



Use of silicone rubbers in food-contact applications

Currently all food contact materials are regulated by the Food Contact Framework Regulation 1935/2004 of which the purpose is to "ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interest of consumers". The article 3 of this regulation is "key" as providing general but essential requirements.

This regulation stipulates that specific measures may be developed by the Commission for various groups of materials and articles for food contact as listed in the annex 1 of this regulation.

Currently such specific measures exist for ceramics, regenerated cellulose and plastics; for other groups of food contact materials, no EU regulations have been developed so far.

Specific measures for silicone rubbers are not foreseen to be developed yet at the Community level as this represents a very low priority for the European Commission. This means that silicone rubbers are and will remain subject to national provisions until a harmonised process is completed.

Members of the silicone industry place strong emphasis on protecting health, safety and the environment and produce silicone materials that can be used in the manufacturing of articles intended for food contact applications such as the well-known household baking moulds but not only.

For this purpose, and in addition to their usual procedures for quality assurance, silicone manufacturers also ensure all components comply with any binding texts from the EU Member States, which deals with silicone resins/elastomers intended to be used in contact with food. In this prospect, the following are examples of existing documents that are frequently referred to:

- French Arrêté of 25 Novembre 1992
(<http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=ECOC9200161A>)
- German BfR Recommendation XV (<http://bfr.zadi.de/kse/index.htm?lang=en>)
- Compliance to one of these texts automatically implies compliance to the EU framework Regulation 1935/2004, as laid down by its Article 6.

It has to be observed however that the ultimate responsibility for compliance resides with the rubber manufacturer and that it is his role to take every reasonable action to ensure his products are suitable for use with food, will not pose a health hazard, and are safe within the spirit of the legislation. In making this determination, the applicability of specific regulatory clearances may be considered, as well as the potential for migration of impurities – e.g. byproducts, breakdown products, or residual starting materials – to food from the use of the product.

CES is confident that the silicone products its members produce are safe if used as specified (i.e. well cured and post-cured).

If you would like to know more about this topic, please contact Dr M. De Poortere, CES Secretary General, at the address below. Customers are recommended to contact their suppliers:

CES (Centre Européen des Silicones) C/o Cefic
Attention Dr M. De Poortere
Tel : + 32 2 676 73 69 Fax : +32 2 676 7359

