

1. SCOPE

- This section deals with composite materials and objects in which the plastic layer is in direct contact with food products, especially:

- Plastic/aluminium composite;
- Plastic/aluminium/paper composite;
- Plastic/paper/aluminium composite;
- Plastic/paper composite;
- Covering/plastic/paper composite (this type of composite is particularly used for manufacturing caps; the covering is made up of a "hot melt" material or a lacquer, the plastic part is often a metalised polyester).

Note: the paper part could be a flat or corrugated cardboard.

The following elements are not concerned:

- Cans (in steel or aluminium) and all covered metallic objects which are subject to specific sheets;
- Materials and objects which are not intended, under normal terms of use or in any reasonably expected conditions, to be in contact with foodstuffs, for example: floor, ceiling and wall coverings, vehicle dashboards, aprons, tablecloths, food trays. However, honeycomb trays in direct contact with foods are included.

2. Restrictions of use for materials

- Restrictions of use may exist for materials containing some additives. All useful information shall be communicated to the laboratories.
- Recycled materials which do not have the same guarantees as the new materials for which they could substitute themselves, cannot be used in contact with food according to CSHPF [The Upper Council for Public Hygiene in France] notification dated 7/9/93 on recycled materials (published in the BOCCRF [Official Bulletin for Competition, Consumption and Repression of Fraud] dated 31/12/93).

Before the marketing of such materials, a file shall be presented to the AFSSA [French Food Safety Agency] notification. The file shall particularly contain information relating to the waste sources used, the quality of the waste collection, the sorting methods used, the decontamination process implemented and its efficacy, the conformity of the finished material with the regulations and controls carried out on all manufacturing operations to prove that the finished materials thus produced meet the regulations relating to materials intended to be in contact with foodstuffs.

3. Definition of inertia criteria

3.1 Texts to be used

3.1.1 Regulatory texts

Order dated 27/08/87 relating to aluminium and its alloys.

3.1.2 Other texts (to be used provisionally whilst waiting for specific regulation)

At each manufacturing stage of the composite, the producer shall check that the various constituents used appear in the positive lists.

- Order of 2/01/2003 relating to materials and objects in plastic put or intended to be in contact with foodstuffs, food and drink products (directive 2002/72/CE of 6th August, 2002).
- Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.
- Other texts relating to plastic materials (circulars, circular letters, instructions etc) put together in Brochure No. 1227 of the Official Journal.
- For plastic/paper composites where the plastic layer may not act as a "barrier", the paper shall meet the appropriate requirements (see sheet relating to paper and cardboard).
- Resolution of the European Council AP (96) 5 on surface coating intended to come into contact with foodstuffs.

3.2 Criteria to be used

At each manufacturing stage of a material or an object, the producer shall check that the various constituents used appear in the positive lists.

When the product or material is finished, the manufacturer or the user shall check that the inertia criteria are met, i.e.:

- The positive list and the limits of use have been respected, evidence of conformity from suppliers,
- Overall migration in accordance with the order of 2/01/2003.
- Specific migration* of monomers and/or residual quantity of monomers in the material or object in accordance with the order of 2/01/2003.
- Specific migration* of additives and/or quantity in the material of object
- Chemical composition of the aluminium;
- If necessary, Criteria defined in the sheet covering paper and cardboard .

* Checking specific migration limits is not obligatory if it can be established that the result of the overall migration test implies that the specific migration limits have not been exceeded, or that the specific migration limit cannot be exceeded even if all the residual substance migrated.

Respect of the specific migration limits can be checked by determining the quantity of the substance in the material provided that a relationship between this quantity and the value of the specific migration of the substance has been established either by a suitable experiment, or by the application of generally recognised diffusion models (order dated 2/01/2003, article 8).

4. Acceptability limits

- Overall migration limit laid down in the *order dated 2 January 2003* (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount which does not exceed the analytical tolerance defined below will be considered conform to the order (art.8 and chapter VI of the order annex):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limits of monomers and/or maximum residual quantities of monomers in the material or the object (article 7 and chapter I of the 2/01/2003 order annex).
- Specific migration limits of additives and/or maximum quantities in the material or object if necessary, specified in the above text (particular article 7 of chapter II of the the 2/01/2003 order annex)
- Specific migration limit of epoxy derivatives, the limits are specified in the order of 2 April 2003.
- Limits of the composition of the aluminium and its components, laid down in the order dated 27/08/87.
- If necessary, limits mentioned in the sheet covering paper and cardboard.

5. Rules to check the criteria defined in paragraph 3.

- In order to check the migration criteria, the manufacturer shall give the following information to the laboratory:

- Material references;
- Nature of monomers and additives subject to specific limits of migration or maximum quantities, without revealing confidential information;
- Contact conditions (duration and temperature);
- Type of foods in contact or simulator liquids.

- Test conditions according to directive 82/711/CEE amended by directives 93/8/CEE and 97/48/CEE, and directive 85/572/CEE (Order dated 2/01/2003, article 8):

- Temperature and contact duration;
- simulator liquids (chosen according to the foodstuffs concerned) (for composites with a metallic layer, when the migration in the simulators exceed the fixed limits, a specific determination of the iron or aluminium migration (according to the metal of the layer) shall be carried out and the laboratory shall propose migration tests of these elements in the foods themselves.)
- Methods to be used for overall migration according to the standards in the set NF EN 1186, CEN/TS 14234 dated March 2003 (Polymer coverings on paper and board) and XP CEN/TS 14235 dated April 2003 (Polymer coverings on metallic substrates).
- Methods to be used for specific migration according to the experimental standards relating to the measurement of specific migrations from the series prEN 13130-1 to 28 or technical specifications CEN/TS of series 13130 part 1 to 28 and the current works of CEN/TC 194 SC1 about the determination of the BADGE, BFDGE and their derivatives as well as the NOGE and its derivatives.