

## Faq

*Within the EU, in order to export materials for contact with foodstuffs that have not been subjected to the harmonised regulations, must an EU manufacturer ensure that the material complies with the legislation of the country or does compliance with his o*

In the absence of harmonized specific measures, the Regulation (EC) No 1935/2004 of 27 October 2004 does not prevent Member States from maintaining or introducing national provisions provided they respect the principle of mutual recognition.

This follows from the 'Cassis de Dijon' of February 20, 1979 (Case 120/78) the Court of Justice (ECJ) and judgments which followed: any product legally manufactured and marketed in a Member State should in principle be allowed on the market of any other Member State.

The Regulation (EC) No. 764 / 2008 of the European Parliament and the Council of 9 July 2008 established procedures for its implementation. It defines the rights and obligations of national authorities and economic operators wishing to sell products legally manufactured and marketed in another Member State, to the extent of the restrictions on these products are in force, according to state regulations. The regulation also addresses the burden of proof in establishing the procedural conditions under which national authorities may derogate from the principle of mutual recognition.

*Who is responsible for the compliance with regulations of materials designed to come into contact with foodstuffs?*

All persons responsible for the introduction into the national market of a product are subject to the general compliance requirement defined in item L.212-1 of the consumer code which states: "As soon as products are introduced onto the market, they must comply with the current requirements concerning the safety and health of persons, the fairness of commercial transactions and the protection of consumers. **The person responsible for introducing a product onto the market is therefore required to check that it complies with current requirements.** If required by authorized agents to apply Chapters II to VI, **he must provide proof of the checks and controls carried out**".

The raw material's suitability for contact with foodstuffs is guaranteed by the supplier. The latter shall supply his client with a certificate, which the client shall require (mutual obligation, Order N°92/631). For further details, Note N°2004/64 dated 06/05/04 gives a table which lists the various cases concerning responsibilities (See general sheet concerning the regulations for contact with foodstuffs enclosed with the note).

*Does EC marking make it possible to demonstrate that a material is suitable for contact with foodstuffs?*

The requirements concerning suitability for contact with foodstuffs are not defined in the so-called "new approaches" directives concerned by EC markings. Moreover, there are no European standards that describe specifications concerning suitability for contact with foodstuffs. The only European standards existing in this sector describe analysis protocols.

EC marking does not, therefore, make it possible to demonstrate a material's suitability for contact with foodstuffs

*For how long is a report giving the results of analyses of suitability for contact with foodstuffs valid?*

In its note N°2004/64 dated 06/05/04, the DGCCRF states that the validity is 5 years. If any changes liable to cause a modification material or object's inertia occur during this period, the tests must be repeated

*Must materials for which no specific European or French regulatory text exists meet the requirements concerning suitability for contact with foodstuffs?*

All materials designed to come into contact with foodstuffs are subject to regulation N°1935/2004, which lays down the following principles concerning suitability for contact with foodstuffs:

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- They must not pose any human health hazard.
- They must not modify the composition of the foodstuffs.
- They must not modify the organoleptic properties of the foodstuffs.

In France and for certain materials not subject to special requirements, the DGCCRF states in its note N°2004/64 dated 06/05/04 which checks must be conducted to demonstrate compliance with regulation N°1935/2004.

### *Can recycled materials be used for contact with foodstuffs?*

Recycled manufacturing products (re-pulped) can be used for the manufacture of materials in contact with foodstuffs. However, the French higher public health council (CSHPF) has decided against the use of recycled materials that do not give the same guarantees as the new materials that they replace (Note dated CSHPF dated 7/11/93). In the case of plastics, a dossier shall be deposited with the DGCCRF giving proof that the recycled materials are equivalent in their composition and inertia to the materials that they replace. In the case of papers and cardboards, the DGCCRF accepts the use of recycled products as long as they meet the requirements laid down in the Guide to good professional practices (1998).

### *Must materials that are not in direct contact with foodstuffs meet the requirements of these regulations?*

In the case of multi-layer materials, the regulations states that all the layers must comply, even those not in direct contact with the foodstuffs. In other cases (for example, secondary packaging used to transport pre-packed foodstuffs), the requirements of these regulations do not appear to have to be applied, subject to no substance being able to permeate the layer in direct contact in order to contaminate the foodstuff.

### *Are there inks for use in contact with foodstuffs?*

Direct contact between an ink, even when varnished, and a foodstuff is not permitted by the DGCCRF, which bases its decision on the French higher public health council's (CSHPF) notice dated 7/11/95. This position is based on the fact that printing inks may, in the event that they come into direct contact, be easily dissolved by the foodstuffs or be partially or fully transferred. Moreover, the constituents in printing inks and varnishes have not all been subject to a complete toxicological assessment. Given the major risk of transfer, the use of a printing ink in direct contact may be equivalent, in terms of consumer exposure, to the direct printing of foodstuffs such as the marking of eggs and of animal carcasses, the inks for which are the subject of special requirements (See Directive N°94/36/CE).

### *Is the “glass/fork” symbol (Regulation N°1935/2004) mandatory for identifying materials suitable for contact with foodstuffs?*

This symbol is not mandatory but regulation N°1935/2004 requires that materials or objects designed to come into contact with foodstuffs bear one of the following three indications:

- The “glass/fork” symbol (Regulation N°1935/2004)
- Marked “for contact with foodstuffs”
- Marked “suitable for foodstuffs”

Exception: Objects which, by their form, are clearly designed to come into contact with foodstuffs (e.g.: crockery, cooking utensils etc.).

### *How can you be sure that a plastic designed for use in a microwave oven is suitable for contact with foodstuffs?*

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A plastic designed for contact with foodstuffs in a microwave oven must comply, like all plastics, with the requirements of Directive 2002/72/CE by taking into account the temperature reached in the oven by the material in contact with the foodstuff. In order to determine the conditions for migration tests to be conducted, this temperature must be measured in accordance with the protocol in standard NF EN 14233 (February 2003) or correctly conduct migration tests under the most severe temperature conditions (100°C for aqueous media and 175°C for fatty media).

*Do the regulations concerning materials in contact with foodstuffs include requirements concerning contact with the mouth?*

Regulation N°1935/2004 allows for specific directives for each material including requirements concerning mouth contact. Currently, the only requirements of this type concern rubbers used in teats and dummies and figure in Directive N°93/11/CE, which lays down migration limits for nitrosamines and N-nitrosable substances in reconstituted saliva.

*Must drinking water distribution installations comply with the regulations concerning materials in contact with foodstuffs?*

All materials forming the drinking water distribution system are subject to a circular issued by the French general health directorate's health monitoring sub-directorate, Bureau VS4. It is a question of checking the inertia of the materials by rapid screening tests and fine analytical techniques and a cytotoxicity test. Only three laboratories are authorized to conduct these analyses (the Paris city water research and inspection centre, the Vandoeuvre public health hygiene and research laboratory and the Institut Pasteur in Lille).