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FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

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

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Final Business and Regulatory Impact Assessment (BRIA)

1. Title of Proposal

1.1 The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011.

2. Purpose and intended effect

➤ Objectives

2.1 The policy objective is to make national Regulations to provide for the execution and enforcement, in Scotland, of the European Commission Regulation (EU) No. 284/2011 (“the EU Kitchenware Regulation”), which sets down additional import controls applicable from 1 July 2011. The EU Kitchenware Regulation aims to reduce the risk of non-compliant plastic kitchenware from the People’s Republic of China and Hong Kong (together referred to as “China” in this document) 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 2009/10), 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.

➤ Legislative Background

EU Legislation on Plastic Food Contact Materials

2.2 Harmonised EU rules on plastic food contact materials were until recently laid down by Commission Directive 2002/72/EC (as amended) relating to plastic materials and articles intended to come into contact with foodstuffs. This Directive has been consolidated in the form of a new EU Regulation¹, which applied from 1st May 2011, with the relevant requirements remaining unaltered. These requirements are implemented in Scotland by The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009². The legislation requires that PAAs should not be detectable using the detection limit of 0.01 milligrams per kilogram of food and for total formaldehyde 15 mg/kg.

Background

2.3 Significant numbers of notifications and alerts have been received via the Rapid Alert System for Food and Feed (RASSF) pursuant to Article 50 of Regulation 178/2002³, concerning food contact materials imported from China into the EU, releasing into food or food simulant⁴ 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 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 Annex II, point 2 (requirements for the release of PAAs) and Annex I, Table 1 (requirements for formaldehyde) of the new Regulation respectively.

2.4 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

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

² SI 2009 No. 205

³ 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

⁴ 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 food contact materials into food.

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.

- 2.5 Similarly, levels of formaldehyde have been released into food that are higher than those authorised in EU legislation from melamine plastic kitchenware also originating in or consigned from China.
- 2.6 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.
- 2.7 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".
- 2.8 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 exported 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.
- 2.9 Commission Regulation (EU) No. 284/2011 ("the EU Kitchenware Regulation") was published in the Official Journal (OJ) of the EU on 23rd March 2011 (Ref: OJ, L77, 23.03.2011, pg 25-29), came into force on 12th April 2011 and is directly applicable throughout the EU as of 1st 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>

- 2.10 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)

- 2.11 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 formerly laid down in Part A of Annex V and in Section A of Annex II of Commission Directive 2002/72/EC and now contained in Commission Regulation

(EU No. 10/2011 ("the new Regulation"). 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 new Regulation as set out above.

Prior notification of consignments

- 2.12 Article 4 requires importers or their representatives to provide prior notification to the competent authority at the First Point of Introduction (FPI) 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

- 2.13 Where Member States decide to designate specific FPIs (as allowed by Article 5 of the EU Kitchenware Regulation) 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 Commission of the internet address. The Commission will display the links to the national lists of these points of introduction on its website for information purposes. Among the FPIs designated in the UK is Grangemouth port in Scotland. Information about FPIs designated in the UK is also available on the FSA website at

http://www.food.gov.uk/foodindustry/imports/banned_restricted/kitchenware

Controls at the First Point of Introduction

- 2.14 The competent authority at the First Point of Introduction into the EU shall 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

- 2.15 The competent authority at the FPI may authorise the onward transportation of consignments pending the results of the checks as outlined in 2.14 above. Appropriate arrangements are to be put in place to ensure that the consignments remain under the continuous control of the competent authority and cannot be tampered with in any way pending the results of the checks.

Release for free circulation

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

Reporting to the Commission

- 2.17 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.

Consignments that do not comply with the EU Kitchenware Regulation

- 2.18 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.
- 2.19 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 2.20, below.
- 2.20 In respect of consignments for which a declaration is not provided or where a notice described in paragraph 2.19 above has been served, is not provided within the timescale specified or for those consignments found 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.

Proposed National Regulations

- 2.21 This proposal is for a Scottish Statutory Instrument (SSI) entitled The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011. The objective of the proposed Regulations is to provide enforcement provisions for the EU Kitchenware Regulation, by:
- designating local authorities as having responsibility for the enforcement of the EU Kitchenware Regulation in Scotland;
 - providing for offences of contravening certain provisions of the EU Kitchenware Regulation;
 - providing 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.

First Points of Introduction (FPI)

- 2.22 As indicated in 2.13 above and as allowed by Article 5 of the EU Kitchenware Regulations, products subject to the requirements of that Regulation would enter the UK at a designated FPI.
- 2.23 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 will be borne by importers of the melamine kitchenware where Local Authorities seek to recover costs. The consultation process had revealed that there may be some scope for large businesses to claim costs back from Chinese importers if consignments are found to be non-compliant with EU law but otherwise businesses will bear the burden. Potential benefits to business may arise from improved compliance as the quality and likelihood of products being non-compliant diminishes with the enforcement of this regulation.
- 2.24 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.

Rationale for Government intervention

- 2.25 Chemical migration from food contact materials and articles can have a negative impact of 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.

3. Consultation

Within Government

- 3.1 Scottish Government officials from the Health, Rural Affairs and Enterprise Directorates were kept apprised of the development of the European Regulation during the negotiating process in Brussels.
- 3.2 The Food Standards Agency (FSA) consulted the Scottish Government's Better Regulation and Industry Engagement team during the preparation of the consultation. Officials from the Legal Directorate were closely involved in the drafting of the Scottish Statutory Instrument. Scottish Government officials from the Health, Rural Affairs and Legal Directorates were included in the recent consultation on the draft Regulations.

Public Consultation

- 3.3 In Spring/Summer 2010, during the course of European negotiations, the FSA conducted an informal consultation on the Commission's draft proposal. Responses to the consultation played a key role in shaping the draft in its current form.
- 3.4 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.
- 3.5 A public consultation was carried out in Scotland on the proposed national Regulations and earlier draft of the Business and Regulatory Impact Assessment, from 20 May to 10 June 2011. The FSA received two responses to the consultation: one from Scottish Government's Law Reform Division and one from a Local Authority. The former response indicated contentment with the proposals in relation to offences and penalties.
- 3.6 The Local Authority questioned the necessity for ports to be designated, given that existing ports are currently capable of handling the products in question without designation. It was also suggested that the 'familiarisation costs' for enforcement authorities cited in the Business and Regulatory Impact Assessment had been underestimated.
- 3.7 The Local Authority asserted that the additional costs associated with these controls would likely be passed on from importers to customers (including SMEs), rather than to Chinese exporters.
- 3.8 The parallel consultations throughout the rest of the UK elicited 10 responses, several of which came from Port Health Authorities (PHAs) and concerned drafting details. These comments have been acted upon where necessary.
- 3.9 Enforcement authorities were generally supportive of the proposed control measures and the enforcing Regulations for the increased protection from exposure to harmful chemicals that they provide to UK citizens. It was indicated that costs for familiarising ("familiarisation costs") with the requirements of new legislation were underestimated. The enforcement authorities asked for further guidance on consistent execution of the Regulations.

Business

- 3.10 As part of the BRIA engagement process required by Scottish Government, face-to face meetings were arranged with Scottish stakeholders. Details of this are summarised in the 'Scottish Firms Impact Test' section.
- 3.11 Among the industry respondents to the consultations throughout the UK were Food Solutions, which represents the interests of small food businesses.
- 3.12 There was a general consensus amongst industry respondents that familiarisation costs had been underestimated. Industry suggested that it would be unable to pass the additional costs associated with these controls on to Chinese exporters. Industry also highlighted the costs of storing consignments subjected to random 10% checks and held pending analytical results and the costs associated with sourcing relevant products from countries other than China, should they opt to do so. Industry also raised the possibility that the charity/voluntary sector could potentially be affected, although no comments were received from this sector.
- 3.13 Stakeholders were asked to provide evidence to support their views on the additional costs, over and above their commercial activities, of the proposed Regulations; however, none were able to quantify these costs in their comments, or provide supporting evidence.

4. Options

Option 1 – Do Nothing. Do not provide for the execution and enforcement of the EU Kitchenware Regulation in Scotland

- 4.1 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 UK's obligation (under the Treaty on the Functioning of the European Union to put in place provisions for its enforcement would not be fulfilled which would be likely to lead to the UK being subject to infraction proceedings.
- 4.2 This option would also mean allowing China to continue to export polyamide and melamine plastic kitchenware into Scotland without additional targeted controls, thus exposing Scottish consumers to the risk of ingesting primary aromatic amines and formaldehyde with potential adverse health effects.

Option 2 – National Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation in Scotland

- 4.3 This option provides a significant measure of control that would minimise the potential health risks. The control will, however, place some financial costs on businesses that use, sell and import such products into Scotland. We understand, however, that in some instances (i.e. where importers produce are not compliant with the law) 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.
- 4.4 This also ensures that enforcement authorities can fulfil the requirements placed upon them and the Courts can impose penalties that are consistent with those that apply elsewhere in Scottish food law. It also provides for defences to alleged offences in certain specified circumstances.

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.

- 4.5 This option has been tried 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 Directive 2002/72/EC. This option would not fulfil the requirements of the EU Kitchenware Regulation and would therefore not be fit for purpose.
- 4.6 As a result, Option 2 is the preferred option that will achieve the requirements of the EU Kitchenware Regulation.

Sectors and groups affected

Industry

- 4.7 This proposal will affect UK retailers, wholesalers and importers of plastic products from China. Businesses potentially affected by this proposal are not identified by a standard industrial classification code (SIC), and as such, it is difficult to provide accurate estimates of the precise number of businesses that will face an impact. Where appropriate, an attempt has been made to estimate the number of retailers and wholesalers *potentially* affected using the Interdepartmental Business Register (IDBR⁵) and the number of importers through the consultation process.

Retailers

- 4.8 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 policy⁶. 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.

Wholesalers

- 4.9 The number of wholesalers affected is derived from the IDBR⁷ 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. Some responses from consultation indicate that this is the case and that the number of wholesalers is likely to be much lower than that which is reported here.⁸ However we believe including only 100 wholesalers is likely to be an underestimate. Thus, to be conservative and ensure we have captured the full extent of wholesalers who may be affected by this legislation, we have used the figures provided by IDBR.

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

⁶ 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

⁷ Categories for wholesalers; 46.49 Wholesalers of other household goods.

⁸ Estimate ranges begin from only 100 first tier wholesalers.

Importers

- 4.10 The IDBR does not identify importers as a distinct category; and as such we have no robust data regarding the total number of importers that may be affected. However as an approximation, industry body membership data (obtained from consultation) indicates that the total number of nylon kitchenware importers in the UK is approximately 150. Some large retailers will also import directly, but this is covered by the retail section above.
- 4.11 Table 1 displays the number of retailers and wholesalers affected by the proposal by country. Note that we currently have no information regarding the country level disaggregation of importers. The split has been estimated using the proportion of businesses in each of the countries in the other sectors using IDBR data. This is not therefore an accurate representation but may be used as an indicative estimate in the absence of robust data.

Table 1: Sectors Affected

	England	Wales	Scotland	NI	UK
Retailers	34,020	2,175	3,835	1,460	41,490
Wholesalers	4,860	140	220	120	5,340
Importers	125	7	13	5	150
Total	39,005	2,322	4,068	1,585	46,980

Source: IDBR and consultation process

Note: Totals may not sum due to rounding

Source: IDBR

- 4.12 HM Revenue and Customs (HMRC) and Local Authorities 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. HMRC may also incur costs for delaying consignments awaiting release into free circulation, pending receipt of documents, from Enforcement Authorities confirming their compliance with the EU Kitchenware Regulation, and subsequent release. These costs will ultimately be recovered from the FSA and so although HMRC will initially incur these costs the FSA will bear the final burden.

Benefits

Option 1 – Do nothing

- 4.13 There will be no benefit to the consumer, since the risk to their health could be compromised as a result of the high levels of chemical migrants associated with polyamide and melamine kitchenware. With respect to businesses the lack of enforcement provision may be a benefit due to the removal of the financial burden of import charges. However, there would be an increased risk of financial detriment to the sector as a whole through reputational damage if illegal imports were subsequently identified in other parts of the distribution chain.

Option 2 - National Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation in Scotland

- 4.14 This option would ensure that enforcement authorities within Scotland 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

- 4.15 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.
- 4.16 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.

Costs

Option 1 – Do Nothing

Costs to the Consumer

- 4.17 This is the baseline against which other costs are compared. The costs associated with this option are predominantly to public health. Excessive levels of 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 Scotland without additional targeted controls, consumers will be exposed to the risk of ingesting primary aromatic amines and formaldehyde with potentially serious health consequences

Option 2 - National Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation in Scotland

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

Costs to Enforcement Authorities

One-off Costs

- 4.19 There will be a one-off cost to enforcement authorities for reading and familiarising with the new Regulations. Each Local Authority (LA) in its district is responsible for enforcing the legislation with respect to food safety and/or food hygiene, and thus has the responsibility for enforcing the food contact materials legislation. Officers from the Environmental Health Service of the LA will be responsible for enforcing and thus familiarising themselves with these Regulations. However, in line with UK cost determination, we have used a range for the hourly wage rate using an EHO wage rate of £20.45⁹ as the lower bound, and a TSO hourly wage rate of £22.09¹⁰ as the upper bound rate, with the midpoint being £21.27¹¹.
- 4.20 We have estimated that 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 an enforcement officer by both the time required to read and disseminate the new Regulations

⁹ 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).

¹⁰ 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).

¹¹ (£20.45 + £22.09)/2

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.

- 4.21 In Scotland, enforcement of the Regulations will be carried out by Local Authority enforcement officers. Using the best estimate of £42.54 for each of the 32 enforcement authorities in Scotland results in a total familiarisation cost for Scotland of £1,361. Table 2 displays the familiarisation cost by location.

Table 2 - 'One-Off' costs to Local Authorities and Port Health Authorities in the UK (Best Estimate)

Country	England	Wales	Scotland	NI	UK
Number of LAs	354	22	32	26	434
Familiarisation cost (LA)	£15,058	£936	£1,361	£1,106	£18,461
Number of PHAs	39	1	N/A	N/A	£40
Familiarisation cost (PHA)	£2,488	£64	N/A	N/A	£2,552
Training cost (PHA)	£17,550	£450	N/A	N/A	£18,000
Total Familiarisation cost (LA+PHA)	£17,546	£1,000			£21,013
Total One-off Cost (All familiarisation + Training)	£35,096	£1,450	£1,361	£1,106	£39,013

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

Ongoing Costs

- 4.22 In addition to reading and familiarisation costs, it is expected that a procedure for recording information arising from the controls will be established, and reports forwarded to the Commission on quarterly basis. The cost of this administrative work is irrecoverable.
- 4.23 In a recent (2010) trial conducted by Suffolk Coastal Port Authority at Felixstowe, 1,657 consignments of plastic items were identified on manifests over a 10 week period, most of which will be captured under the EU Kitchenware Regulation.
- 4.24 Estimates of costs for a typical enforcement authority, as exemplified by Felixstowe, are shown in Table 3 below. Note that each port will charge varying fees to business and thus evidence from Felixstowe is used indicatively and does not necessarily provide an accurate representation of costs to enforcement authorities across the whole UK.

Table 3– Cost of activities at Felixstowe Port

	Activity – Document receipt & check	Time taken	Officer / £30 hrs on costs	Admin / £22 hrs on costs
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
	Sub total			£38.57
	Activity – Examination sampling & analysis			
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	30 mins	£25.00	
4	Sampling time (assuming simple sampling protocol)			
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: Note Storage costs have been discussed separately in the cost section below	£400.00	
	Sub total			£462.50
	Activity – Charge for Onward transportation arrangements			
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	
	Sub total			£25.00
	Total: excluding cost of tests and recording and submitting data			£59.17
	Total			£526.07

Source: Port of Felixstowe Suffolk

Irrecoverable admin costs

- 4.25 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 calculated by multiplying the hourly wage rate of a member of staff carrying out the reporting (£22, as shown in Table 3) 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. The cost is not recoverable.

- 4.26 Evidence shows that approximately 180 consignments of plastic tableware, as per the SIC code used above, came into Scotland. Using the information within Table 3, the total administrative costs for Scotland are calculated by multiplying the cost of reporting each consignment (£4.40) by the total number of consignments (approx 180), resulting in an annual reporting cost to enforcement authorities of £792.

Recoverable compliance costs

- 4.27 Enforcement authorities will **initially** incur costs associated with administrative checks, sampling and analysis and onward transportation. The costs highlighted here would be recovered from businesses. As table 5 indicates, the total cost of these actions (excluding analysis fees for tests and recording and submitting data) will cost approximately £59.17 per sampled consignment. In addition, all consignments entering the UK will be charged for the activities associated with document receipt and check. Table 4 details total activity costs incurred by Local Authorities (excluding sampling tests fees) that will be recovered from business.

Table 4: Summary of additional costs

Activity Type	Cost	Consignments affected	Total cost
Activity Document receipt and check	£34.17	34,000	£1,161,667
Activity Examination sampling and analysis	£62.50	3,400	£212,500
Activity Charge for onward transportation	£25.00	3,400	£85,000
Total	£0.00	-	£1,459,167

Source: Data from Port of Felixtowe

Recoverable sampling and analysis costs

- 4.28 Enforcement authorities will incur sampling and analysis costs as each sampled consignment will need to be tested. 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. Evidence from consultation suggests that for the most part importers **will not** be able to recover these costs from Chinese exporters particularly if the goods are sampled and found to be compliant with the legal requirements. If the products are found to be non-compliant then large businesses are more likely to be able to recover costs from Chinese exporters due to their strong buying power. SMEs however are unlikely to be able to claim back costs in the same way. Evidence from consultation has suggested that SMEs will not be able to recover costs from exporters under any circumstances.
- 4.29 The sampling and analysis cost per consignment comprises a test for formaldehyde and a test for PAAs. Each product will only be tested for **either** PAAs or Formaldehyde; nylon kitchenware will be tested for formaldehyde and melamine kitchenware for PAAs. Costs of these tests vary greatly between laboratories and prices have been quoted ranging from between £395 and £617 for formaldehyde and between £395 and £917 for PAAs. Using the upper and lower bounds yields a best estimate of £506 for formaldehyde and £656 for PAA. In the absence of robust evidence, we have assumed there will be an equal split of each type of test. Multiplying the average sampling cost by the estimated number of consignments being sent for analysis each year (3,400), results in a total annual cost of £1,975,400, which will be charged back to industry (see industry cost section).

- 4.30 Using the model outlined above ($180 \times 10\% \times £581$), the total annual sampling cost for Scotland would be £10,458.

Total ongoing costs to Enforcement Authorities

- 4.31 Accounting for the fact that most of the costs discussed above will be recovered, ongoing cost to enforcement authorities is as detailed below:

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.

Note:

These costs are for the UK as a whole

Costs to HM Revenue and Customs (HMRC)

- 4.32 There will be a one-off cost to HMRC for reading and familiarising with the new Regulations. We estimate that one member of HMRC staff per Port 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.
- 4.33 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 (£23.87¹²) by the time taken to become familiar with the regulation (2 hours).
- 4.34 At present we are aware of 3 ports in Scotland where these products are imported, thus the familiarisation cost to HMRC in Scotland would be £143.

Ongoing Costs to HMRC

- 4.35 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.
- 4.36 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).

¹² 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).

Costs to Industry

One-off Costs

- 4.37 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 familiarisation 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 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.
- 4.38 It will cost each business £31.15 to become familiar with the new Regulations which is based on an hourly wage rate of £15.57¹³ 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 Scotland (4,068 as shown in table 1) which totals £127,000 approx in Scotland. The breakdown of costs is displayed in Table 6 below.

Table 6: Familiarisation Costs to

	All Retailers and Wholesalers					
Country	Micro	Small	Medium	Large	Importers	Total
England	£1,098,135	£97,822	£11,559	£3,518	£3,879	£1,214,913
Wales	£65,890	£5,438	£580	£200	£231	£72,339
Scotland	£115,500	£9,459	£997	£349	£405	£126,710
NI	£44,888	£3,774	£413	£138	£158	£49,371
UK	£1,324,413	£116,494	£13,549	£4,205	£4,672	£1,463,333

Source: IDBR and consultation process

Industry Note: Totals may not sum due to rounding

- 4.39 As the number of importers of kitchenware products was not available from IDBR it has not been possible to disaggregate the figures in the same way as for the retailers and wholesalers above. We have therefore made an assumption about the proportion of businesses in each of the countries based on the proportions presented by the IDBR data. This is not an accurate measure but is indicative of the likely distribution.

Ongoing Costs

Sampling costs

- 4.40 Importers will be charged by Local Authorities for their products being sent to public analysts for sampling. As detailed under the 'Costs to Enforcement' section, 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 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 detailed in paragraphs 4.29 – 4.30, our best estimate for the sampling and analysis cost in Scotland is £10,458. Responses from consultation have indicated that large businesses may be able to recover some of these costs from Chinese exporters if samples taken are found to be non-compliant. For any compliant samples however, costs will not be

¹³ 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).

recovered. Consultation responses have also indicated that SMEs will be unable to recover any of these costs from the Chinese exporters. Without further evidence regarding the likelihood of finding non-compliant samples and the volume of trade accounted for by Large businesses in this sector it is not possible to estimate the proportion of costs that may be passed back to China. For the purpose of this analysis we have therefore conservatively assumed that all costs will be borne by UK Industry.

Storage costs

- 4.41 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. As each port charges a different fee we've use the example of the Port of Felixstowe to illustrate the likely costs involved. (See table 7 below.)

Table 7: Storage Charges

Size of Container	Detainment charge from day 6 to day 12	Total Cost day 6 to 12*	Detainment charge from day 13 onwards	Total cost day 13 onwards**	Cost per container for 20 days	Cost per container 2 weeks (best estimate)
Up to 20 foot	£13.60	£95.20	£36.70	£293.60	£388.80	£168.60
Over 20 foot	£27.20	£190.40	£73.40	£587.20	£777.60	£337.20
Total All Consignments (up to 20 foot)						£573,240
Total All Consignments (over 20 foot)						£1,146,480

Source: Port of Felixstowe

*daily fee multiplied by 7 days

**daily fee multiplied by 8 days

Source: Port of Felixstowe

- 4.42 Consultation with PHAs indicates that each consignment that is sampled will require storing until the analysis results are available. As approximately 10% of all consignments containing melamine plastic kitchenware products will be sampled, this means that all 3400 sampled consignments will require storing at the port for a period of time. Guidance for the EU Commission suggests that consignments could be held for up to 3 weeks but that the intention would be to have the tests carried out in two weeks or less. Therefore as a best estimate we have assumed that consignments may require storing for on average 2 weeks. The Port applies a daily storage fee (see Table 7) 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), cumulative daily storage fees for a total of 14 days range from £168.60 to £337.20 per container. This yields a total cost to industry of between £573,240 and £1,146,480.

- 4.43 For Scotland, as above we have anticipated half the consignment requiring storage resulting in a total annual cost to industry for 20 days storage of between £1,517 and £3,035.

Demurrage costs

- 4.44 Consultation responses have highlighted that, in addition to charges made for storage, containers held at port will also incur demurrage fees (charged by the shipping line) at approximately £60-£120 per day for each additional day that the container is held in port.

We are advised that each shipping company will make charges after differing periods of time but beginning at around 14 days is average. As we've assumed in the storage costs section above that on average containers will be held for two weeks, it seems reasonable to assume here that a maximum of 50% of containers will be held for up to 20 days. Using the sample rate of 10% (18) and assuming 50% (9) of these will be held for 20 days, then the cost in Scotland would range between £540 and £1,080¹⁴ annually, with a best estimate of £810.

Total Ongoing costs to Industry

Note that the annual costs presented below are quoted in constant prices. This means that the costs have been adjusted for any impact that inflation may have on rising prices over the period

Table 8: Ongoing Costs to Industry

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)
costs	£1.98	£1.98	£1.98	£1.98	£1.98	£1.98	£1.98	£1.98	£1.98	£1.98	£19.75	£17.00
Detainment fee	£0.99	£0.99	£0.99	£0.99	£0.99	£0.99	£0.99	£0.99	£0.99	£0.99	£9.91	£8.53
Demurrage Fees	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£0.15	£1.53	£1.32
PHA costs	£1.46	£1.46	£1.46	£1.46	£1.46	£1.46	£1.46	£1.46	£1.46	£1.46	£14.59	£12.56
Total Costs	£4.58	£4.58	£4.58	£4.58	£4.58	£4.58	£4.58	£4.58	£4.58	£4.58	£45.79	£39.41

Note: These costs are for the UK as a whole; for England only see summary table

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.

Foregone Earnings

- 4.45 Industry may face further costs associated with loss of earnings for foregone sales as a result of consignment detainment. If businesses do not have enough products in stock to compensate for product detainment, this could potentially be a costly issue. Some consultation responses have highlighted potential problems in this area particularly around season/festival specific produce, e.g. Halloween. Storage of up to 20 days at specific times of year could mean that the goods cannot be sold in the limited sales period available. Consulted parties were not able to provide estimates of the likely scale/magnitude of such sales losses due to uncertainties around the underlying data, i.e. how often one of their containers will be sampled and how long it will be held at port, and as such it has not been possible to provide a quantification of these costs. Any estimates would also be dependent on the time of year.

Costs of product destruction

- 4.46 EU guidance does not automatically necessitate destruction of products if they do not comply with the EU regulation.¹⁵ In the possible scenario that the plastic kitchenware is destroyed as

¹⁴ £120*1700 consignments

¹⁵ The competent authority should place under official detention a consignment that does not comply with the applicable food contact materials legislation and, having heard the business operators responsible for the consignment; it could take the following measures:

(a) order that such plastic kitchenware be destroyed, in particular in cases where the consignment is injurious to human health or is unsafe;
 (b) order that such plastic kitchenware be re-dispatched outside the Union; (c) order that such plastic kitchenware be used for purposes other than those for which it was originally intended; (d) if the plastic kitchenware has already been placed on the market, monitor it or, if

a result of containing excessive levels of PAA and formaldehyde, the importer would initially bear the costs. However, we anticipate that some of the costs incurred could be recovered from the Chinese exporter. Again, it is more likely that large businesses will be able to recover full costs, whereas this may be more difficult for SMEs. We have been unable to quantify the costs associated with destruction due to the underlying uncertainties that caused importers to be unable to provide evidence. However, we anticipate that where costs are incurred, they will diminish over time for two reasons: 1) 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) if importers have to bear the costs they will switch to suppliers with a reputation for adhering to the standards set. In addition, as there is scope under EU guideline for not requiring destruction of produce, we anticipate that this would be used only as a last resort.

Food Standards Agency costs

- 4.47 The FSA will incur charges from HMRC for compliance checks for the 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.

Ongoing Costs¹⁶

Table 9: 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 (UK)	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£3.01	£2.59

Note: These costs are for the UK as a whole; for England only see summary table

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.

Risks

- 4.48 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.

necessary, order its recall or withdrawal before taking one of the measures referred to above.

¹⁶ Note that all costs in the ongoing costs section are attributable to the UK as a whole. In order to estimate the proportion of costs that may reasonably be attributed to Scotland only we have assumed a proportionate split based on the IDBR country based distribution of businesses. This does not necessarily provide an accurate representation but is useful for indicative purposes and will serve as the best estimate in the absence of robust data.

- 4.50 Consumer safety and the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials to the food itself may be compromised.
- 4.51 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. As a consequence, the familiarisation costs to industry are likely to be overestimated.
- 4.52 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.
- 4.53 We have had to make assumptions regarding the number of consignments that will be tested and therefore detained.

EU Guidance

- 4.54 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 Guidelines¹⁷ for laboratories on 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

5. Scottish Firms Impact Test

- 5.1 As part of the BRIA engagement process required by Scottish Government, face-to face meetings were arranged with Scottish stakeholders. FSA officials met to discuss the Regulations with an importer, a retailer, a port manager and enforcement officer.
- 5.2 No specific concerns were raised by the importer and retailer contacted. The operator of the port handling the bulk of kitchenware imports to Scotland, and the Local Authority, expressed no major concerns, as facilities are in place to handle the additional controls. Whereas the port operator and enforcement officer anticipated that any costs would be charged to the importer and passed back to the Chinese exporter, the importer expected costs would pass to the customer.
- 5.3 It was stressed that process of designation of a 'First Point of Introduction', should be simple. The application of specific import codes would simplify the control process, as HMRC would automatically log into the system when carrying out checks.
- 5.4 The Federation of Small Businesses has been consulted throughout the negotiations on the EU Kitchenware Regulation in an earlier consultation. We understand that importers and their representatives will pass the cost to the manufacturers in China, before polyamide and

¹⁷ 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.

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 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.

6. Competition Assessment

- 6.1 We have fully considered the questions posed in the Office of Fair Trading (OFT) competition assessment test¹⁸ 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.

7. Test run of business form

- 7.1 Commission Regulation 284/2011 introduces a specific form of Declaration to accompany every consignment of polyamide and melamine plastic kitchenware from China and Hong Kong. This is not a new requirement as other plastics Regulations require a 'Declaration of Compliance' form to be provided.

8. Sustainability

- 8.1 Impacts under the three pillars of sustainable development (environmental, economic and social) have been and continue to be considered in the preparation of this BRIA. 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 kitchen entering the retail market in Scotland are compliant with that Regulation. This option will also provide a significant measure of control that would minimise the potential health risks to consumers.

9. Legal Aid Impact Test

- 9.1 The Legal Aid Team have been informed of the proposal and confirm that the proposal will not introduce new criminal sanctions or civil penalties therefore there are no legal aid implications.

10. Enforcement, sanctions and monitoring

Enforcement

- 10.1 The purpose of The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 is to provide enforcement authorities with the necessary powers to prevent non-compliant polyamide and melamine plastic kitchenware originating in or consigned from China from entering the market in Scotland.
- 10.2 Enforcement of any new Regulation in Scotland is primarily the responsibility of the 32 LA's in Scotland as defined by the Food Safety Act 1990.

Sanctions

¹⁸ http://www.oft.gov.uk/shared_oftrreports/comp_policy/oft876.pdf

- 10.3 No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation. A person found guilty of an offence under these Regulations is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a fine not exceeding the statutory maximum. These penalties are in line with The Food Safety Act 1990.

Monitoring

- 10.4 The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including enforcement authorities, as part of the ongoing policy process. FSA mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

11. Implementation and delivery plan

- 11.1 The new Regulation requires Member States to adopt and publish national legislation to implement its requirements by 1 July 2011.
- 11.2 The publication of the Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 will be communicated to stakeholders by email, letter and monthly Enforcement Report. This will be done shortly after publication on legislation.gov.uk website.
- 11.3 The FSA will work with enforcement authorities where problems arise or suspected infringements of the instrument arise.

12. Post-implementation review

- 12.1 It is anticipated that The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 will be reviewed not less than five years after 1 July 2011 (i.e., the date from which the EU Kitchenware Regulation applies in Member States).

13. Summary and recommendation

- 13.1 The FSA recommends Option 2, to implement national regulations (the Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011) to implement the Commission Regulation which aims to reduce the risk on non-compliant plastic kitchenware from China entering the Scotland. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law. Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

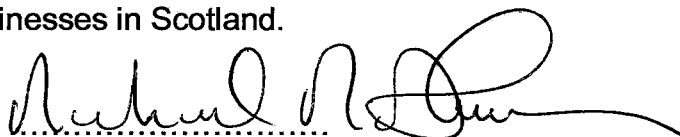
14. Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental social policy and administrative
1 Do Nothing	Importers could continue to import plastic kitchenware from China without the added costs imposed by the new Regulation.	Consumers will be exposed to the risk of ingesting PAAs and formaldehyde with potentially serious health impacts at a huge cost to the UK.
2 National Regulations to provide for the execution and enforcement of the EU Kitchenware Regulation in Scotland	<p>Minimise the potential risk to consumers of exposure to harmful levels of substances migrating from plastic kitchenware.</p> <p>Provide enforcement authorities with the statutory powers to prevent non-compliant plastic kitchenware from being placed on the market.</p>	<p>Cost to industry (Scotland):</p> <p>Familiarisation: £127,000.</p> <p>Sampling costs (annual): £10,458</p> <p>Storage (annual): £1517 - £3035</p> <p>Cost to enforcement authorities (Scotland):</p> <p>Familiarisation: £1,361.</p> <p>Administrative (annual): £792</p> <p>Sampling (annual): £10,458</p> <p>Cost to HMRC (Scotland) - £143</p> <p>Cost to FSA (UK) - £300,625</p>
3 Non-regulatory option – EC 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.	

11. Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Ministers signature



Ministers title

Minister for Public Health

Date

21/6/11

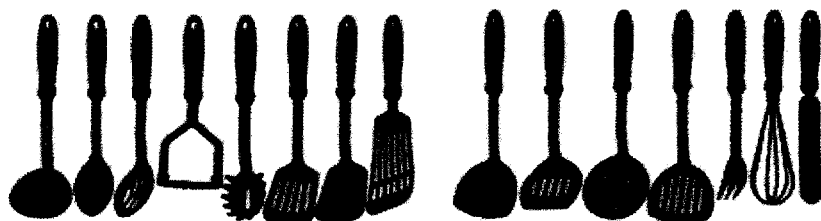
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Annex 1

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 2

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 3

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).

