

Title: The Plastic Kitchenware (Conditions on Imports from China) (England) Regulations 2011 Lead department or agency: Food Standards Agency Other departments or agencies:	Impact Assessment (IA)
	IA No: FOOD0026
	Date: 27 April 2011
	Stage: Implementation
	Source of intervention: EU
	Type of measure: Secondary legislation

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

Ministerial Sign-off For implementation 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.

Please sign: _____ Please date: _____
 Signed by the responsible Minister: *X* *Ho* *X* Date: *16/6/2011*

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 ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ 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...?	Impact	Page ref within IA
Statutory equality duties¹ Statutory Equality Duties Impact Test guidance	No	19
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	19
Small firms Small Firms Impact Test guidance	No	19
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	Throughout
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	19

¹ 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	Bet Estimate -37.63

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	1.45		4.23	37.63

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

Total cost in England only of £42.26m (constant prices). Total one off costs of £1.45m broken down: £1.41m familiarisation cost to industry; £41k one-off cost to enforcement authorities (including familiarisation and training); £1.9k familiarisation cost to HMRC and a familiarisation cost to the FSA *across the entire UK* of £162.

Total average annual costs across England of £4.23m broken down: £3.67m in annual costs to industry; £124k 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.

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

Consignments held in Ports may result in loss of earnings for industry. Where products do not comply with the EU regulation they may be destroyed. If costs cannot be recovered from Chinese exporters, this will result in an additional cost to 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 chemicals migrating from polyamide and melamine plastic kitchenware being imported from China. This will benefit consumer health by reducing the level of carcinogenic risk from PAAs and reducing risks associated with formaldehyde, which has the potential to cause adverse health effects.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
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The number of affected businesses is likely to be an overestimate which will result in an overestimate of familiarisation costs to industry. The number of plastic imports from China may decrease over time because of increased costs; however we lack the evidence to forecast future levels of imports; as such we may have overestimated the annual costs. Costs have been presented as those to England; annual costs cannot be broken down accurately as they are based on UK imports figures but we have provided indicative estimates based on the IDBR split of businesses. Costs to the FSA cannot be broken down by location and are UK wide.

Direct impact on business (Equivalent Annual) £m):	In scope of OIOO? Measure qualifies as
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Costs: 3.94	Benefits: N/A	Net: 3.94	No	IN/OUT
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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 ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ 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...?	Impact	Page ref within IA
Statutory equality duties¹ <u>Statutory Equality Duties Impact Test guidance</u>	No	19

Economic impacts		
Competition <u>Competition Assessment Impact Test guidance</u>	No	19
Small firms <u>Small Firms Impact Test guidance</u>	Yes	19

Environmental impacts		
Greenhouse gas assessment <u>Greenhouse Gas Assessment Impact Test guidance</u>	No	
Wider environmental issues <u>Wider Environmental Issues Impact Test guidance</u>	No	

Social impacts		
Health and well-being <u>Health and Well-being Impact Test guidance</u>	No	Throughout
Human rights <u>Human Rights Impact Test guidance</u>	No	
Justice system <u>Justice Impact Test guidance</u>	No	
Rural proofing <u>Rural Proofing Impact Test guidance</u>	No	

Sustainable development		
<u>Sustainable Development Impact Test guidance</u>	No	19

¹ 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
	Commission Directive 2002/72/EC, as amended http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm
	Commission Regulation (EU) No. 284/2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:077:0025:0029:EN:PDF
	Commission Regulation (EU) No. 10/2011 http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

+ Add another row

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

	Y ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs	1.45	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Annual recurring cost	4.23	4.23	4.23	4.23	4.23	4.23	4.23	4.23	4.23	4.23
Total annual costs	5.68	4.23	4.23	4.23	4.23	4.23	4.23	4.23	4.23	4.23
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	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 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 England by The Plastic Materials and Articles in Contact with Food (England) Regulations 2009². 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 178/2002³, 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 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 Annex II, point 2 (requirements for the release of PAAs) and Annex I, Table 1 (requirements for formaldehyde) of the new Regulation 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.

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.

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.
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 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 23rd March 2011 (Ref: OJ, L77, 23.03.2011, pg 25-29), came into force on 11th 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>
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 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 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 (FPIs) as required 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 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. Information about the FPIs designated in the UK, will also be available on the FSA website.

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 of the EU Kitchenware Regulation, 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.

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 60 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;
 - 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;
17. 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)

18. As indicated in 12.3 above and as required by Article 5 of the EU Kitchenware Regulation, products subject to the requirements of that Regulation would enter the UK at a designated FPI.
19. 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.
20. 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

21. 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.
22. 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

23. 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 in some instances (i.e. where importers' products 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.
24. 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.

25. 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.
26. Thus, option 2 is the preferred option that will achieve the requirements of the EU Kitchenware Regulation.

Sectors Affected

Industry

27. This proposal will affect UK retailers, wholesalers and importers of plastic products from China. Businesses potentially affected by this measure are not identified by a specific 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

28. 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

29. 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 the number of wholesalers is likely to be much lower than that which is reported here.⁸ Estimated ranges start at only 100 first tier wholesalers but we believe this is likely to be an underestimate. Thus, to be conservative and ensure we have captured the full extent of wholesalers that may be affected by this legislation, we have used the figures provided by IDBR.

Importers

30. 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.
31. Table 1 displays the estimated number of businesses 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

32. 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 Food Standards Agency (the FSA) and so although HMRC will initially incur these costs the FSA will bear the final burden.

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.

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 consequences.

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 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 presented a range for the hourly wage rate using an EHO hourly salary of £20.45⁹ as the lower bound, and a TSO hourly salary of £22.09¹⁰ as the upper bound; the midpoint is £21.27¹¹.
36. We have estimated that one enforcement officer per LA will typically invest one hour to read and familiarise themselves with the new Regulations and that PHAs will require a further one hour to assimilate this information. In addition, we have estimated that each enforcement officer (in each PHA or LA) will spend a further hour disseminating key information to staff within the organisation; this results in a total of two hours for familiarisation in each LA and three hours per officer in each PHA.
37. Familiarisation costs are quantified by multiplying the hourly rate of a TSO/EHO by both the time required to read, assimilate and disseminate the new Regulations and the total number of enforcement authorities.
38. For LAs, 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 Local authority of between £40.90 and £44.17¹², with a best estimate of £42.54. For PHAs, using the same range of salaries and a time investment of three hours, results in a familiarisation cost for each PHA of between £61.35 and £66.26 with a best estimate of £63.80. This yields a total familiarisation cost in England ranging from £16,870 to £18,222 with a best estimate of **£17,546**. Table 2 displays the familiarisation cost by location using the best estimate.

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

¹² Note that wage rates have been estimated by taking the median rate and uplifting by 30% to account for overheads. This means that figures reported are to two decimal places and when multiplied the numbers may not accurately sum due to rounding.

39. Responses from the consultation process have indicated on the whole that time spent initially familiarising with the regulation is reflected by this estimate. However, the responses also indicated that PHAs may require further familiarisation/training. One PHA suggested that 12 members of its enforcement team would be sent on a training course to ensure they could adequately enforce the legislation at a cost of £75 per officer. This additional requirement was not reflected by other PHAs however, in order to attempt to provide an estimate of the potential costs involved, we have assumed that on average each PHA will require additional training for six¹³ members of staff at a cost of £75 per person.

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

Equivalent Annual Net Costs (EANC)

40. 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 formula¹⁴. Under Standard HMT Green book guidance a discount rate of 3.5% is used.
41. A total one-off cost to enforcement authorities in England affected by this proposal is an estimated £35,096. This yields an EANC of approximately £4,077 in England over 10 years. Table 3 displays the breakdown of the EANC per country.

Table 3: Equivalent Annual Costs to Enforcement Authorities (by location)

Country	EAC
England *	£4,077
Wales **	£168
Scotland	£158
NI	£128
UK	£4,532

Ongoing Costs¹⁵

42. 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 will need to be forwarded to the Commission on a quarterly basis. This will require additional work for PHAs. The cost of this administrative work is not recoverable.

¹³ Taking 6 as the midpoint of 0 and 12 to obtain an average estimate.

¹⁴ EANC = PVNCB/ $a_{t,r}$, Where $a_{t,r}$ is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left(\frac{1}{1+r_i} \right)$$

PVNCB 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.

¹⁵ 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 England 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.

43. 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.
44. Estimates of costs for a typical Port Health enforcement as exemplified by Felixstowe are shown in table 4 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 PHAs across the whole UK.

Table 4 – Cost of activities at Felixstowe Port

	Activity – Document receipt & check	Time Involved	Officer (£50 inc on costs)	Admin (£22 inc 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	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

ERTS (Enhanced Remote Transit Shed)

Unrecoverable administrative costs

45. 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. This cost is not recoverable.

Recoverable compliance costs

46. Table 4 also details other costs associated with complying with this regulation. 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 4 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 5 details total activity costs incurred by Local Authorities (excluding sampling tests fees) that will be recovered from business.

Table 5: 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

47. Enforcement authorities will also 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.
48. 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).

Total Ongoing Costs to Enforcement Authorities

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

Table 6: 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

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.

Costs to HM Revenue and Customs (HMRC)

50. 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 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;
51. The familiarisation cost to HMRC is quantified by multiplying the cost per organisation by the time required to read and disseminate the new Regulations. The familiarisation cost per organisation equates to £47.74¹⁶ (the hourly wage rate of a public sector worker £23.87¹⁷ multiplied by the time taken to become familiar with the regulation (2 hours). For the 39 PHOs in England, this generates a one off familiarisation cost to HMRC of approximately £1,862.

Equivalent Annual Costs (EAC)

52. 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 £216 over 10 years. Table 7 displays the familiarisation cost and EAC¹⁸ by location.

Table 7: Equivalent Annual Costs to HMRC (by location)

Country	Number of PHO's	Total	EAC
England	39	£0	£216
Wales	1	£0	£6
Total	40	£0	£222

Ongoing Costs to HMRC

53. 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.

¹⁶ Note that wage rates have been estimated by taking the median rate and uplifting by 30% to account for overheads. This means that figures reported are to two decimal places and when multiplied the numbers may not accurately sum due to rounding.

¹⁷ 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).

¹⁸ EAC = PVNCB/a_r, Where a_r is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left(\frac{1}{1+r_i} \right)$$

PVNCB 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.

54. In accordance with Cabinet Office directives, HMRC could recover some costs from the FSA as the lead Agency in the UK. 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

55. 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 these sectors, there will be a one-off cost for reading and familiarising 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, which is a total of two hours.
56. It will cost each business £31.15¹⁹ to become familiar with the new Regulations (based on an hourly wage rate of £15.57²⁰ 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, wholesale and importing businesses affected in England (39,005 as shown in table 1) which totals approximately £1.2m in England. The breakdown of costs is displayed in the table below:

Table 8: Familiarisation Costs to Industry

Country	All Retailers and Wholesalers				Importers	Total
	Micro	Small	Medium	Large		
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

Note: Totals may not sum due to rounding

57. 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 has been done 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.

Equivalent Annual Net Costs (EAC)

58. As with enforcement authorities above, the one-off cost to industry must also be expressed as equivalent annual costs (EAC²¹). Total one-off costs to industry in England have been estimated

¹⁹ Note that wage rates have been estimated by taking the median rate and uplifting by 30% to account for overheads. This means that figures reported are to two decimal places and when multiplied the numbers may not accurately sum due to rounding.

²⁰ 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).

²¹ EACNB = PVNCB/a_{t,r}, Where a_{t,r} is the annuity rate given by:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left(\frac{1}{1+r_i} \right)$$

PVNCB 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.

at £1.21m. This yields an EAC for industry in England of approximately £141k over 10 years. Table 9 displays the breakdown of the EAC per country.

Table 9: Equivalent Annual Costs to Industry

Country	EAC
England	£141,143
Wales	£8,404
Scotland	£14,721
NI	£5,737
UK	£170,003

Ongoing Costs²²

Sampling Costs

59. Importers will be charged by Port Health Authorities for their products being sent to public analysts for sampling. As discussed 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 have estimated 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 being carried out. As detailed in paragraph 47 our best estimate for the sampling and analysis cost is £1,975,400. 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 but that SMEs will be unable to recover any of these costs. However even for large businesses for any compliant samples, costs will not be recovered. 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

60. 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. Each port charges different fees and so we've used the example of the Port of Felixstowe to illustrate the likely costs involved. See table 10 below:

Table 10: 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

²² 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 England 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.

61. 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 10) 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 a range based on the cost of storing each size. Using costs provided by the Port of Felixstowe (see table 9 above), 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.

Demurrage costs

62. Responses from consultation 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% and assuming 50% of these will be held for 20 days results in 1700 affected consignments and a cost ranging between £102²³k and £204k²⁴ annually, with a best estimate of £153k.

63. Other Recovered PHA Costs

As detailed in the 'costs to enforcement authorities' section above, PHAs will seek to recover additional administrative costs associated with document checking, onward transportation and sampling. Table 5 provides detail on the breakdown of this; the total cost amounts to approximately £1,459,167 annually.

Total Ongoing costs to Industry

64. 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 11: 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

65. Industry may face further costs as a result of consignment detainment associated with loss of earnings for foregone sales. 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

²³ £60*1700 consignments

²⁴ £120*1700 consignments

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

66. EU guidance does not automatically necessitate destruction of products if they do not comply with the EU regulation.²⁵ 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 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 underlying uncertainties which has meant importers were unable to provide evidence, but we anticipate that where costs are incurred 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. 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 (FSA)

67. 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 £300,625²⁶ for each consignment being checked and the annual review. There will also be a one-off cost of £162 for HMRC set up fee.

Equivalent Annual Net Costs (EANC)

68. 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.

Ongoing Costs²⁷

²⁵ 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 necessary, order its recall or withdrawal before taking one of the measures referred to above.

²⁶ £300,560+ annual fee of £64.60

²⁷ 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 England 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.

Table 12: 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.

Total Costs Summary

69. A table summarising all one-off and ongoing annual costs to affected parties has been provided below for reference. Please note that all costs reported so far in the ongoing costs sections and one-off costs to the FSA section are attributable to the UK as a whole. In order to estimate the proportion of costs that may reasonably be attributed to England 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.

Table 13: Costs Summary Table

	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)
One off costs												
Enforcement												
Authorities	£0.004	£0.004	£0.004	£0.004	£0.004	£0.004	£0.004	£0.004	£0.004	£0.004	£0.041	£0.035
Industry	£0.141	£0.141	£0.141	£0.141	£0.141	£0.141	£0.141	£0.141	£0.141	£0.141	£1.411	£1.215
HMRC	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.002	£0.002
FSA	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000	£0.000
Total	£0.145	£0.145	£0.145	£0.145	£0.145	£0.145	£0.145	£0.145	£0.145	£0.145	£1.455	£1.252
Ongoing costs	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00
Enforcement												
Authorities	£0.12	£0.12	£0.12	£0.12	£0.12	£0.12	£0.12	£0.12	£0.12	£0.12	£1.24	£1.07
Industry	£3.80	£3.80	£3.80	£3.80	£3.80	£3.80	£3.80	£3.80	£3.80	£3.80	£38.02	£32.72
HMRC	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00
FSA	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£3.01	£2.59
Total	£4.23	£4.23	£4.23	£4.23	£4.23	£4.23	£4.23	£4.23	£4.23	£4.23	£42.26	£36.38
Grand Total	£4.37	£4.37	£4.37	£4.37	£4.37	£4.37	£4.37	£4.37	£4.37	£4.37	£43.72	£37.63

Note: All costs have been presented on an annual basis. For one off costs the equivalent annual cost value is used.

Benefits

Option 1 – Do nothing

70. 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

71. 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

72. 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.
73. 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; it's not possible to provide more information, as no one type of cancer can be isolated because PAAs are genotoxic. In such instances it is not possible to quantify the benefits to consumer health. Excessive levels of formaldehyde can have potential adverse health effects. For further detail on this please see Annex 4.

Consultation

74. 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 EU Kitchenware Regulation. The FSA has continued to liaise with many of these stakeholders and has kept them abreast with developments.
75. 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.

Formal Public Consultation

76. The FSA conducted a formal public consultation from 28 April to 27 May 2011, seeking comments on a draft of this instrument and an earlier draft of the Impact Assessment. The EU Kitchenware Regulation was also included in the consultation package. Once more, Enforcement Authorities and their representative bodies, trade associations, individual companies (both large and SMEs), the UKBA, HMRC and the UK's Official Control Laboratories were consulted.
77. The FSA received 10 responses to the consultation from Enforcement Authorities, industry and trade associations representing the interests of small food businesses and large retailers. Comments focused mainly on the estimated costs associated with the new legislation as reflected in the draft Impact Assessment.
78. There were several comments on the draft Regulations from Port Health Authorities (PHAs) on drafting detail and these have been acted upon where necessary.
79. Enforcement authorities were generally in support of the proposed control measures and the Regulations enforcing them for the increased protection they provided UK citizens, from exposure to harmful chemicals. They indicated that costs for familiarising themselves ("familiarisation costs") with the requirements of new legislation were underestimated. The PHAs asked for further guidance on consistent execution of the Regulations.
80. There was a general consensus amongst industry 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.

81. Stakeholders were asked to provide evidence to support their views in relation to additional costs over and above their commercial activities of the proposed Regulations; however, none were able to quantify the additional costs in their comments or provide evidence to support their views.
82. A full summary of comments received in response to the consultation will be published on the FSA's website.

Enforcement

83. 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

84. 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

85. 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 Guidelines²⁸ 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

Risks

86. 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.
87. 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.
88. 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.

²⁸ 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.

89. 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.
90. We have had to make assumptions regarding the number of consignments that will be tested and therefore detained.

Specific Impact Tests

Competition Assessment

91. We have fully considered the questions posed in the Office of Fair Trading (OFT) competition assessment test²⁹ 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

92. Stakeholders, including the Department for Business Innovation and Skills (BIS), and the Federation of Small Businesses have been consulted throughout the negotiations on the EU Kitchenware Regulation, in an earlier informal consultation and throughout the formal consultation process. From responses to the consultation we understand that large business importers may be able recover some of the costs of testing and sampling from the Chinese exporters if products are found to be non-compliant but it will not be possible to recover costs if products are compliant with the regulation. Consultation responses further indicated that from SMEs cost recovery will not be possible at all even if products are found to be non-compliant 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.

Sustainability

93. 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

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

²⁹ http://www.offt.gov.uk/shared/oftr/reports/comp_policy/oftr876.pdf

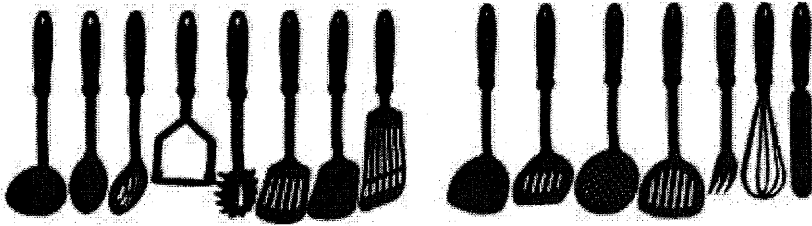
Annex 1: Post-Implementation Review (PIR) Plan

<p>Basis of the review: To review progress on how businesses operators are complying with the controls imposed on polyamide and melamine plastic kitchenware from China/Hong Kong.</p>
<p>Review objective: To ensure that new controls on consignments of polyamide and melamine plastic kitchenware from China/Hong Kong continue to provide an appropriate level of protection from chemicals migrating into foods from such products and that they are being reasonably achieved by business operators.</p>
<p>Review approach and rationale: We will continue to communicate with port health authorities and enforcement authorities so that any unforeseen difficulties that may arise can be dealt with promptly and hopefully to the satisfaction of all parties.</p>
<p>Baseline: Number of non-compliance reported via the Rapid Alert System for Feed and Food (RASFF) previously (2009/2010 there were 64 RASFFS notifications for such products). The general expectation is that the number of notifications will decrease once these control measures are in place.</p>
<p>Success criteria: The new controls could see the number of RASFFS and non-compliant products being reduced. This will mean few products being removed from retail outlets and fewer consignments being rejected, where products following sampling and analysis at ports are shown to be complying with the legislation.</p>
<p>Monitoring information arrangements The Agency will work with enforcement authorities where problems or suspected infringements of the new legislation arise. The effectiveness of the proposed Regulations will also be monitored under the Statutory Review, which the Agency is required to carry out every five years on EU Regulations for which the FSA oversees in relation to enforcement.</p>
<p>Reasons for not planning a review: N/A</p>

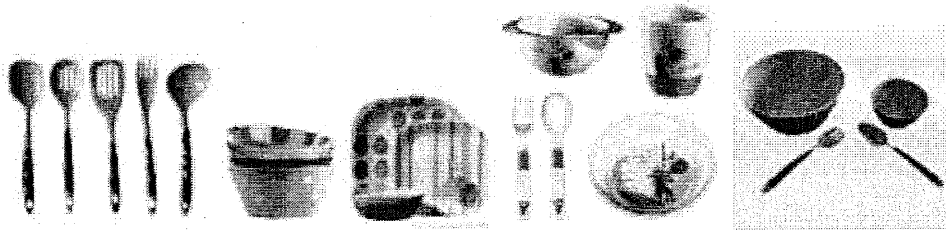
Annex 2

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 respectively 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 "As low as Reasonably Possible" (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).