EXPLANATORY MEMORANDUM TO THE

PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDEMENT) (ENGLAND) REGULATIONS 2004

2004 No. 3113

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty

2. Description

2.1 This instrument implements two EU Directives.

2.2 The first Directive, 2004/13/EC, extends the period in which the chemical known as BADGE may be used in food contact plastics, adhesives and coatings to 31 December 2005. It is intended that better scientific data be produced to allow a more informed risk assessment to be made on its continuing use beyond that date, it also clarifies the manner of the labelling of some cans with coatings made from this and 2 other substances.

2.3 The second Directive, 2004/1/EC, prohibits the use of azodicarbonamide as a blowing agent in food contact plastics from 2 August 2005.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 The Plastic Materials and Articles in Contact with Food Regulations 1998 implement harmonised EU measures contained in adopted EC Directives on materials and articles intended to be brought into contact with food that are manufactured from plastic. The Directives include lists of substances that can be used in the manufacture of these food contact plastics and any restrictions on that use that is necessary to safeguard human health and the nature and quality of the foodstuff. In our Regulations, SI 2002 No. 2364 amended the 1998 Regulations in relation to earlier EU-harmonised provisions on the use of BADGE[1], BFDGE[2] and NOGE[3] and their derivatives in the manufacture of food contact plastics, adhesives and coatings.

4.2 This latest Commission Directive, 2004/13/EC, sets out to do two things. It extends the provisional authorisation of the use of BADGE in the manufacture of food contact plastics, coatings and adhesives for a further 12 months until 31 December 2005; it also provides that where a coded date or indication is used the competent authorities and enforcement officers shall have the actual date made available upon request. This extension of the

[1] 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (otherwise known as 'BADGE')
[2] Bis(-hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (otherwise known as 'BFDGE')
[3] Novolac glycidyl ethers (known as 'NOGE')

provisional authorisation of the use of BADGE is important in allowing the industry to complete the final stages of their scientific work to produce data that will enable a full scientific risk assessment to be made about the continuing use of BADGE beyond 2005. The provision on date marking is an important clarification of the manner of the date of filling to be applied to containers that have a coating, which contains the substances BADGE, BFDGE or NOGE. This date confirms that the containers comply with the requirements that only those filled or brought into contact with food before 1 March 2003 may be placed on the market, and only then providing they are marked with the date on which they were filled.

4.3 The legal provision permitting the use of azodicarbonamide as a blowing agent in food contact plastics occurs in SI 2000 No. 3162, where Regulation 11 brings in Schedule 2 amendments and item 27a, makes the addition of azodicarbonamide to Schedule 2 in the 1998 Regulations. The legislation reflects a consolidation of earlier EC harmonised measures and covers England. There are separate but parallel Regulations for Scotland, Wales and Northern Ireland.

4.4 Commission Directive 2004/1/EC has been adopted with agreement from all EU Member States to prohibit the use of azodicarbonamide as a blowing agent in food contact plastics from 2 August 2005. It requires therefore the amendment of the current entry in the Regulations on azodicarbonamide to bring this prohibition into effect. It also provides that materials and articles brought into contact with food before 2 August 2005 may continue to be placed on the market provided the date of filling appears on them. The directive repeats the provision on date marking outlined in paragraph 4.2 above. The prohibition on the use of azodicarbonamide reflects scientific concern for the amount found to have migrated into some re-sealable jars of baby food from the flexible gasket used to seal the jar so as to minimise the growth of bacteria in the food.

4.5 It is therefore necessary to make consequential amendments to The Plastic Materials and Articles in Contact with Food Regulations 1998 if these measures are to be implemented in England for the protection of consumers and for clarity in the enforcement of the law. Although the EC Directive allows Member States until 29 January 2005 to enact legislation to bring these measures into force, these Regulations are to be brought into force by 30th December 2004 to ensure that there is no gap in the provision that allows continuing use of BADGE. To wait until the last moment to enact these provisions would leave a gap of 28 days, from 1st January 2005 to 28th January 2005 in which, effectively, industry would be prohibited from using the substance for the purposes described in the legislation.

5. Extent

5.1 This instrument applies to England. Separate but parallel legislation is being enacted for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 Not applicable.

7. Policy Background

7.1 It is the intention that the law on materials and articles intended to be brought into contact with food should protect human health from the chronic effect over a person's lifetime of the consumption of food contaminated with chemicals used in the manufacture of the materials and articles. It also aims to protect the nature and quality of the food concerned and to provide the industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each EU Member State.

7.2 The European Commission, taking account of the opinions of the European Food Safety Authority on the use of these substances routinely amends technical lists of substances containing limits on their use. Substances that are deemed to cause unacceptable risk to consumer health, particularly among vulnerable people, may be prohibited from use. Member States and industry at European and national level have been fully consulted about these proposals. The proposals here are in line with Government policy to reduce the risk to consumers of exposure to chemicals and are therefore fully supported by the Government.

8. Impact

8.1. The Food Standards Agency fully consulted all stakeholders on the proposals that led to these amending Regulations and the proposed regulations themselves. The outcome confirmed that the measures proposed to implement Commission Directive 2004/13/EC have no specific extra requirements that lay any new financial burdens, it merely extends an existing deadline by which the use of a substance must cease and clarifies the manner in which some materials will have to be date marked.

8.2 The primary business sector, that will be affected by those parts of the proposed Regulations that implement directive 2004/1/EC, will be the manufacturers of food contact plastics; specifically those companies producing particular type of gaskets used to hermetically seal jarred foods, including some baby foods. They have the responsibility of finding an alternative substance to azodicarbonamide to manufacture this type of sealing gasket.

8.3 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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TRANSPOSITION NOTE: ***THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDMENT) (ENGLAND) REGULATIONS 2004***

- These Transposition Notes set out how the main elements of Directives 2004/1/EC and 2004/13/EC will be transposed into English law in the above Statutory Instrument.
- All references to the 1998 Regulations are to The Plastic Materials and Articles in Contact with Food Regulations 1998 (S.I. 1998/1376), as amended.

Directive 2004/1/EC – amending Directive 2002/72/EEC as regards the suspension of the use of azodicarbonamide as a blowing agent.

Articles	**Objectives**	Implementation	Responsibility
Article 1	The Article replaces the current text in column 4 of Section A of Annex III in EC Directive 2002/72/EC concerning the additive azodicarbonamide with the reference number 36640. The new text is: "For use only as a blowing agent. Use prohibited as from 2 August 2005."	In regulation 2(1) (interpretation) of the 1998 Regulations the definition of "the Directive" is extended to include the amendments in Directive 2004/1. (See regulation 3(b))	Secretary of State
Article 2.1	States that Regulations to enforce this Directive must be in force by 2 August 2005 and shall be published and communicated to the European Commission.	The Regulations will come into force on 30th December 2004, but the prohibition on the use of azodicarbonamide will only take effect on its due date of 2nd August 2005.	
Article 2.2 First paragraph	Requires that EU Member States apply the provisions of Article 1 to prohibit the sale and importation into the EU of plastic food contact materials and articles manufactured using azodicarbonamide as a blowing agent from 2 August 2005.	These are applied by amending Part 1 of Schedule 2 of the 1998 Regulations, at item 27A in column 4, to add the words "Use prohibited as from 2nd August 2005". (See regulation 5)	
Article 2.2 Second paragraph	Requires Member States to exempt such goods filled with food before 2 August 2005 and for the date of filling, or a coded version, to be on the material or article. Where a coded form of the date of filling is used, the actual date must be made available to the competent authorities upon request.	Regulation 10 (offences) of the 1998 Regulations is amended by the addition of paragraphs (23) and (24) to provide for a defence if it can be proved that the food was brought into contact with the material or article before 2 August 2005, and the filling date was marked on the material or article. The actual date in any coded date indication must be made available to the Food Standards Agency and the enforcement authority upon request. (See regulation 6(c))	

Articles	**Objectives**	Implementation	Responsibility
Article 2.2 Third paragraph	Requires that this date marking shall be without prejudice to the requirements of Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs.	Regulation 10 (offences) of the 1998 Regulations is amended to provide for a defence if it can be proved that the date indication complies with the labelling durability provisions of EC Directive 2000/13 (See regulation 6(c))	Secretary of State

Directive 2004/13/EC – amending Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs.

Articles	**Objectives**	Implementation	Responsibility
Article 1.1	To extend the period during which a particular substance may be used in the manufacture of food contact plastics, adhesives and coatings. The Article replaces the date of "31 December 2004" with "31 December 2005" in the second paragraph of Article 2 of the 2002 Directive	The definition of Commission Directive 2002/16 in the 1998 Regulations is extended to include the amendments made by Directive 2004/13, (see regulation 3(a)). The necessary date changes are made to regulations 4A(1)(a), 5(1)(b)(i) and 8A and Schedule 1 Part I of the 1998 Regulations, (see regulation 4).	Secretary of State
Article 1.2	To clarify the manner of the date mark on materials and articles manufactured using substances known as BFDGE and NOGE. The Article replaces Article 5 of the earlier Directive and in so doing reiterates that the preceeding three articles of that earlier Directive shall not apply to materials and articles brought into contact with foodstuff before 1 March 2003 and permits them to be offered for sale provided they are date marked with the date they were filled with foodstuff. Importantly, the date code is now expressly allowed to be an indication of the date, providing the actual date can be ascertained by competent authorities and enforcement officers upon request.	Paragraph (19) of regulation 10 (offences) of the 1998 Regulations is amended to provide for a defence if food was brought into contact with the defined adhesive, material or article before 28 February 2003, provided there is the necessary date of filling indication on the material or article filled with food, and that indication is applied in such a way as to meet the durability requirements of the EC labelling Directive. (See regulation 6(a) and (b)). If a date code is used, the actual date must be disclosed to the Food Standards Agency and the enforcement authority on request. (See regulation 6(c))	

Articles	**Objectives**	Implementation	Responsibility
Article 2	Requires that Regulations to enforce this Directive must be in force by 29 January 2005.	These amending Regulations will come into force on 30th December 2004. The Regulations need not come into force until 29 January 2005 according to the Directive, but because the current date until which the substance known as BADGE may be used is set at 31 December 2004, to wait beyond that date to bring these amending Regulations into force would in effect prohibit the use of BADGE unnecessarily. Bringing these amending Regulations into force in December avoids that and allows manufacturers to rightly continue their lawful business in relation to their use of BADGE in the food contact adhesives and other materials and articles.	Secretary of State