

## EXECUTIVE NOTE

### THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2009 S.S.I. 2009 /30

#### Description

1. The above instrument was made in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), 31 and 48(1) of the Food Safety Act 1990 and paragraph 1A of Schedule 2 to the European Communities Act 1972. The instrument is subject to negative resolution procedure.

#### 2. Policy Objective

- 2.1 This instrument implements Commission Directive 2008/39/EC (“the new Directive”)<sup>1</sup> that amends Commission Directive 2002/72/EC (“the 2002 Directive”). This amendment, the fifth 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 conditions for their safe use. The changes to these lists of substances are made periodically when the European Food Safety Authority (EFSA) 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 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 new Directive makes to the original 2002 Directive provide:

- a) it lays down the dates by which the list of additives that may be used in the manufacture of food contact plastics will be closed and makes interim arrangements for those additives that were the subject of an application for authorisation by the deadline of December 2006;
- b) it sets a date of 31<sup>st</sup> December 2009 up to which additives not on the positive list may continue to be used. This period will enable EFSA to obtain any additional information it might need for its risk assessment of the additives in question;
- c) it prohibits the use of additives not on the Community list of additives (the positive list), including the provisional list, from 1<sup>st</sup> January 2010;
- d) it permits the trade in and use of plastic materials and articles intended to come into contact with food and complying with the Directive 2002/72/EC, as amended, from 7<sup>th</sup> March 2009;
- e) it prohibits from 7<sup>th</sup> March 2010 the manufacture and importation into the Community of food contact plastic materials and articles that do not comply with the Directive, as amended. In effect this creates a phase-out period for substances that have either been removed from the Community list, or have not been adopted on to it;
- f) it also routinely updates the lists of authorised substances, taking into account the published opinions of EFSA.

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<sup>1</sup> A copy of Commission Directive 2008/39/EC is attached to this note.

- 2.2 This instrument revokes the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008 (SSI 2008/127) and re-enacts their provisions, amended to take into account the provisions of the new Directive. As such, this instrument will constitute the only specific legislation in Scotland controlling the substances that may be used in the manufacture of plastics intended to come into contact with food.

### **3. Policy Background**

- *What is being done and why*

- 3.1 The purpose of 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. Government intervention, through implementation of significant amendments to the main European Commission 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.

- 3.2 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 Scotland 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*

- 3.3 The opportunity is being taken to continue with a rolling consolidation in this area. This will ensure that we reduce the number of places in which substance restrictions and other substance usage information is recorded (which would be the case if we simply amended existing legislation). This will help those that need to refer to the Regulations.

### **4. Consultation**

- 4.1 The Food Standards Agency fully consulted all stakeholders on the Regulations for Scotland. Two hundred and eleven stakeholders were consulted on these proposals. These ranged from sector specific organisations, such as those representing industry sectors, to those with a wider interest in food contact plastics. We also consulted enforcement authorities, public analysts, Scottish Federation of Small Businesses, consumer organisations and other non-governmental organisations.

In total three responses were received; one from Scottish Beef Association; one from Aberdeen City Council and one from East Ayrshire Council. Their comments are summarised below:

- The Scottish Beef Association accepts the recommendation to enact the legislation to comply with the Commission Directive and fully agree with the draft RIA.
- Aberdeen City Council had no comment to make on this occasion.
- East Ayrshire Council agrees with the continued use of ambulatory references which avoids the need to introduce a new statutory instrument each time any of the Annexes to Commission Directive 2002/72/EC is updated.

## **5. Guidance**

5.1 Guidance for businesses has been developed and formed part of the stakeholder consultation on the proposed Regulations. Stakeholders were also asked to comment on the guidance, only one comment was received:

- East Ayrshire Council also commented that the Guidance document is clear and will assist industry in implementing the requirements.

The Guidance document will be sent to stakeholders and will also be published on the Agency's website at [www.food.gov.uk](http://www.food.gov.uk).

## **6. Financial Effects**

6.1 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 Union 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.

6.2 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.

6.3 A Regulatory Impact Assessment has been prepared and is available at the address below.

**Food Standards Agency Scotland**  
**2 February 2009**

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## **FULL REGULATORY IMPACT ASSESSMENT**

### **THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2009**

## 1. Title of Proposal

1.1 The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009.

## 2. Purpose and Intend Effect

- Objective

- 2.1 To reduce the long term health risks to consumers in Scotland arising from ingesting chemicals used in the manufacture of plastic food contact materials and articles that may migrate into food and to provide EU harmonised Regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence.
- 2.2 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 Scotland to make them as plain as possible to those that need to refer to them. This decision was taken with industry support.
- 2.3 The proposal is for a Scottish Statutory Instrument (SSI) entitled The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009. The objective of the proposed Regulations is to implement by 7th March 2009 in Scotland in its entirety the provisions of European Commission Directive 2008/39/EC (“the new Directive”) that routinely amends Directive 2002/72/EC (“the principal Directive”) relating to plastic materials and articles intended to come into contact with food. England, Wales and Northern Ireland will make similar legislation.
- 2.4 The proposed Regulations will also revoke *The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008* (SSI 2008/261) (“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.
- 2.5 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 are 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. If you disagree with this assessment, please provide evidence to support your views. **However, no comments were received.**

- **Background**

2.6 Harmonised EU rules on food contact plastics are laid down by 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 for 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 (SCoFAH) 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 Scotland, *The Plastic Materials and Articles in Contact with Food (Scotland) 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).

2.7 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) 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;
- iii) 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);
- 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) Prohibit 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.

2.8 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 for by EFSA is not provided. The provisional list is available from the EC website at:

- **Rationale for Government Intervention**

2.9 Chemical migration from food contact plastics can create 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.

2.10 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 long term health risks to consumers arising from chemical contamination of foods they eat; and
- meet the inter-governmental 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.

2.11 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.

### **3 Consultation**

- **Within Government**

3.1 Other government departments including the Scottish Government DG Health & Wellbeing and DG Rural Affairs & Environment were kept informed of progress in negotiations relating to the European Directive through regular progress reports. To date, no adverse comments have been received from any departments.

- **Public Consultation**

3.2 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, Scottish Federation of Small Businesses 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 Consultation**

- 3.3 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.
- 3.4 Two hundred and eleven stakeholders have been consulted on these proposals. These included industry, research institutes and consumer groups. We also consulted enforcement authorities, public analysts, Scottish Federation of Small Businesses and others interested in policy issues relating to food contact materials.
- 3.5 Three responses were received; one from Scottish Beef Association; one from Aberdeen City Council and one from East Ayrshire Council. Their comments are summarised below:
- 3.6 The Scottish Beef Association accepts the recommendation to enact the legislation to comply with the Commission Directive and fully agree with the draft RIA.
- 3.7 Aberdeen City Council had no comment to make on this occasion.
- 3.8 East Ayrshire Council agrees with the continued use of ambulatory references which avoids the need to introduce a new statutory instrument each time any of the Annexes to Commission Directive 2002/72/EC is updated. They also commented that the Guidance document is clear and will assist industry in implementing the requirements.

## **4 Options**

- **Option 1 - Do Nothing**

- 4.1 This contradicts the UK Government's commitment to meeting its 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.
- 4.2 Failure to fully implement the new Directive would mean that 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.

- **Option 2 - Fully Implement Commission Directive 2008/39/EC.**

- 4.3 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 the 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 SCoFCAG. 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 harmonisation EU rules across all MS.

## **5. Costs and Benefits**

- **Sectors and groups affected**

- 5.1 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 Scotland'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.

- 5.2 Local authorities will continue to benefit from the greater clarity of having the relevant rules and powers contained in one consolidated document.
- 5.3 Charities and voluntary organisations are unaffected by this proposal.
- 5.4 Businesses and LAs will all need to read the new regulations and take appropriate actions to achieve high levels of compliance.

## Benefits

- **Option 1**

- 5.5 There are no incremental benefits for this Option.

- **Option 2**

- 5.6 The recommended option (Option 2) of implementing the provisions of the new Directive into a single consolidated Scottish Statutory Instrument (SSI) 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 non-discriminatory competitive environment both domestically and throughout the EU, which it 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.
- 5.7 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 5.24 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 are asked to comment on our assessment that using only substances from a formal list of substances provides financial benefits. If you disagree, please provide evidence to support your views. ***However, no comments were received from enforcement authorities nor businesses.***

## Costs

- **Option 1**

- 5.8 As explained in paragraph 4.2, the UK has a legal obligation to ensure that the provisions are in place to provide for the implementation of the Commission Directive in full. Failure to do so could result in infraction proceedings against the UK Government, which may result in financial penalties.

- **Option 2**

- 5.9 The cost is based on the fact that Option 2 fully meets the requirements of the proposal.
- 5.10 It is estimated that there will be one-off administration cost to industry and enforcement authorities arising from reading and familiarising themselves with the new Regulations and these are summarised below:

## Costs to Enforcement Authorities

- 5.11 Each local authority (LA) in its area is 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 be affected by these proposals. There may also be ongoing and unchanged cost 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.
- 5.12 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 32 local authorities in Scotland. We have estimated that one enforcement officer in each of the 32 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 £17.89/hour (based on the 2007 Annual Survey of Hours and Earnings (ASHE) data for EHOs updated by 30% to include overheads). This equates to an approximate one-off cost to LAs of £1,150.

## Costs to Industry

- 5.13 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 section paragraph 5.23. The costs to industry are summarised below.
- 5.14 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>2</sup> Thus, the potential impact for a one-off cost to businesses is based on the same principles as those for LAs. If we assume businesses are roughly equally spread by population size then 1,040 businesses in Scotland could be affected by the proposal.
- 5.15 About 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 @ £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 £41,300.
- 5.16 Stakeholders were asked to comment on the assumption that a one-off administration cost associated with the reading and familiarising 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 on the estimates.

## Impact on Other Government Departments Bodies

- 5.17 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 the legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

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<sup>2</sup> Mintel, April 2003

## Economic, Social and Environmental

- 5.18 The social and environmental costs arising from these proposals are negligible. Furthermore, environmental benefits arising from the greater EU harmonisation of these rules permits the move away from some substances that are already persistent in the environment.
- 5.19 Rural areas, disabled people and members of the ethnic communities are not affected by these proposals any differently to others. Charities and voluntary organisations are unlikely to be affected by these proposals.
- 5.20 The Food Standards Agency's remit is to protect the interests 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 impact on the other Government principles of sustainable development.

### **Consultation questions**

Stakeholders were asked to comment 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. If you disagree with this assessment, please provide evidence to support your views.

Stakeholders are 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. Please provide evidence to support your views. ***No adverse comments were received.***

### **Guidance on the proposed Regulations**

- 5.21 The guidance mentioned in paragraph 5.14 above, is aimed primarily at those businesses that are likely to be affected by the proposed Plastic Materials and Articles in Contact with Food (Scotland) 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.
- 5.22 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 reduced risk of illness through exposure to substances that might migrate and might be associated with various 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, 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 reports 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>
- 5.23 The 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 the 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 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 vulnerable people, may be prohibited for use.

- 5.24 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 the EFSA, or because risk assessments have deemed that the substances should no longer be used (e.g. total ban on the substance azodicarbonamide).

## **6 Small Firms Impact Test**

- 6.1 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. The Scottish Federation of Small Business were included in the consultation process and did not raise any concerns.

## **7 'Test Run' of Business Forms**

- 7.1 The Regulation requires 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.

## **8 Competition Assessment**

- 8.1 A competition filter assessment has been carried out and the results indicate 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.

## **9 Enforcement, Sanctions and Monitoring**

### **• Enforcement**

- 9.1 Enforcement of the proposed Regulations is primarily of LAs as defined by the Food Safety Act 1990 and designated in our Regulations. While the making of legislation in Scotland is the function of the Scottish government, the enforcement of food is primarily (but not solely) the responsibility of 32 LAs in Scotland. The proposed Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 will be enforced by these authorities in the normal way.

### **• Sanctions**

- 9.2 No changes to the sanctions are being proposed to those contained in the current Regulations. 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 term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a term of imprisonment not exceeding twelve months or to a fine not exceeding the statutory maximum or both. These penalties are in line with The Food Safety Act 1990.

- **Simplification**

9.3 The opportunity is being taken to maintain a simplified single set of Regulations that avoid numerous amendments. This will 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 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. This will help those that need to refer to the Regulations.

- **Monitoring**

9.4 The authorities in Scotland 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.

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

9.5 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 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 also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which will be reviewed in March 2010.

## **10 Implementation and delivery plan**

10.1 Statutory Instrument will be laid before Parliament in February 2009 with a coming into force date of 7<sup>th</sup> March 2009.

10.2 Guidance for businesses has been developed and has been sent to all stakeholders consulted, informing them of the changes in these proposals. The guidance will also be 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. This note 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.

## **11 Post-implementation review**

11.1 Member States are obliged under the Commission Directive to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with that Regulation. We shall, therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations and work with enforcement authorities where problems or suspected infringements of the Regulations arise. The effectiveness of the SSI will also be monitored via feedback from stakeholders as part of the ongoing policy process. We shall also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from these Regulations, which will be reviewed in March 2010.

## **12 Summary and recommendations**

12.1 The Agency believes that the advantages of full implementation of the proposals within the Plastic Materials and Articles in Contact with Food (Scotland) 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 law in Scotland and that the 2008 Regulations are revoked. Industry fully supports the pursuit of

Option 2 which has the desired effect in achieving the means of adequate implementation of the new Directive. **Option 2 is therefore recommended as a means of achieving this.**

### Summary costs and benefits table

12.2 The cost implications arising from the new Directive as outlined in option 2 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 will implement the requirements of Commission Directive 2008/39/EC, the resources implications are negligible. Guidance prepared on the new Regulations for industry will help minimise costs to business.

Option	Total cost per annum: - economic, environmental, social - policy and administrative	Total benefit per annum: economic, environmental, social	Groups affected
1	Infraction proceedings against the UK Government	None	Enforcement authorities Manufacturers of food packaging, importers and distributors Consumers
2	The cost implications for both industry and enforcement may include a small administration cost of reading the new Regulations.  There will also be the 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 increase.	Increased level of consumer confidence as the UK will enjoy the same enforcement level of protection as the EU. The new Scottish Regulations will ensure that measures, which are applicable throughout the EU are in place, thereby facilitating trade and creating a 'level playing field' and facilitating further trade. Will give enforcement authorities greater clarity provided by the measures within the Regulation.	Enforcement authorities Manufacturers of food packaging, importers and distributors Consumers

### 13 Declaration and publication

*I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs*

**Signed** .....

**Date**

**Minister's name, title, department**

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### Contact Point

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