

This note explains the basis for proposing a Statutory Instrument to be called the Plastic Materials and Articles in Contact with Food (England) Regulations 2006. It explains why the proposal for the Statutory Instrument is being made in this way and it explains the provisions it contains. It should be read in conjunction with the draft Statutory Instrument before making any comment to the Food Standards Agency as part of its consultation on the Instrument.

Reasons for changing the rules

A new European Regulation (EC) No. 1895/2005, on the restrictions of use of certain epoxy derivatives intended to come into contact with foods came into force on 9 December 2005 and is directly applicable throughout the EU. It revokes two earlier European Commission Directives, namely 2002/16/EC and 2004/13/EC that made provisions on the use of these substances in food contact plastics, adhesives and coatings.

The proposed Statutory Instrument, the Plastic Materials and Articles in Contact with Food (England) Regulations 2006, provides for the enforcement, in England, of Regulation (EC) No. 1895/2005 by the food enforcement authorities. It also provides for offences where products subject to the provisions are in breach of them, defences against alleged breaches of the European Regulations and for penalties to apply upon conviction for an offence under them. The proposed Statutory Instrument will also revoke *The Plastic Materials and Articles in Contact with Food Regulations 1998* (SI No. 1998/1376) and its five amendments. This removes from the statute the provisions of the two revoked EC Directives. However, these 1998 Regulations also enacted the provisions of Commission Directive 2002/72/EC on plastic materials and articles in contact with food and its two amending Directives, namely 2004/1/EC and 2004/19/EC, and those provisions are re-enacted in the proposed Statutory Instrument. This has enabled those provisions to be contained in a single set of regulations, rather than be spread across five regulations, and to make use of current legal drafting practice. This makes the proposed Statutory



Instrument easier to understand for those that need to refer to, it or comply with it or enforce it.

Commission Regulation (EC) No. 1895/2005 on the Restriction of use of Certain Epoxy Derivatives in Materials and Articles Intended to come into Contact with Food (Repealing Directive 2006/16/EC), and its enforcement.

The EC Regulation permits the use of 2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE) in food contact plastics, adhesives and coatings providing any migration is within a specific migration limit of 9 milligrams per kilogram of food or food simulant, including its hydrolysed derivatives. This limit can be taken as 9 milligrams per six decimetres squared in cases where articles are containers or are comparable to containers or which can be filled with a capacity of less than 500 millilitres or more than 10 litres or where sheet film or other material which cannot be filled or for which it is impracticable to estimate the relationship between the surface area and the quantity of food with which the material is in contact. Where BADGE migration occurs with particular chlorohydrins the sum of their migration may not exceed 1 milligram per kilogram of food or food simulant or 1 milligram per six decimetres squared in the specific cases above. The EC Regulation permits trade in the use of materials and articles containing BADGE throughout the EU from 1 January 2006 and re-affirms the ban on the use of BFDGE (Bis(4-hydroxyphenyl)methane bis (2,3-epoxypropyl)ethers) and NOGE (Novolac glycidyl ethers) from 1 January 2006.

The EC Regulation also requires that, at marketing stages but not the retail stage, materials and articles containing BADGE and its derivatives shall be accompanied by a written declaration of compliance in accordance with Regulation (EC) No. 1935/2004 (Article 16). Compliance must be documented and that documentation has to be made available to the competent authorities on demand.

Enforcement requirements for EC Regulation 1895/2005

The proposed Statutory Instrument for England provides for Food Authorities, as defined by the Food Safety Act 1990, to enforce the provisions of Regulation (EC) No. 1895/2005 and The Plastic Materials and Articles in Contact with Food (England) Regulations 2006

Regulation 13, 14 and 15 make provisions relevant to the new EC Regulation.

Regulation 13 provides for the EC Regulation to be enforced by the enforcement authorities and makes transitional provisions regarding those substances called BFDGE and NOGE in the EC Regulation and creates offences relating to the manufacture and trade in goods containing them.

Regulation 14 provides for the execution and enforcement of the EC Regulation and the regulation proposed for England.

Regulation 15 provides for offences relating to contravention of the regulations, the obstruction of and failure to assist or misleading of enforcement officers. It also provides for the penalties that will apply on conviction for an offence under the regulations.

Government chemist

Article 11(5) of Regulation (EC) 882/2004 places a duty on Member States to ensure that those accused of breaching food law have access to an expert second opinion when evidence is based on scientific analysis. For that reason, regulation 19 of the proposed Regulations for England provide that any defendant, as well as any court and any prosecutor, has the right to request a referral to the Government chemist. This provision has to be specifically made in food contact material regulations because this provision normally derives from The Food Safety (Sampling and Qualifications) Regulations 1990. However, those Regulations are specifically disapplied (by regulation 2 and Schedule 1 of those Regs) to the Materials and Articles in Contact with Food (England) Regulations 2005. We have therefore always made free standing provisions in food contact materials regulations that reflect the provisions of the disapplied 1990 Regulations. **We would welcome any comment that you may care to make on the inclusion of this provision and the manner in which it is made.**

Other changes

The proposed Statutory Instrument will revoke in their entirety the Plastic Materials and Articles in Contact with Food Regulations 1998 and its five sets of amending regulations in so far as they apply in relation to England. This is the start of work that will simplify and consolidate those six current sets of Regulations into one. The purpose of doing this is to make it easier for businesses, Food Authorities and enforcement laboratories to understand and comply with the law. Thus the following Regulations will be revoked:

- the Plastic Materials and Articles in Contact with Food Regulations 1998 (SI 1998 No. 1376);
- the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2000 (SI 2000 No. 3162);
- the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002 (SI 2002 No. 2364);
- the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002 (SI 2002 No. 3008);
- the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2004 (SI 2004 No. 3113) and
- the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2005 (SI 2005 No. 325)

We would welcome comments on our intention in doing this and on the approach we have taken through this draft Statutory Instrument.

Who will be effected by the new Regulations?

European Regulation No. 1895/2005 consolidates most of the provisions already in place and contained in two EC Directives. The main change arising from this Regulation is a relaxation in the limit of migration from packaging into food for BADGE and hydrolysed derivatives. It also, as required by Regulation (EC) No. 1935/2004, provides that

declarations of compliance with the law shall accompany the materials and articles covered by the 2005 European Regulation at all marketing stages other than the retail stage and that appropriate documentation be available to demonstrate that compliance. It requires that this documentation shall be made available to the authorities on demand.

Given that the use of these substances is governed by the European Regulation, and that the proposals in the regulations for England will deal with enforcement of the European Regulation the proposals here will principally affect food authorities and enforcement laboratories. They revoke existing provisions from revoked EC Directives that required enforcement action and provide for the enforcement of the provisions that arise from the European regulation. The offences, defences and penalties provided for in the proposed England regulations will affect those brought before the Courts where alleged breaches of the European regulations arise. They are in line with those in the Food Safety Act 1990.