

## **GUIDANCE**

### **THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) (No.2) REGULATIONS 2006.**

**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 businesses that manufacture, use, or sell materials and articles made from plastic that are intended for use in contact with food. It may also be of use to others with an interest in the legislation, such as enforcement authorities. These guidance notes provide a short summary of the changes proposed by the new Regulations in so far as they apply to England only. The devolved administrations in Wales, Scotland and Northern Ireland will make separate but parallel legislation.

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

Within the European Union it is the responsibility of the manufacturer, importer or distributor of food contact materials and articles, or those who place them in contact with food prior to sale, to ensure that their products comply with the appropriate legislation. Unlike the system administered by the Food and Drug Administration (FDA) in the United States of America that many businesses will be familiar with, there is no system of prior approval or authorisation of food contact materials within the EU. Instead of approving the product, constituents of the materials, such as monomers and other starting substances, are subject to specific, conditional authorisation at EC level. It is likely that, in the event of prosecution for an alleged offence under these Regulations, defendants might avail themselves of the defence of 'due diligence' provided for in the Food Safety Act 1990, as amended. In order to succeed, such a defence would most likely require evidence that the defendant had taken all reasonable precautions to avoid committing the alleged offence, including, probably, documentary evidence that the goods complied with the law.

## The European Legislation

The European Commission and the Member States of the European Union are working towards a fully harmonised set of rules that will apply to food contact materials and articles across the EU. The aim is to protect consumers from any harmful effects of eating food contaminated by chemicals that might have migrated from materials and articles with which the food had been in intentional contact or from which it might reasonably be expected that a substance might migrate into the food. In addition to protecting consumers, this harmonisation will provide businesses with one set of rules to comply with throughout the EU instead of a plethora of national rules in different EU Member States. Since the principal legislation on plastic food contact materials and articles was introduced in 1990, it has been regularly amended as better scientific understanding has developed about the nature and detection of chemical migrants from food contact materials and articles.

The Plastic Materials and Articles in Contact with Food (England) (No. 2) Regulations 2006 that are the subject of this guidance, implement EC Directive 2005/79/EC which contains the latest of these regular amendments. Thus, changes to the lists of substances and the restrictions that apply to some of them are given legal force in England by these Regulations. The Regulations will also revoke the recent 2006 Regulations and re-enact their provisions, amended to take into account the provisions of EC Directive 2005/79/EC. This will complete the second part of a two-stage strategy to consolidate the principle and several amending regulations and to simplify, in England, the rules they contain. The first part of the Strategy was completed with the coming into force of those first 2006 Regulations. This second part of the strategy will simplify the regulations by reducing the number of places in which substance restrictions and other substance usage information are recorded. This will help those that need to refer to the technical lists of substances authorised for use in the manufacture of food contact plastics by ensuring that they have as few documents to consult as possible and that we reduce the risk of error that may arise in repeating those detailed technical lists in our regulations.

For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. These amendments include new substances and amend entries for existing ones following risk assessment made by the European Food Safety Authority (EFSA). In particular, for epoxidised soybean oil (ESBO), a specific limit of migration from food contact plastics into food has been established for its use in PVC gaskets used to seal the lids of glass food jars. This Specific Migration Limit (SML) is 60 milligrams of ESBO per kilogram of food or food simulant. Along with the restrictions in the 2005 EC Directive for other substances, materials and articles compliant with this limit may be traded and used from 19 November 2006. The manufacture and import of non-compliant materials and articles is prohibited from 19 November 2007. This allows time for the manufacturers of these materials and articles to

change the constituents of their products where necessary, without risking the safety of foodstuffs and their ability to comply with the law.

However, for PVC gaskets containing ESBO used to seal the lids of glass food jars containing infant and follow-on formulae, or containing processed cereal-based foods and baby foods for infants and young children, the SML for ESBO has been set at half the limit for other applications. The limit in these cases is 30 milligrams per kilogram of food or simulant. Additionally, the EC Directive requires that the ESBO-containing gaskets used in these applications be compliant with this migration limit by 19 November 2006. This lower migration limit takes account of the fact that babies and infants can consume proportionately higher amounts of food from this source than adults, given their much smaller body weight. This lower limit will also ensure that infants and young children who regularly eat these foods will not exceed the amount considered safe to consume daily over a lifetime - the Tolerable Daily Intake level that has been set for ESBO. Goods manufactured using ESBO and compliant with the rules in place before this change takes effect on 19 November 2006, may continue to be placed on the market providing they are marked with the date of filling or a code representing that date.

### **Summary of Changes**

The new Regulation made in England, The Plastic Materials and Articles in Contact with Food (England) (No.2) Regulation 2006 will:

- revoke in their entirety, The Plastic Materials and Articles in Contact with Food Regulation (England) 2006 (SI 2006 No. 1401) and re-enact their provisions taking into account the provisions of Directive 2005/79/EC;
- simplify the rules by, wherever possible, making direct references in our Regulations to the Annexes which list all the substances that may be used in the manufacture of food contact plastics of Directive 2002/72/EC and subsequent amendments thereof;
- establish a SML of 60 milligrams per kilogram of food or food simulant for ESBO for its use in PVC gaskets used to seal the lids of glass food jars;
- halve this 60 milligrams per kilogram limit for PVC gaskets containing ESBO which are used to seal glass jars containing infant and follow-on formulae, or for containing processed cereal-based foods and baby foods for infants and young children;
- allow goods manufactured using ESBO and compliant with the rules in place before this change takes effect on 19 November 2006 to continue to be placed on the market providing they are marked with the date of filling or a code representing that date;
- prohibit the manufacture and import of non-compliant materials and articles from 19 November 2007.

## Further Information

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

Nasreen Shah,  
Food Standards Agency,  
Chemical Safety Division,  
Branch 4, Food Contact Materials Unit,  
Room 515C,  
Aviation House,  
125 Kingsway,  
London WC2B 6NH.  
Tel: 020 7276 8553  
Fax: 020 276 8514  
E-mail: [nasreen.shah@foodstandards.gsi.gov.uk](mailto:nasreen.shah@foodstandards.gsi.gov.uk)

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

[www.food.gov.uk/industry/foodcontactmaterials](http://www.food.gov.uk/industry/foodcontactmaterials)

The information that is available includes explanatory notes on all food contact material legislation, including Council of Europe resolutions and policy statements, European Regulations and European Commission Directives, United Kingdom research and development and chemical surveillance. The results of completed surveillance can be viewed from this point, although work predating the formation of the Agency 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 Division  
Food Contact Materials Unit  
September 2006