

**EXPLANATORY MEMORANDUM TO**  
**THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD**  
**(ENGLAND) REGULATIONS 2008**

**2008 No. 916**

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

**2. Description**

2.1 This instrument implements European Commission Directive 2007/19/EC that amends Commission Directive 2002/72/EC. This amendment, the fourth to the 2002 Directive, routinely updates 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. The changes to these lists of substances are made periodically when the European Food Safety Authority has revised an existing opinion or issued a new one on the safe use of a substance. This opinion establishes the amount of a substance that may be ingested daily by a person over a lifetime without harmful health effects. Those opinions are used by the European Commission as the basis for proposals to be agreed with EU Member States as has been the case here. Other amendments that the 2007 Directive makes to the original 2002 Directive provide:

- a) clarity about the detail required in compliance declarations that must accompany goods being traded up to the retail stage;
- b) distinction between the terms ‘plastic multi-layer’ and ‘plastic functional barrier’ and defines the function of such a barrier;
- c) removal of the suspension imposed on the use of azodicarbonamide as a foaming agent in the plastic in favour of an outright ban;
- d) clarification that gaskets used to seal glass food jars are subject to the rules laid down in the 2002 Directive whilst providing time for manufacturers to obtain authorisation for the use of the additives they employ in making these gaskets;
- e) for the use of a new food simulant to test more accurately for chemical migration into milk products;
- f) for the use of a reduction factor to more accurately calculate migration into fatty food types;
- g) the dates from which compliant goods may be traded and from which non-compliant goods may not be manufactured or imported into the Community..

2.2 This instrument revokes the Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 and re-enacts their provisions, amended to take into account the provisions of Commission Directive 2007/19/EC. As such, this instrument will constitute the only specific legislation in England controlling the substances that may be used in the manufacture of plastics intended to come into contact with food.

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

3.1 None

### **4 Legislative Background**

4.1 The Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 (SI 2006 No. 2687) implemented harmonised EU measures contained in European Commission Directives on plastic materials and articles intended to be brought into contact with food. The Directives include lists of substances that can be used in the manufacture of these food contact plastics and any restrictions on that use necessary to safeguard human health and the nature and quality of the foodstuff. The harmonised European rules on food contact plastics are laid down by Commission Directive 2002/72/EC as amended.

### **5 Extent**

5.1 This instrument applies in relation 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**

7.1 It is the intention that the law on food contact materials and articles should protect consumers from any harmful health effect, arising from the routine ingestion of substances that may have migrated into food from those materials and articles. 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.

### **8. Impact**

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, consumer organisations and other non-governmental organisations.

8.2. Two consultations were carried out, first in October 2007 and then again in February 2008. The second consultation was conducted to ensure stakeholders had the opportunity to comment on the insertion of the remaining transitional provisions of the amending Directive, which provide for the date by which goods complying with the provisions of the Directive may be placed on the market and dates from which non-compliant goods will be prohibited from manufacture or import into the European Community.

8.3. The primary business sector that will be affected by the regulatory proposals will be manufacturers of food contact plastics, importers and those producing gaskets for use in glass food jars. Comments from industry were overall very positive and in favour of the Agency's proposal to amend the food contact plastics legislation in England. However, one trade association representing manufacturers of plastic packaging raised concerns on the need for detailed information in their compliance declarations; they felt this would increase their administrative tasks, and the affect small and medium sized businesses. They were not however, able to quantify this in any way in their comments, nor did they do so in Europe when they made the same points in the negotiations on the 2007 Directive that this instrument implements. The proposals will apply equally to all areas of legislation on food contact plastics and thus, the provisions equally affect all businesses involved. Rural areas and members of the ethnic communities of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are also unaffected by these proposals.

8.2 An Impact Assessment is attached to this memorandum.

## **9. Contact**

Richard Sinclair or Nasreen Shah at the Food Standards Agency  
Telephone: 0207 276 8538 or 0207 276 8553  
e-mail:  
[richard.sinclair@foodstandards.gsi.gov.uk](mailto:richard.sinclair@foodstandards.gsi.gov.uk)  
[nasreen.a.shah@foodstandards.gsi.gov.uk](mailto:nasreen.a.shah@foodstandards.gsi.gov.uk)).

**TRANSPPOSITION NOTE: THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2008**

- These Transposition Notes set out how the main elements of Directive 2007/19/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 and 2005/79/EC
- Any reference to the 2006 Regulations are to The Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 (SI 2006/2687)

**Directive 2007/19/EC – amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (OJ No. L97, 12.4.2007, p.50)**

Articles and Annexes of Directive 2007/19	Objectives	Implementation in the Plastic Materials and Articles in Contact with Food (England) Regulations 2008	Responsibility
<p>Article 1(1) (a) amending Article 1(2) of the parent Directive</p> <p>And</p> <p>Article 1 (1) (b) amending Article 1(4) of the parent Directive</p>	<p>Article 1(1) amends Article 1(2) relating to the definition of plastic materials and articles (a) materials and articles and parts thereof consisting exclusively of plastic, (b) plastic multi-layer materials and articles, (c) plastic layers or plastic coatings, forming gaskets in lids that together are composed of two or more layers of different types of materials.</p> <p>Article 1(1)(b) amends Article 1(4) by making it clear that the Directive shall not apply to materials and articles composed of two or more layers, when one or more does not consist exclusively of plastics, even if the one intended to come into direct contact with foods does consist exclusively of plastic.</p>	<p>These provisions are implemented by regulation 2: No further change is needed because the definition operates by reference to the Directive itself.</p>	<p>Secretary of State for Health</p>
<p>Article 1(2)</p>	<p>Article 1(2) inserts a new Article 1(a) providing definition for ‘plastic functional barrier’, “plastic multi-layered materials and articles” and “non-fatty foods”.</p>	<p>These provisions are implemented by regulation 2 inserting 3 new definitions</p>	
<p>Article 1(3)</p>	<p>Article 1(3) replaces Article 2 of the parent Directive, which deals</p>	<p>This provision is implemented by regulation 9(1)-(4)</p>	

	with the overall migration limits. In particular paragraph 2 requires that for plastic materials and articles intended to come into contact with food, or that are already in contact with food intended for infants and young children, the overall migration for this particular group shall always be 60 mg/kg.		
Article 1(4)	The Article amends Article 4(2) of the parent Directive by setting out the application of test for compliance with the specific migration limits in stimulant D. The date of 1 July 2006 is replaced by 1 <sup>st</sup> May 2008	This provision is implemented in Schedule 1 paragraph 4, where the operative date is the coming into force of these Regulations	
Article 1(5)	<p>The Article inserts a new Article 4c which deals with the use of additives in the manufacture of plastic layer or plastic coatings in lids.</p> <ul style="list-style-type: none"> <li>• 4c(a) allows for the use of additives listed in Annex III and the restrictions and or specifications that apply;</li> <li>• 4c(b) – allows for the continued use of additives not listed in Annex III until further review subject to national law.</li> <li>• 4c(c) allows Member States discretion to continue to authorise additives for the manufacture of plastic layers or plastic coatings in lids (as referred to in Article 1(2)(c) at national level</li> </ul>	<p>This provisions is already implemented by regulation 5(1) and (2)</p> <p>As there are no national provisions or authorisations in the UK, as such there is no application of 4c(b) and (c)</p>	
Article 1(5)	The Article inserts Article 4d on the use of additives acting purely as polymerisation aids (PPAs) which are not intended to remain in the finished article.	As for 4c above	
Article 1(5)	This Article inserts Article 4e on prohibiting the use of azodicarbonamide in the manufacture of food contact plastics	No need to implement further, as temporary ban is made permanent.	
Article 1(6)	This Article replaces Article 5a(2) of the parent Directive which relates to the declaration of	No need to implement, as this is consequential amendment of an internal reference in the	

	compliance	Directive.	
Article 1(7)	This Article inserts an additional paragraph in Article 7 of the parent Directive dealing with the specific migration limits for materials and articles in contact with food intended for infants and young children.	This provision is implemented by regulations 6(3) and 7(3)	
Article 1(8)	This Article inserts a new Article 7a, which sets out the provisions for multi-layered plastic materials and articles.	This provision is implemented by regulation 11	
Article 1(9)	This Article inserts a new paragraph 5 in Article 8 which provides verification of compliance on the new provisions for certain phthalates.	This provision is implemented by regulation 13(1)(c)	
Article 1(10)	This Article amends Article 9 of the parent Directive by inserting revised provisions on pre-retail declarations and information required in accordance with Article 16 of Regulation (EC) No. 1935/2004. The declaration issued by the business operators is required to contain certain specified information in accordance with the new Annex VIa to the parent Directive.	This provision is implemented by regulation 14 and Schedule 4.	
Article 1(11) and Annex I, II and III	This Article and Annex I insert into Annex I to the parent Directive new points 2a, 2b, and 5a relating to correction of analytical results.  Annexes II and III are implemented by reference	As regards Annex I, these provisions are implemented in Schedule 2, paragraphs 6-8 (point 2a), 9 (point 2b) and 13 (point 5a).  As regards Annexes II & III, no further implementation is necessary	
Article 1(12) and Annex IV	The text in Annex IV is inserted as Annex IVa to the parent Directive, which deals with lipophilic substances to which the FRF (fat reduction factor) applies.	This provision is implemented by Schedule 2 and paragraph 6 making a cross-reference to Annex IVa.	
Article 1(13) and Annex V	Annex V to the parent Directive is amended in relation to primary aromatic amines	This provision is implemented by regulation 10	
Article 1(13) and Annex VI	Amends the notes to the 'restrictions and specifications' in Annex VI to the parent Directive	No further implementation is necessary, as these notes are referred to in Annexes II and III, which are themselves implemented by reference.	
Article 1(14) and Annex VII	The amending text in Annex VII inserts a new Annex VIa to the parent Directive in relation to declaration of compliance.	This provision is implemented in Schedule 4	

Article 2 and Annex VIII	Amends the Annex to Directive 85/572/EEC: Point1  Point 2  Point 3	Implemented by Schedule 2, paragraph 9(a); Schedule 3, Part 4, paragraph 4(2) Schedule 3, Part 4, section 7 (milk products) of the table in paragraph 5	
Article 3(1)	Requires that Member States implement the requirements of the amending Directive by 1 May 2008 and that implementing measures shall be published and communicated to the European Commission	The Regulations will come into force on 1 <sup>st</sup> May 2008 in England.	
Article 3(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 2007/19/EC from 1 <sup>st</sup> May 2008	The coming into force of the Regulations on 1 <sup>st</sup> May 2008 has the effect of meeting this requirement.	
Article 3(1)b	Requires Member States to prohibit the manufacture and import into the Community from 1 <sup>st</sup> July 2008 of lids containing gaskets which do not comply with the restrictions and specifications for certain plasticisers. (Those specifications may include transitional periods)	This provision is implemented by Regulation 22(3)(a)(i) and (c)	
Article 3(1)(c)	Prohibits the manufacture and import into the Community from 1 <sup>st</sup> July 2008 of plastic materials and articles intended to come into contact with food, which do not comply with the restrictions and specifications for certain phthalates.	This provision is implemented by Regulation 22(3)(a)(ii) and (c)	
Article 3(1)(d)	Prohibits the manufacture and import into the Community from 1 <sup>st</sup> May 2009 of plastic materials and articles (other than those mentioned in sub-paragraphs (b) and (c)) intended to come into contact with food, which do not comply with the provisions of the parent Directive as amended by Directive 2007/19/EC.	This provision is implemented by Regulation 22(3)(b) and (c)	

## 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 2008</b>	
<b>Stage:</b> Implementation	<b>Version:</b> 3	<b>Date:</b> 27 <sup>th</sup> March 2008
<b>Related Publications:</b>		

**Available to view or download at:**

<http://www..food.gov.uk>

**Contact for enquiries:** Nasreen Shah

**Telephone:** 020 7276 8553

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

Chemical migration from food contact plastics can detrimentally affect consumer health. Intervention is necessary to implement significant amendments to the main European Commission Directive on plastic materials and articles intended to come into contact with food.

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

The policy objectives are two-fold:

- a) 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 migrate into the food; and
- b) 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.
2. To successfully negotiate and implement EU harmonised measures. This preferred option is achieved through provisions of Directive 2007/19/EC. It meets the Governments commitment to fulfil its EU obligations and contributes towards the protection of consumers from ingesting harmful levels of chemicals that could migrate

**When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?** June 2009

**Ministerial/CEO Sign-off** For final proposal/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.*

Signed by the responsible Minister

**Dawn Primarolo** .....Date: **31/03/08**

## Summary: Analysis & Evidence

Policy Option: 2

Description: The Plastic Materials and Articles in Contact with Food (England) Regulations 2008

<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 = £172,000 One-off cost borne by local authorities £16,800
	<b>One-off</b> (Transition)	<b>Yrs</b>	
	<b>£ 188,800</b>	1	
	<b>Average Annual Cost</b> (excluding one-off)		
	<b>£ 0</b>		<b>Total Cost (PV)</b> <b>£ 188,800</b>
Other <b>key non-monetised costs</b> by 'main affected groups' Transitional costs arising due to initial admin burdens for firms, LA's and Porth Health Authorities through the reading of the new legislation and amending of the Community list of authorised monomers and other starting substances - however, these costs are not thought to be significant			

<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 a formalisation of existing procedures and an increase in consumer confidence.			

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years	<b>Net Benefit Range (NPV)</b> <b>£ N/K</b>	<b>NET BENEFIT (NPV Best estimate)</b> <b>£ -188,800</b>
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What is the geographic coverage of the policy/option?	England			
On what date will the policy be implemented?	1 May 2008			
Which organisation(s) will enforce the policy?	LA's and PHA's			
What is the total annual cost of enforcement for these organisations?	£ 16,800			
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	Small	Medium	Large
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

## Evidence Base (for summary sheets)

### Rationale for Government Intervention

1. These proposals fulfil the UK Government's policies of meeting its EU obligations to bring into effect in law harmonised rules that:
  - Reduce the chronic and acute long term health risks to consumers arising from chemical contaminants in food they eat and
  - Meet the intergovernmental Lisbon Agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules within which businesses can compete on an equal footing that are not over burdensome.
2. Doing nothing will mean that the UK Government will fail to implement its policies. It would also create the potential for the UK to become liable for infraction proceedings. It would not be possible to implement only parts of this proposal.
3. The Food Standards Agency believes that the adoption of these proposals provides for the continuation of consumer protection against food contamination by chemicals whose ingestion would carry serious long-term and unacceptable risk to consumer health, particularly among more vulnerable people. Full implementation of Commission proposal will contribute to the achievement of improved uniform standards across the EU, benefiting both consumers and businesses.

### OPTION 1 – DO NOTHING

#### Costs

4. This contradicts the UK Government's commitment to meeting its EU obligations and fulfilling its policy on consumer protection in this area. It would also create potential for the UK to become liable for infraction proceedings and it would not be possible to implement only parts of the 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. Failure to fully implement the Commission Directive would mean that prevailing national legislation would no longer accord with Community provisions. In addition, UK consumers would not have the same health protection as consumers in the rest of the EU from the effect of excessive consumption of substances dealt with in these proposals.

#### Benefits

5. There are no identifiable benefits, (economic, social or environmental) associated with Option 1.

### OPTION 2 – IMPLEMENT THE PROVISIONS OF COMMISSION DIRECTIVE 2007/19/EC IN FULL

6. This option fully meets the UK Government's commitment to fulfil its EU obligations and contribute significantly to the up-to-date means 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 throughout the negotiations that developed the Commission Directive to the point of its adoption by the Commission as a formal proposal and we supported its adoption at the Standing Committee on the Food Chain and Animal Health. Under EC Treaty obligations we are required to implement the Commission Directive. Businesses and enforcement authorities want the harmonisation of rules between Member States of the EU that

the implementation of the Commission Directive provides. This view was expressed by stakeholders who commented on the consultation carried out in 2006, when these provisions were last amended; they particularly found that full implementation provides scope for a favourable balance between benefits and necessary costs.

### **Administrative Costs**

#### **Costs: Option 2**

7. The cost analysis is based on the fact that Option 2 fully meets the requirements of the proposal.
8. It is estimated that there will be one-off administrative costs to industry and enforcement authorities for reading and familiarising themselves with the new Regulations and these are summarised below.

### **Costs to Enforcement Authorities**

9. In order to estimate the likely additional administrative burden for enforcement authorities in reading and familiarising with the new single set of Regulations, we have estimated the time that enforcement authorities will typically invest in these activities. There are approximately 469 local authorities in the UK, and we have estimated that one environmental health officer (EHO) in each of the 469 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 person uses one more hour for dissemination to key staff within the organisation. Thus, the time is valued at £17.89/hour (based on 2007 Annual Survey of Hours and Earnings (ASHE) data for EHOs). This equates to an approximate one-off administration cost to enforcement authorities of £16,800.
10. The price base year used to calculate the costs to enforcement authorities is 2007, as the Annual Survey of Hours and Earnings (2007) are used.
11. It is estimated that the total spend for enforcement authorities and port health authorities in relation to food safety is in the region of £98.3 million
12. Local authorities are responsible for enforcing the legislation with respect to food safety and also have the responsibility for enforcing food contact materials legislation, and will therefore be affected by these proposals. There may also be an ongoing and unchanged admin cost to enforcement authorities for monitoring and enforcing the new Regulations. However, given that this is an existing responsibility under other food contact materials legislation, the cost is unlikely to be increased.

### **Costs to Industry**

13. 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. Thus the potential impact for a one-off cost to businesses is based on the same principles as those for LAs. A third of the 13,000 packaging businesses produce plastic materials and articles intended to come into contact with food and these are the 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 @ £19.84/hour (this is based on the 2007 ASHE (2007) for 'Production and process engineers' (including the assumption of 30% overheads)); this equates to an approximate one-off administrative cost to industry of £172,000.

14. The one-off administration costs borne by businesses and enforcement authorities have been revised to reflect the data used in the ASHE 2007 survey.
15. 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 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.
16. 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. No comments were received from the enforcement authorities on the estimates nor from businesses.

### **Impact on other Government Departments**

17. Government departments, such as the Food Standards Agency (“the Agency”) will 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.

### **Benefits**

#### **Option 2**

18. The recommended option (Option 2) of implementing the provisions of the Commission Directive into a single consolidated Statutory Instrument (SI) will bring together in one place the amending provisions with existing requirements. Businesses involved in the manufacture of plastic food contact materials are generally likely to gain from the measures in the Commission Directive by ensuring a non-discriminatory 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.
19. This option also minimises 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 the risk of illness through exposure to substances that might migrate and might be associated with various adverse effects on 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 estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The report is available on the DEFRA website at:

<http://statistics.defra.gov.uk/esg/evaluation/chemcont/default.asp>

### **Risk Assessment**

20. The European Food Safety Authority (EFSA) is responsible for carrying out risk assessments and gives its opinion 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 the protection of public health from any harmful substances that may arise from 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 contain additional safety margins that are built in when determining the level of a substance that may be allowed to migrate into food. The European Commission routinely 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 more vulnerable people, may be prohibited from use.
21. Commission Directive 2007/19/EC 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 (e.g. total ban on the substance azodicarbonamide).

## Specific Impact Tests: Checklist

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

## INTRODUCTION

1. The proposal is for a Statutory Instrument entitled: The Plastic Materials and Articles in Contact with Food (England) Regulations 2008. The objective of the proposed Regulations is to implement in England and in its entirety the provisions of Commission Directive 2007/19/EC (“the Commission Directive”) that routinely amends Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food, by 1 May 2008. Scotland Wales and Northern Ireland will make similar legislation.
2. The proposed Regulations will also revoke the *Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006* (SI 2006/2687) and re-enact them with necessary amendments thus implementing in one consolidated instrument, Directive 2002/72/EC as most recently amended by the Commission Directive.

## BACKGROUND

3. Harmonised European Union rules on food contact plastics were originally laid down by Commission Directive 2002/72/EC 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 for public health arising from the migration of chemicals from food contact materials into food. The latest of these amendments are contained in Directive 2007/19/EC that the regulatory proposals here would implement. The Commission Directive also amends Council Directive 85/572/EEC, which lays down the list of simulants to be used for testing migration of constituents of plastic materials in contact with food. In England, the Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 implement the provisions of Directives 2002/72/EC and 85/572/EEC as amended in each case.
4. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. In particular, the Commission Directive provides for new limitations on the use of and migration limits for certain plasticisers including epoxydised soybean oil (ESBO) and some phthalates. Directive 2007/19/EC will also:
  - i) Revoke the current suspension on the use of azodicarbonamide as a blowing agent in food contact plastics and replace it with an outright ban;
  - ii) Clarify that gaskets in metal lids fall under the scope of Directive 2002/72/EC and provide time for manufacturers to apply for the evaluation of specific additives used in their manufacture. Thus the positive list of authorised additives that is intended for future adoption in relation to plastic materials and articles will not apply to the manufacture of gasket lids. The transitional use of other additives for the manufacture of gasket lids is the subject of an earlier consultation dealing with an EU time-limited Regulation [*Commission Regulation (EC) No. 372/2007/EC laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food*].
  - iii) Ban the manufacture and importation into the European Union (EU) of those gaskets in lids which do not meet these restrictions and or specifications;
  - iv) Provide clarification for the term ‘plastic multi-layer’ and distinguish it from ‘plastic functional barrier’. There are also provisions for the use of plastic functional barriers to help in reducing the migration of substances below a Specific Migration Limit (SML);

- v) Require detailed information on compliance declarations and require that certificates of compliance should attest to the restrictions and/or specifications applicable to them;
- vi) Amend Council Directive 85/572/EEC by introducing a fat (consumption) reduction factor (FRF) which can provide a better estimation of consumer exposure to substances migrating into fatty foods;
- vii) Prohibit as from 1 July 2008 the manufacture and importation into the Community of lids containing a gasket which do not comply with the restrictions and specifications for substances listed under Ref Nos<sup>1</sup>. 30340, 30401, 36640<sup>2</sup>, 56800, 76815, 76866, 88640 and 93670 laid down in Directive 2007/72/EC, as amended by Directive 2007/19/EC;
- viii) Prohibit as from 1 July 2008 the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with restrictions and specifications for phthalates Ref No. 74560, 74640 74880, 75100, and 75105 laid down in Directive 2002/72/EC as amended by Directive 2007/19/EC; and
- ix) Without prejudice to point (vii) and (viii) above, prohibit as from 1 May 2009 the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with Directive 2007/19/EC as amended by Directive 2007/19/EC.

## **Consultation**

### **• Within Government**

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

### **• Public Consultation**

- 6. During the course of negotiations with the European Commission, the Food Standards Agency officials have frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities and interested parties with an interest in policy issues related to food contact materials. The proposal has also been discussed at regular meetings with stakeholder groups that are likely to be directly affected by the requirements of Directive 2007/19/EC. 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 four years; in 2002, 2004, and 2005 and again in February and March 2006, when these proposals were last amended. Earlier consultations did not raise any adverse comments from stakeholders on these proposals.

### **• Results of the Consultation**

- 7. Two separate consultations were carried out on the proposals to implement the provisions of Directive 2007/19/EC. One hundred and thirty two stakeholders were consulted on the proposals and five responses were received from the first consultation. These were from the British Plastics Federation (trade association for the plastic packaging industry (BPF), the Government Chemist (LGC), Lacors, Vegetarian Economy and Green Agriculture (VEGA) and one from the Government of Thailand.

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<sup>1</sup> These reference No's are for the plasticisers used in gaskets in lids coming into contact with fatty foods as provided for by Regulation (EC) No. 372/2007, which lays down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food

<sup>2</sup> This reference is to Azodicarbonamide which is now banned outright.

8. The BPF supported the implementation of the Commission Directive through the Plastic Materials and Articles in contact with Food (England) Regulations 2008. They expressed general concern about the extent of information required by compliance declarations in the Directive being implemented. They also felt that this would increase the burden of administrative tasks which would require a significant number of extra people time and would affect small and medium size businesses. They also added that the need to disclose information in some instances would be anti-competitive. However, they were not able to quantify the burden in monetary terms or support their contention, nor did they do so during the course of negotiating the content of the Directive that is being adopted. The need for compliance declarations is not a new burden on industry, as this is an existing requirement under Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in Directive 2007/19/EC. The BPF added further that the additional cost of REACH compliance would also be a contributory factor. However, again they were unable to quantify or provide evidence to support their views.
9. The Agency believes that REACH has no direct implications for the control of chemical migration from food contact materials and articles. The principles of positive approval and assessment are already part of the regulatory regime for the chemicals used in materials and articles intended to come into contact with food. REACH provides that chemicals used in articles are safe and that safer alternatives are used where they exist and requires that uses of chemicals have to be registered; food contact materials and articles manufacturers need to therefore register the use they make of chemicals.
10. Substance authorisation is needed where positive lists apply for substances used in the manufacture of food contact materials and articles. Such lists apply to food contact plastics and regenerated cellulose fibre manufacture. Risk assessments of these substances are carried out by the European Food Safety Authority. Whereas, the risk assessment and evaluation of substances for REACH are carried out by the European Chemical Agency (ECHA) in Helsinki and the Health and Safety Executive (HSE) in the UK. REACH came into effect on 1 June 2007 and requires that all substances and their uses are registered in the period from June 2008 to December 2008.
11. The LGC fully supports the Agency's view that Option 2 has the means of achieving full implementation of the Commission Directive. They feel that the proposals are broadly consistent with effective regulation and that the revisions to the layout of the proposed Regulations, which preserve much of the structure of their predecessors, would also assist local authorities in exercising their powers effectively, when enforcement action needs to be considered. This view was also supported by LACORS.
12. The comments from the Thai authorities were not specific to the proposed Regulations but covered issues in the Commission Directive and to the Specific Migration Limits (SML) for epoxydised soybean oil and other plasticisers. The comments have been noted by the Agency and forwarded to the European Commission to respond. The Thai authorities have been informed accordingly.
13. The Vegetarian Economy and Green Agriculture supported the Agency's pursuit of Option 2 in implementing the provisions of Directive 2007/19/EC.
14. Consultation comments on drafting detail have been acted upon where necessary.
15. There were no further comments from the second consultation which ended on 21 March 2008.

### **Carbon Impact Assessment**

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

### **Human Rights**

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

## **Rural Proofing**

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

## **Policy and Administration Costs**

19. There will be a small one-off administration cost to businesses for reading the proposed Regulations; however, this is unlikely to be significant. The Agency has developed and circulated guidance for businesses on the proposed Regulations; such guidance will help minimise costs to businesses of reading the new Regulations.

## **Enforcement**

20. Enforcement of the proposed Regulations is primarily the responsibility of local authorities. While the making of legislation in the UK is the function of central government, the enforcement of food law is primarily (but not solely) the responsibility of the 469 or so local authorities in the UK, and more specifically Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs), together with port health authorities at some sea ports and airports.

21. Local authorities and port health authorities are responsible for enforcing a large proportion of Regulations in relation to food safety and are already doing so in respect of all the legislation on materials and articles intended to come into contact with food. The proposed Plastic Materials and Articles Intended to Come into Contact with Food (England) Regulations 2008 will be enforced by these authorities in the normal way.

22. The Food Standards Agency also has an enforcement role with regard to the EC Regulation 1935/2004 in respect of declarations of compliance, as indicated in Article 16 of that Regulation. Article 9(1) and 9(2) of 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. This is not any new burden on industry, as this is an existing requirement under Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in Directive 2007/19/EC

## **Sanctions**

23. No changes to the sanctions are being proposed to those contained in the current Regulations, which are considered to be proportionate and the minimum needed to enable the policy to be implemented effectively. A person found guilty of an offence under these and other Regulations dealing with materials and articles in contact with food is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both. These penalties are in line with The Food Safety Act 1990.

## **Compensatory simplification**

24. The opportunity is being taken to continue to simplify the Regulations to ensure that we reduce the number of places in which substance restrictions and other substance usage information is recorded. An earlier simplification of the regulation of food contact materials legislation was carried out in two stages, first in February 2006 and then again in March 2006. This will help those that need to refer to the EU technical lists of substances by ensuring that they have as few documents to consult as possible, as well as reducing the risk of errors that may arise in repeating those lists in our regulations.

## **Monitoring**

25. The authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with 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/>

26. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Food Standards Agency will work with enforcement authorities where problems 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. We shall continue to routinely talk to industry to ensure that no foreseen difficulties arise from these Regulations. The proposed Regulations will be reviewed in June 2009.

### **Implementation and delivery plan**

27. The English Statutory Instrument will be laid before Parliament with a coming into force date of 1<sup>st</sup> May 2008.

28. Guidance for business has been developed and sent to all stakeholders consulted, informing them of the changes in these proposals. The guidance has also been published on the Agency's website at [www.food.gov.uk](http://www.food.gov.uk). Information about the new Regulations will also be disseminated in an explanatory note, which covers current issues on food contact materials and any future ones under discussion by the European Commission and Member States. The explanatory information is updated periodically and is a useful tool, which is designed to provide a general introduction to EU harmonised legislation and its implementation in the UK.

### **Summary and recommendation**

29. The Agency believes that the advantages of full implementation of the proposals within the Plastic Materials and Articles in Contact with Food (England) Regulations 2008 will benefit industry, 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 materials and articles in contact with food. We recommend that Directive 2007/19/EC is implemented into English law and that the 2006 No.2 Regulations are revoked. Therefore, Option 2, which has the support of the respondents, is recommended as the means of achieving this.

## **Abbreviations used in the Impact Assessment**

ASHE - Annual Survey of Hours and Earnings

BPF – British Plastics Federation

EC - European Commission

ECHA – European Chemical Agency

EFSA – European Food Safety Authority

EHO – Environmental Health Officer

ESBO – Epoxydised soybean oil

EU – European Union

FRF – Fat Reduction Factor

HSE – Health and Safety Executive

LA – Local Authority

LGC – Government Chemist

PHA – Port Health Authority

REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals.

SI – Statutory Instrument

SML – Specific Migration Limit

TSO – Trading Standards Officer

## **Competition Assessment**

The proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small. The proposals do not include any new or additional burden, as the Commission Directive they implement is merely amending existing legislation on food contact plastics and does not introduce any new provisions. Furthermore, the requirement in Article 9 (1) and (2) for detailed information on compliance declarations as indicated in the EU Annex attached, does not raise any new burden on industry. This requirement is an existing requirement under Article 16 of Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in the Commission Directive.

## **Small Firms Impact Test**

We do not consider that the impact on small businesses in general to be significant. This view has been supported by industry following earlier consultations (February and March 2006), which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness.

## **Sustainable development**

The Food Standards 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. Charities and voluntary organisations are also unlikely to be affected by these proposals.

## **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.