

**Explanatory Memorandum
The Plastics Materials and Articles in Contact with Food (Amendment)
(Wales) Regulations 2009**

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

1. Description

1.1 This instrument implements European Commission Directive 2008/39/EC (“the new Directive”) that amends Commission Directive 2002/72/EC. This amendment, the fifth to the 2002 Directive, routinely updates the lists of monomer substances and additives permitted for use in the manufacture of food contact plastics and lays down any necessary conditions for their safe use. Chemical migration from food contact plastics can detrimentally affect consumer health. The changes to these lists of substances are made periodically when the European Food Safety Authority (EFSA) has revised an existing opinion or issued a new one on the safe use of a substance. This opinion establishes the amount of a substance that may be ingested daily by a person over a lifetime without harmful health effects. Those opinions are used by the European Commission as the basis for proposals to be agreed with EU Member States as has been the case here. Other amendments that the new Directive makes to the original 2002 Directive:

- a) it lays down the dates by which the list of additives that may be used in the manufacture of food contact plastics will be closed and makes interim arrangements for those additives that were the subject of an application for authorisation by the deadline of December 2006;
- b) it sets a date of 31st December 2009 up to which additives not on the positive list may continue to be used. This period will enable EFSA to obtain any additional information it might need for its risk assessment of the additives in question;
- c) it prohibits the use of additives not on the Community list of additives (the positive list), including the provisional list, from 1st January 2010;
- d) it permits the trade in and use of plastic materials and articles intended to come into contact with food and complying with the Directive 2002/72/EC, as amended, from 7th March 2009;
- e) it prohibits from 7th March 2010 the manufacture and importation into the Community of food contact plastic materials and articles that do not comply with the Directive, as amended. In effect this creates a phase-out period for substances that have either been removed from the Community list, or have not been adopted on to it;
- f) it also routinely updates the lists of authorised substances, taking into account the published opinions of EFSA.

1.2 This instrument revokes the Plastic Materials and Articles in Contact with Food (Wales) (No. 2) Regulations 2008 (WSI 2008/1682 W.162) and re-enacts their provisions, amended to take into account the provisions of Commission Directive 2007/19/EC. As such, this instrument will constitute the only specific legislation in Wales controlling the substances that may be used in the manufacture of plastics intended to come into contact with food.

2. Matters of special interest to the Subordinate Legislation Committee

2.1 The instrument breaches the 21 day rule. Member states are required under European law to transpose and implement the provisions of the Commission Directive by 7 March 2009. The Food Standards Agency supports the Commission Regulation and considers that, to protect consumer health, a bilingual Statutory Instrument should be brought into force as soon as practicable. The measures contained in the draft SI are consistent with the need to ensure that consumers are being protected, whilst recognising the need for proportionality. All companies operating within the EU will be required to meet the restrictions set out in the new Regulations – this is not just an issue for the UK. Not to make the legislation in Wales within a similar timeframe to the rest of the UK, may lead to accusations of compromised public health safeguards for the consumers. It would also be confusing for manufacturers as different rules relating to plastics in contact with foodstuffs would apply in Wales. Due to the length and technical nature of the SI it has not been possible to make these Regulations through the negative procedure route as they will not meet the coming into force date.

3. Legislative Background

3.1 Welsh Ministers have the powers to make the proposed Regulations pursuant to sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), 31 and 48(1) of the Food Safety Act 1990. Functions transferred to the National Assembly for Wales are now exercisable by Welsh Ministers by virtue of section 162 and paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006.

3.2 The Plastic Materials and Articles in Contact with Food (Wales) (No.2) Regulations 2008 (SI 2008/1682 W.162) implemented harmonised EU measures contained in European Commission Directives on plastic materials and articles intended to be brought into contact with food. The Directives include lists of substances that can be used in the manufacture of these food contact plastics and any restrictions on that use necessary to safeguard human health and the nature and quality of the foodstuff. The harmonised European rules on food contact plastics are laid down by Commission Directive 2002/72/EC as amended.

4. Purpose and intended effect of the legislation

4.1 It is the purpose and intention that the law on food contact materials and articles should protect consumers from any harmful health effect, arising from the routine ingestion of substances that may have migrated into food from those materials and articles. The intention is to protect consumers from substances that might be carcinogenic, mutagenic or

toxic to reproduction. The legislation also aims to protect the nature and quality of the food concerned; to provide clear and consistent conditions for the trade in goods and to provide the enforcement authorities and industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty seven Member States. It also our aim to simplify the way the 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. This decision was taken in the light of industry support.

4.2 The opportunity is being taken to maintain a simplified set of Regulations that avoid numerous amendments. This will ensure that we reduce the number of places in which substance restrictions and other substance usage information is recorded. An earlier simplification of the regulation of food contact materials legislation was carried out in a two stage consolidation and simplification exercise in February and March 2006. Since then we have continued to propose simplified single-set of Regulations to minimise the burden on businesses and enforcement authorities. This will help those that need to refer to the Regulations.

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

5. Implementation

5.1 It is intended that these Regulations should come into force on 7 March 2009. Parallel legislation is also being made to come into force in England, Scotland and Northern Ireland on 7 March 2009.

6. Consultation

6.1 Details of the consultation undertaken are included in the Regulatory Impact Assessment below

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, however no comments were received. The Guidance has been finalised and sent to stakeholders and has also been published on the Agency's website at www.food.gov.uk .

Regulatory Impact Assessment

8. Options

8.1 Option 1: Do nothing. Doing nothing contradicts the Government's commitment to meeting its EU obligations and fulfilling its policy on consumer protection in this area. It would also create potential for the UK to become liable for infraction proceedings and it would not be possible to implement only parts of the proposal. It would contradict the important role the UK plays in negotiating the adoption of these rules to achieve its wider policy objectives for consumers and business and it would leave the regulation of food contact materials deficient in many ways in comparison with the main food legislation that now applies across the rest of the EU. Failure to fully implement the Commission Directive would mean that prevailing national legislation would no longer accord with Community provisions. In addition, UK consumers would not have the same health protection from the effect of excessive consumption of substances dealt with in these proposals as consumers in the rest of the EU.

8.2 Option 2: Fully implement the provisions of Commission Directive 2008/39/EC in full. This option fully meets the Governments commitment to fulfil its EU obligations and contributes significantly to our agreed policy objective of protecting consumers from ingesting harmful levels of chemicals that could have migrated from plastic materials and articles that were intended to be brought into contact with the food. The UK was involved with the Commission and other Member States (MS) throughout the negotiations that developed the new Commission Directive to the point of its adoption by the Commission as a formal proposal and we supported its adoption at the Standing Committee on the Food Chain and Animal Health (SCoFCAH). Under Treaty obligations we are required to implement Commission Directive 2008/39/EC. It is in the interest of businesses and enforcement authorities to have harmonised EU rules across all Member States.

9. Benefits

9.1 **Option 1:** There are no identifiable incremental benefits; (economic, social or environmental) associated this Option.

9.2 **Option 2:** The recommended option (Option 2) of implementing the provisions of the new Directive into a single consolidated SI will bring together in one place the amending provisions of the Directive with the existing requirements. Businesses involved in the manufacture of plastic food contact materials are generally likely to gain from the measures in the new Directive by ensuring a non-discriminatory competitive environment both domestically and throughout the EU, which in turn may facilitate further trade. They will benefit from maintaining and/or increasing consumer confidence in their products by complying with improved health protection measures throughout the EU.

9.3 Industry will also benefit from having clearer rules regarding permitted substances they may incorporate into the plastic material. This arises because permitted substances are risk assessed at EU level and any necessary health-related restrictions are provided for them; the alternative is that every business using a substance not specifically regulated would carry out its own research in order to make its own risk assessment. Having formal lists of permitted substances avoids all the duplication of the past among separate businesses and saves considerable sums across the industry as a whole.

10. Sectors and groups affected.

10.1 The primary business sectors affected by these proposals will be those that manufacture, use, import or sell plastic food packaging and other plastic materials and articles intended for food contact. The proposals would apply equally to all businesses across Wales's food contact plastics industry, its commercial customers and those that convert and/or import plastic food contact materials and articles, whether small or large. The food and drink packaging industry is highly fragmented and diverse, accounting for approximately a third of the turnover of the food and drink packaging sector.

10.2 Local authorities and port health authorities are responsible for enforcing the legislation with respect to food safety. Local Authorities will continue to benefit from the greater clarity of having the relevant rules and powers contained in one consolidated document.

10.3 Government Departments, such as the Food Standards Agency ("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. The Food Standards Agency's remit is to protect the interests of consumers in relation to food safety, both now and in the future. In doing so, the Agency will take sustainable development into account in all of its activities and policy decisions. The proposal has a positive impact on public health, without any significant impact on the other Government principles of sustainable development.

10.4 A competition filter assessment has been carried out and the results indicate that the proposed Regulations that implement the new Directive are unlikely to hinder the number or range of businesses or the ability for operators to compete. As such, the proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small and apply equally across all food contact industries. The proposals do not contain a strong competition element nor any new or additional burden as the new Directive they implement is amending existing legislation on food contact plastics. This is unlikely therefore to impact on businesses operating in this area, nor in their competitiveness or incentive to compete.

10.5 Rural areas and members of the ethnic communities of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are also unaffected by these proposals.

11. Costs

11.1 **Option 1.** European Community Regulations are binding in their entirety and directly applicable in all EU Member States from the date that they take effect. This option contradicts the UK Government's commitment to meeting its EU obligations and fulfilling its policy on consumer protection in this area. It would also create potential for the UK to become liable for infraction proceedings which in turn may result in financial penalties.

11.2 It would contradict the important role the UK plays in negotiating the adoption of these rules to achieve its wider policy objectives for consumers and business and it would leave the regulation of food contact materials deficient in many ways in comparison with the main food legislation that now applies across the rest of the EU. Failure to fully implement the Commission Directive would mean that prevailing national legislation would no longer accord with Community provisions. Businesses would have to comply with the proposals being made here for their goods to be legally compliant elsewhere in the EU. In addition, UK consumers would not have the same health protection as consumers in the rest of the EU from the effect of excessive consumption of substances dealt with in these proposals.

11.3 **Option 2.** The cost analysis is based on the fact that Option 2 fully meets the requirements of the proposal.

Administrative Costs

11.4 It is estimated that there will be one-off administrative costs to industry and enforcement authorities for reading and familiarising themselves with the new Regulations and these are summarised below.

Costs to Enforcement Authorities

11.5 Each Local Authority and Port Health Authority in its area is responsible for enforcing the legislation with respect to food safety and/or food hygiene; and thus has the responsibility for enforcing food contact materials legislation and will be affected by these proposals. There may also be an ongoing and unchanged admin cost to enforcement 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 annual incremental costs from this new piece of legislation.

11.6 In order to estimate the likely additional administrative burden for enforcement authorities in reading and familiarising with the new single set of Regulations, we have estimated the time that enforcement authorities will typically invest in these activities. There are approximately 469 local authorities in the UK, 22 of which are in Wales, and we have estimated that one environmental health officer (EHO) in each of the 469 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 person uses one more hour for dissemination to key staff within the organisation. Thus, the time is valued at £17.89/hour (based on 2007 Annual Survey of Hours and Earnings (ASHE) data for EHOs). This equates to an approximate one-off administration cost to enforcement authorities of £16,800.

Costs to Industry

11.7 There will be a one-off cost to industry arising from reading and familiarising themselves with the proposed Regulations. The Agency will develop guidance for businesses on the proposed Regulations and such guidance will minimise costs to businesses of reading the Regulations. A brief summary of the guidance is given at section 13 paragraph, 13.1. The costs to industry are summarised below.

11.8 Plastic packaging accounts for approximately a third of the turnover of the food and drink packaging sector. The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. A 2003 study of the UK's packaging industry identified 13,000 packaging companies in the UK; combined they employ 250,000 people.¹ Thus, the potential impact for a one-off cost to businesses is based on the same principles as those for LAs. If we assume businesses are roughly equally spread by population size then 1,040 businesses in Scotland could be affected by the proposal.

11.9 About third of the packaging businesses produce plastic materials and articles intended to come into contact with food and these are businesses that would need to comply with the new Regulations. It is assumed that one person per business reads the Regulations and it takes them an hour to do this. In addition, a further hour may be required to disseminate the requirements of the Regulation to key staff within the organisation. Their time is valued @ £19.84/hour (this is based on the 2007 ASHE (2007) for 'Production and process engineers' (including the assumption of 30% overheads)); this equates to an approximate one-off administrative cost to industry of £41,300.

11.10 Stakeholders were asked to comment on the assumption that a one-off administration cost associated with the reading and familiarising with the new Regulations. Our estimates were based on one person per business reading the Regulations and taking them an hour to do so and in addition, a further hour to disseminate the requirements of the Regulation to key staff within the organisation. Stakeholders were also asked to comment and provide evidence on any other costs that might be associated with the new Directive or the proposed Regulations and whether they introduce any additional burden. No comments were received in Wales on the estimates neither from enforcement authorities nor from businesses.

12 Guidance on the proposed Regulations

12.1 The guidance is aimed primarily at those businesses that are likely to be affected by the proposed Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2009. It is aimed at those businesses that manufacture, use, import or sell plastic materials and articles intended for use in contact with food. It 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 changes proposed and have been produced to provide formal non-binding advice on the requirements of the draft Regulations and should be read in conjunction with the legislation itself.

¹ Mintel, April 2003

12.2 This option also minimises 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 health benefits 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 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 reports 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>

12.3 The EFSA is responsible for carrying out risk assessments and gives its opinions on substances used in the manufacture of food contact plastics based on risk assessment dossiers submitted by industry seeking approval for use of a particular substance. These opinions are given on the basis of protection of public health from any harmful substances that may arise from the consumption of food into which the substance may have migrated. Any resulting limits contained in the EFSA's opinions have margins of safety to ensure that the health of consumers who may eat contaminated foodstuffs would not be affected over their lifetime. The resulting European Commission proposals reflect these safety margins when determining the level of a substance that may be allowed to migrate into food. The Commission routinely amends these technical limits and refines definitions of categories used for limiting migration as scientific understanding of the substances and their health effects improves. Substances that are deemed to cause unacceptable risk to consumer health, particularly among vulnerable people, may be prohibited for use.

12.4 The new Directive reflects improved scientific knowledge of particular chemicals in relation to human health and changes the lists of substances that may be used in manufacturing food contact plastics. Some substances have been deleted from the Community list of permitted monomers and additives either because satisfactory data has not been submitted by applicants for completion of the necessary risk assessment by the EFSA, or because risk assessments have deemed that the substances should no longer be used (e.g. total ban on the substance azodicarbonamide).

13. Consultation

Within Government

13.1 The Food Standards Agency (FSA) has sole policy responsibility for ensuring food safety. Other Government departments including the Devolved administrations in Wales, Scotland and Northern Ireland, Department of Health, The Department for Business Enterprise and Regulatory Reform, the Foreign and Commonwealth Office and the Cabinet Office were kept informed of progress throughout the negotiations relating to the

Commission Directive through regular progress reports. To date, no adverse comments have been received from any department.

Public consultation

13.2 The Food Standards Agency fully consulted all stakeholders throughout the UK on the proposed Regulations. Within Wales over two hundred stakeholders were consulted. These ranged from food industry organisations to sector specific organisations, enforcement authorities and the National Assembly. There were no responses to the public consultation within Wales.

13.3 Within Northern Ireland, 82 stakeholders were consulted. There were no responses to the public consultation exercise. Scotland consulted over a hundred and fifty stakeholders were consulted, there were three responses from the Scottish Beef Cattle Association, Aberdeen City Council and East Ayrshire Council. All agreed with the recommendation supported the draft Regulatory Impact Assessment.

13.4 In England, one hundred and thirty two stakeholders were consulted on these proposals. These ranged from food industry organisations to sector specific organisations, such as those representing manufacturers of food contact plastics, coated cans and multi layered bonded packaging, as well as others with an interest in food contact plastics. The Food Standards Agency also consulted enforcement authorities, the Department for Business and Regulatory Reform, Enterprise Directorate, the Department of Environment, Food and Rural Affairs, Office of Fair Trading, consumer organisations and other non-governmental organisations.

13.5 In total four responses were received; one from LACORS, one from Laboratory of the Government Chemist (LGC), one from Suffolk Coastal Port Health Authority (PHA) and one from the Association of Port Health Authorities (APHA). Their comments are summarised below:

- i) LACORS commented that whilst they appreciate the opportunity of being asked to comment, they felt that the changes proposed were largely of a technical nature, as such they were not providing any substantial comments.
- ii) The LGC fully supported the continued use of ambulatory references to EU legislation, provided that simple clear guidance was available in the shape of a flow chart. Such guidance would assist enforcement authorities, businesses, and analytical laboratories to prepare for implementation, as well as to contribute appropriately to the evidence base for risk management decisions. The LGC also commented that any costs borne by them would be in relation to any chemical analysis linked to enforcement action, but felt this would be unlikely for the foreseeable future.
- iii) There were a number of comments received from the PHA on the proposed Regulations, where these relate to drafting detail and specific provisions within the Regulations; these have been acted upon where necessary and amendments have been made accordingly. Other

comments concentrated largely on their level of involvement as enforcers. The PHA commented that they did very little work on food contact materials legislation due to the complexity and lack of knowledge, but has started to take interest in this area due to the increased number of Rapid Alerts. The PHA also commented that due to the lack of any direct funding covering this area of enforcement, activity will dictate the resources which can be allocated, but felt that the ability to act upon documentation will be advantageous.

iv). Comments from the APHA are made on behalf of the 68 seaports and airport local authorities. The APHA commented that costs to enforcement authorities at borders were understated based on the assumption that enforcement activity may change due to increased documentary checks. If there is a need to carry out documentary checks on imported products under the proposed Regulations at borders, then consideration needs to be given to incorporate cost recovery elements into legislation (similar to products of animal origin. The APHA also commented that training requirements had not been sufficiently accounted for. However, the APHA neither quantified nor provided revised additional costs.

14. Small Firms Impact Test

14.1 The Agency does not consider the impact on small businesses in general to be significant. This view has been supported by industry following earlier consultations (June and October 2007), 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 Federation of Small Business were included in the consultation process and did not raise any concerns.

15. 'Test Run' of Business Forms

15.1 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.

16. Enforcement, Sanctions and Monitoring ***Enforcement***

16.1 Enforcement of the proposed Regulations is primarily of LAs as defined by the Food Safety Act 1990 and designated in our Regulations. While the making of legislation in Wales is the function of the Welsh Assembly Government the enforcement of food safety is primarily (but not solely) the responsibility of 22 Unitary Local Authorities and Port Health Authority in Wales. The proposed Plastic Materials and Articles in

Contact with Food (Amendment) (Wales) Regulations 2009 will be enforced by these authorities in the normal way.

Sanctions

16.2 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.

Simplification

16.3 The opportunity is being taken to maintain a simplified single set of Regulations that avoid numerous amendments. This will ensure that we reduce the number of places in which substance restrictions and other substance usage information is recorded. An earlier simplification of the regulation of food contact materials legislation was carried out in a two stage exercise in February and March 2006. Since then we have continued to propose simplified single-set regulations to minimise the burden on industry and enforcement authorities. This will help those that need to refer to the Regulations.

Monitoring

16.4 The Food Standards Agency and local authorities in Wales 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/researchinfo/contaminantsresearch/>

16.5 The Food Standards Agency 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 or suspected infringements of the Regulations arise. The effectiveness of the proposed Regulations will also be monitored via feedback from stakeholders as part of the ongoing policy process. We shall also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which will be reviewed in March 2010.

17. Implementation and delivery plan

17.1 Statutory Instrument will come into force on 7th March 2009.

17.2 Guidance for businesses has been developed and has been sent to all stakeholders consulted, informing them of the changes in these proposals. The guidance will also be published on the Agency's website at www.food.gov.uk. Information about the

new Regulations will also be disseminated in an explanatory note, which covers current issues on food contact materials and any future ones. This note is updated periodically and is a useful tool, which is designed to provide a general introduction to EU harmonised legislation and its implementation in the UK.

18. Post-implementation review

18.1 Member States are obliged under the Commission Directive to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with that 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. The effectiveness of the WSI will also be monitored via feedback from stakeholders as part of the ongoing policy process. We shall also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from these Regulations, which will be reviewed in March 2010.

19. Summary and recommendations

19.1 The Food Standards Agency believes that the advantages of full implementation of the proposals within the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2009 will benefit businesses, enforcement authorities and consumers. The measures proposed are important in providing essential consumer health protection and improved product information. They also provide businesses with harmonised rules and greater transparency in the authorisation of new substances for use in plastic materials and articles in contact with food. We recommend that the new Directive is implemented into law in Wales and that the 2008 Regulations are revoked. Industry fully supports the pursuit of Option 2 which has the desired effect in achieving the means of adequate implementation of the new Directive. **Option 2 is therefore recommended as a means of achieving this.**

Summary costs and benefits table

19.2 The cost implications arising from the new Directive as outlined in option 2 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2009 will implement the requirements of Commission Directive 2008/39/EC, the resources implications are negligible. Guidance prepared on the new Regulations for industry will help minimise costs to business.

Option	Total cost per annum: - economic, environmental, social - policy and administrative	Total benefit per annum: economic, environmental, social	Groups affected
1	Infraction proceedings against the UK Government	None	Enforcement authorities Manufacturers of food packaging, importers and distributors Consumers
2	<p>The cost implications for both industry and enforcement may include a small administration cost of reading the new Regulations.</p> <p>There will also be the cost to enforcement authorities for monitoring and enforcing the new Regulations. However, given that this is an existing responsibility under other food contact materials legislation, the cost is unlikely to increase.</p>	<p>Increased level of consumer confidence as the UK will enjoy the same enforcement level of protection as the EU. The new Welsh Regulations will ensure that measures, which are applicable throughout the EU are in place, thereby facilitating trade and creating a 'level playing field' and facilitating further trade.</p> <p>Will give enforcement authorities greater clarity provided by the measures within the Regulation.</p>	Enforcement authorities Manufacturers of food packaging, importers and distributors Consumers