

**EXPLANATORY MEMORANDUM TO THE
PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD
(AMENDMENT) (ENGLAND) REGULATIONS 2005**

2005 No. 325

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 EU Directive 2004/19/EC.

2.2 Directive 2004/19/EC routinely amends Commission Directive 2002/72/EC by updating the lists of permitted monomers and additives that may be used in the manufacture of food contact plastics. The legal status of the monomers and additives is revised where the European Food Safety Authority has revised an existing opinion or issued a new one on the safe level of a substance that may be ingested daily by a person over a lifetime. These intake levels are converted into safe migration levels into food in the legislation.

2.3 Additionally to updating the lists of substances, Directive, 2004/19/EC aims to: prepare the ground for a Community positive list for additives; deal with situations where substances have controls in more than one Directive; and, put safeguards in place to ensure compliance with limits in foodstuffs where substances that might migrate from food contact materials and articles may also be used as food additives.

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. The harmonised European rules on food contact plastics are laid down by Commission Directive 2002/72/EC as amended. These rules are routinely amended as technical and scientific knowledge develops. The rules are implemented in Great Britain by The Plastic Materials and Articles in Contact with Food Regulations 1998 (SI 1998 No. 1376), as amended in England (by SIs 2000 No. 3162, 2002 No. 2364, 2002 No. 3008 and 2004 No. 3113). Similar amendments have been made to Regulations to reflect these changes in Scotland, Wales and Northern Ireland. The new

European amending Directive has therefore to be implemented by amending the Regulations currently in place.

- 4.2 This latest amendment, arising from Commission Directive, 2004/19/EC, sets out to do three things that are reflected in the proposed regulations discussed here.
- 4.3 Firstly, it makes routine amendments to the Community list of permitted monomers in Annex II to Directive 2002/72/EC and the incomplete list of additives in Annex III to that Directive that are in our regulations. These amendments include new substances and amend the entries for others following the adoption of recommendations made the European Food Safety Authority. Regulations 9-16 of the proposed amending Regulations give effect to this change.
- 4.4 Secondly, it begins the process of creating a Community positive list for additives permitted for use in the manufacture of food contact plastics. The European Commission is required to nominate a date, by 31 December 2007, for closing the list of additives used in the manufacture of food contact plastics, as the first step in creating a positive list of additives. The Commission shall establish by 31 December 2007 a provisional list of additives containing those that are, at 31st December 2006, already authorised in one or more EU Member States and for which the necessary data stipulated by the EFSA has been submitted. In support of the establishment of a closed or positive list of additives the European Commission requires Member States to provide for the submission of the required data by 31 December 2006 to the EFSA for any additive that is to be entered on the provisional list. Regulation 6 of the proposed amending Regulations gives effect to this change.
- 4.5 Finally, the new amending Directive clarifies the relationship between Directive 2002/72/EC and directives on food additives and flavours, where substances may be authorised for use in food and in plastic food contact materials. Therefore the Directive proposes that additives used in the manufacture of food contact plastics that are also authorised food additives shall not migrate into foodstuffs: in quantities having a technological function in the final foodstuffs; in excess of the amounts permitted by food additives rules; or, where they are not authorised as an additive in a particular food, in excess of the amount permitted by Directive 2002/72/EC, as amended. Although the amendment permits national rules to be applied, pending the adoption of Community provisions, governing the use of additives in 'active' food contact materials, none have been adopted in the United Kingdom. Regulation 5 of the proposed amending Regulations give effect to this change.
- 4.6 It is 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. It is proposed to implement the requirements of this Directive in one set of Regulations that have to be in force by 1 September 2005.

4.7 However, the amendments introduced by 2004/19/EC result in the transfer of certain monomers and other starting substances from a list (Annex II B) that authorises their use only until 31st December 2004, to listed (Annex II A) substances authorised without time limit. As a consequence, from 1st January 2005 until they are amended, our 1998 Regulations will be out of step with EC law and it will technically be an offence to use those time limited monomers still listed in Section B of Part 1 of Schedule 1 of the 1998 Regulations, which have in fact been given permanent authorisations in 2004/19/EC. Therefore it is proposed that, between 1st January 2005 and the coming into force of the new amending regulations, those monomers in Section B of Part 1 of Schedule 1 of the 1998 Regulations which have now been given permanent authorisations at EC level may continue to be used by manufacturers of plastic food contact materials.

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. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction. 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 primary business sector that will be affected by the regulatory proposals will be the manufacturers of food contact plastics. However, the consultation outcome confirmed that the measures, amending the lists of substances that may be used in food contact plastics manufacture, have no specific extra requirements that lay any new financial burdens.

8.2 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

Richard Sinclair or Nasreen Shah at the Food Standards Agency (Telephone: 020 7276 8538 or 020 7276 8553) (e-mail: richard.sinclair@foodstandards.gsi.gov.uk or nasreen.shah@foodstandards.gsi.gov.uk).