

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

**This Explanatory Memorandum has been prepared by the Food Standards Agency
Wales and is laid before the National Assembly for Wales.**

1. Description

1.1 This instrument provides for the enforcement in Wales of Commission Regulation (EC) No. 372/2007 (“the Commission Regulations”), which lays down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food. This instrument will put in place offences that may be prosecuted before the Courts where alleged breaches of the Commission Regulation arise; defences against alleged breaches under particular circumstances and penalties that the Courts may apply upon conviction for an offence. This instrument which will apply to Wales is to be a short-lived measure to last until 30 June 2008, when the Commission Regulation expires.

2. Matters of special interest to the Subordinate Legislation Committee

2.1 None.

3. Legislative Background

3.1 Welsh Ministers have the required powers under section 16(2) and 17(1) and 2 and 26(1)(a), 2(a) and (3) and 48 (1) of the Food Safety Act 1990, and Standing Order 24. The provisions of the Act were transferred from the National Assembly for Wales to Welsh Ministers under the provisions of the Government of Wales Act 2006. The Regulations are subject to the negative resolution procedure.

3.2 Gaskets in lids intended to come into contact with food fall under the scope of Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs which, as last amended by Directive 2005/79/EC, is given effect in Welsh law under other Regulations¹. However, the Directive applies to materials and articles, and parts thereof, which consist exclusively of plastics or are composed of two or more layers consisting exclusively of plastics. Gaskets in metal lids could alternatively be regarded as a plastic part of a material or article and thus covered by Directive 2002/72/EC or as a plastic coating on a metal substrate, and hence, not covered by that Directive. Consequently, there are separate rules across Member States that may pose a barrier to trade. As such, it has been necessary to clarify the position regarding gaskets in lids and fix transitional specific migration limits (SMLs). These SMLs will apply to the sum of a number of plasticisers used in gaskets in lids coming into contact with fatty foods and permit the free circulation within the Community of those products affected. At the same time, those lids that pose a significant risk are immediately excluded from the market. The Commission Regulation also provides industry with sufficient time to finalise the

¹ The Plastic Materials and Articles in Contact with Food (Wales) (No.2) Regulations 2006

development of gaskets that are compliant with the SMLs laid down in Directive 2002/72/EC, as amended by Directive 2007/19/EC².

3.3 The plasticisers with transitional SML's are:

- Epoxidised soybean oil (ESBO);
- Acetylated mono- and diglycerides of fatty acids;
- Polyester of adipic acid with glycerol or pentaerythritol, esters and even numbered, unbranched C12- C22 fatty acids;
- Tri-n-butyl citrate;
- Glycerol monolaurate diacetate and 12-(Acetoxy) stearic acid, 2,3-bis(acetoxy)-propyl ester; and,
- Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropylene-glycol with adipic acid, also end-capped with acetic acid or fatty acids C₁₂-C₁₈ or n-octanol and/or n-decanol

3.4 The European Regulations make provisions that will remain in force until that amendment takes effect in our national law from 1 July 2008.

4. Purpose and intended effect of the legislation

4.1 The purpose of these proposals is to meet the Government's commitment to honour its EU obligations within the European Union and reduce the risk to consumers of health effects arising from the consumption of harmful levels of chemicals in food. The proposal will make provisions for the enforcement of Commission Regulation (EC) No. 372/2007 which lays down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food ("the Commission Regulations"). It will put in place offences that may be prosecuted before the Courts where alleged breaches of the Commission Regulation arise, defences against those alleged breaches under particular circumstances and penalties to apply on conviction of an offence under them.

4.2 The proposed Regulations, which will apply to Wales, are to be a short-lived measure to last until June 2008, when the European Regulation expires. They will provide for the enforcement of that European Regulation in Wales, by the enforcement authorities. 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 8 February. Parallel legislation was introduced in England on 29 October 2007. Parallel legislation was also made in Scotland and Northern Ireland during November.

² Commission Directive 2007/19/EC amending Commission Directive 2002/72/EC and Directive 85/572/EC relating to plastic materials and articles intended to come into contact with food.

5.2 Guidance for businesses 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. 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.

6. Consultation

6.1 A formal consultation on the proposals with interested parties in Wales concluded on 17 August. There were no responses from over 50 interested parties in Wales. In England, some 130 organisations were consulted on these proposals, including representatives from food industry organisations to manufacturers of affected materials and articles, enforcement authorities, the Enterprise Directorate (formerly the Small Business Service (SBS)), Forum of Private Businesses (FPB), consumer organisations and other non-government organisations. Industry and enforcement authorities fully supported the 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 will not prevent the Commission Regulation from applying in Wales; it is already legally binding and applicable throughout the EU. However, enforcement authorities would not have the necessary powers to enable them to enforce it. Therefore, the obligation to put in place provisions for its enforcement, for offences to be prosecuted and for penalties for those found to be in breach of the Regulation will not have been fulfilled. This would lead to the Government being cited in infraction proceedings by the Commission.

8.2 Option 2: Put in place the domestic regulations which provide for the execution and enforcement of the Commission Regulation. This option meets the Government's commitment to fulfil its EU obligations and contributes significantly to providing for the up-to-date means of protecting consumers from ingesting harmful levels of chemicals that could have migrated from the materials or articles that were intended to be brought into contact with the food. As the Commission Regulation is already in force, we are required to provide for its enforcement in Wales. This ensures that the enforcement authorities can fulfil the requirements placed upon them and the Courts can impose the penalties that are in line with penalties that apply elsewhere in our food law. It also provides for defences in law for those against whom offences may be alleged in Court. This option is also supported by the LGC, which provides scope for a favourable balance between benefits and necessary costs.

9. Sectors and groups affected.

9.1 Typically, businesses affected by these proposals are those that manufacture and/or import food packaging, including, those companies that specifically manufacture gaskets for use in lids using the substances with restrictions laid down in the Commission Regulation.

9.2 Local authorities and port health authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.

9.3 Government departments, such as the Food Standards Agency will be affected as and when they carry out any surveys on foods. 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.

9.4 The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003³, a study of the UK's packaging industry identified 13,000 packaging companies in the UK; half of them had a turnover less than £10 million, and 85% could be classified as small to medium size enterprises.

9.5 Food packaging end uses represent a significant proportion of sales and employ 8,000 people, with annual sales of PAFA (Packaging and Films Association) members exceeding £2 billion. A key objective of PAFA is to support measures which assure high standards and quality of packaging materials, including safety for their intended use. The association seeks to play an active and constructive role in the formulation of sensible policy and legislation, at both EU and UK level. PAFA supports the development of proportionate and workable legislation, and appropriate enforcement policies, that are consistent with principles of good regulatory practice. The potential commercial impact of the proposals applies equally to all businesses involved small or large - a view supported by PAFA.

10. Benefits

10.1 **Option 1:** There are no identifiable incremental benefits for this Option.

10.2 **Option 2:** This option would provide enforcement authorities with the necessary powers to enforce the Commission Regulation. Also, local authorities and port health authorities will benefit from the greater clarity provided by that Regulation and from the power of enforcement devolved to them by these Regulations.

10.3 This option will also ensure that the potential for consumers being exposed to harmful levels of substances migrating from food contact materials and articles, to the food itself, are minimised. Whilst the potential health benefits are difficult to quantify they are likely to include reducing the risk of illness through exposure to substances that might migrate and might be associated with various adverse effects on human health. This option may therefore reduce such burden on the health service through prevention of chronic illness. A 1999 report (conducted by the Department of Environment, Food and Rural Affairs DEFRA)), presenting economic evaluation of UK policy on chemical contaminants in food

³ Mintel, April 2003

estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The report is available at the following website

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

10.4 Businesses involved in the manufacture of food contact materials and articles will gain from the Regulations by ensuring a non-discriminatory competitive environment both domestically and throughout the EU, which in turn may facilitate further trade. Although PAFA were unable to provide comments directly related to the proposal (as none of their members, to their knowledge are involved in the manufacture of gaskets or gaskets in lids), they did however, support the development of proportionate and workable legislation, and appropriate enforcement policies, that are consistent with principles of good regulatory practice.

10.5 This option would provide enforcement authorities with the necessary powers to enforce the Commission Regulation. Also, local authorities and port health authorities will benefit from the greater clarity provided by that Regulation and from the power of enforcement devolved to them by these Regulations.

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. The UK therefore, has a legal obligation to ensure that the provisions are in place to provide for the enforcement of the Commission Regulation in full. Failure to do so will result in infraction proceedings against the UK Government, which may result in financial penalties. It would also leave the UK enforcement authorities without any domestic legislation for the enforcement and execution of the Commission Regulation.

11.2 **Option 2.** It is difficult to estimate the costs to the enforcement authorities without details of the precise regime that will operate; for example what proportion of an authority's budget may be allocated for checking compliance with the new limits. The Food Standards Agency believes that the incremental financial costs to enforcement authorities are unlikely to have a significant cost impact and is likely to be minimal, if any. Local authority enforcement bodies have always had responsibility for the enforcement of food contact materials legislation. The proposed Regulations merely provide the means by which this role can be extended to cover the Commission Regulation. There were no comments from enforcement authorities on any likely financial costs associated with the enforcement provisions of the Commission Regulation.

11.3 The Food Standards Agency believes that these proposals place no new burdens on businesses. Industry are aware that restrictions for certain substances used in gaskets in lids might be set, as such it is the responsibility of businesses to ensure that they satisfy the requirements of the European Regulation. The Agency has developed guidance for businesses on these new Regulations. Such guidance will help minimise cost to businesses of the new Regulations. There may be some incidental costs to business or reading the new legislation, however this is likely to be minimal. This view was supported by the LGC, who indicated that the administrative burden on businesses, and most or all SMEs, is minimised by legislation that presents their rights transparently. Indeed, the

migration limits established by the European Regulation provide business with clear controls and the flexibility to move away from the use of substances that could be harmful to human health in the long term. At the same time it allows industry sufficient time to finalise the development of gaskets that are compliant with the SML laid down in Directive 2002/72/EC, as amended by Directive 2007/19/EC.

12. Competition Assessment

12.1 The Competition Filter Test has been completed and it has confirmed that none of the options raise competition concerns. The provisions for enforcement powers to the proper authorities in England do not place any hindrance on the competitiveness of business, nor does the alignment of penalties for offences with those that apply elsewhere in food law. As these proposals relate to offences where breaches arise, defences that might apply in the event of prosecution for alleged offences and penalties that apply on conviction for the offence, they are unlikely to raise any competition concerns. This view is supported by the Office of Fair Trading.

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 indicate a disadvantage to any particular business sector. The consultation carried out in October 2005 did not indicate any disadvantage to any particular business, or company. The proposals apply equally to all existing and new manufacturers of gaskets in lids intended to be brought into contact with food.

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 and Regulatory Reform (BERR – previously the Department of Trade and Industry), the Foreign and Commonwealth Office and the Cabinet Office were kept informed of progress in negotiations relating to the European Regulation through regular progress reports. To date, no adverse comments have been received from any departments.

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. An informal consultation was carried out in October 2005 and the proposal was also discussed during regular meetings

with stakeholder groups that are likely to be directly affected by the requirements of the Commission Regulation.

13.3. Because of the short nature of the Commission Regulation, the formal consultation in England was limited to six weeks as opposed to the normal 12 weeks. Formal consultation on these regulatory proposals for England involved organisations with an interest in food contact plastics; companies that manufacture gaskets for lids; food packaging manufacturers and processors, enforcement authorities, consumer organisations and port health authorities were also consulted. Other organisations who may wish to comment on food contact plastics legislation contained within these proposals were also consulted. One hundred and thirty two stakeholders were consulted on these proposals in England. These ranged from food industry organisations to sector specific organisations such as those manufacturers of materials and articles intended to come into contact with food and others with an interest in food contact materials legislation. We also consulted enforcement authorities, the Enterprise Directorate (formerly the Small Business Service (SBS)), Forum of Private Businesses (FPB), consumer organisations and other non-government organisations. No comments were received from either organisation of any financial costs to small businesses from this proposal.

13.4 Only three responses were received and these were from; Packaging and Films Association (PAFA), which is one of the trade associations representing major UK manufacturers of plastic and cellulose films, as well as companies that print and convert speciality packaging materials; one from the Laboratory of the Government Chemist (LGC); and one from a private individual. All three respondents were in full support of the Agency's proposal to provide for the enforcement of the Commission Regulation and the means by which this was being done. Consultation comments on drafting detail have been acted upon where necessary.

13.5 A formal consultation on the proposals with interested parties in Wales concluded on 17 August. There were no responses from over 50 interested parties in Wales.

14. Post Implementation Review

14.1 We 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 SI 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.

14.3 Review of the Regulations will not be necessary as they put in place interim measures which are only valid until the end of June 2008.

15. Summary

15.1 The proposals here provide for the effective enforcement of the Commission Regulation and they also provide businesses with harmonised rules that apply across the European Union.

15.2 The Agency believes that the advantages of full implementation of the proposals that are the subject of this regulatory impact assessment will benefit industry, enforcement authorities and consumers. The measures proposed are important in providing the means for improved enforcement and essential consumer health protection and improved products. Industry fully supports the pursuit of Option 2 which has the desired effect in achieving the means of adequate enforcement of Regulation 372/2007/EC.