

EXECUTIVE NOTE

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

Description

1. The above instrument was made under the powers in section 6(4), 16(2), 17(1) and (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 and after consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council. The instrument is subject to negative resolution procedure.

Policy Objective

2. This instrument implements European Commission Directive 2005/79/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.
3. This instrument also revokes the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006 [SSI 2006/314] and re-enacts their provisions, amended to take into account the provisions of Commission Directive 2005/79/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.

Legislative Background

4. The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006 implement 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.

Policy Background

5. 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 five 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.
6. This latest amendment, arising from Directive 2005/79/EC, sets out to amend the lists of substances by, where necessary, setting new restrictions on their use on the basis of new information that has become available. In particular, for epoxidised soybean oil (ESBO), a specific limit of migration from food contact plastics into food has been established for its use in PVC gaskets used to seal the lids of glass food jars. The Specific Migration Limit (SML) is 60 milligrams of ESBO per kilogram of food or food simulant. The manufacture and import of non-compliant materials and articles is prohibited from 19 November 2007. This allows time for the manufacturers of these materials and articles to change the constituents of their products where necessary, without risking the safety of foodstuffs and their ability to comply with the law.
7. However, for those ESBO-containing PVC gaskets used to seal the lids of glass food jars containing infant and follow-on formulae, or containing processed cereal based foods and baby foods for infants and young children, the SML for ESBO has been set at 30 milligrams per kilogram of food or food simulant. Additionally, the EC Directive requires that the gaskets containing ESBO used in these applications be compliant with this migration limit by 19 November 2006. This lower migration limit takes into account the fact that babies and infants can consume proportionately higher amounts of food from this source than adults, given their much smaller body weight. This lower migration limit will help ensure that infants and young children who regularly eat these foods will not exceed the amount considered safe to consume daily over a lifetime - the Tolerable Daily Intake. The SML of 60 milligrams of ESBO per kilogram of food or food simulant remains unchanged for all other applications.
8. Goods in sealed glass jars manufactured using ESBO and compliant with the rules in place before this change takes effect on 19 November 2006, may continue to be placed on the market providing those jars are marked with the date of filling or a code representing that date (being a date earlier than 19 November 2006).

Consultation

9. One hundred and seventy nine stakeholders were consulted on the draft Regulations, ranging 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, the Scottish Federation of Small Businesses and consumer organisations. One response was received. Industry fully supports the Agency's proposal to amend food contact plastics legislation in Scotland and particularly welcomed the consolidation into a single instrument.

Other Administrations

10. Similar Regulations will apply in England, Wales and Northern Ireland.

Impact

11. 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 and those producing PVC gaskets containing ESBO that are used for sealing glass infant and baby food jars. However, consultation has confirmed that the measures proposed impose no new financial burdens. Indeed this view was further supported by industry who stated that these proposals would not disproportionately affect small or medium-sized firms nor would they hinder competitiveness. The proposals 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. A view echoed by industry. Charities and voluntary organisations are unaffected by these proposals.
12. A Regulatory Impact Assessment has been prepared and is available at the address below.

Contact

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Food Standards Agency Scotland
25 October 2006

FULL REGULATORY IMPACT ASSESSMENT

THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) (NO.2) REGULATIONS 2006 SSI/2006/517

1 Title of proposal

These Regulations are to be known as The Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006

2 Purpose and intended 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 2005/79/EC relating to plastic materials and articles intended to come into contact with food in its entirety, via the Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006. This will routinely update restrictions on the use of certain substances in the manufacture of food contact plastics and provide for particular restrictions on the use of epoxidised soybean oil (ESBO) in the manufacture of sealing gaskets used in the lids of glass food jars.

2.3 It will also revoke the Plastic Materials and Articles in contact with Food (Scotland) Regulations 2006 and re-enact their provisions, amended to take into account the requirements of EC Directive 2005/79/EC. Similar measures are being undertaken by Scotland, Wales and Northern Ireland, which will culminate in parallel, but separate legislation. This will complete the second part of a two stage strategy to simplify, in Scotland, the rules they contain. This will complete the second part of a two-stage strategy to simplify, in Scotland, the rules they contain. The first part of the strategy was completed with the coming into force of those first 2006 Regulations. This second part of the strategy will ensure that we reduce the number of places in which substance restrictions and other substance usage information are recorded. This will help those that need to refer to the technical lists of substances by ensuring that they have as few documents to consult as possible as well as reduce the risk of error that may arise in repeating those lists in our regulations.

2.4 The Regulations being proposed will need to be in place by 19 November 2006.

- **Background**

2.5 Harmonised European rules on food contact plastics are laid down by Commission Directive 2002/72/EC. These rules are routinely amended as technical and scientific knowledge enables experts within the European Food Safety Authority to evaluate or re-evaluate any risk for public health arising from the migration of chemicals from food contact materials into food. The latest of these amendments is contained in Commission Directive 2005/79/EC that these proposals would implement. In Scotland, the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006 implemented the requirements of Directive 2002/72/EC. They also revoked and consolidated *The Plastic Materials and Articles in Contact with Food Regulations 1998* and five sets of amending regulations into one comprehensive set of Regulations.

- ◆ **Simplification**

2.6 We are now, in this second of our two stage simplification process, proposing to revoke those 2006 Regulations and re-enact their provisions taking into account the provisions of Directive 2005/79/EC. Within this proposal we are not reproducing the detailed, technical lists of substances that are given in the EC Directive, instead the proposal makes appropriate references to those lists. This avoids the risk of error in the lists, as they would appear in schedules in our regulations, it also avoids unnecessary duplication that would complicate ensuring compliance for businesses and monitoring compliance by the authorities. In doing this, it is our intention to continue to make Regulations simpler, easier to understand, easier to comply with and easier to enforce.

◆ ESBO

2.7 For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. In particular, for ESBO, a specific limit of migration from food contact plastics into food has been established for its use in PVC gaskets used to seal the lids of glass food jars. This Specific Migration Limit (SML) is 60 milligrams of ESBO per kilogram of food or food simulant. Along with the restrictions in the 2005 EC Directive for other substances, materials and articles compliant with this limit may be traded and used from 19 November 2006. The manufacture and import of non-compliant materials and articles is prohibited from 19 November 2007. This allows time for the manufacturers of these materials and articles to change the constituents of their products where necessary, without risking the safety of foodstuffs and their ability to comply with the law.

2.8 However, for PVC gaskets containing ESBO used to seal the lids of glass food jars containing infant and follow-on formulae, or containing processed cereal-based foods and baby foods for infants and young children, the SML for ESBO has been set at half the limit for other applications. The limit in these cases is 30 milligrams per kilogram of food or simulant. Additionally, the EC Directive requires that the ESBO-containing gaskets used in these applications be compliant with this migration limit by 19 November 2006. This lower migration limit takes account of the fact babies and infants can consume proportionately higher amounts of food from this source than adults, given their much smaller body weight. Goods manufactured using ESBO and compliant with the rules in place before this change takes effect on 19 November 2006, may continue to be placed on the market providing they are marked with the date of filling or a code representing that date.

• Rationale for government intervention

2.9 The Food Standards Agency (FSA) believes that the adoption of these proposals provides essential powers to enforce the modernised and harmonised regulatory framework that removes trade barriers and allows for technological innovation. Consumer protection will continue in an area of food control where inadequate controls could have serious long-term implications for the prevention of human cancers, gene mutations and reproductive defects arising from the ingestion of amounts of substances known to carry, or are seriously suspected of carrying, an unacceptable risk to consumer health, particularly among more vulnerable people. Stakeholders were asked to comment on the possible health costs arising from these proposals, in relation to chemical contamination of foodstuffs from materials and articles that are brought into contact with food. However, no comments were received.

2.10 Doing nothing will mean that the Government will fail to implement the first and last of these policies in failing to implement the provisions of Directive 2005/79/EC. 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. If their goods were to be considered legally compliant elsewhere in the EU, they would have to comply with the proposals being made here.

3 Consultation

• Within government

3.1 The Scottish Federation of Small Businesses were routinely consulted on these proposals. The Department of Health was also contacted about health affects. There were no comments on the particular issues being discussed hear.

- **Public consultation**

3.2 Key European consumer and industry sector representative organisations have been involved in the development of these proposals. In the UK all organisations on the Agency's database of contacts with an interest in the development of policy, issues and legislation in plastic food contact materials were consulted on the initial development of proposals in 2002, again in 2004, 2005 and again in February 2006 when those proposals were last amended. Informal meetings with the key industry sector have taken place when these proposals were being negotiated. Formal consultation on these regulatory proposals for Scotland will involve not just those organisations with an interest in food contact plastics, but also those manufacturing PVC gaskets containing (ESBO). Enforcement authorities, consumer organisations and others who may wish to comment on the food contact plastics legislation contained within these proposals were also consulted.

- **Result of Consultation**

3.3 One hundred and seventy nine stakeholders were consulted on these proposals. These ranged from food industry organisations to sector specific organisation, such as those representing manufacturers of food contact plastics, coated cans and multi-layered boned packaging and others with an interest in food contact plastics. We also consulted enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations.

3.4 Only one response was received from East Ayrshire Council noting the change in the Regulation.

4 Options

Two options have been considered

- **Option 1 – Do nothing.**

4.1 These proposals fulfil the Government's policies of meeting its EU obligations; of keeping food safe by reducing the risks to consumers from chemical contamination; of meeting the Lisbon agenda to improve the competitiveness of businesses in Europe by providing harmonised rules within which businesses compete; and, of simplifying the laws in Scotland. Doing nothing will mean that the Government will fail to implement the first and last of these 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. In addition 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.

- **Option 2 - Fully implement Commission Directive 2005/79/EC**

4.2 This option meets the Governments 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. It will do this without stifling innovation and technological development that is so necessary to businesses because it increases the harmonisation of rules across the EU. The UK was involved with the Commission and other Member States throughout the informal and formal negotiation of this Directive in the EC working group and the Standing Committee on the Food Chain and Animal Health. Under EC legislation we are required to implement Directive 2005/79/EC. Enforcement authorities want the improved clarity contained in these proposals, consumers want the improved public health protection given by these proposals and businesses want the harmonisation of rules between Member States of the EU that implementation of this EC Directive in Scotland provides.

5 Costs and benefits

Sectors and groups affected

- **Benefits**

5.1 Benefits arising from option 1 (see paragraph 4.1) are minimal if any. Food contact plastic manufacturing companies would still have to comply with the Directive that these proposals implement, as it is enacted throughout the rest of the EU. Failure to do so would impair the companies' continuing access to the EU market for their products, as most businesses involved operate in a European and even global basis.

5.2 Benefits are maximised under option 2 (see paragraph 4.2). By implementing these measures in full, the Government ensures that UK consumers benefit from increased health protection. Consumers in the UK and throughout the EU will enjoy the same degree of protection from the potential contamination of foodstuffs from substances that may migrate from food contact plastics. This increase in consumer protection is based around the prevention of the public health costs that could be associated with migration of potential genotoxic carcinogens from plastic packaging to food. Full implementation ensures that manufacturers and suppliers of the materials and articles that are the subject of these rules enjoy the benefits of a set of rules that are applied throughout the single market of the EU and that rules move closer to full harmonisation.

5.3 Consumers of foods placed in contact with the materials and articles subject to the provisions in the EC Directive will be assured that there are proper deterrent measures in place to dissuade manufacturers from breaching the EC Directive that seeks to protect their health. Thus, they shall not be exposed to levels of substances assessed to be harmful.

5.4 All enforcement authorities and business that need to refer to the proposed regulations for Scotland will be able to refer to a single set of regulations governing the implementation of the EC Directive and the manufacture of food contact plastics using a wide range of other substances. The proposed single set of regulations will contain the new provisions of Directive 2005/79/EC without duplicating the complex technical lists of substances and restrictions.

5.5 Stakeholders were particularly asked to provide information on the potential benefits on the number of hours possibly reduced/saved and at what level of operator, as a result of having a set of regulations that are easier to understand. The FPA commented that consolidation of the legislation into a single instrument would simplify commercial documentation and aid clarity that would result in administrative savings. However, the FPA were unable to quantify these. The FPA advised that they were unable to estimate the likely savings in terms of public health expenditure that might be incurred as a result of these proposals, but they fully supported the establishment and adoption of statutory limits for food contact substances that accorded with the latest scientific findings of the European Food Safety Authority, in relation to the protection of consumer health.

- **Costs**

5.6 These proposals place no new burdens on businesses, as they simply amend existing EU provisions on food contact plastics. This view is supported by the FPA who stated that they did not foresee any additional costs to manufacturers of food contact plastics arising from the re-introduction of existing Community provisions, statutory defences and penalties for offences. The business sectors most likely to be affected are the manufacturers of food contact plastics and those producing PVC gaskets containing ESBO for use in sealing glass food jars. The FSA does not anticipate any cost implications for businesses arising from these proposals. Indeed, the migration limits established by the EC Directive being implemented by these proposals provide businesses with clear controls and the opportunity to move away from the use of substances that could be more harmful to human health in the long term. This view is supported by the FPA, who have stated that the proposals maximise consumer protection as regards health effects arising from ingestion of chemical substances in food.

5.7 The FSA does not anticipate new cost implications for enforcement authorities arising from these proposals, they simply reinstate their responsibilities that exist under current provisions in the 2006 Regulations that these proposals would revoke. Enforcement authorities were particularly asked to comment on the cost implications to enforcement authorities. However, no comments were received.

- **Economic, Social and Environmental**

5.8 The economic, social and environmental costs from these proposals are negligible. The proposals apply equally to all areas of legislation on food contact materials and articles and thus, the provisions equally affect all businesses involved. Rural areas and members of the Ethnic communities or any particular racial group are not affected by the proposals, any differently to others. Charities and voluntary organisations are unaffected by these proposals. Indeed, this view

is supported by the FPA, who stated that the social impact arising from these proposals is negligible and that the proposals will not impact on racial harmony or equality. They also noted that the reduction in the size of the Regulations from 72 to 32 pages, and the associated energy and material savings arising from their publication in paper form would be beneficial to the environment.

6 Small Firms Impact Test

6.1 The FPA represents UK plastic film producers converters and users with a broad membership ranging from small-localised businesses to large, multi national corporations. The FPA supported the Agency's view that these proposals would not disproportionately affect small or medium sized firms, nor would they hinder competitiveness.

6.2 The FPA fully support the implementation of Commission Directive 2005/79/EC. They commented that whilst it was difficult to furnish precise cost/benefit figures in respect of the new legislation, they were confident that failure to fully implement the provisions of the Directive would present a significant burden to business. As a result of differing requirements for plastics sold in Scotland, compared to those exported to other Member States, the FPA stressed that consolidation of the legislation into a single instrument will simplify commercial documentation and aid clarity and will also result in administrative savings. The FPA also stated that failure to fully implement the Directive would mean that prevailing national legislation would no longer accord with Community provisions.

6.3 The companies involved in this area are represented through their national trade bodies to those at European level. The Agency believes that the financial implications for small and medium sized businesses are likely to be negligible. One of the trade associations (the Metal Packaging Manufacturers Association (MPMA)), representing closure manufacturers supports this view.

6.4 The packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003¹, a study of the UK's packaging industry identified 13,000 packaging companies in the UK, combined they employ 250,000 people. The study also revealed that half of all packaging companies have a turnover less than £10 million, and that 85% are small to medium size enterprises. Plastic packaging accounts for approximately a third of the turnover of the food and drink packaging sector.

6.5 In 2001, the industry employed approximately 100,000 people in around 2,700 companies – 85% of which are described as small-to micro-sized companies. The potential commercial impact of the proposals applies equally to all businesses involved small or large. The figures are representative of the packaging industry as a whole and do not reflect a particular sector or packaging type.

7 “Test Run” of business forms

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

8 Competition assessment

¹ Mintel, April 2003

8.1 The provision for implementing Commission Directive 2005/79/EC does not place any hindrance on the competitiveness of businesses or on enforcement authorities by reinstating their responsibilities that exist under current provisions in the 2006 Regulations.

8.2 Industry and businesses have been closely involved at European level, principally through representation by British businesses in the development of these harmonised EU rules that these proposals relate to and they have not raised any issues that indicate a disadvantage to any particular business sector. The proposals apply equally to all existing and new manufacturers of plastic materials and articles intended to be brought into contact with food and will not therefore disadvantage any particular business sector, nor company.

9 Enforcement, sanctions and monitoring

Enforcement and Sanctions

9.1 Businesses that use the substance referred to in the EC Directive in the manufacture of food contact plastics and PVC gaskets will be affected in so far as they will have returned to them access to defences in the event of prosecution for an alleged offence, but they will also be subject to the reintroduction of the penalties provided for in the proposed regulations if convicted of that offence.

9.2 Responsibility for the enforcement of The Plastic Materials and Articles in Contact with Food (Scotland) (No.2) Regulations 2006 is returned to the responsibility of the local authority, following the removal of the responsibility by revocation of the 2006 Regulations that these proposed Regulations replace. Enforcement in this way is common practice in our food law.

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 fine or imprisonment for a term not exceeding two years or both; on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both. These penalties are in line with The Food Safety Act 1990.

9.4 The Food Standards also has an enforcement role with regard to the EC Regulation 1935/2004 in respect of declarations of compliance. Article 5 of the Regulation requires that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation.

Monitoring

9.5 Member States are obliged under the provisions of the European Regulation to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this 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. We shall also continue routinely 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 by 26th October with a coming into force date of 19 November 2006.

10.2 Guidance for business 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. 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 FSA will continue to consult with Local Authorities, industry and other stakeholders to evaluate the effectiveness of and experience with the legislation. In accordance with the Scottish Executive’s IRIS unit guidelines, this RIA will be reviewed, as appropriate, in order to establish that it is “fit for purpose”. Therefore not adding any additional burdens to businesses. In line with Scottish Executive guidance we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed with 10 years.

12 Summary and recommendation

12.1 The FSA believes that the advantages of full implementation of the proposals within the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006 will benefit industry, enforcement authorities and consumers. The measures proposed are important in providing essential consumer health protection and improved product information. They also provide businesses with harmonised rules and greater transparency in the authorisation of new substances for use in materials and articles in contact with food. The Flexible Packaging Association supports this view. We recommend that Directive 2005/79/EC is implemented into law in Scotland and the 2006 Regulations are revoked. **Therefore, Option 2 is recommended as the means of achieving this**

Summary costs and benefits table

12.2 The cost implication arising from Option 2 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006 will implement the requirements of Commission Directive 2005/79/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	0	0
2	Businesses are likely to benefit from administrative savings arising from the simplification that stem from the consolidation.	The cost implications for businesses arising from these proposals are likely to be negligible.

13 Declaration and publication

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

Signed by the responsible Minister LEWIS MACDONALD.....

Date 25th October 2006.....

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