

GUIDANCE

THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD AMENDMENT (SCOTLAND) REGULATIONS 2004. (SSI No.2004/....)

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, in Scotland, manufacture, use by way of filling with foodstuff for sale or sell, plastic materials and articles 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. Similar provisions are being made by the devolved administrations in Wales, England and Northern Ireland and those provisions should be consulted regarding the law in those jurisdictions.

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, there is no harmonised system of prior approval or authorisation of food contact materials within the EU, although some constituents of the materials, such as monomers and other starting substances, are subject to 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 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.

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 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 contact and that were intended for that purpose. In addition, 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 Amendment (Scotland) Regulations 2004 that are the subject of this guidance implement two EC Directives by amending the Plastic Materials and Articles in Contact with Food Regulations 1998. They are the first Regulations to be made in Scotland in 2004 to amend the 1998 Regulations, which have already been amended a number of times.

Two years ago, the 1998 Regulations were amended in relation to the provisions governing the use of BADGE¹, BFDGE² and NOGE³ and their derivatives and a strict time limit was placed on their continued use. By implementing Commission Directive 2004/13/EC, these Regulations extend the provisional authorisation for the use of BADGE, for a further 12 months to allow for more scientific data to be produced to enable a full safety assessment to be made. The rules on the use of BFDGE and NOGE are unchanged. The second amendment is in relation to azodicarbonamide, which earlier amending legislation added as item 27A to the list of additives in Part 1 of Schedule 2 to the 1998 Regulations and permits its use as a blowing agent in the manufacture of food contact plastics. The current amending Regulations now prohibit the use of azodicarbonamide as a blowing agent from 2nd August 2005, by implementing the requirements of European Commission Directive 2004/1/EC. This prohibition comes as a result of a breakdown substance, semicarbazide, being detected in baby food in some jars that had sealing gaskets made using azodicarbonamide.

The Main changes brought about by the amending Regulations are:

Epoxy derivatives

- Commission Directive 2004/13/EC, amending Commission Directive 2002/16/EC on the use of certain epoxy derivatives, is relatively straightforward and sets out to do two things. Article 1

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')

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. This is implemented by amending regulation 4 of these new amending Regulations, while regulation 6 changes certain paragraphs of the original regulation 10 that concern defences to breaches of the Regulations. Article 2 seeks to clarify how the date of filling may be shown on containers that have a coating, which contains BADGE, BFDGE or NOGE. It makes clear that the containers must comply with the requirement that only those containers 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. The proposal also provides that as an alternative a coded date may be used, an 'indication' as the Directive calls it, and that the competent authorities and enforcement officers shall have the actual date made available to them on request.

Azodicarbonamide

- In regulation 5 of these new amending Regulations, the provisions of Article 1 of Directive 2004/1/EC as regards to the suspension of the use of azodicarbonamide as a blowing agent in food contact plastics is brought into effect. The new Regulations amend the entry on azodicarbonamide, which was permitted as a blowing agent in food contact plastics without restriction, and now prohibit its use as from 2nd August 2005. In addition, Article 2(2) of the Directive, as implemented by a new paragraph (23) inserted into regulation 10 of the 1998 Regulations, provides that materials and articles filled before 2nd August 2005 may continue to be placed on the market provided the date of filling or an indication of it appears on them. The Directive in effect mirrors the provision on date marking outlined by the above requirement in Directive 2004/13/EC.

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/foodcontactmaterials

Information includes explanatory notes on legislation, including European Council and Commission Directives, 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, Hygiene, Additives & Shellfish Branch

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