

Regulation (EC) No.1935/2004 The Materials and Articles in Contact with Food (England) Regulations 2005 SI2005 No: 898

SI 2005 No. 898 provides for the enforcement of Regulation (EC) 1935/2004 in England and came into force on 29th April 2005.

REGULATION (EC) 1935/2004

Introduction

This Regulation dated 27th October 2004 repeals and replaces Directive 89/109/EEC and entered into force on the 3rd December 2004. It concerns the placing on the market of materials and articles intended to come into contact directly or indirectly with food.

It applies to materials and articles which:

- are intended to be brought into contact with food, or
- are already in contact with food, or
- can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal conditions of use.

Scope

The new Regulation changes the scope of the previous Directive, resulting in practice in a wider applicability. Whereas the previous Directive was interpreted as only being applicable to materials and articles in direct contact with food, the new Regulation specifically covers materials and articles in indirect contact.

Applicability to Corrugated Packaging

In practice the previous Directive was taken as only being applicable to corrugated packaging where the inner surface was in direct contact with food. Account was previously taken of the possibility of taint and odour transferring from the packaging to the food but not, within the context of the Directive, if the packaging was not in direct contact.

The new Regulation will require a judgement to be made on whether packaging not in direct contact still falls within the scope of the Regulation because of a transfer of constituents. In the great majority of cases it can be assumed that corrugated board packaging is not 'reasonably expected' to transfer its constituents to food when not in direct contact. This would imply the exclusion of corrugated board packaging from the scope of the Regulation in this case.

Requirements

Corrugated packaging judged to be covered by the Regulation has to meet the requirements of Article 3 of the Regulation, which are essentially unchanged from Article 2 of the previous Directive. This means it must be manufactured in accordance with good manufacturing practice so that under normal and foreseeable conditions of use it does not transfer its constituents to food in quantities which could endanger human health or bring about an unacceptable change in the composition of the food or deterioration in its organoleptic characteristics (essentially its taste and smell).

Conformance to the Requirements

Most manufacturers of corrugated packaging employ good manufacturing practices and use only materials which do not endanger human health (see note below on paper sources). To this extent they meet the requirements of the Regulation.

However the requirement that the organoleptic characteristics of the food being packed are unaffected by its packaging is more difficult to assess. The corrugated packaging manufacturer is not normally in a position to assess the interactions which may occur given the diversity of food packed in similar containers and the complexity of the interactions particularly relating

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to taint and odour. Thus, while the manufacturer will be in a position to give assurances on the absence of constituents endangering health, the users of the packaging, (principally the packer/filler) should be asked to satisfy themselves on the ultimate suitability of the packaging for the food being packed.

Advice to members

For applications which clearly involve direct contact with food, no changes in existing procedures to satisfy the general requirements of the new Regulation appear to be needed. Because members have previously been advised to consider aspects such as taint and odour for applications not previously considered as falling under the legislation, there is also unlikely to be any practical change in procedures here. For the vast majority of current applications for corrugated packaging where there is a functional barrier between the food and the packaging, that is where the corrugated packaging is the secondary or tertiary packaging, the Regulation does not apply.

It is recommended that, for the small number of cases for which the position is not clear, the issue is discussed between the packaging manufacturer and the customer.

Traceability Requirements

It should be noted that for packaging covered by the Regulation, there are requirements for traceability which will come into effect from 27th October 2006.

The Regulation requires that:

- traceability of materials shall be ensured at all stages,
- business operators shall, by means of labelling or relevant documentation or information, allow identification of the businesses from which and to which materials or articles and substances or products used in their manufacture are supplied, and
- this information shall be made available to competent authorities on demand.

It is expected that most ISO 9000 systems will provide a compliant system for corrugated manufacturers.

Labelling

The new wording "**For Food contact**" is introduced, or alternatively, as in the previous Directive, a specific indication or symbol is required, as well as the name or trade name and address or registered office of the manufacturer responsible for placing the article in the market. The labelling shall be adequate to ensure traceability.

NOTE ON SOURCES OF PAPER FOR CORRUGATED BOARD

Where **Kraft** liners or **Semi-Chemical** fluting materials are specified, the main source of fibre is directly from the tree. Most sources of both materials are now including recycled fibres, their source of recovered fibre usually being mill tailings or carefully selected waste such as boxes collected by supermarkets.

Where **Test** liners or **Recycled** flutings are specified, the source of fibre is recovered paper in a multitude of forms: newspapers; corrugated cases; paper sacks; paperboard cartons or any other product that has been made from paper and board.

Kraft Liners, Semi-Chemical Flutings: (Based On Virgin Fibres)

Generally, mills are prepared to state that these will meet the requirements of 1935/2004.

Test Liners, Chip Liners, Waste-Based Flutings: (Containing Substantial Amounts Of Recycled Fibres)

Whilst, to our knowledge, no problems have been traced to these types of packaging materials, because of their origins (a very wide variety of sources of recovered fibre) it is not possible to give a blanket guarantee of their acceptability. Therefore their suitability for contact with food is usually limited by the manufacturing mill. Specifically the mills making waste-based materials will not issue a clearance against 1935/2004 for use in direct contact with fatty or oily foods.

It is worthwhile noting that the United States of America Food and Drug Administrative Code of Federal Regulations (F&DA) section 21, paragraph 167.260

states that pulp from reclaimed fibre may be safely used as a component of articles used in ---packing--- or holding food. This is subject to certain provisions set out in the section.

Manufacture Of Corrugated Packaging

In converting liners and fluting into corrugated packaging, there are three basic components typically added to the paper and board:

- i Corrugator Adhesive - which is starch and water with very small quantities of caustic soda and borax. The caustic and borax together normally constitute less than 0.015% of the total board weight.
- ii Flexographic Ink - predominantly water based in the corrugated board industry - normally added at a level of less than 5% of the total board weight.

Inks consist of pigments (usually ground natural minerals or oil based compounds) and resin binders. No heavy-metals or dangerous solvents are used in modern corrugated flexographic inks.

- iii Glue Flange Adhesive - which is normally applied at less than 0.1% Of the total board weight, and comprises a Polyvinyl Acetate water based emulsion.

Usually these three components are **not** in direct contact with the foodstuffs packed. If, however, liquids or oils could leach these components from the board their concentrations would be so low that it is unlikely that any harmful effects would be seen.