

Regulation

The European regulation that deals with the sanitary security of materials and items that come into contact with foods comes under the *DG–Sanco (General Directorate of consumers' health and protection)* within the *European Commission*. The competences of this general directorate include the food safety.

The capacity to contact with food and materials is controlled by the Regulation CE n°1935/2004. Materials and items included are:

- packaging and conditioning,
- containers and cookwares,
- materials, machines and materials used for production, storage or transport of foods,
- nipples and lollipops.

Foodstuffs included are foods and drinks which are:

- either finished or intermediate products,
- intended for human nutrition.

Excluded products a.o. :

- coating materials,
- static drinking water distribution systems.

Specific regulations or directives describe the inertness criteria for some materials (Plastics, ceramics, regenerated cellulose film and partly regenerated for rubbers) and also the modalities to check the conformity.

Specific regulations or specific directives contain the inertness criteria which depend on the nature of materials. For some materials (plastics for instance), there is a list of authorised materials in Europe (positive lists) that are completed by lists of materials authorised on the national level (colorants for plastics in France, for instance). Those materials are the only one authorised in the manufacturing of materials. The authorisation of a material is delivered by the DG–Sanco with downstream aspects of the standing Committee of the food chain and animal health, once the favorable opinions of the scientific authorities such as the *European Food Safety Authority (EFSA)* and previously the Scientific Committee on Food end. Those opinions are distributed over the Internet. When there is no existing specific requirement for a material, the inertness principle quoted in the regulation still applies. Industrialists have to demonstrate that the principles have been met.

The regulation CE n°1935/2004, specific regulations and specific directives represent the European regulation of materials in contact. Some specific directives were transposed into national legislation in form of orders by material. Regulations were not transposed and apply as is In France.

When there is no specific regulation or directive for a material, the existing *national provisions* apply, which is the case in France for rubber, silicone, stainless steel, aluminium, for instance. Moreover, France extended the scope of this regulation to materials in contact with feedingstuffs.

To help industrialists to demonstrate their product conformity, the *DGCCRF (French Administration)* published the general fact sheet relevant to the regulation of materials in contact with foods (see the Brochure n°1227 published to the OJ) that contains the responsibilities of different actors in the chain and explains the application of the inertness principle in fact sheets by material.

Several resolutions of the *Council of Europe* concerning materials in contact with foodstuffs exist (see the list of resolutions of the Council of Europe). If there is no statutory instrument, those resolutions may be used

Regulation

again as recommendations (see the resolution Framework Resolution ResAP (2004) 1 in the case of quahogs in France).

The provisions in respect of material hygiene and packaging are included in the regulation of foodstuffs. The regulation 852/2004 of the Hygiene package determines the requirements in respect of foodstuff hygiene (as an alternative to the Directive 93/43/CE that has been repealed since January 1st 2006). This regulation contains specific provisions applicable to conditioning and packaging of foodstuffs.