

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

**2005 No. 898**

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 provides for, in England, the enforcement of one EC Regulation and revises the penalties that may be applied for infringements of that Regulation. It also revokes one set of 1987 Regulations and re-enacts provisions from those 1987 Regulations that should remain in force. Finally, it implements one EC Directive.

2.2 The EC Regulation (Regulation (EC) No. 1935/2004) came into force on 3 December 2004. This instrument designates, at regulation 12, the authorities having the responsibility to enforce the EC Regulation, and provides for that enforcement by prescribing the penalties that the Courts may impose on conviction for an offence under the Regulation. These penalties are in line with those that apply under other food-related law through the Food Safety Act 1990. A major part of the Materials and Articles in Contact with Food Regulations 1987 was concerned with implementing the provisions of EC Directive 89/109/EEC, which the EC Regulation has now repealed, therefore this instrument repeals those 1987 Regulations. However, some provisions in the 1987 Regulations implemented EC measures on vinyl chloride monomer and regenerated cellulose film and those provisions are re-enacted by this instrument. The one EC Directive newly implemented by this instrument, European Commission Directive 2004/14/EC, brings up to date the European harmonised rules relating to the manufacture of materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

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**3. Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

**4. Legislative Background**

- 4.1 The Materials and Articles in Contact with Food Regulations 1987, (1987 No 1523) and the 1994 amending Regulations (1994 No. 979) implemented, Council Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs; Council Directive 78/142/EEC relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs; and, Commission Directive 93/10/EEC, as amended by Directive 93/111/EC, on materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
- 4.2 Those 1987 Regulations are revoked by this Instrument in as much as they apply in relation to England, following the revocation of Council Directive 89/109/EEC by Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with foodstuff. However, as Council Directive 78/142/EEC and Commission Directives 93/10/EEC and 93/111/EC remain in force, those parts of the 1987 Regulations that had implemented them in England are re-enacted in this instrument.
- 4.3 The two Commission Directives cited above established a positive list of substances that can be used in the manufacture of coated and uncoated regenerated cellulose film. Some of the substances in the positive list have conditions restricting their use in the manufacture of these food contact materials. In particular, uncoated film must not transfer adhesives or colourants in detectable quantities, and coated film must not transfer ethylene glycol or di(ethylene) glycol, by themselves or together, in quantities exceeding 30 milligrams per kilogram of food. Synthetic casings made of regenerated cellulose films that have coatings on the food contact side of greater than 50 milligrams per square decimetre of film are, at present, excluded from the scope of the legislation.
- 4.4 This latest Commission amending Directive, 2004/14/EC, amends Directive 93/10/EEC and was adopted in January 2004. The amending provisions of the Directive provide that the uncoated, cellulose coated and plastic coated regenerated cellulose film intended for food contact applications are subject to the conditions laid down and to manufacture from only the substances listed. It also applies the conditions laid down in Directive 2002/72/EC on plastic materials and articles intended to come into contact with foodstuffs, to those regenerated cellulose films coated with plastics.

## **5. Extent**

- 5.1 This instrument applies in relation to England only. 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 principle purpose of the restrictions imposed on the use of the chemicals to which restrictions apply is to minimise the risk to consumer health from exposure to chemicals that may be carcinogenic, mutagenic or toxic to reproduction. It also aims to protect the nature and quality of the food concerned and to provide businesses in 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. One of the principal changes brought about by the European Regulation is that it allows for the same rules to apply across the EU. The Regulation also, for the first time permits for intended migration of substances by regulating the use of 'active' and 'intelligent' materials and articles, which are designed to inter-act with the food.
- 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 that contain conditions on their use in the manufacturing process. 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 European proposals that have been adopted and that have led to this Instrument. The outcome confirmed that the measures proposed to implement Commission Directive 2004/14/EC have no specific extra requirements that lay any new financial burdens. It takes into account the technological developments that have taken place since the adoption of the original Directive in 1993. These include the fact that 3 substances in the phthalates group are no longer used by the industry and can be removed from the positive list. The authorisation of this new material accords with European environmental requirements laid down in adopted measures on packaging waste.
- 8.2 Industry has been closely involved at European level in the development of this proposal and has not raised any issues of a disadvantage accruing to any business sector. The proposal applies equally to all materials and articles, and specific parts of the proposal apply to all materials and articles made from regenerated cellulose film or that contain vinyl chloride monomer, which are intended to come

into contact with food. They will therefore not disadvantage any particular business sector.

8.3 A Regulatory Impact Assessment is attached to this memorandum.

## **9. Contact**

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