

EXECUTIVE NOTE

The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008 SSI 2008/127

Description

1. The above instrument was made in exercise of the powers conferred by sections 16(2), 17 (1) and (2), 26(1)(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 European Commission Directive 2007/19/EC that amends Commission Directive 2002/72/EC. The amendment to the 2002 Directive updates the lists of permitted monomers and additives and their conditions of use in the manufacture of food contact plastics. The legal status of the monomers and additives is revised periodically where the European Food Safety Authority has revised an existing opinion or issued a new one on the safe level of a substance that may be ingested daily by a person over a lifetime and where that opinion has been accepted by the European Commission and the Member States.
- 2.2 This instrument also revokes the Plastic Materials and Articles in Contact with Food (Scotland) (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 main legislation in Scotland controlling the substances that may be used in the manufacture of plastics intended to come into contact with food.

3. *Legislative Background*

- 3.1 The Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006 (SSI 2006 No. 517) 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 that is 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.

4. *Policy Background*

- 4.1 It is the intention that the law on materials and articles intended to be brought into contact with food should protect human health from any chronic health effect over a person's lifetime.

Such chronic effect may arise from the consumption of food containing chemicals used in the manufacture of food contact materials and articles. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction. Legislation also aims to protect the nature and quality of the food concerned 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 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.

- 4.2 This latest amendment, arising from Directive 2007/19/EC, sets out to amend the lists of substances by, where necessary, setting new restrictions on their use on the basis of new information becoming available. The 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 particular, the Commission Directive provides for new limitations on the use of and migration limits for certain plasticisers including epoxidised soybean oil (ESBO) and some phthalates. The Directive also seeks to revoke the current suspension on the use of azodicarbonamide as a blowing agent in food contact plastics and replaces it with an outright ban. The Directive also clarifies that gaskets in metal lids fall under the scope of Directive 2002/72/EC and provides 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 was contained in a European Commission (EC) time limited Regulation [*Commission Regulation (EC) No. 372/2007/EC laying down the transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food*]. That Regulation will cease to have effect from 1 July 2008.
- 4.3 Additionally, the Directive bans the manufacture and importation into the EU of those gaskets in lids which do not meet these restrictions and specifications. The Directive also provides for the term ‘plastic mult-layer’ and distinguishes 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). The Directive also requires detailed information on compliance declarations and require that certificates of compliance should attest to the restrictions and/or specifications applicable to them and 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.
- 4.4 The amending Directive also provides 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 may not be manufactured or imported into the European Community

5. Consultation

- 5.1 The Food Standards Agency fully consulted all stakeholders on the proposed Regulations for Scotland. One hundred and ninety six stakeholders were consulted on these proposals, from food industry organisations to manufacturers of affected materials and articles. We included others interested such as enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations.

5.2 Two consultations were carried out, first in November 2007 and then again in February 2008. The second consultation was conducted to ensure that stakeholders had the opportunity to comment on the insertion of the remaining transitional provisions of the amending Directive, which provide for the dates 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.

6. Other Administrations

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

7. Impact

7.1 The primary business sector that will be affected by the regulatory proposals will be manufacturers of food contact plastics, importers and those producing gaskets containing ESBO that are used for sealing glass infant and baby food jars and other plasticisers. The consultation in Scotland produced no comments. In England comments from industry were overall very positive and in favour of the Agency's proposal to amend the food contact plastics legislation. However, one trade association representing manufacturers of plastic packaging raised concerns on the need for in depth information on compliance declarations, which they felt would increase the burden of administrative tasks, and the profound effect this may have on small and medium sized businesses. They were however, unable to quantify this in monetary terms. 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 unaffected by these proposals.

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

Food Standards Agency Scotland

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Contact: Fiona Bruce, Food Standards Agency Scotland, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ fiona.bruce@foodstandards.gsi.gov.uk

www.food.gov.uk



FULL REGULATORY IMPACT ASSESSMENT

**THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND)
REGULATIONS 2008**

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

- 1.1 These Regulations are to be known as The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008.

2. Purpose and Intend Effect

- **Objective**

- 2.1 The purpose of this proposal is to meet several policy objectives. These are: to fulfil our obligations within the European Union; to reduce the risk to consumers of health effects arising from the consumption of harmful levels of chemicals in food; to meet the Lisbon Agenda to improve business competitiveness through harmonised EU legislation; and, to simplify the laws in Scotland.
- 2.2 Our proposal will have the effect of implementing Commission Directive 2007/19/EC relating to plastic materials and articles intended to come into contact with food in its entirety. This will routinely update restrictions on the use of certain substances in the manufacture of food contact plastics. In other areas it will provide particular restrictions for the sum of certain plasticisers and clarify the position that gaskets used in lids fall under the scope of Directive 2002/72/EC.
- 2.3 It will also revoke The Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006 and re-enact the provisions taking into account the amending provisions of Directive 2007/19/EC.
- 2.4 The policy being enacted through these proposals in relation to the EU harmonised legislation applies across the United Kingdom. In consequence, similar, parallel legislation will be made in England, Wales and Northern Ireland.

- **Background**

- 2.5 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 Scotland, the Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006 implement the provisions of Directives 2002/72/EC and 85/572/EEC as amended in each case.
- 2.6 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 a substance 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 the manufacture and importation into the Community of lids containing a gasket which do not comply with the restrictions and specifications for Ref Nos¹. 30340, 30401, 36640², 56800, 76815, 76866, 88640 and 93670 laid down in Directive 2007/72/EC, as amended by Directive 2007/19/EC from 1 July 2008;
- viii) Prohibit 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 from 1 July 2008; and
- ix) Without prejudice to point (b) and (c) above, prohibit 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 2002/72/EC as amended by Directive 2007/19/EC from 1 May 2009.

- **Rationale for Government Intervention**

¹ 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

² This reference is to Azodicarbonamide which is now banned outright.

- 2.7 These proposals fulfil the Government's policies of meeting its EU obligations to bring into effect in law EU harmonised rules that:
- reduce the chronic 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 and that are not over burdensome.
- 2.8 Doing nothing will mean that the Government will fail to implement its policies. 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 this proposal. Failure to implement these proposals in Scotland would not change the position for any business trading in the EU single market. They would have to comply with the proposals being made here if their goods were to be legally compliant elsewhere in the EU.
- 2.9 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. The introduction of harmonised statutory controls reduces the potential for uncertainty or dispute in interpreting the requirements of the Commission Directive.

3. Consultation

- **Within Government**

- 3.1 Departmental economists and the Agency's Better Regulation Unit have been consulted about these proposals. 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. No adverse comments have been received from any departments.

- **Public Consultation**

- 3.2 During the course of negotiations with the European Commission, Food Standards Agency officials have frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities, Scottish Federation of Small Businesses and interested parties with an interest on 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 five years; in 2002, 2004, and 2005 and again in February and March 2006, when these proposals were last amended. Earlier consultation did not raise any adverse comments from stakeholders on these proposals.
- 3.3 Formal consultation on these regulatory proposals for Scotland will not just involve those organisations with an interest in food contact plastics, but also other food packaging manufacturers, importers and processors, enforcement authorities and consumer

organisations. Other organisations who may wish to comment on food contact plastics legislation contained within these proposals are also being consulted.

- **Result of Consultation**

- 3.4 One hundred and ninety six stakeholders were consulted on these proposals, from food industry organisations to manufacturers of affected materials and articles. We included others interested such as enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations. Two consultations were carried out. First in November 2007 and then again in February 2008. The second consultation was conducted to ensure that stakeholders had the opportunity to comment on the insertion of the remaining transitional provisions of the amending Directive, which provide for the dates 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.
- 3.5 In Scotland we had no comments from Industry or enforcement authorities. In England comments from Industry were overall very positive and in favour of the Agency's proposal to amend food contact plastics legislation. However, a trade Association representing the plastic packaging sector raised concerns on the issue of the need for in depth information on compliance declarations and felt that this will increase the burden of administrative tasks, and the profound effect this may have on small and medium size businesses. However, they were unable to quantify the burden in monetary terms.

4. Options

- **Option 1- Do Nothing**

- 4.1 Doing nothing contradicts the 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 from the effect of excessive consumption of substances dealt with in these proposals as consumers in the rest of the EU.

- **Option 2 - Fully Implement Commission Directive 2007/19/EC.**

- 4.2 This option fully meets the Government's commitment to fulfil its EU obligations and contributes significantly to the up-to-date means of protecting consumers from ingesting harmful levels of chemicals that could have migrated from plastic 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 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 legislation we are required to implement Commission Directive 2007/19/EC. Businesses and enforcement authorities want the harmonisation of rules between Member States of the EU that implementation of the Commission Directive provides. This view was supported by stakeholders who commented on the consultation carried out in 2006, when these provisions were last amended. Stakeholders particularly found that full implementation provides scope for a favourable balance between benefits and necessary costs.

5. Costs and Benefits

- **Sectors and groups affected**

- 5.1 The proposals extend harmonisation across the EU on substances that may be used and the conditions that apply to their use in the manufacture of plastic food contact materials and articles. The proposed measures should have equal effect across the European food contact plastics industry, its commercial customers and those that manufacture and/or import plastic food packaging.
- 5.2 Local authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected by these proposals.
- 5.3 Government departments, such as the Food Standards Agency will be affected as and when they carry out any surveys on foods. 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.

Benefits

- **Option 1**

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

- **Option 2**

- 5.5 For businesses, the benefits associated with each option are dependent upon the size of the individual business. However, businesses involved in the manufacture of plastic food contact materials and articles are generally likely to gain from the measures in the 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.
- 5.6 Local authorities will benefit from the greater clarity provided by the measures contained within the Commission Directive. They will also benefit from the power of enforcement devolved to them by the proposed Regulation in Scotland.
- 5.7 This option will also ensure that the potential for consumers being exposed to harmful levels of substances migrating from food contact materials and articles, to the food itself, is minimised. Whilst the potential health benefits are difficult to quantify they are likely to include reducing the risk of illness through exposure to substances that might migrate and

might be associated with various adverse effects on human health. This option may therefore, reduce such burden on the health service through prevention of chronic illness³.

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 It is difficult to estimate the costs to the enforcement authorities without details of the precise regime that will operate; for example what proportion of an authority's budget may be allocated for checking compliance with the proposed Regulations. It is possible; however, that there may be a one-off administrative cost to industry and enforcement authorities, largely in terms of reading and familiarising themselves with the proposed Regulations. There may also be an ongoing and unchanged administrative 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.

5.10 The Food Standards Agency believes that these proposals place no new burdens on businesses. Industry is aware of its responsibility to ensure that they satisfy the requirements of the Commission Directive and to comply with its provisions. Any costs which industry may face and whether this occurs or not will depend on the nature and demand for their products and level of competition in the market. However, the Agency believes that such costs are likely to be insignificant, as earlier consultations have not raised any adverse comments in relation to financial burdens. Indeed, the amending provisions of Directive 2007/19/EC provide business with clear controls and the flexibility to move away from the use of substances that could be harmful to human health in the long term.

- **Economic, Social and Environmental**

5.11 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.

5.12 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.

5.13 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

³ A 1999 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 at the following website:

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

into account in all of its activities and policy decisions. The proposals are unlikely to have any specific impact on sustainability.

- **Policy and administration costs**

5.14 The Food Standards Agency believes that the policy and administration costs are likely to be minimal. There will be a small one-off administration cost to businesses for reading the new legislation; however, this is unlikely to be significant. The Agency will also develop guidance for businesses on the proposed Regulations; such guidance will help minimise the costs to business of reading the new Regulations.

6. Small Firms Impact Test

6.1 The companies involved in this area are represented through their national trade bodies to those at European level. The Scottish Federation of Small Businesses were consulted about the financial implications for small businesses arising from this proposal. We also contacted small businesses to ascertain the impact of the proposal and encouraged them to provide comments.

6.2 The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003⁴, a study of the UK's packaging industry identified 13,000 packaging companies in the UK; combined they employ 250,000 people, half of them had a turnover less than £10 million, and 85% could be classified as small to medium size enterprises.

6.3 The Packaging and Films Association (PAFA) represents the major UK manufacturers of plastic and cellulose films as well as companies that print and convert speciality packaging materials. Food packaging end uses represent a significant proportion of sales and employ 8,000 people, with annual sales of PAFA members exceeding £2 billion.

7 'Test Run' of Business Forms

7.1 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.

8 Competition Assessment

8.1 A competition filter assessment has been carried out and the results indicate that these proposals are unlikely to have any significant effects on competition in the UK marketplace. Option 2 will not have any significant differential impact on businesses already active or involved in the manufacture of food contact materials and articles. Businesses and their relevant trade associations have been fully consulted during negotiations on the amending Commission Directive.

8.2 Industry and businesses have been closely involved at European level in the development of these proposals and have not raised any issues that indicate a disadvantage to any particular business sector. The proposals apply equally to all plastic materials and articles intended to

⁴ Mintel, April 2003

be brought into contact with food and will not therefore disadvantage any particular business sector.

9 Enforcement, Sanctions and Monitoring

• Enforcement

- 9.1 Local 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 in Contact with Food (Scotland) Regulations 2008 will be enforced by these authorities in the normal way.
- 9.2 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.

• Sanctions

- 9.3 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.

• 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 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 also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from these Regulations.

10. Implementation and delivery plan

- 10.1 The Scottish Statutory Instrument will be laid before Parliament during March 2008 with a coming into force date of 1st May 2008.

10.2 Guidance for businesses 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. 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 Directive. The authorities in Scotland routinely monitor foodstuffs on sale to the public to ensure compliance with regulations. The results of this work are published and are openly available. 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.

12. Summary and recommendations

12.1 The proposal here implements Commission Directive which provides businesses with harmonised rules that apply across the European Union.

12.2 The Agency believes that the advantages of full implementation of the proposals that is the subject of this regulatory impact assessment will benefit industry, enforcement authorities and consumers. We recommend that the Commission Directive is enforced and implemented into law in Scotland and the 2006 Regulations are revoked and remade with necessary amendments. Industry fully supports the pursuit of Option 2 which has the desired effect in achieving the means of adequate enforcing and implementing of the Commission Directive. **Option 2 is therefore recommended as a means of achieving this.**

- **Summary costs and benefits table**

12.3 The cost implications arising from Option 2 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008 will implement the requirements of Commission Directive 2007/19/EC, the resource implications of which are negligible.

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	None	Infraction proceedings against the UK Government
2	<p>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.</p> <p>Will give enforcement authorities greater clarity provided by the measures within the Regulation.</p> <p>Ensure that the potential for consumers being exposed to harmful levels of substances migrating from food contact materials and articles, to the food itself, is minimised.</p>	<p>The cost implications for both industry and enforcement may include a small administration cost of reading the new Regulations.</p> <p>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.</p>

13. Declaration and publication

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

Signed S. ROBISON.....

Date 19 March 2008

Shona Robison, Minister for Public Health

Contact Point

Fiona Bruce
 Contaminants, Hygiene, Additives & Shellfish Branch
 Food Standards Agency Scotland
 6th Floor, St Magnus House
 25 Guild Street
 Aberdeen
 AB11 6NJ

Tel No 01224 285170 Fax No 01224 285168
 E-mail: fiona.bruce@foodstandards.gsi.gov.uk