Are your cleaning tools food safe and compliant with legislation?

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Food producers are under increasing pressure from food authorities, auditors and their customers to provide evidence of compliance with all areas of food safety.

This includes requests for food safety documentation in relation to the plastic cleaning equipment they use, especially that used in direct contact with food, and on food contact surfaces.

Unfortunately, for a number of reasons, this documentation can often be difficult to obtain.

New manufacturers of plastic cleaning equipment to the food industry, especially those from China and emerging markets, are often unaware of the strict European food contact legislation relating to the use of these products, and neglectful of the appropriate testing or documentation in support of them.

Even established European based equipment manufacturers can fall foul of the requirements, failing to use food safe materials in the construction of their products, and providing poor or confusing compliance documentation (testing conducted by an independent, accredited laboratory has shown that it repeatedly failed to meet all of the required EU food contact requirements, under the test conditions used).

Consequently, purchasers of equipment must be aware of the appropriate food contact material requirements, and ensure that they have access to valid, documented evidence of compliance with these.

Legal requirements

In Europe, there are a number of relevant pieces of legislation related to ensuring the quality and safety of the food in contact with these items. These include:

- **Regulation EC 178/2002** – on the general principles of food law.

Article 14 states that food shall not be placed on the market if it is considered to be:
- Injurious to health.
- Unfit for human consumption.

- **Regulation EC 852/2004** – on the hygiene of foodstuffs which states that food business operators must have in place:
- The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.
- All articles, fittings and equipment with which food comes into contact are to be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination.

- **Regulation EC 1935/2004** – Framework Regulation on materials and articles intended to come into contact with food.

This establishes the general principles governing the safety of all materials and articles intended to come into contact with foods both directly and indirectly and ensures compliance with GMP. Materials approved within this Regulation will be labelled with the 'Glass & Fork' symbol.

- **Regulation EC 2023/2006** – Good Manufacturing Practice for materials and articles intended to come in contact with food. Requires businesses to have documented systems which apply to all sectors and to all stages of manufacture.

These both state that under normal or foreseeable conditions of use materials must not transfer their constituents to food in quantities that:
- Endanger human health.
- Cause an unacceptable change in the composition of the food.
- Cause a deterioration in the food's organoleptic characteristics.

- **Regulation EC 10/2011** (and recent subsequent amendments) – Plastic materials and articles intended to come into contact with food.

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Plastic materials and articles coming into contact with food may transfer toxic substances to them. Regulation 10/2011 establishes specific requirements applicable to the manufacture and marketing of plastic materials and articles that:
- Are intended to come into contact with food.
- Are already in contact with food.
- Which can reasonably be expected to come into contact with food.

These materials and articles and parts thereof may be composed:
- Exclusively of plastics.
- Of several layers of plastics.
- Of plastics combined with other materials, i.e., plastic layers in multi-material multi layer materials and articles. Only the substances included in the Union list set out in Annex I of the Regulations may be intentionally used as monomers, other starting substances and additives in the manufacture of plastic materials and articles.

Plastics and epoxy resins

For the purpose of Regulation EC 10/2011 'plastic' means the macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules.

Epoxy resins, also known as polyepoxides are a class of reactive prepolymers and polymers, which contain epoxide groups.

Epoxy resins may be reacted (cross-linked) either with themselves through catalytic homopolymerisation, or with a wide range of co-reactants including polyfunctional amines, acids (and acid anhydrides), phenols, alcohols, and thiols.

These co-reactants are often referred to as hardeners or curatives, and the cross-linking reaction is commonly referred to as curing.

Reaction of polyepoxides with themselves or with polyfunctional hardeners forms a thermosetting polymer, often with strong mechanical properties as well as high temperature and chemical resistance.

In order to prevent any risk to human health, Regulation 10/2011 sets overall and specific migration limits applicable to substances constituting the materials and articles in question,

These migration limits correspond to the maximum amount of substances that materials and articles may transfer to food. They are expressed in mg of substance per kg of food (mg/kg).

Additionally, Regulation EC 1895/2005 restricts the use of, and lays down, specific migration limits for certain epoxy derivatives in materials and articles intended to come into contact with food, ie:
- 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, referred to as 'BADGE' (CAS No 001675-54-3), and some of its derivatives.

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- bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, referred to as 'BFDGE' (CAS No 039817-09-9).
- Other novolac glycidyl ethers, referred to as 'NOGE'.

Plastics and epoxy resins have a wide range of industrial applications, including their use in the manufacture of food industry cleaning equipment.

As such they are subject to migration testing in compliance with Regulations 10/2011 and 1895/2005.

Guide to terms used

'Specific migration limit' (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants.

'Overall migration limit' (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants.

'Food simulant' means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials.

Migration testing should be conducted by an independent, accredited laboratory using the prescribed test methods, for example:

- **BS EN 1186-2:2002** – Materials and articles in contact with foodstuffs. Plastics. Test methods for overall migration into olive oil by total immersion.
- **BS EN 1186-3:2002** – Materials and articles in contact with foodstuffs. Plastics. Test methods for overall migration into aqueous food simulants by total immersion.

All plastic materials and articles must comply with specific migration limits and overall migration limits. Migration test certificates should be available for inspection by legislators, auditors and customers on request.

The manufacturer of the plastic equipment must draw up an accompanying, written 'Declaration of Compliance' in accordance with Article 16 of Regulation EC 1935/2004, containing the information set out in Annex IV of Regulation EC 10/2011, including:

- The identity and address of the business operator issuing the declaration of compliance.
- The identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles.
- The identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles.
- The date of the declaration.
- Confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/200.
- Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restriction.
- Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directive 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food.
- Specifications on the use of the material or article, such as:
  - Type or types of food with which it is intended to be put in contact.
  - Time and temperature of treatment and storage in contact with the food.
  - Ratio of food contact surface area to volume used to establish the compliance of the material or article.

Declarations of Compliance must be made available on request, to legislators, auditors and customers, for all food contact cleaning equipment made from plastics and epoxy resins.

Some European markets may additionally request food contact approval in compliance with the US Food and Drug Administration (FDA). It should be noted that compliance with FDA food contact requirements alone is not sufficient within Europe.

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In compliance with these legal requirements, and in support of the food industry, Declarations of Compliance and details of FDA compliances for individual Vikan products can be found on www.vikan.com. Migration test certificates are also available on request. ■

References are available from the author on request