

## GUIDANCE

### THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (AMENDMENT) (ENGLAND) (No.2) REGULATIONS 2002. (SI No.2002/3008)

**WARNING:** this guidance has been prepared to provide information about the Regulations, it should not be taken as an interpretation of the law. It is not a substitute for the Regulations nor should it be read in isolation from, but in conjunction with, them.

#### **Who should read this note.**

This guidance is aimed primarily at companies that manufacture, use or sell plastic materials and articles that are intended for use in contact with food. It may also be of interest to others with an interest in the legislation, such as enforcement authorities.

#### **Why you should read this note - compliance.**

Within the European Union it is the responsibility of the manufacturer, importer or distributor to ensure that their products comply with the appropriate legislation. Unlike the system administered by the Food and Drug Administration in the United States of America, there is no system of prior approval of food contact materials and articles within the EU.

#### **Purpose of the changes to legislation.**

The European Commission and the Member States of the European Union are working towards a fully harmonised set of rules that will apply across the EU. The aim is to protect consumers from any harmful effects of eating food that may have been contaminated by chemicals that might have migrated from materials and articles with which the food has been in contact. This harmonisation will also provide businesses with one set of rules to comply with throughout the EU. Since the principle legislation on plastic food contact materials and articles was introduced in 1990, it has been regularly amended as better scientific understanding has developed.

The Regulations that are the subject of this guidance amend *The Plastic Materials and Articles in Contact with Food Regulations 1998*. They are the second regulations to be made in England in 2002 to amend the 1998 Regulations. The first, *The Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002*, implemented European Commission Directives 2001/62/EC and 2002/16/EC and two small parts of 2002/17/EC that had a bearing on matters within those other two Directives. These Regulations implement the remainder of Directive

2002/17/EC and come into force on 28<sup>th</sup> February 2003. Similar regulations will come into force in Scotland, Wales and Northern Ireland.

The main changes brought about by these new amending regulations are:

- the addition of new monomers to the list of permitted monomers in Section A, Part I to the 1998 Regulations;
- amendment of the lists of additives in Parts I and II of Schedule 2 to the 1998 Regulations;
- necessary amendments to some details in the monomers list;
- changes to restriction entries for certain monomers; and
- the taking forward of definitions from the 1998 Regulations and implementation of some expressions in European Commission Directive 2002/17/EC that are not already in national laws.

### **Plastic food contact materials.**

Materials and articles are those that, in their finished state, are intended to come into contact with food, but not covering or coating substances that are part of the food and may be eaten with it. Materials and articles used in public and consumers' water supply systems are also outside this legislation. For the purposes of this legislation plastics are the organic macromolecular compounds obtained from molecules with a lower molecular weight by polymerisation, polycondensation, polyaddition or any other similar process or by chemical alteration of natural molecules. Other substances or matter may be added to these macromolecular compounds. Substances that are excluded from these compounds include silicones, paper and paperboard, particular regenerated cellulose film and some surface coatings.

### **Conformity deadlines.**

The new Regulations, by means of Regulation 4, implement Article 2(b) of EC Directive 2002/17/EC by amending Regulation 10 of the 1998 Regulations. The amendment here inserts new paragraphs (21) (a) and (b) and (22) into the 1998 Regulations. Unlike Directive 2002/17/EC, where offences are created for acts that occur after given dates, these Regulations work by providing for defences where it can be proved that the acts took place before a given date. Thus, under the 2002 (No.2) Regulations, there is a defence provision on proof that the offence was committed in relation to a plastic article or material manufactured or imported into the European Community before 1<sup>st</sup> March 2004. However, where those plastic materials and articles contain divinylbenzene, a similar defence provision only applies on proof that they were made or imported into the European Community before 28<sup>th</sup> February 2003 when these particular Regulations come into force.

## **Monomers and other starting substances**

The amendments to the lists of monomers and other starting substances arise from the published opinions of the European Commission's Scientific Committee on Food. These opinions set the daily limits for the amount of a substance that may be safely ingested by a person over a lifetime. Those limits are converted by the Commission into migration limits from a food contact material or article using additional conservative assumptions. These opinions by the Scientific Committee may be time bound where more data is needed. Opinions will also be revised where new scientific evidence makes this necessary.

Implementation of the amendments by Directive 2002/17/EC, Annex 1 (b) (i), (ii) and (iii), to the lists of monomers and other starting substances in Directive 90/128/EEC, is given effect in the 1998 Regulations by Regulation 5 of the 2002 (No.2) Regulations. The substances are listed in Schedule 1 Parts I, II and III to the 2002 (No.2) Regulations. Regulation 5 (c) gives effect to Annex 4 (b) of 2002/17/EC. This adds a series of notes (numbers 23 to 26) that define the meaning of the expression "SML(T)" in specific instances where the sum of the migration of a number of specific substances shall not exceed a given limit.

## **Additives**

Similarly, for additives Regulation 6 of the 2002 (No.2) Regulations with Schedule 2 Parts I, II, III and IV amends the 1998 Regulations in accordance with Directive 2002/17/EC Annexes 2 (a) (I), (ii) and (iii) and 2(b) (I) and (ii).

## **Further Information**

If you have any questions about these or any other regulations governing food contact materials and articles, please contact:

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Other information about food contact materials is available from the Agency's website at:

[www.food.gov.uk/industry/food\\_contact\\_materials](http://www.food.gov.uk/industry/food_contact_materials)

Information available includes explanatory notes on legislation, including European Council and Commission Directives and Council of Europe resolutions; research and development; and, chemical surveillance. The results of completed surveillance can be viewed from this point,

although older work can be accessed from the site archive. You can also access information about the work of The Working Party on Chemical Contaminants from Food Contact Materials in determining and reviewing work on research and development in this area.

Chemical Safety and Toxicology Division,

Food Contact Materials Unit.

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