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FOOD STANDARDS AGENCY SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

EXECUTIVE NOTE

The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006 SSI/2006/314

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(2) 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 provides for the consolidation of the 1998 Plastic Materials and Articles in Contact with Food Regulations as amended, and for the enforcement in Scotland of Commission Regulation (EC) No. 1895/2005, on the restrictions of use of certain epoxy derivatives intended to come into contact with food. As such, the instrument will constitute the main legislation in Scotland controlling the substances that may be used in the manufacture of plastics that are intended to come into contact with food, and setting limits on the degree to which those plastics are permitted to transfer their constituents to food.

Legislative Background

3. The Plastic Materials and Articles in Contact with Food Regulations 1998 (SI 1998/1376) implemented harmonised EU measures contained in adopted EC Directives on materials and articles intended to be brought into contact with food that are manufactured from plastic. 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. In our Regulations, SI 2002 No. 2364 and SI 2004 No. 3113 amended the 1998 Regulations in relation to earlier EU-harmonised provisions on the use of BADGE[1], BFDGE[2] and NOGE[3] and their derivatives in the manufacture of food contact plastics, adhesives and coatings.

[1] 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (otherwise known as 'BADGE')
[2] Bis(-hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (otherwise known as 'BFDGE')
[3] Novolac glycidyl ethers (known as 'NOGE')

4. This instrument will provide for the enforcement, in Scotland by local authorities and port health authorities, of the European Regulation, which replaces Commission Directives 2002/16/EC and 2004/13/EC. Provisions relating to this enforcement include identifying offences that may be prosecuted before the Courts where alleged breaches of the European regulations arise, and providing for defences and transitional arrangements in accordance with the EC Regulation.

5. This instrument will also revoke The Plastic Materials and Articles in Contact with Food Regulations 1998 in Scotland. These 1998 Regulations not only enacted the earlier provisions on epoxy derivatives, they have also enacted the provisions of EC Directive 2002/72/EC and its subsequent amendments on food contact plastics, and in consequence have undergone several major amendments. In view of all the changes to the original 1998 Regulations, the existing five amendments to those Regulations and this sixth amendment would have presented an unmanageable set of regulations for the businesses that have to abide by them and to others who have to work with them, such as enforcement authorities, enforcement laboratories, the Courts and those professionals that act in a consultative capacity to others. Hence the decision to consolidate.

Policy Background

6. 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 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 five EU Member States.

Consultation

7. 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. Two responses were 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

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

Impact

9. The primary business sector that will be affected by the regulatory proposals will be manufacturers of food contact plastics, and those that use the substance 2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropy) ether (BADGE) and certain of its derivatives, in the manufacture of food contact plastics, adhesives and coatings.

However, the consultation confirmed that the measures proposed have no specific extra requirements that lay any new financial burdens. Charities and voluntary organisations are unaffected by these proposals.

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

Contact

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Food Standards Agency Scotland
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FOOD STANDARDS AGENCY
SCOTLAND
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FULL REGULATORY IMPACT ASSESSMENT

THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2006 SSI/2006/314

1 Title of proposal

1.1 These Regulations are to be known as The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006.

2 Purpose and intended effect

- **Objective**

2.1 The purpose of these proposals is to meet four policy objectives. We are seeking to protect human health from consumption of food containing harmful levels of chemicals migrating from materials and articles with which the food has intentionally been placed in contact. Such materials and articles will commonly be food packaging, adhesives and coatings used in the packaging and articles used in the handling and storage of the food. We are also seeking to prevent these chemicals from changing the nature and quality of the food. We are seeking to provide a harmonised set of rules across the European Union with which businesses have to comply to replace and prevent further, purely national rules within EU Member States. The proposals therefore come about from the UK supported adoption in the EU of a European Regulation that achieves these objectives throughout the European Union. Finally, as part of our regulatory simplification programme, we are seeking to consolidate The Plastic Materials and Articles in Contact with Food Regulations 1998 and five amending regulations into one set of regulations. This will make it easier for businesses and others that have to refer to the Regulations to understand their provisions.

2.2 These proposals will have the effect of providing for enforcement by the enforcement authorities in Scotland of Commission Regulation (EC) No. 1895/2005, on the restrictions of use of certain epoxy derivatives in materials and articles intended to come into contact with food. They will also put in place offences that may be prosecuted before the Courts where alleged breaches of the European regulations arise, defences against those alleged breaches under particular circumstances and penalties to apply upon conviction for an offence under them. They will also revoke existing national provisions in our Regulations for Scotland that govern these substances.

2.3 The policy being enacted through these proposals in relation to this EU-harmonised legislation applies across the United Kingdom. In consequence similar, parallel legislation will be made in England, Wales and Northern Ireland.

- **Background**

2.4 A new European Regulation No. (EC) 1895/2005 completely replaces two EC Directives, 2002/16/EC and 2004/13/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with food and, in so doing, updates the provisions of those Directives. We need to provide for the enforcement of that European Regulation, for the application of penalties where offenders are convicted by the Courts, and we need to remove current national provisions that enacted the now revoked EC Directives on these substances. Those older enacting provisions are contained within the Plastic Materials and Articles in Contact with Food Regulations 1998, as amended.

2.5 Removing the provisions on epoxy derivatives from The Plastic Materials and Articles in Contact with Food Regulations 1998 (SI No. 1998/1376) will cause extensive

amendment of those Regulations that also enact the provisions of EC Directive 2002/72/EC on food contact plastics. That Directive has also been amended several times, so not only would this proposal be a major further amendment to the 1998 Regulations, but it would follow five other sets of amending regulations to the 1998 Regulations. We have therefore taken the view that the existing five amendments to the original 1998 Regulations and this sixth amendment would present too unwieldy a set of regulations to the businesses that have to abide by them and to others who have to work with them, such as enforcement authorities, enforcement laboratories, the Courts and those professionals that act as consultants.

2.6 The proposed Regulations that this Regulatory Impact Assessment discusses therefore propose a major simplification of the law. They will consolidate all extant provisions on food contact plastics into one comprehensive set of regulations and revoke original provisions on epoxy derivatives while making the necessary provisions in Scotland for the enforcement of the new European Regulation on certain epoxy derivatives and for offences to be prosecuted, for defences against alleged breaches of the Regulations and for penalties to apply upon conviction for any offence under that Regulation.

- **Rationale for government intervention**

2.7 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 business compete; and, of simplifying the laws in Scotland.

2.8 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 for technological innovation. Consumer protection will continue in an area of food control where inadequate controls would have a 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.

3 Consultation

- **Within government**

3.1 The Scottish Federation of Small Businesses has been consulted on these proposals. We also contacted the Scottish Executive Health Department about health affects. No comments were received from either organisation.

- **Public consultation**

3.2 Key European consumer and industry sector representative organisations have been involved in the development of the European Regulations that these proposals deal with in relation to Scotland. In the UK all organisations on the Agency's database of contacts with an interest in the development of policy, issues and legislation in food contact materials were consulted on the initial development of proposals in 2002, again in 2004 when those proposals were last amended, and informal meetings with the key industry sector have

taken place as the European Regulations that give rise to these proposals were being negotiated. Formal consultation on these regulatory proposals for Scotland involved not just those organisations with an interest in epoxy derivatives, but also those with an interest in food contact plastics who may wish to comment on the simplification of food contact plastics legislation contained within these proposals.

- **Results of the Consultation**

3.3 One hundred and seventy nine stakeholders were consulted on these proposals. Organisations consulted ranged from food industry organisations to sector specific organisations, such as those representing manufacturers of coated cans and multi-layered bonded packaging, and to those with an interest in food contact plastics. We also consulted enforcement authorities, the Scottish Federation of Small Businesses Service and consumer organisations. Two responses were received in Scotland both of whom were content with the new Regulation.

4 Options

- **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 business 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. The European regulation will still apply, but the obligation to put in place provisions to enable its enforcement, to provide for offences to be prosecuted, for defences for those that could have been prosecuted and to provide for penalties to be applied to those that could have been found to be in breach of those Regulations will not have been fulfilled and the Government would inevitably be cited in infraction proceedings by the European Commission.

- **Option 2 – Fully implement the necessary requirements that will support the European Regulation only**

4.2 To implement these proposals will add some minor provisions to the Plastic Materials and Articles in Contact with Food Regulations 1998 to enable the enforcement of the European Regulation, to provide for offences, defences and penalties to be applied to those in breach of the Regulation. These 1998 Regulations would be used for this because they already contain provisions on the use of substances in the manufacture of food contact plastics and the European regulation also covers food contact plastics in the context of the use of certain epoxy derivatives in their manufacture. It was used to enact earlier European measures on these particular substances. These 1998 Regulations will also therefore require extensive amendment to revoke those older European provisions that have themselves been revoked by the new European Regulation. To do this without any attempt at consolidation will leave six sets of amending regulations to the 1998 regulations, thus making it very difficult for those needing to consult these Regulations to follow the legal provisions in them. This would undoubtedly hamper their efforts to understand and comply with the legislation.

- **Option 3 - Fully implement the necessary requirements that will support the European Regulation and simplify national regulations**

4.3 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 which their food was intentionally brought into contact with. It will do this without stifling innovation and technological development that is so necessary to businesses. As the EC Regulation is already in force, we are required to provide for its enforcement in Scotland, for offences to be created and for defences to apply in particular circumstances and for penalties to apply upon conviction for an offence. This ensures that the enforcement authorities can fulfil the requirements placed upon them and that the Courts can impose penalties that are in line with others elsewhere in our food law. It also provides for defences in law for those against whom offences may be alleged in Court. Simplification will allow six sets of regulations to be consolidated into one set of Regulations and brought up to date with modern drafting practice that will make them more understandable and, therefore, easier to comply with.

5 Costs and benefits

- **Sectors and groups affected**

5.1 Provisions for the enforcement of the European regulation will affect the enforcement authorities by returning to them the responsibilities they currently have under older provisions being revoked by these proposals.

5.2 Businesses that use 2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (otherwise known as BADGE) and certain of its derivatives, in the manufacture of food contact plastics, adhesives and coatings 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.

5.3 Consumers of foods placed in contact with the materials and articles subject to the provisions will be assured that there are proper deterrent measures in place to dissuade manufacturers from breaching the European regulation 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 enforcement of the European Regulation and the manufacture of food contact plastics using a wide range of other substances. The proposed single set of regulations will replace the 1998 Regulations and its five amendments and prevent a sixth amendment from making those regulations even more complex.

- **Benefits**

Economic
Option 1 & 2
5.5 There is no economic benefit from these proposals.

Option 3
5.6 Apart from providing for enforcement, defences and penalties, the proposals here simplify what has become a particularly complex set of regulations because of the number and nature of amendments since 1998. It will immediately save all individuals and organisations with an interest in these provisions, the cost of purchasing five sets of regulations and, more significantly, the resource cost of tracking these five amendments, understanding them and assessing the compliance of products with their requirements.

Environmental
Option 1, 2 & 3
5.7 The Environmental impact arising from these proposals is negligible.

Social
Option 1, 2 & 3
5.8 The Social impact arising from these proposals is negligible.

- **Costs**

Economic
Option 1
5.9 This proposal would make it necessary for individuals to purchase six sets of regulations and incur the cost of tracking these, understanding them and assessing the compliance of products with their requirements.

Option 2
5.10 This proposal provides for enforcement, defences and penalties but would still make it necessary for individuals to purchase six sets of regulations and incur the cost of tracking these, understanding them and assessing the compliance of products with their requirements

Option 3
5.11 This proposal places no new burdens on businesses, they simply provide for the enforcement of a European regulation, for defences against alleged offences and for penalties upon conviction for an offence. The Food Standards Agency does not anticipate any cost implications for businesses arising from these proposals; this view has been supported by industry.

5.12 There were substantive comments on the RIA in relation to the cost implications. The trade associations that represent the packaging industry, overall fully supported the Agency's proposal to amend the food contact plastics legislation in UK and particularly welcomed the consolidation into one single instrument. They also supported the Agency's recommendation to pursue Option 3. Industry was unable to provide specific estimates of savings. However, they fully agreed with the Agency's assessment that any additional cost to businesses arising from the proposed Regulations would be negligible. They envisaged that some unquantifiable administration and financial savings would arise as a result of the simplification. However, they could be no more specific than that. FSA are following this up with the relevant stakeholders with the intention of estimating cost saving as part of the Agency's regulatory Simplification Plan.

5.13 The Food Standards Agency does not anticipate new cost implications for enforcement authorities arising from these proposals they reinstate their responsibilities

that exist under current provisions in the 1998 Regulations that these proposals would revoke.

Environmental
Option 1, 2 & 3

5.14 The Environmental costs arising from these proposals are likely to be negligible.

Social
Option 1
5.15 With this proposal there would be no proper deterrent measures in place to dissuade manufacturers from breaching the European regulations, therefore increasing the risk to consumers from chemical contamination.

Option 2 & 3
5.16 There are unlikely to be any social costs arising from these proposals.

5.17 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 are not affected by the proposals, any differently to others. Charities and voluntary organisations are unaffected by these proposals.

6 Small Firms Impact Test

6.1 During consultation on these proposals one organisation commented that there might be some cost implications for smaller business operators in relation to costs to cost product testing, but they were unable to provide any specific amounts. 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 the proposal. They did not respond.

6.2 The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003[4], 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.

6.3 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.

7 "Test Run" of business forms

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

[4] Mintel, March 2003

8 Competition assessment

8.1 Industry and businesses have been closely involved at European level in the development of these proposals and has 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 be brought into contact with food and will not therefore disadvantage any particular business sector, nor company. This view was supported by the packaging industry who confirmed that these proposals would not disproportionately affect small or medium sized firms and nor would it hinder competitiveness.

9 Enforcement, sanctions and monitoring

Enforcement and Sanctions

9.1 The enforcement of The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006 is returned to the responsibility of local authorities, following removal of the responsibility by revocation of the 1998 Regulations that these proposed Regulations replace. Enforcement by these bodies is common practice in our food law. The responsibility for enforcement of restrictions on the use of the substance BADGE, BFDGE (Bis(4-hydroxyphenyl)methane bis (2,3-epoxypropyl)ethers) and NOGE (Novolac glycidyl ethers) that are now contained in Regulation (EC) No. 1895/2005 is also returned to these bodies following revocation of the 1998 Regulations. The Food Standards Agency also has an enforcement role with regard to the EC Regulation in respect of declarations of compliance.

9.2 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.

Monitoring

9.3 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 on 8 June with a coming into force date of 30 June 2006.

10.2 Guidance for businesses has been developed and sent to stakeholders informing them about the changes in these proposals and this has also been published on the Agency's website. Information about the new legislation will also be disseminated in an explanatory note, which covers current issues and any future ones. This note is updated

periodically and is designed to provide a general introduction to European Union (EU) harmonised legislation and its implementation in the United Kingdom.

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 proposals here provide for the effective enforcement of Commission Regulation 1895/2005, on the restrictions of use of certain epoxy derivatives in materials and articles intended to come into contact with food. They also provide businesses with harmonised rules that apply across the European Union, and simplified rules in one set of Regulations for Scotland.

12.2 The Agency believes that the advantages of full implementation of the proposals that are 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 (EC) No. 1895/2005 is enforced and implemented into law in Scotland and the 1998 Regulations with its existing five amendments are consolidated and revoked. **Option 3 is therefore recommended as the means of achieving this.**

Summary costs and benefits table

12.3 The costs as outlined in Option 3 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006, merely provide for the enforcement of Regulation (EC) No. 1895/2005 and the resources implications are negligible.

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	0	0
2	0	0
3	Businesses are likely to benefit from administrative savings arising from the simplification that stem from the consolidation being proposed.	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 ……..

Date ……..

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