costs, over and above those associated with current relevant commercial activities would the EU Kitchenware Regulations and the national Regulations cause industry in England to incur? Please provide evidence to support your response.**

### **Ongoing Costs**

53. Importers will be charged by Port Health Authorities for their products being sent to public analysts for sampling. As we mentioned under costs to enforcement authorities there are considerable uncertainties regarding the likely costs of sampling due to difficulties in estimating the number of samples likely to be taken and subsequently sent for analysis. We calculated above that approximately 34,000 consignments containing plastic kitchenware articles are imported by the UK annually each containing numerous containers. Sampling will be carried out at a rate of approximately 10% of all consignments which annually results in 3,400 tests carried out. As mentioned in paragraph 44 above the sampling and analysis cost per consignment totals £1,335. When multiplying the total sampling cost by the estimated number of consignments being sent for analysis each year (3,400), results in a total annual sampling cost charged to industry of £4,539,000. Businesses, depending on their size and buying power, may be able to recover these sampling costs from the Chinese exporters. However for smaller businesses this is likely to be more difficult. Without an understanding of the number, size and distribution of the import businesses affected by this and because of the lack of certainty around who will bear the costs it's not possible to quantify at this stage the true monetary impact that will be borne by UK businesses.

### **Consultation Question**

**(12). Are the numbers of consignments used to calculate the cost to businesses (including importers) an accurate representation? Please provide evidence to support your response.**

54. Importers or their representatives may also incur additional costs if their consignments have been stored pending the release of analytical results. For example the Port of Felixstowe charges rent for each day a container remains on the port after a specified timescale. The port also charges a set fee for each consignment; the fees as of July 2010 are indicated in the table below:

**Table 9 - Port of Felixstowe for detaining consignments**

Size of Container	Detainment charge from day 6 to day 12	Detainment charge from day 13 onwards
Up to 20 foot	£13.00	£35.00
Over 20 foot	£26.00	£70.00

Source: Port of Felixstowe

55. As we cannot predict the exact number of consignments that will require storing we have assumed that half of 3,400 consignments randomly inspected, 1,700 consignments will require storing for 20 days each. The Port applies a set storage fee for each container based on the length of the detention and the size of the container, as we cannot be sure of the size of the containers being stored we have used range based on the cost of storing each size. Using costs provided by the Port of Felixstowe (see table 9 above) we believe that the set storage fee for 20 days ranges from £35 to £70 per container. Assuming that 1,700 consignments will be stored for 20 days, we anticipate a total annual cost to industry of between £60k and £119K with the best estimate of £89k, based on 1,700 consignments being charged for 20 days of storage at a cost per consignment of between £35 and £70.

### **Consultation Question**

**(13). Do you have any evidence to quantify the daily fee referred to in paragraph 53? (The costs in Table 9 are based on a set fee). Please provide evidence to support your response.**

**Table 10 – Ongoing Industry costs**

On-going costs to Industry	Year 0 (m)	Year 1 (m)	Year 2 (m)	Year 3 (m)	Year 4 (m)	Year 5 (m)	Year 6 (m)	Year 7 (m)	Year 8 (m)	Year 9 (m)	Total Cost (m)	Present Value (m)
Sampling costs	£4.54	£4.54	£4.54	£4.54	£4.54	£4.54	£4.54	£4.54	£4.54	£4.54	£45.39	£39.07
Detainment fee	£0.09	£0.09	£0.09	£0.09	£0.09	£0.09	£0.09	£0.09	£0.09	£0.09	£0.89	£0.77
<b>Total Industry Costs</b>	<b>£4.63</b>	<b>£46.28</b>	<b>£39.84</b>									

*The present value presents a discounted total cost. Discounting is a technique used to compare future costs (and benefits) that occur in different periods and is based on the principle that, generally, people place a higher value on money today than in the future, which is why future costs are discounted.*

56. Industry may incur costs if their products have been stored pending the release of analytical results. This may result in lost earnings for businesses if they do not have enough products in stock to compensate for their imported products being stored. We are not certain whether businesses would lose revenue from their products being stored and do not have the necessary information to quantify the effects if this was the case.
57. In the possible scenario that the plastic kitchenware is destroyed as a result of containing excessive levels of PAA and formaldehyde, the importer would initially bear the costs. However we anticipate that any costs incurred would be recovered from the Chinese exporter. Again, it is probably more likely that large businesses will be able to recover full costs whereas this may be more difficult for SMEs. At present we are unable to quantify the costs associated with this but we anticipate that they will diminish over time for two reasons 1) that if kitchenware suppliers (Chinese exporters) have to bear the costs of destroyed products they will be less likely to infract the EU Kitchenware Regulation in future and 2) that if importers have to bear the costs they will switch to suppliers with a reputation for adhering to the standards set.

### **Consultation Questions**

**(14). Do you agree with our assumption that businesses may incur additional costs for inland storage of consignments pending the release of analytical results? Please provide evidence to support your response.**

**(15). Are the costs of storing consignments whilst awaiting clearance in Paragraph 55 an accurate estimate? Please provide evidence to support your response.**

**(16). What is the potential loss of earnings (if any) to businesses, while awaiting the release of impounded products, if there is a loss, is this affordable? Please provide evidence to support your response.**

**(17). Do you agree that costs recovered by Enforcement Authorities from UK businesses will be passed back by those businesses to the Chinese exporters? Is there any information**

**available to support your response?**

**(18). As the additional controls are specific to polyamide and melamine plastic kitchenware originating, in or consigned from, China, what is the likelihood of businesses sourcing such products from elsewhere and, if so, what additional costs, if any, would be incurred? Please provide evidence to support your response.**

**(19). Do businesses have any comments on the proposed national Regulations in so far as they relate to the provisions for enforcement, defences and penalties?**

**Food Standards Agency (FSA)**

58. The FSA will incur charges from HMRC for compliance checks for release for free circulation of plastic products from China on the FSA's behalf. HMRC will charge the FSA a one-off fee of £161.50 to set up new proposed measures. HMRC will also charge the FSA an Annual fee of £64.60 for review of the measure. HMRC will then charge a fee of £8.84 to check each import declaration which is sent before the arrival of a consignment. To quantify the cost to the FSA of HMRC checking all import declarations we multiply the charge per check (£8.84) by the number of declarations that will accompany a consignment of plastics from China (approximately 34,000) resulting in an annual cost of checking each declaration of £300,560. This results in total annual cost of £300,625 for each consignment being checked and the annual review. There will also be a one-off cost of £162 for HMRC set up fee.
59. The FSA hope to be able to charge importers of plastics from China for the costs incurred by HMRC carrying out compliance checks on their plastic products. If the FSA are able to do this, aside from the one-off cost of £162.50, this regulation will be cost neutral for the FSA. However, there are numerous uncertainties at this stage about whether it will actually be possible to put in place the infrastructure required in charging the Chinese exporters, as such we have assumed in the analysis that these costs will be borne by the FSA.

**Equivalent Annual Net Costs (EANC)**

60. It is necessary to equivalently annualise the one off cost to the FSA. The one cost component to the FSA totals £162.50, which equates to an equivalent annual cost to the FSA of approximately £19.72 over 10 years.

**Table 11 – Ongoing costs to the FSA**

On-going Agency Costs	Year 0 (m)	Year 1 (m)	Year 2 (m)	Year 3 (m)	Year 4 (m)	Year 5 (m)	Year 6 (m)	Year 7 (m)	Year 8 (m)	Year 9 (m)	Total Cost (m)	Present Value (m)
HMRC Charge and annual review cost	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£3.01	£2.59

*The present value presents a discounted total cost. Discounting is a technique used to compare future costs (and benefits) that occur in different periods and is based on the principle that, generally, people place a higher value on money today than in the future, which is why future costs are discounted.*

**Benefits**

**Option 1 – Do nothing**

61. There are no identifiable incremental benefits for this option.

**Option 2 - Fully implements the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the EU Kitchenware Regulation**

62. This option would ensure that enforcement authorities within England, including port health authorities, have adequate statutory powers to prevent the placing on the market of those materials and articles that fail to meet the requirements of the EU Kitchenware Regulation. This option would also harmonise standards across Member States and prevent any distortion of trade

occurring as a result of there being different regulations in different individual Member States. It also meets the Government's commitment to fulfil its EU obligations and contributes significantly to providing the means of protecting consumers from ingesting harmful levels of chemicals that could have adventitiously migrated from the materials or articles that were intended to be brought into contact with food.

## **Consumers**

63. This option minimises the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles to the food itself.
64. However, the benefit to consumer health is unquantifiable as it is impossible to isolate the benefits of this Regulation to a reduction in ill health from chemical contamination. Excessive levels of PAAs are known to be carcinogenic and excessive levels of formaldehyde can have potential adverse health effects. For further detail on this please see Annex 4.

## **Consultation**

65. In Spring/Summer 2010, during the course of European negotiations, the FSA conducted an informal consultation on the Commission's draft proposal for specific control measures on polyamide and melamine plastic kitchenware originating in or consigned from China. Enforcement authorities and their representative bodies, trade associations, individual companies (both large businesses and SMEs), the UK Border Agency and HM Revenue and Customs and the UK's Official Control Laboratories were targeted. Responses to the consultation played a key role in shaping the draft in its current form. The FSA has continued to liaise with many of these stakeholders and has kept them abreast with developments. It is anticipated that the same stakeholders will be targeted for the consultation on the proposed Regulations.
66. The informal consultation carried out in 2010 raised a number of pertinent issues about cost implications in relation to the EU Kitchenware Regulation from enforcement authorities and industry. These comments informed the UK's approach to discussions in EU Working Group meetings, which led to a substantial reduction in the percentage of consignments to be subjected to random physical checks from the 50% initially proposed by the Commission down to 10%, as reflected in the published EU Regulation.

## **Enforcement**

67. The purpose of The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011 is to provide enforcement authorities, e.g. Environmental Health Officers, Trading Standards Officers and Port Health Officers with the necessary powers to prevent non-compliant polyamide and melamine plastic kitchenware originating in or consigned from China from entering the market in England.

## **Statutory Review**

68. The FSA is required to carry out a review every five years on the way in which EU Regulations for which the FSA has enforcement oversight are enforced in other Member States. The review period begins when the proposed Regulations that are the subject of this Impact Assessment come into force. In carrying out the review, the FSA is required to produce a report that will assess whether the Regulations achieved their intended objectives. The report will also assess if these objectives could be achieved by means that impose less regulation.

## **EU Guidance**

69. The Commission has produced draft EU guidelines to provide guidance on the application of the EU Kitchenware Regulation to assist businesses and enforcement bodies. The Commission's Joint Research Centre (JRC) has also produced draft technical Guidelines<sup>15</sup> for laboratories on

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<sup>15</sup> The technical Guidelines produced by the JRC have been produced in collaboration with its EU official network of National Reference Laboratories and endorsed by the Commission's competent service DG Health and Consumers (DG SANCO) and its network of Member State Competent Authorities.

testing the migration of PAAs from polyamide kitchenware and for formaldehyde from melamine plastic kitchenware. The draft guidelines are currently under discussion with Member States, once agreed; they will be adopted and published. The guidelines, when published, will be available on the Commissions website at:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

## **Risks**

70. For option 1 'Do nothing' - the risk of not having the Regulations in place would mean that enforcement authorities would not have the necessary powers to enable them to enforce the EU Kitchenware Regulation. Therefore, the obligations to put in place the provisions for its enforcement, for offences to be prosecuted and for penalties for those found to be in breach of the EU Kitchenware Regulation will not be fulfilled. This would lead the UK Government being cited in infraction proceedings by the Commission and this in turn could result in financial penalties being incurred. It would also leave the regulation of food contact materials in the UK deficient in comparison with the rest of the EU.
71. Consumer safety may also be compromised and the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials to the food itself.
72. Due to the specific nature of this Regulation and the fact that the plastics sector is not a specified category in the Standard Industry Codes (SIC), we are likely to be overestimating the number of affected businesses. Because we are likely to be overestimating the number of businesses affected it will lead to an overestimation of the familiarisation costs to industry as the number of businesses affected drives the familiarisation cost.
73. The assumptions used to derive the annual costs assume that the number of imports of plastics from China will remain constant throughout the duration of this policy. It is likely that the number of imports of plastics from China will decline after the application of this regulation as a result of costs being imposed on industry, which may lead to plastic imports being sourced from other areas. However, we lack sufficient data to make the assumptions about future imports of plastics from China so are likely to be over estimating the ongoing costs of this policy.
74. We have had to make assumptions regarding the number of consignments that will be tested and therefore detained. We are hoping that this consultation can provide us with more evidence to improve our assumptions we use in the final impact assessment.

## **Specific Impact Tests**

### **Competition Assessment**

75. We have fully considered the questions posed in the Office of Fair Trading (OFT) competition assessment test<sup>16</sup> and conclude that the preferred policy option on the proposed Regulations that enforce the EU Kitchenware Regulation are unlikely to hinder the number or range of businesses or the ability for operators to compete. The proposals are unlikely to significantly affect competition and will apply equally to all importers and retailers of polyamide and melamine plastic kitchenware. The EU legislation is directly binding on all Member States and the businesses that trade within them. Charities and voluntary organisations are also unlikely to be affected by these proposals.

### **Small Firms Impact Test**

76. Stakeholders, including the Department for Business Innovation and Skills (BIS), the Federation of small businesses have been consulted throughout the negotiations on the EU Kitchenware Regulation in an earlier informal consultation. We understand that importers and their representatives will pass the cost to the manufacturers in China, before polyamide and melamine plastic kitchenware are placed on the market; however, we need to consider the possibility that SMEs may find it more difficult to recover cost from Chinese exporters due to their limited market

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<sup>16</sup> [http://www.offt.gov.uk/shared/oftr/reports/comp\\_policy/oftr876.pdf](http://www.offt.gov.uk/shared/oftr/reports/comp_policy/oftr876.pdf)

power. In addition, the incremental costs resulting from this policy will account for a larger percentage of revenue for a smaller firm and it may lack the resources and scale to cope with the additional regulations compared to larger companies.

77. At this stage we have no information regarding how likely it is that small businesses will be adversely affected as a result of this legislation and so we welcome views of small and medium sized businesses and their representative organisations on this issue.

### **Sustainability**

78. Impacts under the three pillars of sustainable development (environment, economic and social) have been and continue to be considered in the preparation of this Impact Assessment. Option 2 is the preferred option as it provides enforcement authorities the necessary powers to enforce the EU Kitchenware Regulation to ensure that polyamide and melamine plastic kitchenware entering the retail market in England are compliant with the that Regulation. This option will also provide a significant measure of control that would minimise the potential health risks to consumers.

### **Race/Gender/Disability equality issues**

79. The FSA believes that the proposal will have no impact on race, gender or disability equality issues.

#### ***Consultation Question***

***(20). Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Kitchenware Regulation and national Regulation? Please provide evidence to support your response.***

## Annex 1: Post Implementation Review (PIR) Plan

<b>Basis of the review:</b>
<b>Review objective:</b>
<b>Review approach and rationale:</b>
<b>Baseline:</b>
<b>Success criteria:</b>
<b>Monitoring information arrangements</b>
<b>Reasons for not planning a review:</b>

## Annex 2

The types of materials that are covered by the EU Kitchenware Regulation are:

Examples of polyamide (nylon) kitchenware include articles such as; cooking spatulas, slotted spoons, tongs, pasta tongs, whisks, etc (see below for info)



Examples of melamine kitchenware includes articles such as; picnic sets, children plates, bowls, cups, ladles, spoons etc (see below for info).



## Annex 3

### FSA Research and Surveillance on Polyamide and Melamine Plastic Kitchenware

The FSA is currently funding a four year programme of surveillance, looking specifically at chemical migrants from food contact materials and articles. The first survey in this series (Food Survey Information Sheet (FSIS) 04/08) was published in August 2008. This survey investigated the migration of formaldehyde, and hexamethylenetetramine (HMTA) expressed as formaldehyde from melamine-ware. The purpose of the survey was to see whether the Total Specific Migration Limit (SML(T)) for formaldehyde and HMTA were being observed. Of the 50 samples that were tested migration was detected from 43 of the samples; most of the levels found were well below the limits set in the legislation, such that 84 per cent of the samples tested were compliant. However, from eight samples formaldehyde levels were clearly above the legal maximum at 6-65 times the SML(T).

The second survey in this series (FSIS 01/10) was published in August 2010, investigated PPA migration from nylon kitchen utensils. The survey was commissioned in response to several notifications raised via the RASFF system concerning non-compliant kitchen utensils imported from the Far East. Results showed that of the 107 samples tested, 35 were not compliant with the legislation. In some cases, levels of PAAs detected in the different utensils varied within each set. This variation resulted in both compliant and non-compliant results for individual articles from the sample set. The varying results may be explained by inconsistencies in the manufacturing processes of the articles.

For both surveys, the FSA took immediate action, working with local enforcement officers and suppliers, to ensure that non-compliant goods were withdrawn from the market. The FSA informed the European Commission and other EU Member States, to enable them to take necessary action.

The surveillance programme has highlighted that polyamide kitchenware and melamine plastic kitchenware originating from the Far East have continued to fail to meet the requirements of the food contact materials legislation.

A summary of both reports can be accessed at the following website addresses:

<http://www.food.gov.uk/science/surveillance/fsisbranch2008/chemicalmigration>

<http://www.food.gov.uk/science/surveillance/fsisbranch2010/fsis0110>

## Annex 4

### Chemical Risk Assessment for Primary Aromatic Amines and Formaldehyde

The International Agency for Research on Cancer classified MDA as group 2B, possibly carcinogenic to humans (IARC, 1987). This classification was based on the results of carcinogenicity by oral administration in mice, rats and dogs. Treatment-related increases in the incidences of thyroid follicular-cell adenomas and hepatocellular neoplasms were observed in both male and female mice. The genetic toxicology profile was also considered by IARC. MDA was mutagenic to *Salmonella typhimurium* in the presence of an exogenous metabolic system. It induced DNA damage in Chinese hamster V79 cells in the presence of an exogenous metabolic system, and induced DNA damage in the liver of rats and sister chromatid exchange in the bone marrow of mice treated in vivo.

The UK Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) advises that it is not possible to identify a threshold for the effects of genotoxic carcinogens, and that there could be some risk even at very low levels of exposure.

Unnecessary exposure to genotoxic carcinogens, such as 4,4 MDA, is undesirable and the ALARP principle should be applied.

Formaldehyde is produced on a large scale and is used in the production of phenolic, urea, melamine and polyacetal resins. Formaldehyde is also used as an intermediate in the manufacture of industrial chemicals and as an aqueous solution (formalin) as a disinfectant and preservative.

In 2007, the European Food Safety Authority's (EFSA) AFC Panel concluded that there is no evidence indicating that formaldehyde is carcinogenic by the oral route, on the basis of recent and previous evaluation. There is evidence that formaldehyde can elicit immune effects such as hypersensitivity and contact dermatitis in sensitive individuals. The World Health Organisation (WHO) Concise International Chemical Assessment Document (CICAD, 2002) suggests that "the concentration of formaldehyde likely to elicit contact dermatitis reactions in hypersensitive individuals may be as low as 30 milligrams per litre".

In 1993 the WHO derived a tolerable daily intake (TDI) of 0.15 milligrams per kilogram, bodyweight per day based on a study that identified a no adverse effect level (NOAEL) for stomach irritation of 15 milligrams per kilogram, bodyweight per day, (this was further endorsed by the WHO in 2004).

**Interested Parties List**

ABC Food Safety Ltd  
Association of Consumer Research  
Association of Port Health Authorities  
ASDA  
Airline Operators Committee (Gatwick)  
Boots  
Brabantia  
British Hardware & Houseware Manufacturers Association  
British International Freight Association (BIFA)  
British Plastics Federation  
British Ports Association  
British Retail Consortium  
Campden & Chorleywood Food RA  
Catering Equipment Suppliers Association  
Ceramic Federation  
Chemical Industries Association  
Costco  
Debenhams  
Federation of Small Businesses  
Food and Drink Federation  
H J Heinz  
HM Revenue and Customs  
House of Frazer  
Homebase  
Home Retail Group  
Homespan (UK) Ltd  
Industrial Packaging Films Association  
John Lewis  
Kitchencraft  
Marks and Spencer PLC  
Matalan  
Morrisons  
Packaging and Film Association  
Port Health Aberdeen  
Port Health Belfast  
Port Health Bristol

Port Health Cardiff  
Port Health Channel Tunnel Dover  
Port Health Channel Tunnel Folkestone  
Port Health Felixstowe  
Port Health Gatwick  
Port Health Glasgow  
Port Health Heathrow  
Port Health (Head Office) London  
Port Health Liverpool  
Port Health Manchester  
Port Health Portsmouth  
Port Health Southampton  
Port Health Tilbury  
Poundland  
Premier Foods (HL Foods Ltd)  
Price Waterhouse Coopers  
Sabichi  
Sainsbury's  
Somersetfield  
Tefal  
Tesco  
The Co-operative Group  
Toysafe  
The Department for Business Innovation & Skills (BIS)  
United Kingdom Border Agency  
Waitrose  
Which  
Wilkinson  
  
Wingyip (Importers, Retailers and Distributors of Chinese Goods)  
  
Bristol City Council Scientific Services  
  
Durham County Council  
  
Hampshire Scientific Services  
  
Kent Scientific Services  
  
Lancashire County Laboratory  
  
Leicestershire County Council, Public Analyst Laboratory  
  
Eurofins Laboratories Ltd.

Somerset Scientific Services

Staffordshire County Council, County Laboratory & Scientific Services

West Yorkshire Analytical Services

Worcestershire Scientific Services

Laboratory of the Public Analyst

Tayside Scientific Services

Glasgow Scientific Services

Edinburgh Scientific Services

Minton, Treharne & Davies Ltd.

Cardiff Scientific Services

Eurofins Laboratories (N.I.) Ltd