

**Explanatory Memorandum**  
**The Plastics Materials and Articles in Contact with Food (Wales)**  
**Regulations 2008**

**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 2007/19/EC that amends Commission Directive 2002/72/EC. This amendment, the fourth 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 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 2007 Directive makes to the original 2002 Directive provide:

- a) clarity about the detail required in compliance declarations that must accompany goods being traded up to the retail stage;
- b) distinction between the terms 'plastic multi-layer' and 'plastic functional barrier' and defines the function of such a barrier;
- c) removal of the suspension imposed on the use of azodicarbonamide as a foaming agent in the plastic in favour of an outright ban;
- d) clarification that gaskets used to seal glass food jars are subject to the rules laid down in the 2002 Directive whilst providing time for manufacturers to obtain authorisation for the use of the additives they employ in making these gaskets;
- e) for the use of a new food simulant to test more accurately for chemical migration into milk products;
- f) for the use of a reduction factor to more accurately calculate migration into fatty food types;
- g) the dates from which compliant goods may be traded and from which non-compliant goods may not be manufactured or imported into the Community.

1.2 This instrument revokes the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2006 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. The Member States are required under European Law to transpose and implement the provisions of Commission Directive by 1 May 2008. Two formal consultations on the proposals were carried out with interested parties in Wales, the later of which concluded on 28 March 2008. The second consultation was conducted to ensure that Welsh stakeholders had the opportunity to comment on the insertion of the remaining transitional provisions of the amending Directive, which provide for the dates by which goods complying with the provisions of the Directive may be placed on the market and dates from which non-compliant goods will be prohibited from manufacture or import into the European Community. Due to the timing of this second consultation, it has not been possible to translate the draft Statutory Instrument into Welsh, due to its length and technical nature, nor has it been possible to make these Regulations through the negative procedure route as they will not meet the coming in to force date.

2.2 The Food Standards Agency supports the Commission Regulation and considers that, to protect consumer health, a 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 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.

### **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) Regulations 2006 (SI 2006/2982 W.273) 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 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 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 1 May 2008. Parallel legislation is also being made to come into force in England, Scotland and Northern Ireland on 1 May 2008.

## **6. Consultation**

6.1 Two formal consultations on the proposals were carried out with interested parties in Wales. The first consultation exercise commenced in October 2007, the second in February 2008 which concluded on 28 March 2008. The second consultation was conducted to ensure stakeholders had the opportunity to comment on the insertion of the remaining transitional provisions of the amending Directive, which provide for the date by which goods complying with the provisions of the Directive may be placed on the market and dates from which non-compliant goods will be prohibited from manufacture or import into the European Community. Over 205 interested parties in Wales were consulted on the proposals, these ranged from sector specific organisations, such as those representing industry sectors, to those with a wider interest in food contact plastics. The Agency also consulted enforcement authorities, the Department for Business and Regulatory Reform, Enterprise Directorate, consumer organisations and other non-governmental organisations. No comments were received in Wales.

6.2 The primary business sector that will be affected by the regulatory proposals will be manufacturers of food contact plastics, importers and those producing gaskets for use in glass food jars. Comments from industry were overall very positive and in favour of the Agency's proposal to amend the food contact plastics legislation in the United Kingdom. However, one trade association in England, representing manufacturers of plastic packaging raised concerns on the need for detailed information in their compliance declarations; they felt this would increase their administrative tasks, and the affect small and medium sized businesses. They were not however, able to quantify this in any way in their comments, nor did they do so in Europe when they made the same points in the negotiations on the 2007 Directive that this instrument implements. The proposals will apply equally to all areas of legislation on food contact plastics and thus, the provisions equally affect all businesses involved. Rural areas and members of the ethnic communities of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are also unaffected by these proposals.

## 7. Regulatory Impact Assessment

7.1 A Regulatory Impact Assessment is included in this Explanatory Memorandum.

### 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 2007/19/EC in full.** This option fully meets the Government's commitment to fulfil its EU obligations and contributes significantly to the up-to-date means 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 throughout the negotiations that developed the 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. Under EC legislation we are required to implement Commission Directive 2007/19/EC. Businesses and enforcement authorities want the harmonisation of rules between Member States of the EU that implementation of the Commission Directive provides. This view was supported by stakeholders who commented on the consultation carried out in 2006, when these provisions were last amended. Stakeholders particularly found that full implementation provides scope for a favourable balance between benefits and necessary costs.

## 9. Benefits

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

9.2 **Option 2:** The recommended option (Option 2) of implementing the provisions of the Commission Directive into a single consolidated Statutory Instrument (SI) will bring together in one place the amending provisions with existing requirements. Businesses involved in the manufacture of plastic food contact materials are generally likely to gain from the measures in the Commission 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 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 the risk of illness through exposure to substances that might migrate and might be associated with various adverse 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 estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The report is available on the DEFRA website at:

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

## **10. Sectors and groups affected.**

10.1 The primary business sector that will be affected by these regulatory proposals are those manufacturers and/or importers of food contact plastics and those producing gaskets for use in glass food jars. 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 and will therefore be affected.

10.3 Government departments, such as the Food Standards Agency will 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. There are carried out to inform consumers, monitor trends assess dietary exposure, and to ensure that the legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

10.4 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 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 as consumers in the rest of the EU from the effect of excessive consumption of substances dealt with in these proposals.

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

### ***Administrative Costs***

11.3 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***

11.4 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.

11.5 The price base year used to calculate the costs to enforcement authorities is 2007, as the Annual Survey of Hours and Earnings (2007) are used.

11.6 It is estimated that the total spend for enforcement authorities and port health authorities in relation to food safety is in the region of £98.3 million

11.7 Local authorities are responsible for enforcing the legislation with respect to food safety and also have the responsibility for enforcing food contact materials legislation, and will therefore 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, the cost is unlikely to be increased.

### **Costs to Industry**

- 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. Thus the potential impact for a one-off cost to businesses is based on the same principles as those for LAs. A third of the 13,000 packaging businesses produce plastic materials and articles intended to come into contact with food and these are the 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 £172.000.
- 11.9 The one-off administration costs borne by businesses and enforcement authorities have been revised to reflect the data used in the ASHE 2007 survey.
- 11.10 As indicated above, any likely costs associated with the new Regulations relate only to the businesses that manufacture plastic materials and articles intended to come into contact with food (including things like food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing machinery and equipment) and are not representative of the whole packaging industry. The proposals would apply equally to all businesses across the UK food contact plastics industry, its commercial customers and those that convert and/or import plastic food contact materials and articles, whether small or large.
- 11.11 Stakeholders were asked to comment on the assumption of a one-off administration cost associated with the reading and familiarisation 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. No comments were received from the enforcement authorities on the estimates nor from businesses.

## **12. Competition Assessment**

- 12.1 The proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small. The proposals do not include any new or additional burden, as the Commission Directive they implement is merely amending existing legislation on food contact plastics and does not introduce any new provisions. Furthermore, the requirement in Article 9 (1) and (2) for detailed information on compliance declarations does not raise any new burdens on industry.

This requirement is an existing requirement under Article 16 of Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in the Commission Directive.

- 12.2 Economically, a lot depends upon the businesses' profit margins as to whether there will be any effect on competition. Some firms may be able to compete in the industry because their costs are equal to, or only just below, their revenues. If their costs increase even a little, and they are unable to pass these costs on to the consumer, then their business will suffer.
- 12.3 Industry and businesses have been closely involved at European level in the development of these proposals and have not raised any issues that can be substantiated and that indicate a disadvantage to any particular business sector. The consultation carried out in October 2007 and February 2008 did not indicate any disadvantage to any particular business, or company. The proposals apply equally to all areas of legislation on food contact plastics and thus, the provisions equally affect all businesses involved.

### **13. Consultation**

#### Within Government

- 13.1 The Food Standards Agency (FSA) has sole policy responsibility for ensuring food safety. Other Government departments including the 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 During the course of negotiations with the Commission, the Food Standards Agency has frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities and other interested parties with an interest on policy issues related to food contact materials. The proposal has also been discussed at regular meetings with stakeholder groups that are likely to be directly affected by the requirements Directive 2007/19/EC. Any comments received from interested of organisations have, where appropriate been incorporated into the UK's negotiating line. Consultations on the initial development of these proposals have spanned four years; in 2002, 2004, and 2005 and again in February and March 2006, when these proposals were last amended. Earlier consultations did not raise any adverse comments from stakeholders on these proposals. A formal consultation on the proposals with interested parties in Wales concluded on 28 March 2008.
- 13.3 Two separate consultations were carried out on the proposals to implement the provisions of Directive 2007/19/EC in Wales, the first in October 2007 and the second concluded on the 28 March 2008. No responses from the 205 interested parties were



received within Wales. In England, one hundred and thirty two stakeholders were consulted on the proposals and five responses were received from the first consultation. These were from the British Plastics Federation (trade association for the plastic packaging industry (BPF), the Government Chemist (LGC), Lacors, Vegetarian Economy and Green Agriculture (VEGA) and one from the Government of Thailand.

- 13.4 The BPF supported the implementation of the Commission Directive through the Plastic Materials and Articles in Contact with Food Regulations 2008. They expressed general concern about the extent of information required by compliance declarations in the Directive being implemented. They also felt that this would increase the burden of administrative tasks which would require a significant number of extra people time and would affect small and medium size businesses. They also added that the need to disclose information in some instances would be anti-competitive. However, they were not able to quantify the burden in monetary terms or support their contention, nor did they do so during the course of negotiating the content of the Directive that is being adopted. The need for compliance declarations is not a new burden on industry, as this is an existing requirement under Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in Directive 2007/19/EC. The BPF added further that the additional cost of REACH compliance would also be a contributory factor. However, again they were unable to quantify or provide evidence to support their views.
- 13.5 The Agency believes that REACH has no direct implications for the control of chemical migration from food contact materials and articles. The principles of positive approval and assessment are already part of the regulatory regime for the chemicals used in materials and articles intended to come into contact with food. REACH provides that chemicals used in articles are safe and that safer alternatives are used where they exist and requires that uses of chemicals have to be registered; food contact materials and articles manufacturers need to therefore register the use they make of chemicals.
- 13.6 Substance authorisation is needed where positive lists apply for substances used in the manufacture of food contact materials and articles. Such lists apply to food contact plastics and regenerated cellulose fibre manufacture. Risk assessments of these substances are carried out by the European Food Safety Authority. Whereas, the risk assessment and evaluation of substances for REACH are carried out by the European Chemical Agency (ECHA) in Helsinki and the Health and Safety Executive (HSE) in the UK. REACH came into effect on 1 June 2007 and requires that all substances and their uses are registered in the period from June 2008 to December 2008.
- 13.7 The LGC fully supports the Agency's view that Option 2 has the means of achieving full implementation of the Commission Directive. They feel that the proposals are broadly consistent with effective regulation and that the revisions to the layout of the proposed Regulations, which preserve much of the structure of their predecessors, would also assist local authorities in exercising their powers effectively, when

enforcement action needs to be considered. This view was also supported by LACORS.

13.8 The comments from the Thai authorities were not specific to the proposed Regulations but covered issues in the Commission Directive and to the Specific Migration Limits (SML) for epoxydised soybean oil and other plasticisers. The comments have been noted by the Agency and forwarded to the European Commission to respond. The Thai authorities have been informed accordingly.

13.9 The Vegetarian Economy and Green Agriculture supported the Agency's pursuit of Option 2 in implementing the provisions of Directive 2007/19/EC.

13.10 Consultation comments on drafting detail have been acted upon where necessary.

13.11 There were no further comments from Wales, England, Scotland and Northern Ireland to the second consultation which ended on 21 March 2008.

#### **14. Post Implementation Review**

14.1 The Food Standards Agency 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 at:

<http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/>

14.2 The Food Standards Agency shall therefore routinely survey materials and articles on the market to ensure compliance with Regulations. The Food Standards 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 continue to routinely talk to industry to ensure that no foreseen difficulties arise from these Regulations. The proposed Regulations will be reviewed in June 2009.

14.3 Guidance for business has been developed and sent to all stakeholders consulted, informing them of the changes in these proposals. The guidance has also been published on the Agency's website at [www.food.gov.uk](http://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 under discussion by the European Commission and Member States. The explanatory information 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.

#### **15. Summary**

- 15.1 These proposals implement a Commission Directive which provides businesses with harmonised rules that apply across the European Union. This is routinely amended to improve the clarity of the rules and to keep the technological innovation. This latter point arises from improving technical and scientific knowledge that enables experts within the European Food Safety Authority (EFSA) to evaluate and re-evaluate risk for public health arising from the migration of chemicals from food contact materials into food. The latest of these amendments are contained in Directive 2007/19/EC that the regulatory proposals here would implement. The Commission Directive also amends Council Directive 85/572/EEC, which lays down the list of simulants to be used for testing migration of constituents of plastic materials in contact with food. In Wales, the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2006 implement the provisions of Directives 2002/72/EC and 85/572/EEC as amended in each case.
- 15.2 The Agency believes that the advantages of full implementation of the proposals that is the subject of this regulatory impact assessment will benefit industry, enforcement authorities and consumers. We recommend that the Commission Directive is enforced and implemented into law in Wales and the 2006 Regulations are revoked and remade with necessary amendments. Industry fully supports the pursuit of Option 2 which has the desired effect in achieving the means of adequate enforcing and implementing of the Commission Directive.
- 15.3 **Option 2 is therefore recommended as a means of achieving this.** The cost implications arising from Option 2 are negligible. The proposed Plastic Materials and Articles in Contact with Food (Wales) Regulations 2008 will implement the requirements of Commission Directive 2007/19/EC, the resource implications of which are negligible.

### Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	None	Infraction proceedings against the UK Government
2	<p>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> <p>Ensure that the potential for consumers being exposed to harmful levels of substances migrating from food contact materials and articles, to the food itself, is</p>	<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>

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