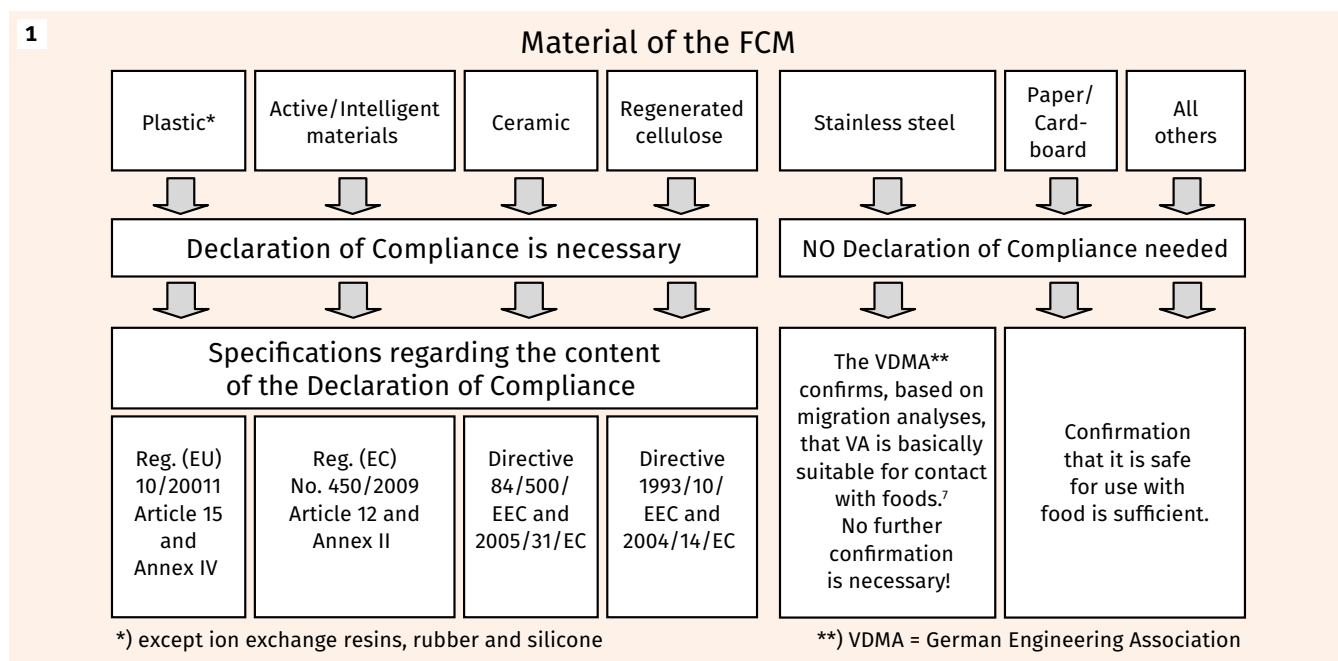


Declarations of Compliance

Food contact materials and the proof of their suitability and fitness – every auditor asks about it, but not every company really knows what it means in detail. Here is an overview.



++ Overview of the requirements relating to Declarations of Compliance for food contact materials, Status in 07/2015

+ Food packagings and machines, items of equipment and similar things that come into contact with baked products during their manufacture, treatment and processing are described legally as Food Contact Materials (FCMs). They must not have any adverse effect on the food or on health under normal, foreseeable conditions of use. I.e. transfer to the food of any constituents that are likely to endanger human health, to change unacceptably the composition of the food or to impair the organoleptic properties of the food is not permissible. The precise definition can be found in Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food¹.

The Regulation also refers to materials and articles, including active and intelligent food contact materials and articles. According to Regulation (EC) No. 1935/2004, Article 2, Paragraph 2, Sub-paragraph (b), **active food contact materials** are "... materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food ...¹. Absorbing inlays are a widespread example of an active FCM (made of cross-linked polyacrylates (= plastic)) in packs of fresh meat and fresh fish products under protective gas. On the other hand, according to Article 2, Paragraph 2, Sub-paragraph (c), **intelligent food contact materials** are "... materials and articles which monitor the condition of packaged food or the environment surrounding the food ...¹". Intelligent FCMs are not very wide-

spread at present, but one example are the time-temperature indicators (TTI System = Time Temperature Indicator System) that are used to monitor whether the refrigeration chain was maintained at all times in the case of foods for which refrigeration is mandatory, and/or whether deep-frozen products were constantly frozen².

In addition to Regulation (EC) No. 1935/2004 mentioned above, there are other **statutory requirements** that apply to FCMs and which must be taken into account:

- +** Commission Regulation (EU) No. 10/2011 of 14 January 2011 on materials and articles made of plastic intended to come into contact with food.
- +** Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- +** Commission Regulation (EC) No. 282/2008 of 27 March 2008 on materials and articles made from recycled plastic intended to come into contact with foods.
- +** Commission Regulation (EC) No. 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.
- +** Commission Directive 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs and Commission Directive 2004/14/EC of 29 January 2004 amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
- +** Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to

ceramic articles intended to come into contact with foodstuffs and Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs.

Food Contact Clearance Certificate or Declaration of Compliance?

It is important for FCM users to know whether a Declaration of Compliance or a Food Contact Clearance Certificate is required. This is governed in Article 16 of Regulation (EC) No. 1935/2004, which defines the materials for which Declarations of Compliance must be prepared, whereas Food Contact Clearance Certificates are sufficient for all other FCMs. Declarations of Compliance are needed for the groups of materials and articles listed in Annex I of the Regulation, insofar as the attachment of a written declaration is required for these in so-called Specific Measures. These Specific Measures, and thus the obligation for a Declaration of Compliance, currently exist for active and intelligent materials and articles and for ceramics, regenerated cellulose and plastics.

What must a Declaration of Compliance look like?

In addition to stainless steel, FCMs made of plastic are the ones most frequently encountered in a bakery. The specifi-

cations for their Declaration of Compliance are defined in Regulation (EU) No. 10/2011³. In this respect it must be noted that some materials are excluded from this obligation. Currently, pursuant to Article 2 (2) of the Regulation, these are ion exchange resins, rubber (e.g. natural rubber, latex and EPDM [Ethylene Propylene Diene Monomer rubber]) and silicone.

Declaration of Compliance for active and intelligent materials and articles are similar in their scope to those for plastics. The legal requirements for a written declaration or Declaration of Compliance for FCMs made of ceramic and regenerated cellulose are slightly less extensive.

Handling Declarations of Compliance

If a Declaration of Compliance is submitted to you, i.e. the user of FCMs, it is essential that you check the information it contains. Above all whether the application conditions stated in it includes the user's precise application. If this is not the case, the user must arrange for appropriate migration analyses and/or conformity tests for the missing application conditions.

Declarations of Compliance usually state the results of migration analyses with so-called food simulants. Which food simulant is to be used for which food is governed in Annex III, Table 2 of Regulation (EU) 10/2011. This makes a basic distinction between 5 simulants.

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Abbr.	Properties	Food simulant	Examples of relevant food groups (baked products, fine baked goods, cookies, cakes and their ingredients)
A	<ul style="list-style-type: none"> hydrophilic 	Ethanol 10% (v/v)	Sugar syrup, honey and the like; Edible nuts in pastries and crême form Deep-fried pastries; Sandwiches, toasted bread, pizza and the like with fatty substances on the surface
B	<ul style="list-style-type: none"> hydrophilic pH < 4.5 	Acetic acid 3% (w/v)	Fruit in the form of puree, preserves, pastes, in its own juice or in sugar syrup (jam, stewed fruit etc.); Vegetables in the form of puree, preserves, pastes, in the own juice (including in vinegar and brine); Fermented milk (yogurt, buttermilk etc.), cream, sour cream
C	<ul style="list-style-type: none"> hydrophilic Alcohol content up to 20 % vol./vol. Significant content of organic constituents 	Ethanol 20% (v/v)	Fruit in the form of puree, preserves, pastes, in its own juice or in sugar syrup (jam, stewed fruit etc.); Vegetables in the form of puree, preserves, pastes, in the own juice (including in vinegar and brine)
D1	<ul style="list-style-type: none"> lipophilic Alcohol content > 20 % vol./vol. Oil in water emulsion 	Ethanol 50 % (v/v)	Milk, milk products, fermented milk (yogurt, buttermilk etc.), cream, sour cream; Fruit in alcoholic medium; Eggs (liquid and boiled/cooked)
D2	<ul style="list-style-type: none"> Lipophilic Free fats on the surfaces 	Vegetable oil	Fine bakery wares, cookies, cakes, bread and other baked products: dry, with fatty substances on the surface; Pastries, cakes, bread, dough and other baked products, fresh, with fatty substances on the surface; Fats and oils
E	<ul style="list-style-type: none"> Dry foodstuffs 	Poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Cereals, flour, semolina, starch, sugar; Fine bakery wares, cookies, cakes, bread and other baked products: dry, without fatty substances on the surface; Pastries, cakes, bread, dough and other baked products, fresh, without fatty substances on the surface

Source: Siebke

++ Table 1: Overview of the food simulants for plastics

The permissible limit values for specific migration (SML [Specific Migration Limits]), i.e. maximum permissible amounts for individual substances, can be found in Article 11 and Annex I of Regulation (EU) 10/2011. The standardized value of a maximum of 10 mg of total released constituents per dm² of area in contact with the foods (mg/dm²) stated in Article 12 applies for the total migration. A different value of a maximum of 60 mg per kg of food simulant applies only for FCMs that are designed to come into contact with foods intended for infants and young children.

Responsibilities for machines and plant:

Basically the requirements for FCMs installed in machines and plant are identical to the information given above (see also figure 1). The situation for plant users is somewhat easier in the case of **new machines**. According to the Machinery Directive⁴, which has been in force since 2006, the proof or harmlessness of the FCMs used in plants must be provided by the machine manufacturer and included with the machine's technical documentation. Either a Declaration of Compliance (in accordance with Regulation (EU) 10/2011) must be attached, e.g. for plastic components, or the machine manufacturer must document the suitability of the materials concerned in the technical documentation⁵. Here again, however, the principle applying is that the plant/machine user must check whether the application conditions stated there include the machine's actual use in practice. If this is not the case, the user must arrange appropriate migration analyses

and/or conformity tests for the missing application conditions, or must request these from the manufacturer of the machine.

To avoid problems at this point, order documents for machines/plant should always contain the concrete purpose for which they will be used, including the type(s) of food that is/are to be processed with/on the machines. This makes it easier for the machine manufacturer to provide the corresponding proofs of suitability with the technical documentation⁵.

For **older machines** or machines that have been in use for some time, the plant manufacturer is often unable to supply a declaration of compliance for the FCMs. In this case the user of the machine must carry out an individual risk assessment. Any recommendations by the BfR (German Federal Institute for Risk Assessment)⁶ that may already exist regarding the material concerned will be helpful for this. A hazard analysis with a risk assessment should cover at least the following points:

- + The nature of the material
- + The duration of contact with the food(s)
- + The nature and properties of the foods with which it comes into contact
- + Other contact conditions (e.g. temperature, protective gas)
- + The type of cleaning (including equipment were necessary)
- + The cleaning agents used
- + The material stressing due to the cleaning
- + The result of the BfR recommendation where necessary

Depending on the outcome of the risk assessment (e.g. low risk, medium risk, high risk for the food), it will be necessary to arrange for action to be taken, e.g. carrying out migration analyses.

Summary

Every user of FCMs must have to hand the proof that their use in contact with food is harmless. Basically no declaration of compliance is necessary for stainless steel, and the statements made by the VDMA⁷ (German Engineering Association) are sufficient here. Declarations of compliance are mandatory at the present time exclusively for FCMs made of plastic, ceramic, regenerated cellulose and active and intelligent materials and articles. A manufacturer’s Food Contact Clearance Certificate is sufficient for all other FCMs. As a basic principle, however, declarations of compliance must always be checked by the user of FCMs before they are used. The important point when doing this is whether the information they contain is applicable to the specific intended use of the FCM in the user’s situation.

Literature

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