Explanatory Memorandum to the Materials and Articles in contact with Food (Wales) Regulations 2010

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Member's Declaration

In my view the explanatory memorandum gives a fair and reasonable view of the expected impact of the Materials and Articles in Contact with Food (Wales) Regulations 2010. I am satisfied that any benefits outweigh any costs.

Gwenda Thomas

Deputy Minister for Social Services
Assembly Minister in Charge of the Proposed Measure

15 September 2010

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1. Description

This Statutory Instrument will transpose into law in Wales 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 and port health authorities as having responsibility for the enforcement of the AIM Regulation in Wales. In addition, it provides for offences of contravening certain provisions of the AIM Regulation 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.

This instrument will also revoke the Materials and Articles in Contact with Food (Wales) Regulations 2007[1]as amended by the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009[2] and the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2009[3]

2. Matters of special interest to the Constitutional Affairs Committee

None.

3. Legislative Background

Welsh Ministers have the required powers to make these Regulations under Sections 16(2) , 17(1) and (2), 26(1)(a),2(a) and (3), 31 and 48(1) of the Food Safety Act 1990, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972. Functions conferred on to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the Food Standards Act 1999, are now exercisable by the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

This instrument is subject to the negative procedure.

4. Purpose and Intended Effect of the Legislation

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[4] ("the Framework Regulation"). This lays down the framework for regulation of all

[1] SI 2007/3252 (W.287)
[2] SI 2009/481 (W.49)
[3] SI 2009/3105 (W.271)
[4] OJ L338, 13.11.2004

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 the Framework Regulation are currently implemented in Wales by the Materials and Articles in Contact with Food (Wales) Regulations 2007 (SI 2007/3252 (W.287)) as amended by the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 (SI 2009/481 (W.49)) and the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2009 (SI 2009/3105 (W.271)) ("the 2007 and 2009 Regulations"). 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.

The AIM Regulation puts in place safety requirements that have to be met by businesses seeking to place on the market active and intelligent food packaging systems that give the foods they contain longer shelf life and enhanced qualities. In addition, the AIM Regulation requires that better information is given regarding the condition of the packaged food. The requirements prevent businesses misleading consumers about the product they are buying. They also lay down the procedure that manufacturers of such packaging must follow to have their product authorised at EU level and provide for dates by which goods must comply with these Regulations and when goods will be in breach of them.

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 to 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 Member States, with detail on the deadline 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 procedures set out in Article 10 and 11 of that Regulation.

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 (EFSA) Guidelines for safety assessment of substances – that is to say by 31st May 2011. The EFSA Guidelines were issued on 30th November 2009[5]

The EU legislation aims to protect the nature and quality of the food concerned and to provide clear and consistent conditions for the trade in goods. One of the purposes of making this instrument is to ensure that the provisions contained in it provide the necessary powers to enforcement authorities for the effective enforcement of the AIM Regulation and to fulfil their statutory obligations. The aim is also to simplify the way rules governing these articles and materials are presented in Wales, to make them as plain as possible to those that need to refer to them.

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

5. Consultation

The Food Standards 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.

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 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.

The Food Standards Agency ("the Agency") fully consulted all stakeholders on the Materials and Articles in contact with Food (Wales) Regulations 2010 ("the 2010 Regulations"). One hundred and thirty two stakeholders in Wales were consulted on these proposals. These included food industry organisations, those manufacturing food contact materials, consumer organisations, as well as those with other interests in food contact materials. We also consulted local enforcement and port health authorities, the Department for Business, Innovation and Skills, the Department of Environment, Food and Rural Affairs, the Office of Fair Trading and other non-governmental organisations. No responses were received to the consultation in Wales. However, five responses were received UK-wide. The comments received broadly supported the Agency's assessment that the proposals do not introduce new or additional costs for businesses and enforcement bodies, other than familiarisation with the 2010 Regulations.

The UK fully supported the Commission's proposal for a specific measure on active and intelligent materials and articles intended to come into contact with food. The final proposal was subsequently adopted by the Standing Committee on the Food Chain and Animal Health.

A summary of the responses is attached at Annex B.

6. Regulatory Impact Assessment

Options:

Option 1 – Do Nothing

Do nothing would mean that enforcement authorities would not have the necessary powers to enforce the AIM Regulation in Wales. The AIM Regulation is already legally binding and applicable throughout the EU. Therefore, this could lead the UK Government being cited in infraction proceedings by the Commission and 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.

It is recommended to make the Materials and Articles in Contact with Food (Wales) Regulations 2010 which would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the AIM Regulation in Wales, which is binding in its entirety and directly applicable to all EU Member States. As a number of provisions of the AIM Regulation are already applicable and corresponding domestic enforcement measures in place, we are required to provide for the enforcement of the remaining provisions in Wales. 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 Welsh food law, and across the UK. It also provides for defences to alleged offences in certain specified circumstances.

Option 2 would also harmonise standards across Member States and prevent any barrier to trade occurring as a result of their being different regulations in different individual Member States. This option may even encourage additional trade 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 in within the EU.

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 the Ministry for Agriculture, Fisheries and Food (“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 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 and Benefits

Option 1

This option is the baseline for comparison.

Option 2
Costs to Enforcement Authorities

There will be a small one-off cost to both businesses and enforcement authorities for reading and familiarising themselves with the new Regulations. The enforcement of food law is devolved to the enforcement authorities. In some cases this is divided between the Environmental Health Departments and the Trading Standards Department of Unitary Authorities in Wales.

Each Local Authority and Port Health Authority (PHA) are responsible for enforcing the legislation in Wales with respect to food safety and/or food hygiene; and thus have responsibility for enforcing the food contact materials legislation and will, as outlined above, be affected by these proposals. The Agency believes that the incremental costs to enforcement authorities are unlikely to have a significant cost impact and is likely to be minimal, if any. Local enforcement bodies have always had responsibility for the enforcement of food contact materials legislation. The proposed Regulations for Wales merely provide the means by which this role can be extended to cover the AIM Regulation.

There are a total of twenty-two Local Authorities and one PHA's in Wales that will be affected by the proposed Regulations. It is expected that one Environmental Health Officer (EHO) from each Local Authority (LA) and PHA will read the Regulations and disseminate information to key staff. For LA's we estimate that each EHO will invest one hour reading and familiarising themselves with the Regulations and a further hour disseminating to key staff in the organisation, meaning a total of two hours for familiarising. A consultation response from one PHA in England indicated that the hourly wage rate used does not appropriately reflect the actual wage. In order to maintain consistency across other impact assessments, we have continued to use the Office for National Statistics (ONS) Annual Survey of Hours and Earnings (ASHE) figure for the EHO hourly wage rate but have increased the amount of time used by PHAs to familiarise themselves with the Regulation from a total of two hours to three hours and 10 minutes. We have not amended the time taken to familiarise by LAs as no consultation responses were received on this. Earlier consultation responses have also indicated that the Trading Standards Officers (TSO's)[6] would need to read and understand these Regulations. We assume that the time taken

[6] The Annual Survey of Hours and Earnings (2009) gives a median hourly pay, excluding overtime, for 'inspectors of factories, utilities and trading standards'.

would be the same as for EHO's. A wage rate of £20.70[7] has been applied to each EHO and TSO which equates to a one-off familiarisation cost of £911.00 for LA's and £70.00 [8] to PHA's.

Costs to Industry

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 by the whole food 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.

The Agency has sponsored two pieces of research on active and intelligent packaging. The first (A03039) was published in June 2004 and found that the then UK market for active and 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 AIM Regulation that these legislative proposals that are the subject of this Regulatory Impact Assessment give full effect to.

The second, (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:

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

http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/a03prog/a03projlist/a03062proj/

We have estimated that a manufacturer of active and intelligent packaging businesses will invest 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 approximately 100 businesses in Wales which may

[7] Wage rate obtained from the Annual Survey of Hours and Earnings (2009) (http://.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage rate of an 'Environmental health officer is used £15.92plus 30% overheads).

[8] PHA total familiarisation cost of £66.00 = 3 hours and 10 minutes (uplifted total familiarisation time) * £20.70 (EHO hourly wage rate including 30% overheads (ASHE))

manufacture and sell active and intelligent materials[9]. This is set out in table 2 below. A wage rate of £25.19[10] 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 £5,039

The Agency will develop guidance for businesses on the proposed Regulations, which will minimise costs to businesses of reading the Regulations.

The guidance is aimed primarily at those businesses that are likely to be affected by the proposed Materials and Articles in Contact with Food (Wales) Regulations 2010. It is primarily 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 2010 Regulations and has been produced to explain clearly the legal requirements of the Regulations and should be read in conjunction with the legislation itself.

Stakeholders were asked to comment on the content, layout, clarity and whether any more simplified guidance was required for small businesses or for particular sectors and, if so, what form the guidance should take. No comments were received from businesses on the guidance.

The costs to industry are summarised in table 1 below.

The familiarisation cost for industry and LA's is summarised in table 1 below, and includes data for the other UK territories. 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.

[9] 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.

[10] Wage rage 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 £19.38 plus 30% overheads).

Table 1

Region	Familiarisation Costs	
	Local Authorities	**Businesses**
England	£18,675	£102,792
Scotland	£1,325	£6,802
Wales	£911	£5,039
N.Ireland	£1,076	£3,023
UK	**£21,987**	£117,656
Rounded	**£22,000**	£118,000

*Including the 39 PHAs in England

Table 2

Region	Number of organisations affected		
	Local Authorities	**Port Health Authorities**	**Businesses**
England	389	39	2,040
Scotland	32		135
Wales	22	1	100
N.Ireland	26		60
UK	**469**	**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 were 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 were 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 comments were received from businesses on the proposed Regulations or on the above specific questions. However there were a number of comments received from enforcement authorities and these are summarised below in the 'consultation comments section below.

Impact on other Government bodies

Government departments, such as the Agency, may also be affected as and when they carry out surveys on foods. This 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 legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

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. Chapter lV, 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 of Option 1

There are no identifiable incremental benefits for Option 1.

Benefits of Option 2

Implementation of the Regulations 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 adventitiously migrated from the materials or articles that were intended to be brought into contact with the food. Implementation would ensure that enforcement authorities can fulfil the requirements placed upon them and the Courts can impose penalties that are consistent with those that apply elsewhere in Welsh food law. It would also provide for defences to alleged offences in certain specified circumstances.

Implementation of the Regulations would harmonise standards across Member States and prevent any barriers to trade occurring as a result of their being different regulations in different Member States. It may even encourage additional trade 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.

Competition Assessment

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 is likely to be minimal and will apply equally across all food contact industries. The EU legislation is already binding in Member States and the businesses that trade within them. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Small Firms Impact Test

The impact on small businesses is not considered to be significant. This view has been supported by industry and the Office of Fair Trading following earlier consultations on directly applicable European Regulations and during the 2006, 2007 and 2009 consultations on the AIM Regulation. No comments were received from this sector to the latest consultation.

Post Implementation Review

Please see Annex A attached for detail.

Annex A

Post Implementation Review (PIR) Plan

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: [If there is no plan to do a PIR please provide reasons here]

Annex B

Summary of comments

1. The Food and Drink Federation circulated the consultation documents to their members, and commented that their members had no substantive comments on the proposed Regulations. British Glass thanked the Agency for consulting them on the proposed Regulations, and commented that it did not consider the manufacture of glass containers as practiced by British Glass members to fall within the scope of the provisions of these Regulations.

2. The Trading Standards Institute (TSI) welcomed the opportunity to comment on the proposed Regulations. In relation to the specific questions on familiarisation costs, they supported the Agency's assumption that the proposal did not introduce new or additional costs for businesses and enforcement bodies, other than familiarisation. The TSI also agrees with the Agency's assessment that no new or additional administrative burdens association with the proposal for enforcement bodies. The TSI further agrees with the Agency's assessment that it would take one hour for enforcement authorities to read the proposed Regulations and are not currently aware of any other costs that might be associated with proposed Regulations and believes that there appear to be no new administrative actions. In relation to the guidance, the TSI are satisfied with the content, clarity and layout of the guidance and believe that a more simplified guidance is not necessary. In addition, the TSI is not currently aware of any other impacts under the specific tests from the proposal.

3. The East of England Trading Standards Association (EETSA) agreed with the Agency's assessment that one hour is a sensible estimate for enforcement officers to familiarise themselves with the requirements. They also agreed that there were no new administrative actions which could be identified. However, they felt that more guidance was needed for LA's to identify the different types of AIMS.

4. The EETSA expressed some concerns on the proposed legislation and sought clarification on a number of points. They enquired that as active materials are proposed to be classified as "ingredients" under Directive 2002/13/EC[11], would (a) the requirements of The Food Labelling Regulations 1996 apply (i.e. will the material need to be included in the list of ingredients; (b) what impact will these have on Quantitative Ingredient Declaration (QUID) calculations; and (c) will they be listed by descending order by weight. In response to the first question, after consulting with colleagues dealing with labelling in the Agency and legal, EETSA were informed that, where ingredients have to be listed then any released active substance should appear in the that list and labelled in accordance with the labelling Regulations mentioned above. In response to the second and third questions, EETSA were informed that as QUID laws relate to the quantity of ingredients used at the mixing bowl stage and the said active ingredients would have

[11] Directive 2000/13/EC of the European Parliament and of the Council of 20th March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

been absorbed after this stage, the QUID rules would not apply. Subsequently the second question would not be relevant.

5. There were several comments from the Suffolk Coastal Port Health Authority (the PHA) on the cost element of the impact assessment. They acknowledged that there would be no new or additional costs to enforcement authorities in familiarising themselves with the proposed Regulations. However, they felt that although elements of the legislation are already in force, the PHA understands that no enforcement is undertaken on such products at the point of import. They commented that there was a low knowledge base at the PHA and feel that due to the complex nature of the legislation and the requirements of active and intelligent materials and articles, they would not be able to achieve the one hour proposed to familiarise themselves with the Regulations. The PHA also commented that, they had conducted a three month trial in this particular area and felt that they had insufficient knowledge to contemplate enforcement of any aspects of the legislation. They added that it was difficult to put an actual figure on the amount of time required to obtain understanding of these requirements to enforcement realistic.

6. Furthermore, the PHA feels that the figure given within the evidence base for an officer's time is too low. They currently use an hourly rate of £33.00 for a PHO to calculated statutory costs for carrying out checks. Included in this figure are staff overheads related to training, shift working premiums, but this excludes overheads for business needs such as rent, electric etc. The PHA charge £45.00 for checking organic documents and £50.00 for Common Entry Documents and costs for administration processes to support the presentation of such documents. For a more realistic estimate on the examination of documentation on the proposed Regulations, are likely to be, if not more time consuming due to the complexity of the them so, a figure of £45-£50 represents the cost to the PHA of each additional document check that would be undertaken. At present, staff time for examination and sampling consignments are currently charged at £89.50 for those consignments where cost recovery is available and this cost is indicative of the cost to the Suffolk PHA of examining any consignments which they would need to examine and sample to determine compliance under this legislation.

7. The PHA commented further that import was not permitted for other materials and articles such as regenerated cellulose film (RCF) when it is not accompanied by a declaration of compliance, however, this did not appear to be the case for other materials covered by this legislation. Non-compliance allowing prevention of import could only be determined by chemical analysis, which would give rise to additional costs.

8. The PHA felt that, as there was no cost recovery provisions in the legislation other than for submission of the third part of the formal sample to the Government Chemist when the defendant of formal proceedings requested it; analytical costs, examination costs and documentary checks would all be additional costs that are unacceptable for the enforcement authority. The PHA commented that work had been carried out in this area, which suggests

that there is a low level of understanding and compliance with these Regulations for businesses. Suffolk PHA undertook a trial in which 100 consignments of plastic goods intended for food contact were identified and documentation requested. Although only basic checks were undertaken on the documents, none of the consignments had the necessary documentation, which could be classed as covering the required information.

9. The PHA added that businesses whose goods are within the scope of the AIM Regulation would incur additional costs and would need more time than currently allocated in the evidence base to familiarise themselves with the new requirements. The PHA also commented that businesses may also incur additional costs by PHA's detaining consignments to request and examine documentation and consignments. The PHA provided an example of charges for containers held by the Port of Health of Felixstowe, depending on the size of the container and the length of time it is held. In addition, the PHA provided costs charged by the Port operator (£82.50) for every consignment which they examine.

10. The PHA feels that there would be additional administrative burdens associated with the proposed Regulations for businesses and enforcement authorities, where enforcement activity is undertaken in the detention of their goods and the presentation of commercial and statutory documentation, as required by the legislation. The PHA also commented that, past experience had shown that they would find a high level of non-compliance amongst declarations of compliance certificates and supporting documentation, resulting in legal action being taken. This in turn, may result in a large administrative burden due to the preparation of case files, and the engagement with legal representatives. However, they were unable either to quantify or provide a breakdown of costs, as they rarely have to resort to legal proceedings in their line of work. The PHA added that the majority of their legislation allows them to refuse importation through the service of legal notices on non-compliant consignments either due to documentary errors or unsatisfactory analytical results.

11. Given that there were no comments from businesses on the proposed Regulations, and the views expressed above are from just one PHA, it would be difficult to estimate the level of any additional or new administrative burden for businesses, other than those outlined by the PHA. Other the comments already provided by the PHA they were unable to comment further on the administrative costs to businesses.

12. The PHA raised a number of technical drafting points with the Agency on which we have responded to them in detail, and also a policy point regarding the powers available to PHAs to reject non compliant contact materials and articles at point of import. Such powers are available in the case of food and feed, but not food contact materials. This is a European law issue and the Agency is examining the best way of taking this up in the appropriate forum.