
STATUTORY INSTRUMENTS

2007 No. 0000

FOOD, ENGLAND

The Plastic Materials and Articles in Contact with Food (Lid Gaskets) (England) Regulations 2007

<i>Made</i>	- - - -	2007
<i>Laid before Parliament</i>		2007
<i>Coming into force</i>	- -	2007

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(2), 26(1)(a) and (3), and 48(1) of the Food Safety Act 1990(a), and now vested in her(b).

In accordance with section 48(4A) of that Act, she has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, application and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Lid Gaskets) (England) Regulations 2007, apply in relation to England only and come into force on [—] 2007.

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- (a) 1990 c. 16. section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred 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 1999 Act, and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act..
- (c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

Interpretation

2.—(1) In these Regulations —

“the Act” means the Food Safety Act 1990;

“the Commission Regulation” means Commission Regulation (EC) No. 372/2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods^(a);

“authorised officer” means any person who is authorised in writing, either generally or specifically, by a food authority or as the case may be a port health authority to act in matters arising under these Regulations;

“food authority” does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple) nor a port health authority;

“import” means import in the course of a business from a state other than a Member State;

“lid” means a lid of the type mentioned in Article 1 of the Commission Regulation;

“port health authority” means —

- (a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984^(b) by section 7(1) of that Act), the Common Council of the City of London; and
- (b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act.

(2) Any other expression used in these Regulations and in the Commission Regulation has the same meaning in these Regulations as it bears in the Commission Regulation.

Enforcement

3. It shall be the duty of each food authority within its area and each port health authority within its district to execute and enforce these Regulations and the Commission Regulation.

Offences and penalties

4.—(1) Any person who —

- (a) contravenes or fails to comply with the requirements of Article 1 of, as read with the Annex to, the Commission Regulation (requirements relating to lids sealed with gaskets containing certain plasticising substances);
- (b) intentionally obstructs any person acting in the execution of these Regulations;
- (c) without reasonable excuse, fails to give to any person acting in the execution of these Regulations or the Commission Regulation any assistance or information which that person may reasonably require; or
- (d) in purported compliance with any requirement mentioned in sub-paragraph (c), knowingly or recklessly supplies information that is false or misleading in any material particular,

is guilty of an offence.

(2) Anyone convicted of an offence under these Regulations is liable —

- (a) in the case of an offence under paragraph (1)(a) —
 - (i) on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both;

(a) OJ No. L92, 3.4.2007, p.9. Recital 2 of the Regulation was corrected by a corrigendum, (OJ No. L92, 3.4.2007).

(b) 1984 c. 22.

- (ii) on summary conviction to a term of imprisonment not exceeding six months or to a fine not exceeding the statutory maximum or both;
 - (b) in the case of an offence under paragraph 1(b), (c) or (d), to a term of imprisonment not exceeding three months or to a fine not exceeding level five on the standard scale or both.
- (3) Nothing in paragraph (1)(c) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate him.

Offences by corporate bodies etc

5. Where an offence under these Regulations which has been committed by a body corporate or a Scottish partnership is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of —

- (a) any director, manager, secretary or other similar officer of the body corporate or any partner of the Scottish partnership, or
- (b) any person purporting to act in such a capacity,

he as well as the body corporate or, as the case may be, the Scottish partnership shall be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

Offences due to the act or default of a third party

6. Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that other person shall be guilty of the offence; and a person may be charged with and convicted of the offence whether or not proceedings are taken against the first mentioned person.

Time limit for prosecutions

7. No prosecution for an offence under these Regulations shall be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.

General defences

8.—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence for the person accused to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.

(2) Without prejudice to the generality of paragraph (1), a person accused of an offence under regulation 4(1)(a) who did not —

- (a) prepare the lid in respect of which the offence is alleged to have been committed; nor
- (b) import it into the United Kingdom,

shall be taken to have established the defence provided by paragraph (1) if he satisfies the requirements of paragraph (3).

(3) A person satisfies the requirements of this paragraph if he proves —

- (a) that the commission of the offence was due to the act or default of some other person who was not under his control, or to reliance on information supplied by such a person;
- (b) that the placing on the market of which the alleged offence consisted was not a placing on the market under his name or mark;
- (c) that either —
 - (i) he carried out all such checks of the lid in question as were reasonable in all the circumstances, or

- (ii) it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied him with the lid in question; and
 - (d) that he did not know and had no reason to suspect at the time the offence was committed that his act or omission would amount to an offence under these Regulations.
- (4) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the person accused shall not without leave of the court be entitled to rely on that defence unless —
- (a) at least seven clear days before the hearing; and
 - (b) where he has previously appeared before the court in connection with the alleged offence, within one month of his first such appearance,
- he has served on the prosecutor a written notice giving such information identifying or assisting in the identification of that other person as was then in his possession.

Procedure where a sample is to be analysed

- 9.**—(1) An authorised officer who for the purposes mentioned in regulation 3 has procured a sample under section 29 of the Act and who considers it should be analysed shall divide the sample into three parts.
- (2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.
- (3) The authorised officer shall —
- (a) if necessary place each part in a suitable container and seal it;
 - (b) mark each part or container;
 - (c) as soon as reasonably practicable, give one part to the owner and notify him in writing that the sample will be analysed;
 - (d) submit one part for analysis in accordance with section 30 of the Act; and
 - (e) retain one part for future submission under regulation 10.

Secondary analysis by the Government Chemist

- 10.**—(1) Where a sample has been retained under regulation 9 and —
- (a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and
 - (b) the prosecution intends to adduce as evidence the result of the analysis mentioned above,
- paragraphs (2) to (7) apply.
- (2) The authorised officer —
- (a) may of his own volition;
 - (b) shall if requested by the prosecutor (if a person other than the authorised officer);
 - (c) shall if the court so orders; or
 - (d) shall (subject to paragraph (6)) if requested by the defendant,
- send the retained part of the sample to the Government Chemist for analysis.
- (3) The Government Chemist shall analyse the part sent to him under paragraph (2) and send to the authorised officer a certificate of analysis.
- (4) Any certificate of the results of testing transmitted by the Government Chemist shall be signed by him or on his behalf, but the testing may be carried out by any person under the direction of the person who signs the certificate.

(5) The authorised officer shall immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the defendant with a copy of the Government Chemist's certificate of analysis.

(6) Where a request is made under paragraph (2)(d) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

(7) In this regulation "defendant" includes a prospective defendant.

Application of various sections of the Food Safety Act 1990

11. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations —

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 30(8) (which relates to documentary evidence);
- (c) section 44 (protection of officers acting in good faith).

Signed by authority of the Secretary of State for Health

Date 2007

Caroline Flint
Minister of State
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to England only, provide for the execution and enforcement of Commission Regulation (EC) No 372/2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods (OJ No. L92, 3.4.2007, p.9) “the Commission Regulation”..

2. The Regulations —

- (a) designate the bodies having the duty to enforce these Regulations and the Commission Regulation (*regulation 3*);
- (b) make it an either-way offence to contravene the requirements of Article 1 of the Commission Regulation, which provides that lids containing gaskets made of plastic materials must comply with the detailed specifications set out in the Annex to that Regulation (*regulation 4(1)(a) and (2)(a)*);
- (c) make it a summary offence to obstruct, fail to give information to or give false information to anyone enforcing these Regulations (*regulation 4(1)(b),(c)&(d) and (2)(b)*);
- (d) provide that individuals responsible for the actions of a corporate body or a Scottish partnership may be co-prosecuted for offences committed by that body or partnership (*regulation 5*);
- (e) provide for the prosecution of a person who causes the commission of an offence under these Regulations by another person (*regulation 6*);
- (f) specify a time limit for commencing a prosecution (*regulation 7*);
- (g) provide for defences of a general nature, such as exercising due diligence etc, to offences under these Regulations (*regulation 8*);
- (h) specify the procedure to be followed when sending a sample for analysis (*regulation 9*);
- (i) make provision for a reference sample to be analysed by the Laboratory of the Government Chemist (*regulation 10*); and
- (j) apply certain provisions of the Food Safety Act 1990 for the purposes of these Regulations (*regulation 11*).

3. A full regulatory impact assessment of the effect that this instrument will have on the costs of business has been prepared and placed in the Library of each of the Houses of Parliament. Copies may be obtained from the Chemical Safety Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

INITIAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

- 1.1 These Regulations are to be known as The Plastic Materials and Articles in Contact with Food (Lid Gasket) (England) Regulations 2007.

2. Purpose and Intend Effect

- **Objective**

- 2.2 The purpose of these proposals is to meet the Government's commitment to honour its EU obligation by making provision 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.
- 2.3 The proposed Regulations, which will apply to England, are to be a short-lived measure to last until April 2008, when the European regulation expires. They will provide for the enforcement of that European Regulation.
- 2.4 They will also put in place offences that may be prosecuted before the Courts where alleged breaches of the European Regulation arise, defences against alleged breaches under particular circumstances, and penalties that may be applied by the courts upon conviction for an offence.
- 2.5 This Regulatory Impact Assessment (RIA) is concerned only with the enforcement of the European Regulation which will extend to England only.
- 2.6 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, Wales and Northern Ireland.

- **Background**

- 2.7 Gaskets and lids intended to come into direct contact with food will come within scope of Commission Directive 2002/72/EC as amended from April 2008 (that Directive is given effect in English law under other Regulations). 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. Since provisions were originally made for gaskets under that Directive, manufacturing technology has developed. This has resulted in an ambiguity in how gaskets in metal lids could be dealt with under the rules. In some cases they may be regarded as a plastic part of a material and thus covered by Directive 2002/72/EC, but in others as a plastic coating on a metal substrate that would not be covered by that Directive. The Directive is therefore being amended to clear up this ambiguity and these transitional European Regulations make provisions that will be in force until that amendment takes effect in our national law by April 2008.
- 2.8 Consequently, to prevent the ambiguity becoming a barrier to trade and to ensure the free flow of goods on the market it has been necessary to clarify the position regarding gaskets in lids and fix transitional specific migration limits (SML) for some substances used in their manufacture. These SML's 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 of those products affected, the lids and foods that pose a significant risk are immediately excluded from the market. The European Regulation also provides industry sufficient time to finalise the development of gaskets that are compliant with the restrictions laid down in Directive 2002/72/EC, as amended by Directive 2007/19/EC¹.

2.9 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 pentaerthritol, 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

2.10 Regulatory proposals to give effect in English law to Directive 2007/19/EC will be the subject of a separate consultation in August 2007 so that it can come into force when this temporary proposal expires in April 2008.

• **Rationale for Government Intervention**

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

- reduce the chronic long term health risks to consumers arising from chemical contamination of foods they eat; and
- meet the inter-governmental Lisbon agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules within which businesses can compete on an equal footing and that are not over burdensome.

To do nothing would leave enforcement authorities without the adequate essential statutory powers needed to prevent the placing on the market of those products that fail to comply with the restrictions in the European Regulation and are directly applicable in all Member States.

2.12 The Food Standards Agency believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and allows technological innovation. Consumer protection will continue in an area of food control where inadequate controls could have serious long-term implications or are seriously suspected of carrying an unacceptable risk to consumer health, particularly among more vulnerable people. The introduction of harmonised

¹ Directive 2007/19/EC, amending Commission Directive 2002/72/EC and 85/572/EC, relating to plastic materials and articles intended to come into contact with food. Published in the Official Journal of the European Communities ((OJ) reference L97, 12.4.2007, pp50-69)

statutory controls would reduce uncertainty or dispute in interpreting the requirements of the European Regulation.

3. Consultation

- **Within Government**

3.1 Departmental economists, the Agency's Better Regulation Unit have been consulted about these proposals. Other government departments including the Department of Health, 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 comments have been received from any departments.

- **Public Consultation**

3.2 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 less formally, during regular meetings with stakeholder groups that are likely to be directly affected by the requirements of the European Regulation.

3.3 Formal consultation on these regulatory proposals for England will not only involve those organisations that manufacture gaskets in lids, but also those with an interest in plastic food packaging, enforcement authorities, consumer organisations and port health authorities.

4. Options

- **Option 1 Do Nothing**

4.1 Doing nothing will not affect the European Regulation having effect in England; 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 those Regulations will not have been fulfilled. This would lead to the Government being cited in infraction proceedings by the European Commission.

- **Option 2 – Fully implement the necessary requirements that will support the European Regulation and provide for its enforcement.**

4.2 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 European Regulation is already in force, we are required to provide for its enforcement in England. 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.

NOTE FOR CONSULTATION - Comments

We would welcome comments on the assertions in paragraph 4.2, that option 2 has the desired effect in support of the proposal. If you disagree with this assessment, please provide evidence to support your view.

5. Costs and Benefits

- **Sectors and groups affected**

- 5.1 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 European Regulation.
- 5.2 Local authorities and port health authorities are responsible for enforcing the legislation with respect to food safety and will therefore be affected.
- 5.3 Government departments, such as the Food Standards Agency will be affected as 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.

Benefits

- **Option 1**

- 5.4 There are no identifiable incremental benefits from following this option.

NOTE FOR CONSULTATION - Comments

We would welcome comments on the assertions in 5.4 that option 1 does not have the desired effect in relation to the foreseeable benefits of the proposal. If you disagree, please provide evidence to support your view.

- **Option 2**

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

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 to various adverse effects on human

health. This option may therefore, reduce such burden on the health service through prevention of chronic illness².

- 5.6 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.

NOTE TO CONSULTATION – Comments

Stakeholders and particularly, enforcement authorities are asked to comment on the proposal in relation to benefits that can be identified. If you disagree with the assertion made in paragraph 5.6, please provide evidence to support your view.

Costs

- **Option 1**

- 5.7 Commission 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 European 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 European Regulation.

- **Option 2**

- 5.8 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. Local authority enforcement bodies have always had responsibility for the enforcement of food contact materials legislation. The proposed Regulations on which we are consulting merely provide the means by which this role can continue under the European Regulation.

NOTE TO CONSULTATION – Comments

Stakeholders and particularly, enforcement authorities are asked to comment on the proposal in relation to costs that can be identified. If you disagree with the assertion made in paragraph 5.8, please provide evidence to support your view.

² A 1999 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 at the following website:

- 5.9 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. Any costs which industry may face and whether this occurs or not will depend on the nature and demand for their products and level of competition in the market. 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 this would allow 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.

NOTE FOR CONSULTATION – Comments

We would welcome comments from stakeholders in our assertion that cost implications arising from these proposals are negligible. However, please inform us if you disagree with our assessment and provide evidence as appropriate on financial costs associated with the European Regulation.

- **Economic, Social and Environmental**

- 5.10 The social and environmental cost arising from these proposals are negligible. Furthermore, the European Regulation permits the move away from some substances that are already persistent in the environment.
- 5.11 Rural areas, disabled people and members of the ethnic communities are not affected by these proposals any differently to others. Charities and voluntary organisations are unlikely to be affected by these proposals.
- 5.12 The Food Standards Agency's remit is to protect the interests of consumers in relation to food, 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 proposals are unlikely to have any specific impact on sustainability. Indeed, the elaboration of the requirement to follow the SML's laid down in the European Regulation arguably ensures the best practice will contribute to reducing waste and loss in manufacturing.

Policy and administration costs

- 5.13 The Food Standards Agency believes that the policy and administration costs are likely to be minimal. There will be a small administration cost to business of reading the new legislation, and as this is a time limited measure, which does not represent any new compulsory action, there will be no administrative burden placed on business.

NOTE FOR CONSULTATION – Comment

We would welcome any comments on our view that any new administrative costs will be minimal. We would also welcome your comments and evidence if you believe that the proposed Regulations introduce any new administrative costs, over and above what a business would do commercially.

6. Small Firms Impact Test

- 6.1 The companies involved in this area are represented through their national trade bodies to those at European level. The Small Business Service (SBS) and the Forum of Private businesses (FPB) will be consulted about the financial implications for small businesses arising from this proposal. We shall also be contacting small businesses to ascertain the impact of the proposal and would encourage them to provide comments.
- 6.2 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.

7 Competition Assessment

- 7.1 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, there are unlikely to raise any competition concerns. This view is supported by the Office of Fair Trading.
- 7.2 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.
- 7.3 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.
- 7.4 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.

8 Enforcement, Sanctions and Monitoring

• Enforcement

- 8.1 Local authorities and port health authorities are responsible for enforcing a large proportion of Regulations with respect of food safety and have done so in respect of all the legislation on materials and articles intended to come into contact with food. Thus the proposed Regulations on which we are consulting merely provide the means by which this role can continue under the European Regulation.

³ Mintel, April 2003

- **Sanctions**

- 8.2 A person who fails to comply with the requirements of Regulation 372/2007 is liable, if convicted of an offence on indictment under Section 4(1)(a) under these proposed Regulations, to a term of imprisonment not exceeding two years or to a fine or both; on summary conviction they are liable to a term of imprisonment not exceeding six months or to a fine not exceeding the statutory maximum or both. These penalties are in line with The Food Safety Act 1990, as amended.

- **Monitoring**

- 8.3 The authorities in England 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. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the 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 also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from these Regulations.

Sections 9-12

Sections 9-12 should be completed after consultation and included in the full RIA.

1.

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1		
2		
3		
4		

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed

Date

Minister's name, title, department

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Circulation List for Public Consultation: Plastic Materials and Articles in Contact with Food (Lid Gasket) (England) Regulation 2007

Name	Company
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Mr Paul Anthony Taylor	
Anton Davis	Alba Plastics
Mr Roger Parry	Amcor Flexibles
Mr Stuart MacConnacher	AMDEA
Dr P Donnelly	APD Scientific Limited
	Association For Consumer Research
Mrs Rita McBrown	Avent Limited
Nicola Smith	Bird and Bird
Dr Steve Owen	Boots PDQ Centre
Mr AJ Newbould	British Coatings Federation Ltd
	British Disposable Products Association
Dr Mercia Gick	British Plastics Federation
Lucy Pearson	British Soft Drinks Association
Alex Cole	Cadbury Schweppes
John Hammond	Campden & Chorleywood Food Research Association
Mr N Byrd	Campden & Chorleywood Food Research Association FRA
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Mr Roger Hamby	CATRA
Dr S Parry	Centre for Analytical Research in the Environment
Dr Joanne Lloyd	Chemical Industries Association
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COMMISSION REGULATION (EC) No 372/2007**of 2 April 2007****laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ⁽¹⁾, and in particular Article 5(1) thereof,

After consulting the European Food Safety Authority (the Authority),

Whereas:

- (1) In 1999 the Scientific Committee for food has assigned to epoxidised soybean oil (ESBO) a tolerable daily intake (TDI) of 1 mg/kg body weight per day. This TDI is translated into a specific migration limit (SML) of 60 mg/kg food for plastic materials and articles in Commission Directive 2002/72/EC ⁽²⁾.
- (2) Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food ⁽³⁾ clarifies that gaskets in lids fall under the scope of Directive 2002/72/EC. It stipulates that Member States have to adopt measures by 1 April 2008 that allow free circulation of gaskets in lids if they comply with SML. Non-compliant gaskets in lids will be prohibited as from 1 June 2008.
- (3) It appears necessary to regulate the placing on the market of those products pending the implementation of Directive 2007/19/EC.
- (4) Indeed, recent data from Member States and Switzerland showed concentrations of ESBO in fatty food, such as sauces and vegetables or fish in oil, reaching up to 1 150 mg/kg. With such high values, the TDI may be exceeded for consumers.
- (5) Recently business operators have shown an interest in using other plasticisers as substitutes for ESBO which

either have a higher TDI or migrate to lesser extent. Therefore specific rules for these substitutes are also necessary.

- (6) Moreover, the legal situation of these products is currently uncertain. Directive 2002/72/EC 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 thus not covered by Directive 2002/72/EC.
- (7) As a consequence, Member States currently apply diverging rules that may pose a barrier to trade.
- (8) It therefore appears proportionate to fix transitional SML for the sum of certain plasticisers used in gaskets in lids contacting fatty foods, so that the free circulation of those products is not endangered, the lids and foods that pose a significant risk are immediately excluded from the market and, at the same time, industry has 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.
- (9) The transitional SML should be set at a level ensuring that normally the TDI will not be exceeded, taking into account the average consumption of the foods concerned and the opinion issued by EFSA on 16 March 2006, which indicated that the level of plasticisers present in 90 % of the fatty food in glass jars is below 300 mg/kg food.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Lids containing plastic layers or plastic coatings, forming gaskets in these lids that together are composed of two or more layers of different types of materials may be placed on the market in the Community if they comply with the restrictions and specifications indicated in the Annex to this Regulation.

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

⁽²⁾ OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35).

⁽³⁾ OJ L 91, 31.3.2007, p. 17.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall apply until 30 June 2008.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 April 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Restrictions and specifications related to plasticisers used in gaskets in lids

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
88640	008013-07-8	Soybean oil, epoxidised (ESBO)	<p>For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T) ⁽¹⁾ ⁽²⁾ = 300 mg/kg of food or food simulants or 50 mg/dm² of the total food contact surface of lid and sealed container.</p> <p>For materials and articles intended for or brought into contact with infant formulae and follow-on formulae as defined by Commission Directive 91/321/EEC on infant formulae and follow-on formulae and products according to Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children SML = 30 mg/kg of food or food simulant.</p> <p>For materials and articles intended for or brought into contact with all other types of foods SML(T) ⁽²⁾ = 60 mg/kg of food or food simulants or 10 mg/dm² of the total food contact surface of lid and sealed container.</p>
30401	—	Acetylated mono- and diglycerides of fatty acids	<p>For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T) ⁽²⁾ = 300 mg/kg of food or food simulants or 50 mg/dm² of the total food contact surface of lid and sealed container.</p> <p>For materials and articles intended for or brought into contact with all other types of foods SML(T) ⁽²⁾ = 60 mg/kg of food or food simulants or 10 mg/dm² of the total food contact surface of lid and sealed container.</p>
76815	—	Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C ₁₂ -C ₂₂ fatty acids	<p>For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T) ⁽²⁾ = 300 mg/kg of food or food simulants or 50 mg/dm² of the total food contact surface of lid and sealed container.</p> <p>For materials and articles intended for or brought into contact with all other types of foods SML(T) ⁽²⁾ = 60 mg/kg of food or food simulants or 10 mg/dm² of the total food contact surface of lid and sealed container.</p>
93760	000077-90-7	Tri-n-butyl acetyl citrate	<p>For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T) ⁽²⁾ = 300 mg/kg of food or food simulants or 50 mg/dm² of the total food contact surface of lid and sealed container.</p> <p>For materials and articles intended for or brought into contact with all other types of foods SML(T) ⁽²⁾ = 60 mg/kg of food or food simulants or 10 mg/dm² of the total food contact surface of lid and sealed container.</p>

(1)	(2)	(3)	(4)
56800	030899-62-8	Glycerol monolaurate diacetate	<p>For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T) ⁽²⁾ = 300 mg/kg of food or food simulants or 50 mg/dm² of the total food contact surface of lid and sealed container.</p> <p>For materials and articles intended for or brought into contact with all other types of foods SML(T) ⁽²⁾ = 60 mg/kg of food or food simulants or 10 mg/dm² of the total food contact surface of lid and sealed container.</p>
30340	330198-91-9	12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)-propyl ester	<p>For materials and articles intended for or brought into contact with foods for which simulant D testing is required by Directive 85/572/EEC SML(T) ⁽²⁾ = 300 mg/kg of food or food simulants or 50 mg/dm² of the total food contact surface of lid and sealed container.</p> <p>For materials and articles intended for or brought into contact with all other types of foods SML(T) ⁽²⁾ = 60 mg/kg of food or food simulants or 10 mg/dm² of the total food contact surface of lid and sealed container.</p>
76866	—	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 C ₁₂ -C ₁₈ or n-octanol and/or n-decanol	SML = 30 mg/kg of food or food simulants or 5 mg/dm ² of the total food contact surface of lid and sealed container.

⁽¹⁾ 'SML' means specific migration limit.

⁽²⁾ SML(T) in this specific case means that the specific migration limit shall not be exceeded by the sum of the migration levels of the substances mentioned with reference numbers 88640, 30401, 76815, 93760, 56800 and 30340.

Corrigendum to Commission Regulation (EC) No 372/2007 of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods

(Official Journal of the European Union L 92 of 3 April 2007)

On page 9, recital 2 is replaced by the following:

- ‘(2) Commission Directive 2007/19/EC of 2 April 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food ⁽³⁾ clarifies that gaskets in lids fall under the scope of Directive 2002/72/EC. It stipulates that Member States have to adopt measures by 1 May 2008 that allow free circulation of gaskets in lids if they comply with SML. Non-compliant gaskets in lids will be prohibited as from 1 July 2008.’

On page 9, footnote 3 is replaced by the following:

‘OJ L 91, 31.3.2007, p. 17, corrected by OJ L 97, 12.4.2007, p. 50.’
