

**EXPLANATORY MEMORANDUM TO**  
**THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD**  
**(ENGLAND) REGULATIONS 2009**

**2009 No. 205**

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty

**2. Purpose of the instrument**

2.1 This instrument maintains existing controls on substances that may be used in the manufacture of plastic materials and articles intended to come into contact with food, and also implements new measures under European Community law. The new measures update the lists of monomer substances and additives permitted for use in the manufacture of food contact plastics and lays down any necessary conditions for their safe use. They also in general prohibit the use of additives not on the Community list of additives (the positive list) from 1<sup>st</sup> January 2010, a measure which will mean that additives will be subject to the same level of controls as are already in place for monomers.

**3. Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

**4. Legislative Context**

4.1 These Regulations newly implement Commission Directive 2008/39/EC (“the new Directive”), which introduces the most recent amendments to the principal European instrument governing plastic food contact materials, namely Commission Directive 2002/72/EC (“the principal Directive”). The principal Directive was previously implemented by the Plastic Materials and Articles in Contact with Food (England) Regulations 2008.

4.2 The principal Directive includes lists of substances that can be used in the manufacture of food contact plastics and any restrictions on that use necessary to safeguard both human health and the nature and quality of the foodstuff.

**5. Territorial Extent and Application**

5.1 This instrument applies to England only. Separate but parallel legislation is being enacted for Scotland, Wales and Northern Ireland.

## **6. European Convention on Human Rights**

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7. Policy background**

- *What is being done and why*

7.1 The purpose of making this instrument is to implement the provisions of the new Directive. Chemical migration from food contact plastics can detrimentally affect consumer health. Most consumers are unable to assess the risk involved when consuming a product because of their lack of knowledge of the chemical migration and production methods and therefore cannot make informed choices about such risk. Legislative intervention, through European legislation that is regularly updated and implemented in the domestic law of the UK and other Member States, is necessary to reduce the risks to health and also to provide greater clarity in enforcement.

7.2 It is the intention that the law on food contact materials and articles should protect consumers from any chronic, harmful health effect over their lifetime arising from the routine ingestion of substances that may have migrated into food from those materials and articles. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction. The legislation also aims to protect the nature and quality of the food concerned; to provide clear and consistent conditions for the trade in goods and to provide the enforcement authorities and industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty seven Member States. It also our aim to simplify the way the rules governing these articles and materials are presented in England to make them as plain as possible to those that need to refer to them. This decision was taken in the light of industry support.

- *Consolidation*

7.3 The policy of maintaining a simplified set of Regulations is being continued. For this reason, rather than implementing the new Directive by amending the 2008 Regulations mentioned in paragraph 4.1, those Regulations have been revoked and re-made in a consolidated instrument that includes the measures introduced by the new Directive. This will ensure that we continue to keep to a minimum the number of instruments to which stakeholders such as business operators and enforcement authorities need to refer.

## **8. Consultation outcome**

8.1 The Food Standards Agency fully consulted all stakeholders on the Regulations for England. One hundred and thirty two stakeholders were consulted on these proposals. These ranged from food industry organisations to sector specific organisations, such as those representing manufacturers of

food contact plastics, coated cans and multi layered bonded packaging, as well as others with an interest in food contact plastics. We also consulted enforcement authorities, the Department for Business and Regulatory Reform, Enterprise Directorate, the Department of Environment, Food and Rural Affairs, Office of Fair Trading, consumer organisations and other non-governmental organisations.

8.2 In total four responses were received; one from LACORS, one from Laboratory of the Government Chemist (LGC), one from Suffolk Coastal Port Health Authority (PHA) and one from the Association of Port Health Authorities (APHA). Their comments are summarised below:

i) LACORS commented that whilst they appreciate the opportunity of being asked to comment, they felt that the changes proposed were largely of a technical nature, and as such they were not providing any substantial comments.

ii) The LGC fully supported the continued use of ambulatory references to EU legislation, provided that simple clear guidance was available in the shape of a flow chart. The LGC was informed that the type of guidance suggested has been prepared and is updated, as and when new and or amendment legislation comes into force and is also published on the Agency's website to download free of charge. Such guidance would assist enforcement authorities, businesses, and analytical laboratories to prepare for implementation, as well as to contribute appropriately to the evidence base for risk management decisions. The LGC also commented that any costs borne by them would be in relation to any chemical analysis linked to enforcement action, but felt this would be unlikely for the foreseeable future.

iii) There were a number of comments received from the PHA on the proposed Regulations. One comment queried whether the draft Regulations had been drafted in such a way that the power to enforce the documentation requirements was deficient. A response was sent to the consultee explaining how the power worked and that there was no deficiency. Other comments concentrated largely on their level of involvement as enforcers. The PHA commented that they did very little work on food contact materials legislation due to the complexity and lack of knowledge, but has started to take interest in this area due to the increased number of Rapid Alerts. The PHA also commented that due to the lack of any direct funding covering this area of enforcement, activity will dictate the resources which can be allocated.

iv) Comments from the APHA are made on behalf of the 68 seaports and airport local authorities. The APHA commented that costs to enforcement authorities at borders were understated based on the assumption that enforcement activity may change due to increased documentary checks. If there is a need to carry out documentary checks on imported products under the proposed Regulations at borders, then consideration needs to be given to incorporate cost recovery elements into legislation (similar to products of animal origin. The APHA also commented that training requirements had not

been sufficiently accounted for. However, the APHA neither quantified nor provided revised additional costs.

## **9. Guidance**

9.1 Guidance for business has been developed and formed part of the stakeholder consultation on the proposed Regulations. Stakeholders were also asked to comment on the guidance, however no comments were received. The Guidance has been finalised and sent to stakeholders and has also been published on the Agency's website at <http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/plasticguidane>

## **10. Impact**

10.1 The primary business sector that will be affected by the regulatory proposals will be manufacturers, importers, converters and fillers of food contact plastics. No comments were received from businesses in this instance. European representative bodies of industry sectors and consumers were routinely involved throughout the European negotiations and their views were taken into account by the European Commission in forming the proposals that led to the new Directive being enacted in these Regulations. However the PHA and APHA did comment that there might be additional costs associated with carrying out extra monitoring and the need for training which had not been taken into account, but they have not quantified the financial impact.

10.2 All respondents were thanked for their comments and where required, responses were sent.

10.3 These proposals have no particular impact on, charities or voluntary bodies; rural areas nor on members of the ethnic communities of any particular racial group.

10.4 Although the impact on the public sector is negligible, there may be an impact on the Food Standards Agency as and when it carries out surveys on foods. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation.

10.5 An Impact Assessment is attached to this memorandum.

## **11. Regulating small business**

11.1 The legislation on food contact plastics will apply to all businesses small and large.

11.2 The impact on small and medium sized businesses is unlikely to be significant. This view has been supported by industry following earlier consultations, which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder

competitiveness. Such businesses are also encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. To date no comments have been received from small businesses.

## **12. Monitoring & review**

12.1 Central and local authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with the Regulations. The results of this work carried out by the Agency are published and are openly available on the Agency's website at:

<http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/>

12.2 We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems arise or suspected infringements of the Regulations arise. The effectiveness of the Regulations will be also be monitored via feedback from stakeholders as part of the ongoing policy process and will be reviewed in March 2010.

## **13. Contact**

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Email: [Richard.sinclair@foodstandards.gsi.gov.uk](mailto:Richard.sinclair@foodstandards.gsi.gov.uk) or

Nasreen Shah, Tel: 020 7276 8553  
Email: [Nasreen.a.shah@foodstandards.gsi.gov.uk](mailto:Nasreen.a.shah@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

**TRANSPOSITION NOTE: THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2009**

- These Transposition Notes set out how the main elements of Directive 2008/39/EC will be transposed into English law in the above Statutory Instrument.
- Any reference to the 2007 Regulations are to The Materials and Articles in Contact with Food (England) Regulations 2007 (SI 2007/2790)
- All references to the parent Directive are to Directive 2002/72/EC as already amended by Directives 2004/1/EC, 2004/19/EC, 2005/79/EC and 2007/19/EC
- Any reference to the 2008 Regulations are to The Plastic Materials and Articles in Contact with Food (England) Regulations 2008 (SI 2006/916)

<b>Directive 2008/39/EC – amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food (OJ No. L63, .07.03.2008, p.6)</b>
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<b>Articles and Annexes of Directive 2008/39</b>	<b>Objectives</b>	<b>Implementation in the Plastic Materials and Articles in Contact with Food (England) Regulations 2009</b>	<b>Responsibility</b>
Article 1(1) amending Article 4 of the parent Directive	Article 1(1) inserts a new first paragraph at Article 4 relating to the Community list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, as set out in Annex III	These provisions are implemented in regulation 5 – paragraphs (1) and (2) have been amended (these set up a prohibition on using any additive other than one in the Community list of additives). A new paragraph (3)(a) has been added to create time limit for materials and articles made in other Member States not on the Community list may continue to be used.	Secretary of State for Health
Article 1(2) amending Article 4(a) of the parent Directive	Article 1(2) amends article 4(a) by replacing paragraphs 3 and 4. Paragraph 3 states that a provisional list of additives that are under evaluation by the Authority shall be made public by the Commission and shall be kept updated. Paragraph 4 states that by way of derogation from the third sub-paragraph of Article 4(1), additives not included in the Community list referred in that Article may continue to be used subject to national law after 1 <sup>st</sup> January 2010 for as long as they are included in the provisional list.	Paragraph 4 of the amended Article 4a is the only provision requiring implementation here, and is implemented by regulation 5(3)(b), which gives effect to the derogation for additives that are not on the provisional list pending a decision on Community Authorisation.	

Article 1(3) and Annexes I to V amending Annexes to the parent Directive	Article 1(3) makes changes to the lists of approved substances and related specifications annexed to the parent Directive.	Implementation is unnecessary as the Annexes are implemented by ambulatory reference in UK legislation.	
Article 2(1)(a)	Requires Member States to permit the trade in and use of plastic materials and articles intended to come into contact with food that comply with the provisions of Directive 2002/72/EC as amended by Directive 2008/39/EC from 7 <sup>th</sup> March 2009	The Coming into force of the Regulations on 7 <sup>th</sup> March 2009 has the effect of meeting this requirement.	
Article 2(1)(b)	Prohibits the manufacture and import into the Community from 7 <sup>th</sup> March 2010 of plastic materials and articles intended to come into contact with food and which do not comply with Directive 2002/72/EC, as amended by Directive 2008/39/EC	The provisions is implemented by regulation 5(3) as read with regulation 3(2) and Schedule 5 (transitional arrangements)	

## Summary: Intervention & Options

<b>Department /Agency:</b> <b>Food Standards Agency</b>	<b>Title:</b> <b>Impact Assessment of THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2009</b>	
<b>Stage:</b> Implementation	<b>Version:</b> 2	<b>Date:</b> January 2009
<b>Related Publications:</b> Commission Directive 2008/39/EC amending Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food		
<b>Available to view or download at:</b> <a href="http://www.food.gov.uk/consultations">http://www.food.gov.uk/consultations</a>		
<b>Contact for enquiries:</b> Nasreen Shah		<b>Telephone:</b> 020 8276 8553

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

Chemical migration from food contact plastics can detrimentally affect consumer health. Most consumers are unable to assess the risk involved when consuming a product because of their lack of knowledge of the chemical migration and production methods and therefore cannot make informed choices about such risk. Government intervention, through the implementation of significant amendments to the main European Commission Directive on plastic materials and articles intended to come into contact with food, is necessary to reduce the risks to health and also to provide greater clarity in enforcement.

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

The policy objectives are two-fold:

- 1) To reduce the long term risks to consumers in England arising from ingesting chemicals used in the manufacture of plastic food contact materials and articles that can migrate into food; and
- 2) To provide EU harmonised Regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence.

### What policy options have been considered? Please justify any preferred option.

1. Do nothing. This would leave the UK open to infraction proceedings from the European Commission, contradicting the important role the UK plays in agreeing EU harmonised measures and leave our regulation of food contact materials deficient in comparison with EU legislation. It would leave industry with having to follow one set of rules for exports to the rest of the EU and another set for the domestic market.

2. To successfully negotiate and implement EU harmonised measures. This preferred option is achieved through provisions of Directive 2008/39/EC. It meets the Government's commitment to fulfil EU obligations and contribute towards the protection of consumers from ingesting harmful levels of chemicals that could migrate into foods.

**When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?** March 2010

**Ministerial/CEO Sign-off** For final proposal/implementation stage Impact Assessments:

***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) the benefits justify the costs.***

Signed by the responsible Minister/Chief Executive\*:

**Dawn Primarolo** .....**Date: 5th February 2009**

\* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament



## Summary: Analysis & Evidence

<b>Policy Option: 2</b>	<b>Description: To successfully negotiate and implement EU harmonised measures</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>	Description and scale of <b>key monetised costs</b> by 'main affected groups' One-off cost borne by businesses = £148,600 One-off cost borne by local authorities = £15,100 One-off cost borne by port health authorities = £1,500
	<b>One-off</b> (Transition) <b>Yrs</b>	
	<b>£ 165,200</b> 1	
	<b>Average Annual Cost</b> (excluding one-off)	
	<b>£ 0</b>	<b>Total Cost (PV)</b> <b>£ 165,200</b>
Other <b>key non-monetised costs</b> by 'main affected groups' are in relation to the amendment of the authorised Community list of authorised monomers, additives and other substances and Government bodies such as the Food Standards Agency may be affected as and when they carry out any surveys on food, e.g. additional research into the migration of substances		

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>	Description and scale of <b>key monetised benefits</b> by 'main affected groups'
	<b>One-off</b> <b>Yrs</b>	
	<b>£ 0</b> 1	
	<b>Average Annual Benefit</b> (excluding one-off)	
	<b>£ 0</b>	<b>Total Benefit (PV)</b> <b>£ 0</b>
Other <b>key non-monetised benefits</b> by 'main affected groups' Increased protection of public health and the preservation of exports to other Member States. Greater clarity for business and enforcement officials through formalisation of existing procedures and maintenance of consumer confidence.		

Key Assumptions/Sensitivities/Risks

Price Base Year 2008	Time Period Years 1	<b>Net Benefit Range (NPV)</b> <b>£ -165,200</b>	<b>NET BENEFIT (NPV Best estimate)</b> <b>£ -165,200</b>
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What is the geographic coverage of the policy/option?	England			
On what date will the policy be implemented?	7 March 2009			
Which organisation(s) will enforce the policy?	LA's and PHA's			
What is the total annual cost of enforcement for these organisations?	£ 16,600			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	No			
What is the value of the proposed offsetting measure per year?	£ N/A			
What is the value of changes in greenhouse gas emissions?	£ Negligible			
Will the proposal have a significant impact on competition?	No			
Annual cost (£-£) per organisation (excluding one-off)	Micro N/K	Small N/K	Medium N/K	Large N/K
Are any of these organisations exempt?	No	No	N/A	N/A

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)		(Increase - Decrease)
Increase of    £ 0	Decrease of    £ 0	<b>Net Impact</b> <b>£ 0</b>

Key:    Annual costs and benefits: Constant Prices    (Net) Present Value

**Reason for Intervention**

1. Chemical migration from food contact plastics can create a negative cost to others through detrimentally affecting consumer health. Most consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed choices about such risk. Government intervention is required to reduce these impacts on health, to address the lack of informed consumer choice and also to provide greater clarity in enforcement.
2. These proposals fulfil the UK Government's policies of meeting its European Union (EU) obligations to bring into effect in law harmonised rules that:
  - Reduce the chronic and acute health risks to consumers arising from chemical contaminants in the food they eat; and
  - Meet the intergovernmental Lisbon Agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules that are not overly burdensome within which businesses can compete on an equal footing.
3. The Food Standards Agency ("the Agency") believes that the adoption of these proposals provides for the continuation of consumer protection against food contamination by chemicals whose ingestion could carry serious long-term and unacceptable risk to consumer health, particularly among more vulnerable people. Full implementation of the Commission proposal will contribute to the achievement of improved uniform standards across the EU, benefiting both consumers and businesses.

**Intended effect**

4. To reduce the long term health risks to consumers in England arising from ingesting chemicals used in the manufacture of plastic food contact materials and articles that may migrate into food by providing harmonised rules within which business can compete. And to provide EU harmonised Regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence.
5. The legislation also aims to protect the nature and quality of the food concerned; to provide clear and consistent conditions for the trade in goods and to provide the enforcement authorities and industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty-seven Member States. It is also our aim to simplify the way the rules governing these articles and materials are presented in England to make them as plain as possible to those that need to refer to them. This decision was taken with industry support.
6. The proposal is for a Statutory Instrument (SI) entitled *The Plastic Materials and Articles in Contact with Food (England) Regulations 2009*. The objective of the proposed Regulations is to implement by 7<sup>th</sup> March 2009 in England in its entirety the provisions of European Commission Directive 2008/39/EC ("the new Directive") that further amends Directive 2002/72/EC ("the principal Directive") relating to plastic materials and articles intended to come into contact with food.
7. The proposed Regulations will also revoke *The Plastic Materials and Articles in Contact with Food (England) Regulations 2008* (SI 2008/916) ("the 2008 Regulations") and re-enact them with necessary amendments, thus implementing in one consolidated instrument the principal Directive as most recently amended by the new Directive.
8. The proposed Regulations will not re-enact a number of provisions in the 2008 Regulations which are considered to be no longer relevant. These are:

- regulation 22(1) (a) to (f) that contain transitional arrangements relating to the manufacture and/or importation of materials and articles into the European Community by given dates and
- regulation 25 that relates to the application for the inclusion of an additive in the Community list of authorised additives. This requirement related to transitional arrangements that were time limited, the time limit has now expired.

### Consultation questions

**Stakeholders were asked to comment on the proposal not to re-enact regulation 22(1) (a) to (f) and regulation 25 of the 2008 Regulations in the proposed new Regulations. No comments were received on this issue.**

### Background

9. Harmonised EU rules on food contact plastics are laid down by the principal Directive and this is routinely amended to improve the clarity of the rules and to keep up with technological innovation. This latter point arises from improving technical and scientific knowledge that enables experts within the European Food Safety Authority (EFSA) to evaluate and re-evaluate risk to public health arising from the migration of chemicals from food contact materials into food. The latest of these amendments are contained in the new Directive which the regulatory proposals here would implement. This Directive was adopted by the Standing Committee on the Food Chain and Animal Health (SCoFCAH) in December 2007 and the adopted proposal was published in the Official Journal (OJ) of the European Union on 7 March 2008 (OJ L63 07.03.2008 p 6-13). In England, *The Plastic Materials and Articles in Contact with Food (England) Regulations 2008* currently implement the provisions of the principal Directive as last amended by Directive 2007/19/EC as read with Commission Regulation (EC) No. 597/2008 (amending Regulation (EC) No. 372/2007).
10. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. As such Annexes II, III, IVa, V and VI of the principal Directive are amended accordingly. The new Directive also:
  - i) Lays down the dates by which the list of additives in food contact plastics will be closed and makes interim arrangements for those additives that were petitioned for authorisation by the deadline of December 2006;
  - ii) Prohibits the use of additives not on the Community list of additives used for the manufacture of plastic materials and articles from 1 January 2010 (the positive list);
  - iii) Routinely updates the lists of authorised substances, taking into account the published opinions of EFSA and sets a date of 31 December 2009 up to which additives not on the positive list may continue to be used. This period until December 2009 is to enable EFSA to obtain any additional information it might need for its risk assessment of those additives on the provisional list;
  - iv) Permits the trade in and use of plastic material and articles intended to come into contact with food and complying with the principal Directive, as amended by the new Directive 2008/39/EC from 7 March 2009; and
  - v) Prohibits as from 7 March 2010 the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food and which do not comply with the principal Directive as amended by the new Directive. In effect this creates a phase-out period for substances that have either been removed from the Community lists, or in the case of additives have not been adopted on to the Community authorised list or the provisional list.

11. The Commission has published its provisional list of those additives that are the subject of an application for authorisation. An additive will be removed from the provisional list either when it is included in the positive list, or when a decision is taken not to include it in the positive list, or if additional information asked by the EFSA is not provided. The provisional list is available from the EC website at:

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

## **Options**

### **Option 1 – Do Nothing**

#### **Costs**

12. This contradicts the UK Government's commitment to meeting EU obligations and fulfilling policy on consumer protection in this area. It would also create potential for the UK to become liable to infraction proceedings. It would not be appropriate to implement only parts of this proposal. It would contradict the important role the UK plays in negotiating the adoption of these rules to achieve its wider policy objectives for consumers and business and it would leave the regulation of food contact materials deficient in many ways in comparison with the main food legislation that now applies across the rest of the EU.
13. Failure to fully implement the new Directive would mean that the prevailing national legislation would no longer accord with Community provisions. Businesses would have to comply with the proposals being made here for their goods to be legally compliant elsewhere in the EU. In addition, UK consumers would not have the same health protection from the excessive consumption of substances dealt with in these proposals as consumers in the rest of the EU.

#### **Benefits**

14. There are no identifiable incremental benefits for this Option.

### **Option 2 – Full Implementation of Commission Directive 2008/39/EC**

15. This option fully meets the UK Government's commitment to fulfil its EU obligations and contributes significantly to our agreed policy objective of protecting consumers from ingesting harmful levels of chemicals that could have migrated from materials and articles that were intended to be brought into contact with food. The UK was involved with the Commission and other Member States (MS) throughout the negotiations that developed the new Directive to the point of its adoption by the Commission as a formal proposal and we supported its adoption at the SCoFCAH. Under Treaty obligations we are required to implement the provisions of the new Directive. It is in the interest of businesses and enforcement authorities to have harmonised EU rules across all MS.

#### **Sectors and groups affected**

16. Any likely costs to industry associated with the new Regulations relate only to the businesses that manufacture plastic materials and articles intended to come into contact with food (including things like food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment) and are not representative of the whole packaging industry. The primary business sectors affected by these proposals will be those that manufacture, use, import or sell plastic food packaging and other plastic materials and articles intended for food contact. The proposals would apply equally to all businesses across England's food contact plastics industry, its commercial customers and those that convert and/or import plastic food contact materials and articles, whether small or large.
17. Local authorities and port health authorities will continue to benefit from the greater clarity of having the relevant rules and powers contained in one consolidated document.
18. Charities and voluntary organisations are unaffected by this proposal.
19. Businesses, LAs and PHAs will all need to read the new regulations and take appropriate actions to achieve high levels of compliance.

## **Costs to Enforcement Authorities**

20. 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 have the responsibility for enforcing food contact materials legislation and will, as outlined above, be affected by these proposals. There may also be ongoing and unchanged costs to food authorities for monitoring and enforcing the new Regulations. However, given that this is an existing responsibility under other food contact materials legislation, there are unlikely to be any annual incremental costs from this new piece of legislation.
21. We have estimated the time that enforcement authorities will typically invest in reading and familiarising themselves with the new single set of Regulations. There are 389 local authorities in England. We have estimated that one enforcement officer in each of the 389 local authorities (LAs) is expected to read the Regulations and that it takes them one hour to do so. In addition, we have estimated that each person uses one hour for dissemination to key staff. Their time is valued at £19.42/hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for EHOs uprated by 30% to include overheads). This equates to an approximate one-off cost to LAs of £15,100.
22. There are 39 Port Health Authorities in England. We have estimated that one enforcement officer in each of the 39 PHAs is expected to read the Regulations and that it takes them one hour to do so. In addition, we have estimated that each person uses one hour for dissemination to key staff. The assumption is made that their wage rates are the same as EHO's and their time is valued at £19.42/hour (based on the 2008 Annual Survey of Hours and Earnings (ASHE) data for EHOs uprated by 30% to include overheads). This equates to an approximate one-off cost to PHAs of £1,500.

## **Costs to Industry**

23. There will be a one-off cost to industry arising from reading and familiarising themselves with the proposed Regulations. The Agency will develop guidance for businesses on the proposed Regulations and such guidance will minimise costs to businesses of reading the Regulations. A brief summary of the guidance is given at paragraph 32. The costs to industry are summarised below.
24. Plastic packaging accounts for approximately a third of the turnover of the food and drink packaging sector. The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. A 2003 study of the UK's packaging industry identified 13,000 packaging companies in the UK; combined they employ 250,000 people.<sup>1</sup> If we assume businesses are roughly equally spread by population size then 11,000 businesses in England could be affected by this proposal.
25. About a third of the packaging businesses produce plastic materials and articles intended to come into contact with food and these are businesses that would need to comply with the new Regulations. It is assumed that one person per business reads the Regulations and it takes them an hour to do this. In addition, a further hour may be required to disseminate the requirements of the regulation to key staff within the organisation. Their time is valued @ £20.27/hour (this is based on the 2008 ASHE (2008) for 'Production and process engineers' (including the assumption of 30% overheads)); this equates to an approximate one-off administrative cost to industry of £148,600.
26. The one-off administration costs borne by businesses and enforcement authorities have been revised to reflect the data used in the ASHE 2008 survey.
27. As indicated above, any likely costs associated with the new Regulations relate only to the businesses that manufacture plastic materials and articles intended to come into contact with food (including things like food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing machinery and equipment) and are not representative

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<sup>1</sup> Food and Drink Packaging, Mintel 2003

of the whole packaging industry. The proposals would apply equally to all businesses across the UK food contact plastics industry, its commercial customers and those that convert and/or import plastic food contact materials and articles, whether small or large.

28. Stakeholders were asked to comment on the assumption of a one-off administration cost associated with the reading and familiarisation with the new Regulations. Our estimates were based on one person per business reading the Regulations and taking them an hour to do so and in addition, a further hour to disseminate the requirements of the Regulation to key staff within the organisation.

### **Impact on Other Government Departments Bodies**

29. Government Departments, such as the Food Standards Agency (“the Agency”), may also be affected as and when they carry out any surveys on foods. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure, and to ensure that legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

### **Consultation questions**

**Stakeholders were asked to comment, with supporting evidence, on whether the assumption that it will take one hour to read and familiarise with the new Regulations is a sensible estimate for enforcement authorities and businesses.**

**Stakeholders were also asked to comment on any other costs that might be associated with the new Directive or the proposed Regulations and whether they introduce any additional burden.**

***Although no comments were received on the above specific questions from the enforcement authorities or businesses on the cost issue associated with either the new Regulations or the new Directive. However, some comments were made about other matters and they are addressed in the ‘consultation comments section below.***

### **Benefits – Option 2**

30. The recommended option (Option 2) of implementing the provisions of the new Directive into a single consolidated SI will bring together in one place the amending provisions of the Directive with the existing requirements. Businesses involved in the manufacture of plastic food contact materials are generally likely to gain from the measures in the new Directive by ensuring a level competitive environment both domestically and throughout the EU, which in turn may facilitate further trade. They will benefit from maintaining and/or increasing consumer confidence in their products by complying with improved health protection measures throughout the EU.
31. Industry will also benefit from having clearer rules regarding permitted substances they may incorporate into the plastic material. This arises because permitted substances are risk assessed at EU level and any necessary health-related restrictions are provided for them (see paragraph 34 below); the alternative is that every business using a substance not specifically regulated would carry out its own research in order to make its own risk assessment. Having formal lists of permitted substances avoids all the duplication of the past among separate businesses and saves considerable sums across the industry as a whole.

### **Consultation question**

**Stakeholders were asked to comment on our assessment that using only substances from a formal list of substances provides financial benefits. However, no comments were received from the enforcement authorities or businesses on the substance issue.**

32. The guidance mentioned in paragraph 23 above, is aimed primarily at those businesses that are likely to be affected by the proposed Plastic Materials and Articles in Contact with Food (England) Regulations 2009. It is aimed at those businesses that manufacture, use, import or sell plastic materials and articles intended for use in contact with food. It may also be of use to others with an interest in the legislation, such as enforcement authorities. The guidance provides a short summary of the changes proposed and have been produced to provide formal non-binding advice on the requirements of the draft Regulations and should be read in conjunction with the legislation itself.
33. Option 2 will also minimise the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles to the food itself. Whilst the potential health benefits are difficult to quantify they are likely to include reduced risk of illness through exposure to substances that might migrate and might be associated with various effects to human health. In 1999, the Department of Environment, Food and Rural Affairs (DEFRA) published a report presenting economic evaluation of UK policy on chemical contaminants in food, which estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The aim of the evaluation was to assess whether current controls on chemical contaminants and naturally occurring toxicants were cost effective and how these could be improved, taking into account the impact of such controls on consumers and the food supply chain. One of the report's conclusions was that the main beneficiaries were consumers, whilst the majority of the quantifiable costs had been borne by central government. The report is available on the DEFRA website at:
- <http://statistics.defra.gov.uk/esg/evaluation/chemcont/default.asp>
34. EFSA is responsible for carrying out risk assessments and gives its opinions on substances used in the manufacture of food contact plastics based on risk assessment dossiers submitted by industry seeking approval for use of a particular substance. These opinions are given on the basis of protection of public health from any harmful substances that may arise from the consumption of food into which the substance may have migrated. Any resulting limits contained in EFSA's opinions have margins of safety to ensure that the health of consumers who may eat contaminated foodstuffs would not be affected over their lifetime. The resulting European Commission proposals reflect these safety margins when determining the level of a substance that may be allowed to migrate into food. The Commission regularly amends these technical limits and refines definitions of categories used for limiting migration as scientific understanding of the substances and their health effects improves. Substances that are deemed to cause unacceptable risk to consumer health, particularly among vulnerable people, may be prohibited for use.
35. The new Directive reflects improved scientific knowledge of particular chemicals in relation to human health and changes the lists of substances that may be used in manufacturing food contact plastics. Some substances have been deleted from the Community list of permitted monomers and additives either because satisfactory data has not been submitted by applicants for completion of the necessary risk assessment by EFSA, or because risk assessments have deemed that the substances should no longer be used.

## **Consultation**

### **• Within Government**

36. Other Government Departments including the Department of Health, the Department for Business, Enterprise and Regulatory Reform, the Foreign and Commonwealth Office, the Cabinet Office and DEFRA were kept informed of progress throughout the negotiations relating to the new Directive through regular progress reports. To date, no adverse comments have been received from any Department

## • Public Consultation

37. During the course of negotiations with the Commission, the Agency's officials have frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities, public analysts and other interested parties with an interest in policy issues related to food contact materials. The proposals have also been discussed at regular meetings with stakeholder groups that are likely to be directly affected by the requirements of the new Directive. Any comments received from interested organisations have, where appropriate, been incorporated into the UK's negotiating line. Consultations on the initial development of these proposals have spanned seven years; in 2002, 2004, 2005, 2006, 2007 and February 2008, when these proposals were last amended.

## • Results of the Consultation

38. Two separate consultations were carried out on these proposals to implement the provisions of the new Directive. An informal consultation was carried out in October 2007, setting out the details of the provisions of the new Directive. However, no comments were received then.

39. One hundred and thirty two stakeholders have been consulted on these proposals. These ranged from food industry organisations to sector specific organisations, such as those representing manufacturers of food contact plastics, coated cans and multi-layered bonded packaging; as well as others with an interest in food contact plastics. We also consulted enforcement authorities, the Department for Business Enterprise and Regulatory Reform, the Enterprise Directorate, DEFRA, the Office of Fair Trading, consumer organisations and other non-governmental organisations.

## • Consultation comments

40. Four responses were received; one from LACORS, one from Laboratory of the Government Chemist (LGC), one from the Suffolk Coastal Port Health Authority (PHA) and one from the Association of Port Health Authorities. Their comments are summarised below:

41. LACORS commented that whilst they appreciated the opportunity to comment, they felt that the proposed changes in the draft Regulations were largely of a technical, scientific and analytical nature, as such, they were not providing any substantial comments, but were happy to support any technical comments made by the Association of Public Analysts.

42. The LGC fully supported these proposals and the continued use of ambulatory references to EU legislation, provided that simple clear guidance was available, e.g. a flow chart. Such guidance would assist enforcement authorities, businesses and analytical laboratories to prepare for implementation as well as to contribute appropriately to the evidence base for risk management decisions. The LGC also commented that any costs borne by them would be in relation to any chemical analysis linked to enforcement action, but felt that this would be unlikely for the foreseeable future.

43. The LGC was informed that the type of guidance suggested has been prepared and updated as and when new and or amending legislation comes into force and is also published and available on the Agency's website to download free of charge.

44. There were a number of comments received from the PHA on the proposed Regulation. One comment queried whether the draft SI had been drafted in such a way that the power to enforce the documentation requirements for imports was deficient. A response was sent to the consultee explaining how the power worked and that there was in fact no deficiency. Other comments concentrated on their level of involvement as enforcers. The PHA added that they did very little work on food contact materials legislation due to the complexity and lack of knowledge, but has started to take interest in this area due to the increased number of Rapid alerts. The PHA also commented that due to insufficient funding covering this area of enforcement, business activity will have to dictate the resources which can be allocated.



45. Comments from the APHA were made on behalf of the 68 seaports and airport local authorities. The APHA commented that costs to enforcement authorities at borders were understated based on the assumption that enforcement activity may change due to the increased documentary checks. If there is a need to carry out documentary checks on imported products under the proposed Regulations at borders, then consideration needs to be given to incorporate cost recovery elements into legislation (similar to products of animal origin).
46. The need to carry out documentary checks is neither a new provision nor a new burden on businesses or enforcement authorities in the new Regulations or the new Directive. This is an existing requirement under Article 16 of Regulation (EC) No. 1935/2004 and Article 9 of Commission Directive 2002/72/EC as amended by the new Directive (which was reinforced further by Article 9(1) and 9(2) in Directive 2007/19/EC) require that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation. As such the Agency believes that no additional costs will be incurred by enforcement authorities by the new Regulations.
47. Further guidance, on legal compliance and best practice for business documentation for materials and articles in contact with food has been developed. The aim of the guidance is to assist businesses and enforcement authorities in understanding their individual responsibilities under the Regulations, such guidance will help in minimising costs to businesses on legal compliance and best practice for documentation. The guidance is currently being consulted on and will be published in September 2009.
48. Prior to the receipt of the above comments, good contact was established with the PHA on 12<sup>th</sup> November 2008, during the Declaration of Compliance Workshop, responsible for one of the largest ports of landing in the UK. As a result, a further successful two hour workshop on 9<sup>th</sup> December was organised involving Felixstowe, Tilbury, Heathrow and others from the APHA. During this workshop participants undertook a detailed exploration of the legislation on food contact materials and its implications for the ports. The workshop also included a look at incidents involving food contact materials over the last three years and the issues they have raised here and some that arose from Felixstowe itself under the Imported Food Programme of surveillance.

### **Administrative Burden Costs**

49. The cost analysis is based on the fact that Option 2 fully meets the requirements of the proposal.
50. No new administrative burdens are identified in the proposal other than those identified as one-off costs to industry and enforcement authorities for reading and familiarising themselves with the new Regulations.

### **Enforcement**

51. Enforcement of the proposed Regulations is primarily the responsibility of LAs and PHAs as defined by the Food Safety Act 1990 and designated in our Regulations. While the making of legislation in England is the function of central government, the enforcement of food is primarily (but not solely) the responsibility of 389 LAs and 39 PHAs in England. In relation to local authorities, there is no clear distinction made on the face of the Regulations between county councils, district councils and unitary authorities. However, in non-unitary council areas in England, the food standards work is carried out by the county council and food hygiene work by district councils. In areas under unitary local government local authorities are responsible for both services.

### **Sanctions**

52. No changes to the sanctions are being proposed to those contained in the current Regulations, which are considered proportionate and the minimum needed to enable the policy to be implemented effectively.

## **Simplification**

53. The opportunity is being taken to maintain a simplified single set of Regulations that avoid numerous amendments. This will ensure that we continue to minimise the number of domestic legal instruments to which stakeholders need to refer. An earlier simplification of the regulation of food contact materials legislation was carried out in a two stage exercise in February and March 2006. Since then we have continued to propose simplified single-set Regulations to minimise the burden on industry and enforcement authorities.

## **Implementation and Review**

54. The proposed Regulations are intended to come into force on 7<sup>th</sup> March 2009. We shall continue to regularly communicate with industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which will be reviewed in March 2010.

## **Monitoring**

55. Central and local authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with the regulations. The results of this work carried out by the Agency are published and are openly available on the Agency's website at:

<http://www.food.gov.uk/science/researchinfo/contaminantsresearch/>

56. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems arise or suspected infringements of the Regulations arise. The effectiveness of the proposed Regulations will also be monitored via feedback from stakeholders as part of the ongoing policy process.

## **Summary and Recommendation**

57. The Agency believes that the advantage of full implementation of the proposals within the Plastic Materials and Articles in Contact with Food (England) 2009 Regulations will benefit businesses, enforcement authorities and consumers. The measures proposed are important in providing essential consumer health protection and improved product information. They also provide businesses with harmonised rules and greater transparency in the authorisation of new substances for use in plastic materials and articles in contact with food. We recommend that the new Directive is implemented into English law and that the 2008 Regulations are revoked.

## specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

**Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.**

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

## **Competition Assessment**

We have fully considered the questions posed in the Office of Fair Trading competition assessment test<sup>2</sup> and conclude that the proposed Regulations that implement the new Directive are unlikely to hinder the number or range of businesses or the ability for operators to compete. As such, the proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small and apply equally across all food contact industries. The proposals do not contain a strong competition element nor any new or additional burden as the new Directive they implement is amending existing legislation on food contact plastics. This is unlikely therefore to impact on businesses operating in this area, nor in their competitiveness or incentive to compete. Charities and voluntary organisations are also unlikely to be affected by these proposals.

## **Small Firms Impact Test**

We do not consider the impact on small businesses in general to be significant. This view has been supported by industry following earlier consultations (June and October 2007), which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness. Such businesses are always encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market.

## **Sustainable development**

The Agency's remit is to protect the interest of consumers in relation to food safety, both now and in the future. In doing so, the Agency will take sustainable development into account in all of its activities and policy decisions. The proposal has a positive impact on public health, without any significant negative impact on the other Government principles of sustainable development.

## **Race equality issues**

Members of the ethnic communities are not affected by these proposals any differently to others.

## **Gender equality issues**

There is unlikely to be any impact on gender equality.

## **Disability equality issues**

Disabled people are unlikely to be affected by these proposals.

## **Carbon Impact Assessment**

The proposal is unlikely to have any significant impact on emissions of greenhouse gases.

## **Human Rights**

It is not considered that this proposal will have a negative impact on the Human Rights of those affected by it.

## **Rural Proofing**

The proposal is unlikely to have any significant impact on rural areas.

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<sup>2</sup> [http://www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft876.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf)