

## EXECUTIVE NOTE

### **The Plastic Materials and Articles in Contact with Food (Lid Gasket) (Scotland) Regulations 2007 SSI/2007/433**

#### **Description**

1. The above instrument was made under the powers in section 16(2), 17(2), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990 and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency. The instrument is subject to negative resolution procedure.

#### **2. Policy Objective**

2.1 This instrument provides for the enforcement in Scotland of Commission Regulation (EC) No. 372/2007 (“the Commission Regulations”), which lays down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food.

2.2 This instrument will put in place offences that may be prosecuted before the Courts where alleged breaches of the Commission Regulation arise; defences against alleged breaches under particular circumstances and penalties that the Courts may apply upon conviction for an offence.

2.3 This instrument which will apply to Scotland is to be a short-lived measure to last until June 2008, when the Commission Regulation expires.

#### **3. Legislative Background**

3.1 Gasket in lids, for glass jars, intended to come into contact with food fall under the scope of Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs which, as last amended by Directive 2005/79/EC, is given effect in Scottish law under other Regulations<sup>1</sup>. However, the Directive applies to materials and articles, and parts thereof, which consist exclusively of plastics. Gaskets in metal lids could alternatively be regarded as a plastic part of a material or article and thus covered by Directive 2002/72/EC or as a plastic coating on a metal substrate, and hence, not covered by that Directive. Consequently, there are separate rules across Member States that may pose a barrier to trade. As such, it has been necessary to clarify the position regarding gaskets in lids and fix transitional specific migration limits (SMLs). These SMLs will apply to the sum of a number of plasticisers used in gaskets in lids coming into contact with fatty foods and permit the free circulation within the Community of those products affected. At the same time, those lids that pose a significant risk are immediately excluded from the market. The Commission Regulation also provides industry with sufficient time to finalise the

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<sup>1</sup> The Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006

development of gaskets that are compliant with the SMLs laid down in Directive 2002/72/EC, as amended by Directive 2007/19/EC<sup>2</sup>.

- 3.2 The Commission Regulations make provisions that will in force until that amendment takes affect in our national law from 1 July 2008.

#### **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 acute adverse effects and from any chronic health effect over a person's lifetime arising from the consumption of food that could be contaminated with chemicals used in the manufacture of the materials and articles. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction. It also aims to protect the nature and quality of the food concerned and to provide the 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 EU Member States

#### **5. Consultation**

- 5.1 One hundred and sixty eight stakeholders were consulted on these proposals. These ranged from food industry organisations to sector specific organisations such as those manufacturers of food contact plastics and more specifically those companies involved in the manufacture of gaskets used in lids intended to come into contact with food. Others with an interest in food contact materials legislation have also been consulted. We also consulted enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations. Industry fully supports the Agency's proposal to provide for the enforcement of the Commission Regulation.

#### **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 Food Standards Agency fully consulted all stakeholders on the proposed regulations. The primary business sector that will be affected by the regulatory proposals will be manufacturers of food contact plastics, including those companies that specifically manufacture gaskets for use in lids using the substances with restrictions laid down in the Commission Regulation. The consultation confirmed that the measures proposed have no specific extra requirements that lay any new financial burdens. The Packaging and Films Association (PAFA) indicated that as none of its member companies were either involved in the manufacture or import of gaskets or of lids containing gaskets intended for food applications, the requirements of the Commission Regulation did not directly apply to their members. However, they fully supported the development of proportionate and workable legislation, and appropriate enforcement policies, that are consistent with the principles of good regulatory practice.

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<sup>2</sup> Commission Directive 2007/19/EC amending Commission Directive 2002/72/EC and Directive 85/572/EC relating to plastic materials and articles intended to come into contact with food.

- 7.2 Rural areas, members of ethnic communities of any particular racial group and disabled people are unaffected by these proposals. Charities and voluntary organisations are also unaffected by these proposals. This view is echoed by industry.
- 7.3 A Regulatory Impact Assessment has been prepared and is available at the address below.

**Food Standards Agency Scotland**  
**18 September 2007**

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## FULL 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 (Lid Gasket) (Scotland) Regulations 2007.

### 2. Purpose and Intended Effect

#### • Objective

- 2.1 The purpose of these proposals is to meet the Government's commitment to honour its EU obligations within the European Union and reduce the risk to consumers of health effects arising from the consumption of harmful levels of chemicals in food.
- 2.2 Our proposal will make provisions for the enforcement of Commission Regulation (EC) No. 372/2007, which lays down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food ("the Commission Regulations"). It will put in place offences that may be prosecuted before the Courts where alleged breaches of the Commission Regulation arise, defences against those alleged breaches under particular circumstances and penalties to apply on conviction of an offence under them.
- 2.3 The proposed Regulations, which will apply to Scotland, are to be a short-lived measure to last until June 2008, when the European Regulation expires. They will provide for the enforcement of that European Regulation in Scotland, by the enforcement authorities.
- 2.4 This Regulatory Impact Assessment (RIA) is concerned only with the enforcement of the Commission Regulation insofar as it applies to Scotland.
- 2.5 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

- 2.6 Gaskets and lids intended to come into direct contact with food will come within scope of Commission Directive 2002/72/EC as amended from 1 May 2008 (that Directive is as currently amended is given effect in Scottish law under other Regulations<sup>3</sup>). However, the Directive applies to materials and articles, and parts thereof, which consist exclusively of plastics or are composed of two or more layers consisting exclusively of plastics. Manufacturing technology has developed since provisions were originally made for gaskets under that Directive. This has resulted in an ambiguity in how gaskets in metal lids could be dealt with under the rules. In some cases they may be regarded as a plastic part of a material and thus covered by Directive 2002/72/EC, but in others as a plastic coating on a metal substrate that would not be covered by that Directive. The Directive is therefore being amended to clear up this ambiguity and this transitional European legislation make provisions that will be in force until 30th June 2008.
- 2.7 Consequently, to prevent the ambiguity becoming a barrier to trade and to ensure the free flow of goods on the market it has been necessary to clarify the position regarding gaskets in

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<sup>3</sup> The Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006 (SSI 2006 No. 517)

lids and fix transitional specific migration limits (SML) for some substances used in their manufacture. These SML's will apply to the sum of a number of plasticisers used in gaskets in lids coming into contact with fatty foods. The Commission Regulation authorises the free circulation of products that comply with these rules, and immediately excludes from the market those lids that pose a significant risk if used in contact with fatty foods. The Commission Regulation also provides industry sufficient time to finalise the development of gaskets that are compliant with the restrictions laid down in Directive 2002/72/EC, as amended by Directive 2007/19/EC<sup>4</sup>.

2.8 The plasticisers with transitional SML's are:

- Epoxidised soybean oil (ESBO);
- Acetylated mono- and diglycerides of fatty acids;
- Polyester of adipic acid with glycerol or pentaerythritol, esters and even numbered, unbranched C<sub>12</sub>- C<sub>22</sub> fatty acids;
- Tri-n-butyl citrate;
- Glycerol monolaurate diacetate and 12-(Acetoxy) stearic acid, 2,3-bis(acetoxy)-propyl ester; and,
- Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropylene-glycol with adipic acid, also end-capped with acetic acid or fatty acids C<sub>12</sub>-C<sub>18</sub> or n-octanol and/or n-decanol

2.9 Regulatory proposals to give effect in Scottish law to Directive 2007/19/EC will be the subject of a separate consultation in October 2007 so that it can come into force when this temporary proposal expires.

- **Rationale for Government Intervention**

2.10 These proposals fulfil the Government's policies of meeting its EU obligations. These are to keep food safe by reducing the chronic long term health risks to consumers arising from chemical contamination of foodstuffs they eat, to reduce the potential for avoidable chemical migration resulting in food incidents and to meet the Lisbon Agenda to improve competitiveness of business in Europe by providing harmonised rules within which businesses can compete.

2.11 To do nothing would leave enforcement authorities without adequate statutory powers to prevent the placing on the market of those products that fail to comply with the restrictions in the Commission Regulation, and that do not conform to the requirements deemed necessary to assure protection of the health of consumers.

2.12 The Food Standards Agency believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and allows technological innovation. Consumer protection will be enhanced in an area of food control where inadequate controls could have serious long-term implications or are seriously suspected of carrying an unacceptable risk to consumer health, particularly among more vulnerable people. The introduction of harmonised statutory controls would reduce the potential for uncertainty or dispute in interpreting the requirements of the Commission Regulation.

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<sup>4</sup> Directive 2007/19/EC, amending Commission Directive 2002/72/EC and 85/572/EC, relating to plastic materials and articles intended to come into contact with food. Published in the Official Journal of the European Communities ((OJ) reference L97, 12.4.2007, pp50-69)

### **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 Commission Regulation 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 Food Standards Agency has frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities, Scottish Federation of Small Businesses and other interested parties with an interest on policy issues related to food contact materials. An informal consultation was carried out in October 2005 and the proposal was also discussed during regular meetings with stakeholder groups that are likely to be directly affected by the requirements of the Commission Regulation.

3.3 Because of the short nature of the Commission Regulation, the formal consultation in July was limited to six weeks as opposed to the normal 12 weeks. Formal consultation on these regulatory proposals for Scotland involved organisations with an interest in food contact plastics; companies that manufacture gaskets for lids; food packaging manufacturers and processors, enforcement authorities and consumer organisations were also consulted. Other organisations who may wish to comment on food contact plastics legislation contained within these proposals were also consulted.

- **Result of Consultation**

3.4 One hundred and sixty eight stakeholders were consulted on these proposals. These ranged from food industry organisations to sector specific organisations such as those manufacturers of materials and articles intended to come into contact with food and others with an interest in food contact materials legislation. We also consulted enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations. No comments were received from these organisations of any financial costs to small businesses from this proposal.

3.5 Only three responses were received two of which were no comment, the other one was from Packaging and Films Association (PAFA), which is one of the trade associations representing major UK manufacturers of plastic and cellulose films, as well as companies that print and convert speciality packaging materials. Consultation comments on drafting detail have been acted upon where necessary.

### **4. Options**

- **Option 1 - Do Nothing**

4.1 Doing nothing will not prevent the Commission Regulation applying in Scotland; it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it. Therefore, the obligation to put in place provisions for its enforcement, for offences to be prosecuted and for penalties for those found to be in breach of the Regulation will not have been fulfilled.

This would lead to the Government being cited in infraction proceedings by the Commission.

- **Option 2 – Fully implement the necessary requirements that will support the European Regulation and provide for its enforcement.**

4.2 This option meets the Government’s commitment to fulfil its EU obligations and contributes significantly to providing for the up-to-date means of protecting consumers from ingesting harmful levels of chemicals that could have migrated from the materials or articles that were intended to be brought into contact with the food. As the Commission Regulation is already in force, we are required to provide for its enforcement in Scotland. This ensures that the enforcement authorities can fulfil the requirements placed upon them and the Courts can impose the penalties that are in line with penalties that apply elsewhere in our food law. It also provides for defences in law for those against whom offences may be alleged in Court.

## **5. Costs and Benefits**

- **Sectors and groups affected**

5.1 Typically, businesses affected by these proposals are those that manufacture and/or import food packaging, including, those companies that specifically manufacture gaskets for use in lids using the substances with restrictions laid down in the Commission Regulation.

5.2 Local authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.

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.

5.4 The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003<sup>5</sup>, a study of the UK’s packaging industry identified 13,000 packaging companies in the UK; half of them had a turnover less than £10 million, and 85% could be classified as small to medium size enterprises.

5.5 Food packaging end uses represent a significant proportion of sales and employ 8,000 people, with annual sales of PAFA members exceeding £2 billion. A key objective of PAFA is to support measures, which assure high standards and quality of packaging materials, including safety for their intended use. The association seeks to play an active and constructive role in the formulation of sensible policy and legislation, at both EU and UK level. PAFA supports the development of proportionate and workable legislation, and appropriate enforcement policies, that are consistent with principles of good regulatory practice. The potential commercial impact of the proposals applies equally to all businesses involved small or large - a view supported by PAFA.

## **Benefits**

- **Option 1**

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<sup>5</sup> Mintel, April 2003

5.6 There are no identifiable incremental benefits from following this option.

- **Option 2**

5.7 This option would provide enforcement authorities with the necessary powers to enforce the Commission Regulation. Also, local authorities will benefit from the greater clarity provided by the Regulation and from the power of enforcement devolved to them by these Regulations.

5.8 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, are 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 illness. A 1999 report (conducted by the Department of Environment, Food and Rural Affairs (DEFRA)), 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>

5.9 Businesses involved in the manufacture of food contact materials and articles will gain from the Regulations by ensuring a non-discriminatory competitive environment both domestically and throughout the EU, which in turn may facilitate further trade. Although PAFA were unable to provide comments directly related to the proposal (as none of their members, to their knowledge are involved in the manufacture of gaskets or gaskets in lids), they did however, support the development of proportionate and workable legislation, and appropriate enforcement policies, that are consistent with principles of good regulatory practice.

## Costs

- **Option 1**

5.10 European Community Regulations are binding in their entirety and directly applicable in all EU Member States from the date that they take effect. The UK therefore, has a legal obligation to ensure that the provisions are in place to provide for the enforcement of the Commission Regulation in full. Failure to do so will result in infraction proceedings against the UK Government, which may result in financial penalties. It would also leave the UK enforcement authorities without any domestic legislation for the enforcement and execution of the Commission Regulation.

- **Option 2**

5.11 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 new limits. The Food Standards Agency believes that the incremental financial costs to enforcement authorities are unlikely to have a significant cost impact and is likely to be minimal, if any. Local authority enforcement bodies have always had responsibility for the enforcement of food contact materials legislation. The proposed Regulations merely provide the means by which this role can be extended to cover the Commission Regulation. There were no comments from enforcement

authorities on any likely financial costs associated with the enforcement provisions of the Commission Regulation.

5.12 The Food Standards Agency believes that these proposals place no new burdens on businesses. Industry are aware that restrictions for certain substances used in gaskets in lids might be set, as such it is the responsibility of businesses to ensure that they satisfy the requirements of the Commission Regulation. The Agency has developed guidance for businesses on these new Regulations (see Para. 9.2). Such guidance will help minimise cost to businesses of the new Regulations. There may be some incidental costs to business or reading the new legislation, however this is likely to be minimal. This view was supported by the Laboratory of Government Chemists, who indicated that the administrative burden on businesses, and most or all Small/Medium Enterprises, is minimised by legislation that presents their rights transparently. Indeed, the migration limits established by the Commission Regulation 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. At the same time it allows industry sufficient time to finalise the development of gaskets that are compliant with the SML laid down in Directive 2002/72/EC, as amended by Directive 2007/19/EC.

- **Economic, Social and Environmental**

5.13 The social and environmental cost arising from these proposals are negligible.

5.14 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.

5.15 The Food Standards Agency's remit is to protect the interests of consumers in relation to food, 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 proposals are unlikely to have any specific impact on sustainability.

- **Policy and administration costs**

5.16 The Food Standards Agency believes that the policy and administration costs are likely to be minimal. There will be a small administration cost to business of reading the new legislation, and as this is a time limited measure, which does not represent any new compulsory action, there will be no administrative burden placed on business.

## **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 these proposal. However, no comment was received.

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

7.1 There are no forms associated with this piece of legislation.

## **8. Competition Assessment**

- 8.1 The Competition Filter Test has been completed and it has confirmed that none of the options raise competition concerns. The provisions for enforcement powers to the proper authorities in Scotland do not place any hindrance on the competitiveness of business, nor does the alignment of penalties for offences with those that apply elsewhere in food law. As these proposals relate to offences where breaches arise, defences that might apply in the event of prosecution for alleged offences and penalties that apply on conviction for the offence, they are unlikely to raise any competition concerns. This view is supported by the Office of Fair Trading.
- 8.2 Economically, a lot depends upon the businesses' profit margins as to whether there will be any effect on competition. Some firms may be able to compete in the industry because their costs are equal to, or only just below, their revenues. If their costs increase even a little, and they are unable to pass these costs on to the consumer, then their business will suffer.
- 8.3 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 consultation carried out in October 2005 did not indicate any disadvantage to any particular business, or company. The proposals apply equally to all existing and new manufacturers of gaskets in lids intended to be brought into contact with food.

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

### **• Enforcement**

- 9.1 Local authorities are responsible for enforcing a large proportion of Regulations with respect of 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 Regulations on which we have consulted merely provide the means by which this role can be extended so as additionally to cover the Commission Regulation.

### **• Sanctions**

- 9.2 A person who fails to comply with the requirements of Regulation 372/2007 is liable, if convicted of an offence on indictment under Section 4(1)(a) under these proposed Regulations, to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction they are liable to a term of imprisonment not exceeding six months or to a fine not exceeding the statutory maximum or both. These penalties are in line with The Food Safety Act 1990, as amended.

### **• Monitoring**

- 9.3 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. 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 talk to industry to ensure that no unforeseen difficulties arise from these Regulations.

## **10. Implementation and delivery plan**

- 10.1 The Statutory Instrument will be laid before Parliament in September 2007 with a coming into force date of 29<sup>th</sup> October 2007.
- 10.2 Guidance for businesses has been developed and will be 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 Regulation to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with that Regulation. 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 SI 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.
- 11.2 The need to review the Regulations will not be necessary as they put in place interim measures which are only valid until the end of June 2008.

## **12. Summary and recommendations**

- 12.1 The proposals here provide for the effective enforcement of Commission Regulation and they also provide 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 the subject of this regulatory impact assessment will benefit industry, enforcement authorities and consumers. The measures proposed are important in providing the means for improved enforcement and essential consumer health protection and improved products. We recommend that Regulation 372/2007/EC is enforced and implemented into law in Scotland. Industry fully supports the pursuit of Option 2 which has the desired effect in achieving the means of adequate enforcement of Regulation 372/2007/EC. **Option 2 is therefore recommended as a means of achieving this.**

- **Summary costs and benefits table**

12.3 The cost implications arising from the EC Regulation and as outlined in option 2 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Lid Gasket) (Scotland) Regulations 2007, merely extend existing statutory controls so as to provide for the enforcement of Regulation (EC) No. 372/2007/EC and the resources implications are negligible. Guidance prepared on the new Regulations for industry will help minimise costs to business.

<b>Option</b>	<b>Total cost per annum: - economic, environmental, social - policy and administrative</b>	<b>Total benefit per annum: economic, environmental, social</b>	<b>Groups affected</b>
1	<ul style="list-style-type: none"> <li>• Infraction proceedings against the UK Government</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>	<ul style="list-style-type: none"> <li>• Enforcement authorities</li> <li>• Manufacturers of food packaging, specifically including those companies manufacturing gaskets in lids intended for food contact, importers and distributors</li> <li>• Consumers</li> </ul>
2	<ul style="list-style-type: none"> <li>• No quantifiable information was received by the Agency following the consultation in 2005 or the recent consultation in May 2007 in respect of Regulation 372/2007/EC.</li> <li>• The cost implications for businesses may include a small administration cost of reading the new Regulations. However, since this is already a legal requirement, this is not a new cost burden; and also, because the Scottish Regulations are a short-lived measure which will expire once the Commission Regulations are no longer applicable.</li> <li>• By enabling enforcement of the Commission Regulation, for defences against alleged offences, and for penalties upon conviction for an</li> </ul>	<ul style="list-style-type: none"> <li>• Increased level of consumer confidence as the UK will enjoy the same enforcement level of protection as the EU.</li> <li>• 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.</li> </ul>	<ul style="list-style-type: none"> <li>• Enforcement authorities</li> <li>• Manufacturers of food packaging, specifically including those companies manufacturing gaskets in lids intended for food contact, importers and distributors</li> <li>• Consumers</li> </ul>

	<p>offence, enforcement authorities might incur some additional resource costs. However these are likely to be negligible.</p>		
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**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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