Food Standards Agency
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Buidheann Inbhe-Bìdhe

EXECUTIVE NOTE

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2010
SSI 2010/327

1. Description

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

2. Policy Objective

2.1. This instrument provides for the enforcement in Scotland of the remaining provisions of Commission Regulation (EC) No. 450/2009 ("the AIM Regulation"), on active and intelligent materials and articles intended to come into contact with food. It will designate local authorities as having responsibility for the enforcement of the AIM Regulation in Scotland.

2.2. This instrument provides for offences of contravening certain provisions of the AIM Regulation and for defences against prosecution for committing an offence in particular circumstances and specifies the penalties that the Courts may impose upon conviction for an offence.

2.3. This instrument will also revoke *The Materials and Articles in Contact with Food (Scotland) Regulations 2007*[1] as amended by *The Materials and Articles in Contact with Food (Scotland) (Amendment) Regulations 2009*[2] and re-enact them with necessary amendments, thus implementing in one consolidated instrument, the AIM Regulations as well as other controls on materials and articles in contact with food

[1] SSI 2007 No. 471
[2] SSI 2009 No. 426

3. Policy background

What is being done and why

3.1. The EU legislation aims to protect the nature and quality of the food concerned and to provide clear and consistent conditions for the trade of goods. The purpose of making this instrument is to provide the necessary powers to relevant authorities for the effective enforcement of the AIM Regulation and to fulfil their statutory obligations.

3.2. The law on *materials and articles intended to be brought into contact with food* aims to protect human health from adverse effects over a person's lifetime arising from the consumption of food that could be contaminated with chemicals used in the manufacture of such materials and articles. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction.

3.3. The legislation also aims 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.

3.4. It is also our aim to simplify the way rules governing these articles and materials are presented in Scotland, to make them as plain as possible to those that need to refer to them. Therefore, the 2007 regulations (as amended in 2009) will be revoked and re-made with the necessary amendments in a consolidated instrument, including the remaining enforcement provisions of the AIM Regulation. The aim being to minimise the number of instruments to which business operators and enforcement authorities must refer.

4. Legislative Background

4.1. The general principles on all food contact materials and articles intended to come into contact with foodstuffs are established in Regulation (EC) No. 1935/2004[3]. This lays down the framework of regulation for all materials and articles intended to come into contact with food, including those classed as 'active; and 'intelligent'. The AIM Regulation is a specific measure within the meaning of Article 5(1)(b) of the framework Regulation. This establishes specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in the framework Regulation for their safe use. The enforcement of provisions for that Regulation are implemented in Scotland by The Materials and Articles in Contact with Food (Scotland) Regulations 2007. This instrument will revoke the 2007 and 2009 Regulations and remake them with necessary amendments taking into account the remaining enforcement provisions of the AIM Regulation.

[3] OJ L338, 13.11.2004

4.2. The AIM Regulation implements safety requirements that have to be met by businesses seeking to place active and intelligent food packaging systems on the market; where such systems give the foods they contain longer shelf life and/or enhanced qualities.

4.3. The requirements prevent businesses misleading consumers about the product they are buying. They also lay down the procedure that manufacturers of such packaging systems must follow to have their product authorised at European Union (EU) level and provide for dates by which goods must comply with these Regulations and when goods will be in breach of them.

4.4. The AIM Regulation also requires that only substances in the Community list of authorised substances may be used in components of active and intelligent materials and articles. In order for substances to be included in the Community list, specific conditions must be met and these have to satisfy the requirements of Article 3 and, where they apply, Article 4 of the framework Regulation for their intended use. The Community list will be established in agreement with the Member States, with detail on the deadlines by which events pertaining to the list must be completed and procedures for drawing up the list. The list will be drawn up in accordance with the applications made under Article 9 of the framework Regulation and adopted by the Commission under the procedure set out in Articles 10 and 11 of the that Regulation.

4.5. Applications for the inclusion of substances in the EU list must be submitted within 18 months of the publication of the European Food Safety Authority (EFSA) Guidelines for safety assessment of substances – that is to say by 31st May 2011. The EFSA Guidelines were issued on 30th November 2009[4]

5. Consultation

5.1. One hundred and sixty stakeholders were consulted on these proposals, from food industry organisations to manufacturers of affected materials and articles. We included interested parties such as enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations. No adverse comments were received.

5.2. Previously, the Food Standards Agency ("the Agency") held two informal consultations with stakeholders in 2006 and later in 2008. Neither consultation raised any pertinent issues about the cost implications in relation to the AIM Regulation from businesses or enforcement authorities. Several comments were raised in the 2008 consultation on points of detail that were noted and where they did not affect overall UK negotiating lines, were raised in discussions with the Commission and other EU Member States resulting in small changes being made to the text of the AIM Regulation

5.3. A further four week consultation was held in September 2009 to put in place provisions for the enforcement of a number of provisions of the AIM Regulation that had to be in place by 19th December 2009. This was to ensure that enforcement

[4] http://ec.europe.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

authorities had the necessary powers to act under the AIM Regulation at the time they become applicable throughout the European Union. These provisions related to particular labelling and declarations requirements for goods placed on the market. They specifically concerned the labelling of parts of the packaging that could be wrongly taken by some consumers to be edible, the written declaration of legal compliance to accompany active and intelligent materials and articles prior to retail sale, and the production, to enforcement authorities on request, of supporting documentation to substantiate the declaration of compliance

5.4. A more detailed analysis of the consultation outcome is contained in the Business Regulatory Impact Assessment.

5.5. All respondents were thanked for their comments.

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. Guidance

7.1. Guidance for business has been developed and formed part of the stakeholder consultation on the proposed Regulations. Stakeholders were also asked to comment on the guidance with no comments received on the matter. The Guidance has been finalised and will be sent to stakeholders and will also be published on the Agency's website at:

http://www.food.gov.uk/scotland/regsscotland/regsguidscot/

8. Impact

8.1. Any impact on businesses from the regulatory proposals is likely to be for familiarisation costs associated with the proposed Regulations. These include the reading and dissemination of the Regulations to key staff within the organisation. The primary business sector that will be affected by the regulatory proposals will be manufacturers, importers, converters and fillers of food contact materials and more specifically those using active and intelligent components in their packaging. These proposals have no particular impact on, charities or voluntary bodies; rural areas nor on members of the ethnic communities of any particular racial group.

8.2. The Agency has sponsored two pieces of research on active and intelligent packaging; the first was published in 2004 and the second in 2009. The first found that the then UK market for active and intelligent packaging was small and concluded that the major impact of any wider introduction of such packaging would fall on sectors of direct food additives, food authenticity and food labelling. Its other findings concerned the nature of legislation on such materials and articles much of which has now been enacted in the AIM Regulation.

8.3. The second sought, among other things to explore the market for these materials and articles. Once again, only a small number of companies were found to be marketing active and intelligent materials in the UK, so the search was extended and over 60 companies worldwide were identified. The products found included oxygen scavengers, moisture absorbers, gas scavengers, carbn dioxide regulators, antimicrobial releasing systems, nitrogen, heat and flavour releasers and monitoring systems.

8.4. Although the impact on the public sector is neglible, there may be an impact on the Food Standards Agency as and when it carries out surveys on foods. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation.

8.5. The Agency may also be affected via its enforcement role with regard to the framework Regulation in respect of declarations of compliance, as indicated in Article 16 of that Regulation. Article 12 and Article 13 of the AIM Regulation requires that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation.

8.6. A Business Regulatory Impact Assessment has been prepared and is available from the Food Standards Agency Scotland, 6th Floor, St.Magnus House, 25 Guild Street, Aberdeen, Ab11 6NJ.

9. Regulating small business

9.1. The legislation on food contact materials and articles will apply to all businesses small and large.

9.2. We do not consider the impact on small businesses to be significant. This view has been supported by industry following earlier consultations on directly applicable European Regulations and during the 2006 and 2008 consultations on the AIM Regulation, which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness. Such businesses are always encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. The Scottish Federation of Small Business were included in the consultation process and did not raise any concerns.

10. Monitoring & review

10.1. The authorities in Scotland routinely monitor foodstuffs on sale to the public to ensure compliance with Regulations. The results of this work carried out by the Agency are published and are openly available on the Agency's website.

http://www.food.gov.uk/science/research/contaminantsresearch/contactmaterials/

10.2. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems arise 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 continue to regularly communicate with industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which will be reviewed in 2011.

11. Contact

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BUSINESS AND REGULATORY IMPACT ASSESSMENT

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2010

1. Title of Proposal

1.1 The Materials and Articles in Contact with Food (Scotland) Regulations 2010.

2. Purpose and Intend Effect

- **Objective**

2.1 To reduce the long term health risks to consumers in Scotland arising from ingesting chemicals used in the manufacture of active and intelligent materials and articles that may migrate into food by providing harmonised rules with which businesses must compy and complete. And to provide an EU harmonised regulatory famework that provided businesses with clear provisions that lead to safe products and thus increase consumer confidence.

2.2 The EC legislation therefore aims to protect the nature and quality of the food concerned; to provide clear and consistent conditions for the trade in goods and the provisions proposed here for Scotland aim to provide the enforcement authorities with the necessary powers and means to fulfil their statutory obligations. It is also our aim to simplify the way the rules governing these articles and materials are presented in Scotland to make them as plain as possible to those that need to refer to them. This decision was taken with industry support.

2.3 This proposal is for a Scottish Statutory Instrument (SSI) entitled The Materials and Articles in Contact with Food (Scotland) Regulations 2010. The objective of the proposed Regulations is to implement the enforcement provisions of Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with foods ("the AIM Regulations"), by:

- designating local authorities as having responsibility for the enforcement of the AIM Regulation in Scotland;
- providing for offences of contravening certain provisions of the AIM Regulation and for defences against prosecution for committing an offence in particular circumstances; and
- specifying the penalties that the Courts may impose upon conviction for an offence.

2.4 The proposed Regulations will also revoke *The Materials and Articles in Contact with Food (Scotland) Regulations 2007* (SSI 2007/471) as amended by the Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2009 ("the 2009 Regulations"), and re-enact them with necessary amendments, thus implementing in one consolidated instrument the AIM Regulations as well as other controls on materials and articles in contact with food. The proposed Regulations will provide for the effective enforcement of the remaining provisions of the AIM Regulation, which are discussed in more detail below.

- **Background**

2.5 The general principles for governing the safety of all materials and articles intended to come into contact with foodstuffs are established in Regulation (EC) No. 1935/2004[1] (the "framework Regulation"). This lays down the framework of regulation of all such materials and articles, including those classed as 'active' and 'intelligent'. The AIM Regulation is a specific measure within the meaning of Article 5(1)(b) of the framework Regulation. This establishes the specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in the framework Regulation for their safe use.

2.6 The AIM Regulation was published in the Official Journal (OJ) of the EU on 30th May 2009 (Ref OJ, 30.05.2009, L135 pg 3-11) and came into force on 18th June 2009 and is directly applicable throughout the EU. Copies of the AIM Regulation are available and can be downloaded freely from the following website:

http://eur-lex.europe.eu/LexUriServ.do?uri=OJ:L2009:135:0003:0011:EN:PDF

2.7 A short four week consultation was held in September 2009 regarding the enforcement of a number of provisions of the AIM Regulation that had to be in place by 19th December 2009. These provisions relate to particular labelling and declaration requirements for goods placed on the market. The December date refers to provisions at Articles 4(f), 11(e) and 2 in the AIM Regulation. Article 14 of that Regulation required that these provisions are put in place by that date. They specifically concern: the labelling of parts of the packaging that could be wrongly taken by some consumers to be edible, for example, a sachet containing a desiccant to prevent the food spoiling being mistaken for a condiment to use on the food; the written declaration of legal compliance to accompany active and intelligent materials and articles prior to retail sale; and the production, to enforcement authorities on request, of supporting documentation to substantiate the declaration of compliance.

2.8 The enforcement provisions mentioned here were implemented in Scotland by the 2009 Regulations[2].

Condition for active and intelligent materials and articles

2.9 Point to note[3]. As explained in paragraph 2.5 above, the AIM Regulation is a specific measure within the meaning of Article 5(1)(b) of the framework Regulation. Many of its requirements reiterate and tie in with the overarching provisions of the framework Regulation and these are already dealt with in existing statutory instruments for Scotland. The AIM Regulation lays down conditions that have to be met for these materials and articles to be placed on the market. That is to say that they must:

(1)be suitable and effective for their intended purpose;

(2)comply with the composition requirements set out in the AIM Regulation; and

[1] OJ Ref L338, 13.11.2004
[2] Scottish Statutory Instrument No. 2009/426
[3] Since the Lisbon Treaty came into force, all references to "Community" are deemed to be references to the EU. However, in the narrative that follows we have used the terms in the legislation.

(3) be manufactured only from substances included in the 'Community list' of authorised substances, once that list has been adopted. However, this provision is followed by an exception that substances not included on the Community list may be used in components of active and intelligent materials and articles if they are:

(a) released active substances that comply with particular conditions;

(b) substances falling within the scope of the Community or national provisions applicable to food, which are added to or incorporated into active materials and articles by techniques such as grafting or immobilisation in order to have a technological effect in the food, provided that they comply with the particular conditions set out;

(c) substances used as components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier and that comply with other conditions set out and are not:

(i) substances classified as 'mutagenic', 'carcinogenic', or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No. 1272/2008[4] of the European Parliament and the Council; or

(ii) substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale. In effect these are those substances commonly referred to as nano substances in Scotland.

Conditions and content for inclusion of substances in the Community list

2.9.1 Substances may be included in the Community list where they satisfy the requirements of Article 3 and, where they apply, Article 4 of the framework Regulation for the intended condition of use of active or intelligent material or article. The information that will be contained in the Community list will specify:

(a) the identity of the substances(s) and function of the substances(s);

(b) the reference number and if necessary, the conditions of use of the substances(s) or component;

(c) if necessary, restrictions and/or specifications of use of the substance(s); and if necessary, conditions of use of the material or article to which the substance or component is added or into which it is incorporated.

[4] On classification, labelling, packaging substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006

Conditions for the establishment of the Community List

2.9.2 These conditions include the means by which the Community list will be established, with detail on the deadlines by which preparatory stages pertaining to the list must be completed and the procedures for drawing up the list. The important deadlines are that the applications for the inclusion of substances in the Community list must be submitted within 18 months of the publication of the European Food Safety Authority's (EFSA) guidelines for the safety assessment of substances. The Guidelines were issued on 30th November 2009, so the deadline for submission of applications is 31st May 2011. The initial Community list will be adopted by the Commission in agreement with the Member States.

Conditions of use for substances not to be included in the Community list and transitional periods

2.9.3 Released active substances, and substances added or incorporated by techniques such as grafting or immobilisation shall be used in full compliance with the relevant Community or national provisions applicable to food (throughout these provisions the latter apply in the absence of the former), and shall comply with the provisions of the framework Regulation and, when applicable, its implementing measures. Additionally, the amount of released active substance shall not be included in the value of the measured overall migration, in cases where an overall migration limit (OML) is established in a specific Community measure for the food contact material in which the component is incorporated. The amount of a released active substance may exceed the specific restriction established for that substance in a specific Community or national measure governing the food contact material it is contained in provided it complies with the Community or national provisions applicable to food.

2.9.4 The migration into food of the substances behind a functional barrier shall not exceed 0.01 mg/kg, and the AIM Regulation refers to the conditions for measuring that migration. This limit shall always be expressed as a concentration in foods and it shall apply to a group of substances, if they are structurally and toxicologically related. In particular, isomers or substances with the same relevant functional group, and it shall include possible set-off transfer.

2.9.5 As a transitional measure, where active and intelligent materials and articles are labelled in accordance with the framework Regulation and placed on the market prior to 19th December 2009, they shall be permitted to be sold until stocks are exhausted. Furthermore, that until the date of application of the Community list, released active substances shall be authorised and used in accordance with the relevant Community provisions applicable to food, and shall comply with the provisions of the framework Regulation and its implementing measures.

Supporting documentation

2.9.6 The AIM Regulation also requires that appropriate documentation be made available to competent authorities on demand to show that products comply with the legislation. In order to demonstrate compliance, the supporting documentation must contain information on the suitability and effectiveness of the active or intelligent material or article, the conditions and detailed results of testing and/or calculations and/or other analysis and evidence on the safety.

- **Rationale for Government Intervention**

2.10 Chemical migration from food contact plastics can create negative cost to others through detrimentally affecting consumer health. Most consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed choices about such risk. Government intervention is required to reduce these impacts on health, to ensure consumers can make informed choices and also to provide greater clarity for the enforcement of the EC Regulation.

2.11 These proposals fulfil the UK Government's policies of meeting its European Union (EU) obligations to bring into effect in law harmonised rules that:

- reduce the chronic and acute long term health risks to consumers arising from chemical contaminants in the food they eat; and

- meet the intergovernmental Lisbon Agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules that are not overly burdensome within which businesses can compete on an equal footing.

2.12 The Food Standards Agency ("the 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 suspected of carrying an unacceptable risk to consumer health, particularly among vulnerable people. The introduction of harmonised and detailed statutory controls also reduces the potential for uncertainty or dispute in interpreting what constitutes safe levels of extraneous substances in foods.

3 Consultation

- **Within Government**

3.1 During the course of negotiations of the AIM Regulation with the European Commission, officials of the Agency have kept other government departments informed of its progress. These include the Scottish Government DG Health and DG Environment. To date, no adverse comments have been received from any departments.

- **Public Consultation**

3.2 One hundred and sixty stakeholders were consulted on these proposals, from food industry organisations to manufacturers of affected materials and articles. Other interested parties such as enforcement authorities, consumer organisations and other non-government organisations were also included. No adverse comments were received.

3.3 The informal consultations carried out in 2006 and 2008 did not raise any pertinent issues about the cost implications in relation to the AIM from enforcement authorities. There were however several comments on points of detail from the 2008 consultation that were noted and, where they did not affect overall UK negotiating lines, were raised in discussions with the Commission and other EU member States. In some cases, small changes to the text of the AIM Regulation resulted.

3.4 A third consultation was carried out in October 2009, dealing with a number of specific provisions relating to particular labelling and declaration requirements for goods placed on the market. They specifically concern the labelling of parts of the packaging that could be wrongly taken by some consumers to be edible, the written declaration of legal compliance to accompany active and intelligent materials and articles prior to retail sale, and the production, to enforcement authorities on request of supporting documentation to substantiate the declaration of compliance. The purpose of this consultation was to ensure that the provisions here were in place by 19th December 2009, as discussed at paragraph 2.7.

- **Consultation With Business**

3.5 The Scottish Federation of Small Businesses, food industry organisations and manufacturers of affected materials and articles were canvassed for their views in the consultation described in above at paragraph 3.2; no adverse comments were received. The informal consultations carried out in 2006 and 2008 did not raise any pertinent issues about the cost implications in relation to the AIM from businesses.

4. Options

- **Option 1 - Do Nothing**

Doing nothing will not prevent the AIM Regulation from 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 AIM Regulation will not be fulfilled. This would lead the UK Government being cited in infraction proceedings by the Commission and these could result in financial penalties being incurred.

- **Option 2 - Fully implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the AIM Regulation and provide for its enforcement.**

This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the AIM Regulation in Scotland, which is binding in its entirety and directly applicable to all EU Member States.

Sectors and groups affected

4.1 Local authorities (LAs) will continue to benefit from the greater clarity of their powers that will be contained in one consolidated document.

4.2 Manufacturing businesses and LAs will all need to read and familiarise themselves with the new Regulations and take appropriate actions to achieve high levels of compliance.

4.3 Consumers will be protected from long term health risks, arising from ingesting chemicals used in the manufacture of active and intelligent materials and articles that may migrate into food.

4.4 Government Departments, such as the Agency may also be affected as and when they carry out any surveys on foods. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure, and to ensure that the legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

4.5 The Agency may also be affected as it also has an enforcement role with regard to the framework Regulation in respect of declarations of compliance, as indicated in Article 16 of that Regulation. Chapter IV, Article 12 and Article 13 of the AIM Regulation require that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation.

Benefits

- **Option 1**

4.6 Businesses and enforcement authorities within Scotland would not have to gain knowledge of the new legislation.

- **Option 2**

4.7 This option meets the Government's commitment to fulfil its EU obligations and contributes significantly to providing for the 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 a number of provisions of the AIM Regulation are already applicable and domestic enforcement measures in place, we are required to provide for the enforcement of the remaining provisions in Scotland. This ensures that the enforcement authorities can fulfil the requirements placed upon them and the Courts can impose penalties that are consistent with those that apply elsewhere in Scottish food law. It also provides for defences to alleged offences in certain specified circumstances.

4.8 This option would harmonise standards across Member States and prevent any barrier to trade occurring as a result of there being different regulations in different individual Member States. Option 2 may even encourage additional trade. It would also prevent the UK from facing potential infraction proceedings from the European Commission and consolidate the important role that the UK plays in negotiating and agreeing standards for materials and articles intended to come into contact with food within the EU.

4.9 Option 2 will also minimise the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles to the food

itself. Whilst the potential benefits to health are difficult to quantify they are likely to include reduced risk of illness through exposure to substances that might migrate and might be associated with various effects on human health. In 1999 MAFF, now the Department of Environment, Food and Rural Affairs (DEFRA), published a report presenting economic evaluation of UK policy on chemical contaminants in food, which estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The aim of the evaluation was to assess whether current controls on chemical contaminants and naturally occurring toxicants were cost effective and how these could be improved, taking into account the impact of such controls on consumers and the food supply chain. One of the report's conclusions was that the main beneficiaries were consumers, whilst the majority of the quantifiable costs had been borne by central government. The report is available on the DEFRA website at:

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

Costs

- **Option 1**

4.10 Failure to fully implement would result in the Agency being liable to infraction proceedings and possible financial penalties. Businesses would have to comply with the proposals being made here for their goods to be legally compliant elsewhere in the EU. Consumers would not have the same health protection from the excessive consumption of substances dealt with in these proposals as consumers in the rest of the EU.

- **Option 2**

Costs to Enforcement Authorities

4.11 Each Local Authority (LA) in its area is responsible for enforcing the legislation with respect to food safety and/or food hygiene and thus have the responsibility for enforcing the food contact materials legislation and will, as outlined above be affected by these proposals. There may also be ongoing and unchanged cost to food authorities for monitoring and enforcing the new Regulations. However, given that this is an existing responsibility under other food contact materials legislation, there are unlikely to be any annual incremental costs from this new piece of legislation.

4.12 We have estimated the time that enforcement authorities will typically invest in reading and familiarising themselves with the new single set of Regulations. There are 32 local authorities in Scotland. We have estimated that one enforcement officer in each of the 32 local authorities (LAs) is expected to read the Regulations and that it takes them one hour to do so. In addition, we have estimated that each person uses one hour for dissemination to key staff. Their time is valued at £20.70[5] per hour which equates to an approximate one-off cost to LAs of £1,325.

[5] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Environmental health officers' is used (£15.63 including 30% overheads)

4.13 Comments received from a Port Health Authority in an earlier consultation on the AIM Regulation indicated that the proposed Regulations will have a greater cost implication than just familiarisation for enforcement authorities. However, they neither quantified nor provided a breakdown of these costs.

Costs to Industry

4.14 Any likely costs to industry associated with the proposed Regulations relate only to the businesses such as manufacturers of active and intelligent packaging systems needing authorisation of the active components in their products and will not be incurred directly by the whole packaging industry. The primary business sectors therefore likely to be affected by these proposals will be those that specifically manufacture and sell active and intelligent materials and articles intended to come into contact with food. For this sector, there will be a small one-off cost for reading and familiarising themselves with the new Regulations. We have estimated that a manufacturer of active intelligent packaging businesses will spend one hour reading and familiarising themselves with the new single set of Regulations. In addition, we have estimated that each person uses a further hour for dissemination to key staff within the organisation, meaning a total of two hours. There are 135 businesses which may manufacture and sell active and intelligent materials[6]. A wage rate of £25.19[7] has been applied for a manager of an organisation who reads the document, which is multiplied by the number of businesses and the reading time to give a familiarisation cost to industry of £6,802.

4.15 The Agency has sponsored two pieces of research on active and intelligent packaging. The first (A03039) was published in June 2004 and it found that the then UK market for active or intelligent packaging was small. It is concluded from the research conducted that the major impact of any wider introduction of such packaging would fall on sectors of direct food additives, food authenticity and food labelling. Its other findings concerned the nature of legislation on such materials and articles much of which has now been enacted in the European AIM Regulation that the legislative proposals that are the subject of this Business Regulatory Impact Assessment give full effect to.

4.16 The second piece of research, (A03062) was published in August 2009. It sought, among other things, to explore the market for these materials and articles. Once again only a small, unquantified number of companies were found marketing active and intelligent materials in the UK, so the search was extended and over 60 companies worldwide were identified. The products found included: oxygen scavengers; moisture absorbers; gas scavengers; carbon dioxide regulators; antimicrobial releasing systems; nitrogen, heat and flavour releasers; and monitoring systems. A summary of both reports can be accessed at the following website addresses:

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[6] Source: The Inter Departmental Business Register is accessible via the Office for National Statistics, http://www.statistics.gov.uk/idbr/idbr.asp; Figures are the sum of premises listed under SIC 11.07 Manufacture of soft drinks; production of mineral waters and other bottled waters, SIC 17.29 Manufacture of other articles of paper and paperboard n.e.c. SIC 25.92 Manufacture of light metal packaging and SIC 82.92 Packaging activities.

[7] Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Production Manager'' is used (£25.19 including 30% overheads).

http://www.food.gov.uk/science/research/contaminantsresearch/contactmaterials/a03prog/a03projlist/a03039proj/

http://www.food.gov.uk/science/research/contaminantsresearch/contactmaterials/a03prog/a03projlist/a03062/

4.17 The Agency is developing guidance for businesses on the proposed Regulations and this guidance will minimise costs to businesses of reading the Regulations. A brief summary of the guidance is given in paragraph 5.28 below. The costs to industry are summarised below.

4.18 As indicated, any likely additional costs associated with the new Regulations relate only to the businesses that manufacture or use in their manufacturing process active and intelligent materials and articles intended to come into contact with food.

4.19 The familiarisation cost for Local Authorities and businesses is summarised in table 1 below, and includes data for the other administrations. Table 2 has been broken down to show the number of organisations in the enforcement sector affected and table 3 indicates the number of businesses affected by the proposals.

Table 1

Region	**Familiarisation Costs**	
	Local Authorities	**Businesses**
England	£17,227	£102,792
Scotland	£1,325	£6,802
Wales	£997	£5,039
N.Ireland	£1,076	£3,023
UK	**£20,604**	**£117,656**
Rounded	**£21,000**	**£118,000**

Table 2

Region	**Number of organisations affected**		
	Local Authorities	**Port Health Authorities**	**Businesses**
England	354	39	2,040
Scotland	32		135
Wales	22	1	100
N.Ireland	26		60
UK	**434**	**40**	**2335**

Table 3

Summary of firms by size	**Micro**	**Small**	**Medium**	**Large**	**Total**
England	1,498	406	109	26	2,040
Wales	73	20	5	1	100
Scotland	99	27	7	2	135
NI	44	12	3	1	60
UK	**1,715**	**465**	**125**	**30**	**2,335**

Notes: Sizes are defined by number of employees per premises as follows: Micro – less than 10 employees; Small – 10-49 employees; Medium – 50-249 employees; Large – more than 250 employees. Source ONS Inter-Departmental Business Register (2009).

Consultation Questions

Stakeholders are asked to comment, with supporting evidence, on whether the assumption that it will take one hour to read and familiarise with the new Regulations is a sensible estimate for enforcement authorities and businesses.

Stakeholders are also asked to comment on any other costs that might be associated with the AIM Regulation or the proposed Regulations and whether they introduce any additional burden.

No adverse comments were received.

Administrative Burden Costs

4.20 The Agency believes that there are no new or additional costs to enforcement authorities or businesses associated with the proposed statutory instrument that is the specific subject of this impact assessment and that will provide for the enforcement provisions of the AIM Regulation in Scotland. The need for compliance declarations, documentation and labelling are not new burdens on enforcement authorities and businesses, as these are existing requirements under the framework Regulation, Articles 4(5) and 4(6) (labelling of active and intelligent materials and articles), 15(e) and 16.

Guidance on the proposed Regulations

4.21 The guidance mentioned in paragraph 5.19 above, is aimed primarily at those businesses that are likely to be affected by the proposed Materials and Articles in Contact with Food (Scotland) Regulations 2010. It is aimed at those businesses that manufacture, use, import or sell active and intelligent materials and articles intended for use in contact with food. The guidance may also be of use to others with an interest in the legislation, such as enforcement authorities. The guidance provides a short summary of the proposed Materials and Articles in Contact with Food (Scotland) Regulations 2010. It has been produced to explain clearly the legal requirements of the Regulations and should be read in conjunction with the legislation itself.

5 Scottish Firms Impact Test

5.1 We do not consider the impact on small businesses to be significant. This view has been supported by industry following earlier consultations on directly applicable European Regulations and during the 2006 and 2008 consultations on the AIM Regulation, which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness. Such businesses are always encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. The Scottish Federation of Small Business were included in the consultation process and did not raise any concerns.

Competition Assessment

5.2 A competition filter assessment has been carried out and the results indicate that the proposed Regulations that enforce the AIM Regulation are unlikely to hinder the number or range of businesses or the ability for operators to compete. The proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be minimal and will apply equally across all food contact industries. The EU legislation is already binding on Member States and the businesses that trade within them. Charities and voluntary organisations will not be affected by these proposals.

'Test Run' of Business Forms

5.3 The Regulation requires that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation. This is not any new burden on industry, as this is an existing requirement under Regulation (EC) No. 1935/2004 and Commission Regulation (EC) No 450/2009.

6 Legal Aid Impact Test

6.1 The AIM Regulations do not introduce new criminal sanctions or civil penalties; therefore, there are no legal aid implications.

7 Enforcement, Sanctions, and Monitoring

- **Enforcement**

7.1. Enforcement of the proposed Regulations is primarily for LAs as defined by the Food Safety Act 1990 and designated in our Regulations. While the making of legislation in Scotland is the function of the Scottish Government, the enforcement of food is primarily (but not solely) the responsibility of the 32 LAs in Scotland. The proposed Materials and Articles in Contact with Food (Scotland) Regulations 2010 will be enforced by these authorities in the normal way.

- **Sanctions**

7.2. No changes to the sanctions are being proposed to those contained in the current Regulations. A person found guilty of an offence under these and other Regulations dealing with materials and articles in contact with food is liable, on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction to a term of imprisonment not exceeding twelve months or to a fine not exceeding the statutory maximum or both. These penalties are in line with The Food Safety Act 1990.

- **Monitoring**

7.3. 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.

http://www.food.gov.uk/science/research/contaminantsresearch/contactmaterials/

7.4. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems arise 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 continue to regularly communicate with industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which will be reviewed in 2011.

8. Implementation and Delivery Plan

Option 1 – Do Nothing

Option 1 will not require a delivery plan or any implementation. Nonetheless, it will not prevent the AIM Regulation from 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 AIM Regulation will not be fulfilled. This would lead the UK Government being cited in infraction proceedings by the Commission and these could result in financial penalties being incurred.

Option 2 – Fully Implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the AIM Regulation and provide for its enforcement.

This option will ensure that the objectives as laid out in paragraphs 2.1 to 2.4 are achieved. Consultations with all interested parties took place, as detailed in paragraphs 3.1 to 3.5, and no adverse comments were received.

Local Authorities are already responsible for the enforcement of food contact material legislation so no significant incremental costs were identified. Only businesses that manufacture or use in their manufacturing process, active and intelligent materials and articles intended to come into contact with food, will incur one-off staff-time familiarisation costs**.**

Interested parties have been kept informed of progress on the implementing measure. Guidance for business has been developed and formed part of the stakeholder consultation on the proposed Regulations. Stakeholders were also asked to comment on the guidance with no comments received on the matter. The Guidance has been finalised and will be sent to stakeholders and will also be published on the Agency's website at:

http://www.food.gov.uk/scotland/regsscotland/regsguidscot/

8.1. **Post Implementation Review**

Basis of the review: To review progress on how the new requirements of the European legislation are being met by business and enforced by authorities one year after implementation
Review objective: To check that Regulations are operating as expected, thus providing appropriate level of protection for consumers. To check that they are being reasonably achieved by industry.
Review approach and rationale: 1). Routine surveys 2). Feedback from industry and enforcement authorities.
Baseline: Number of non-compliant products reported through the RASFF system currently nil
Success criteria: There continue to be no incidents reported through the RASFF system. Fewer products will be rejected and removed from the supply chain if they have the relevant documentation to substantiate the compliance levels, leading to a reduction in wastage.
Monitoring information arrangements: 1). The Agency will work with enforcement authorities where problems arise or suspected infringements of the Regulations arise. 2). Essentially it would be up to manufacturers of such products to demonstrate compliance with the Regulations, the effectiveness of which will be monitored via feedback from stakeholders as part of the ongoing policy process.
Reasons for not planning a PIR: Not applicable

9. Summary and Recommendation

9.1. The Agency recommends Option 2, to fully implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the AIM Regulation and provide for its enforcement. Taking this option allows the Government to fulfil its obligations to implement EU law. It also ensures that Enforcement Authorities can fulfil the requirements placed on them and the Courts can impose penalties consistent with those elsewhere in Food Law. Implementation of this Regulation will ensure that standards across the EU are harmonised, thus removing barriers to trade and allowing Scottish businesses to export products to all Member States.

9.2. Summary Costs and Benefits Table

Option	Total Benefit per annum: -Economic, environmental, social	Total Cost per annum: -Economic, environmental, social - Policy and Administrative
1. Do Nothing	Businesses and enforcement authorities within Scotland would not have to gain knowledge of the new legislation	Risk of infraction proceedings for failure to implement EC 450/2009. Scottish businesses manufacturing AIMs would be unable to trade within the EU. Consumers would not have the same health protection against chemical contamination as consumers in the EU.
2. Fully implement the necessary requirements and make appropriate domestic Regulations for the execution and enforcement that will support the AIM Regulation and provide for its enforcement.	Allows the Government to meet its commitment to fulfil its EU obligations. Ensures Enforcement Authorities can fulfil the requirements placed on them & the Courts can impose penalties consistent with those elsewhere in Food Law. Provides defences for alleged offences in specified circumstances. Harmonises standards across Member States & removes barriers to trade.	One-off financial cost to Enforcement Authorities for familiarisation and dissemination is estimated at £1325. One-off financial cost to industry for familiarisation and dissemination is estimated at £6802. Administrative burdens/ costs- no new or additional costs have been identified. Economic/ social/ environmental cost- negligible.

10. Declaration & Publication

I have read the Business Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Minister's Signature:_____

Title:_____

Date: _____

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