European Legislation on food contact materials:

The Headlines!
1. INTRODUCTION

Within the European Union, the Framework Regulation (EC) 1935/2004 lays down stipulations for materials and articles intended to come into contact with foodstuffs. These materials are called Food Contact Materials, e.g., both packaging materials and kitchen utensils, food processors and other articles used for food manufacturing, food preparation or food presentation, etc.

The harmonization on European level of the legislation on food contact materials fulfills two essential goals:

1. Ensuring the effective functioning of the internal market.
2. Securing a high level of health protection.

The traceability of materials and articles shall be ensured at all stages of manufacturing, processing and distribution and shall be traceable through labeling or documentation.

In this article, the most important headlines and directives of the European legislation will be summarized and migration testing itself will be briefly discussed.

Intertek routinely performs all required testing and actively keeps track of changes occurring in directives and guidelines. In this way Intertek is able to offer support and consultancy to all companies who have requests in this expansive area of legislation.
2. OVERVIEW of the EUROPEAN LEGISLATION

2.1 Legislation applicable to all Food Contact materials:
- (EC) 2023/2006: Good Manufacturing practice

2.2 Legislation on specific groups or components:

2.2.1 Legislation on Plastic materials:
- 2002/72/EC: List of monomers and additives
  - 2004/1/EC: 1st amendment
  - 2004/19/EC: 2nd amendment
  - 2002/79/EC: 3rd amendment
  - 2007/19/EC: 4th amendment
  - 2009/39/EC: 5th amendment
- 78/142/EEC: Limits on Vinyl Chloride
  - 80/766/EEC: Determination of Vinyl Chloride in finished products
  - 81/432/EEC: Determination of Vinyl Chloride in foods
- (EC) 372/2007: Migration limits for plasticizers in gaskets and lids
  - (EC) 597/2008: 1st amendment
- 82/711/EEC: Basic rules for migration testing
  - 93/8/EEC: 1st amendment
  - 97/48/EC: 2nd amendment
- 85/572/EC: List of simulants for migration testing
- (EC) 282/2008: Recycled plastics
- (EC) 1895/2005: Epoxy derivates BADGE/BFDGE/NOGE in plastic materials and/or coatings

2.2.2 Legislation on other materials/groups of materials listed in the Framework Regulation:
- (EC) 450/2009: Active and intelligent materials
- 2007/42/EC: Regenerated Cellulose Film
- 84/500/EEC: Ceramics
- 93/11/EEC: Nitrosamines in elastomers and rubbers
- Paper and board
- Glass
- Active and intelligent materials
- Wood Cork
- Metals and alloys
- Textiles
- Adhesives
- Ion-exchange resins
- Printing inks
- Silicones
- Varnishes and coatings
- Waxes
3. LEGISLATION APPLICABLE TO ALL FOOD CONTACT MATERIALS

3.1 Framework Regulation

On European level, food contact materials and articles are regulated by the Framework Regulation (EC) 1935/2004. The Framework Regulation states the general requirements for materials and articles, including active and intelligent food contact materials which can reasonably be expected to come into contact with food. Those materials shall be shall be manufactured in compliance with good manufacturing practice so that they do not transfer constituents to food in quantities which could:

- endanger human health;
- bring about an unacceptable change in the composition of the food;
- bring about a deterioration in the organoleptic characteristics thereof.

3.1.1. Authorization procedure and traceability

The Framework Regulation contains an authorization procedure for new substances. A declaration of compliance, with the appropriate documentation, shall be available to competent authorities on demand. The traceability of materials and articles shall be ensured at all stages of manufacturing, processing and distribution and shall be traceable through labeling or relevant documentation.

3.1.2 Legislation on specific materials

The Framework Agreement mentions groups of materials where specific measures may be adopted or amended.

Plastics are regulated by the Commission Directive 2002/72/EC and amendments. This is the most extensive legislation concerning food contact.

Currently legislation is also present on recycled plastics, active and intelligent materials, ceramics, regenerated cellulose film and elastomers and rubbers.

3.2 GMP

A Good Manufacturing Practice for materials and articles intended to come into contact with food is regulated by Regulation 2023/2006/EC. The regulation requires implementation of GMP by August 1st 2008. It describes requirements for the quality assurance and quality control system and documentation that need to be retained.
4. LEGISLATION FOR SPECIFIC GROUPS OR COMPONENTS

4.1 Plastics Directive

4.1.1 Plastics Directive 2002/72/EC and amendments
For plastics EU rules are written down in Directive 2002/72/EC. This Directive is the most extensive legislation on European level. It is applicable to materials consisting of plastics or plastic multi-layers exclusively. This Directive has been amended several times: 2004/1EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC.


Authorized substances are monomers and other starting substances listed in this Directive, and may be used for the manufacture of plastic materials and articles, with the restrictions set out therein. Until now, the positive list of additives for plastics is considered as not complete. All additives for which a valid petition has been submitted by 31 December 2006 are on a provisional list of additives. These are not authorized at Community level. On 1\textsuperscript{st} January 2010, the additive list will be considered to be complete.

Migration limits have been set because plastics should not transfer their components into the foodstuff in unacceptable quantities. The transfer of constituents from food contact materials into food is called migration. To ensure protection of health of the consumer and to avoid any contamination of the foodstuff two types of migration limits have been established for plastic materials:

1. an Overall Migration Limit (OML) of 60 mg (of substances)/kg (of foodstuff or food simulants) or 10 mg/ dm\(^2\) (of surface area of material or article) applies to all substances that can migrate from food contact materials to foodstuffs;
2. a Specific Migration Limit (SML) which applies to individual authorized substances and is based on the toxicological evaluation (by European Food Safety Authority) of the substance.

For certain substances, a maximum permitted quantity of that substance, in the finished material or article, is admitted (called QM).

Rules for migration testing (time, temperature and simulants) can be found in Directives 82/711/EEC and 85/572/EEC.

Note: Migration testing can be avoided when the assumed/calculated migration is smaller than the SML. Generally recognized mathematical modeling can be applied.
4.1.2. Rules for migration testing
Directive 82/711/EEC and amendments lay down basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. Directive 85/572/EEC contains a list of foodstuffs and the appropriate simulants to be used. For milk products a change in simulant is introduced in Directive 2007/19/EEC.

Time and temperatures
The test protocol should simulate worst case conditions of storage and usage. Different testing conditions therefore are required for instance storage at room temperature, for storage in a refrigerator or for when warming up in a microwave.

The migration test condition most commonly used is exposure of the simulant(s) to the food contact material for 10 days at 40°C as this simulates storage of food in the packaging at room temperature for more than 24 hours.

Simulants
The choice of the simulant depends on the type of food:
- aqueous food → distilled water
- acidic food → 3% acetic acid
- alcoholic food → 10% ethanol
- fatty food → olive oil
- in some cases olive oil as simulant is replaced by iso-octane and/or 95% ethanol.
- milk product → 50% ethanol
- dry food → MPPO (Modified Polyphenylene oxid or Tenax)

Test methods
Testing conditions are simulated on a laboratory scale and are written down in the European Standards EN 1186 (overall migration) and EN 13130 (specific migration). If possible, the sample taken for testing is the final article in its ready-to-use state. It can be tested by:
- article filling;
- total immersion (double sided);
- by cell (one-sided), used for film or flat surfaces.
4.2 Recycled plastics

In the EU, plastics may be recycled and used in contact with food contact materials if they are safe and in compliance with the new recycling legislation (EC 282/2008).

This regulation shall not apply to the following recycled plastic materials:
- recycled plastic made with monomers and oligomers, derived from chemical depolymerisation;
- recycled plastic made from unused offcuts and scraps that are recycled within the manufacturing site.

The recycling process must be validated, authorized by the EU and managed under a suitable quality system.

4.3 Epoxy derivatives

EC Regulation 1895/2005 concerning certain epoxy derivatives is applicable to plastics, surface coatings and adhesives. The regulation prohibits BFDGE (bis(hydroxyphenyl)methane bis 2,3-epoxypropyl)ethers) and NOGE (novolac glycidyl ethers) and lays down migration limits for BADGE (2,2-bis(4-hydroxyphenyl)propane) (specific migration limit: 9 mg/kg) and BADGE-HCl (specific migration limit: 1 mg/kg).

5. DIRECTIVES AND RESOLUTIONS, OTHER THAN PLASTICS

5.1. Active and intelligent materials

Active and intelligent materials and articles intended to come into contact with food may be placed on the European market if they comply with the restrictions set out in Regulation (EC) 1935/2004 and (EC) 450/2009.

In Regulation (EC) 450/2009, composition restrictions are set out. Only substances which are included in the ‘Community list’ of authorized substances may be used in components of active and intelligent materials and articles.

Additional rules on labeling apply. Non-edible parts shall be labeled with the words ‘Do not eat’ and, where technically possible, the relevant symbol.

Declaration of Compliance and documentation

When marketing active and intelligent materials and articles which are either in direct contact with food, or where their components are intended for manufacturing materials or substances which will be in contact with food, the items shall be accompanied by a written declaration in accordance with Regulations (EC) 1935/2004 and Regulation (EC) 450/2009.
5.2 Ceramics

For ceramics, regulations are written down in Directive 84/500/EEC and Directive 2005/31/EC. Migration limits apply for lead and cadmium. An analytical method is described in the directives.

5.3 Regenerated Cellulose Film (RCF)

Directive 2007/42/EC lays down a list of authorized substances and content levels acceptable in the final article.

5.4 N-Nitrosamines in rubber teats and soothers

N-Nitrosamines in rubber teats and soothers are legislated by Directive 93/11/EEC. N-Nitrosamines may not be released above 0.01 mg/kg article. N-Nitrosatable substances may not be released in concentration above 0.1 mg/kg article. Criteria for the determination are described in the directive.

5.5 Regulation on paper and board

Paper and board materials must comply with the general safety principles of the Framework Resolution (EC) 1935/2004. In absence of a harmonized regulation the Council of Europe (CoE) adopts Resolutions which are not binding unless they are transposed into national laws. The CoE Resolution AP(2002)1 on paper and board nonetheless serves as an important reference in the EU. This CoE Resolution requires that paper and board comply with technical documents with

- a list of substances to be used in the manufacture (technical document 1);
- guidelines on test conditions and methods of analysis (technical document 2);
- guidelines for recycled fibers (technical document 3);
- CEPI guide for good manufacturing practice (technical document 4);
- a practical guide (technical document 5).

Restriction limits (QM) apply for cadmium, lead and mercury (respectively 0.002, 0.003 and 0.002 mg/dm$^2$ paper and board). For pentachlorophenol, a maximum of 0.15 mg/kg paper and board is tolerable.

5.6 Relating resolutions

Finished products may contain other components for which specific European resolutions are available, some examples:

- Resolution AP(89) on colorants in plastics
- Resolution AP (2004)1 on coatings
- Resolution AP(2005)2 on packaging inks
6. THE PERSPECTIVE

More than two decades ago, Europe started to regulate the safety and testing of food contact materials. The first (repealed) Framework Directive dates from 1989. In 2004, the new Framework Agreement 1935/2004 came into force in order to provide the basis for increased harmonization concerning food contact material on European level. In the last several years, a great deal of work and a number of new directives and resolutions in this domain have been published. Still, a lot of work will need to be done.

In the next years, the harmonization plan of the European Union will focus on:

- Super regulation (PIM: plastic implementation) will replace 2002/72/EC and amendments.
- Ceramics, glass, metals, surface coatings, elastomers, regenerated cellulose and paper and board.

More information regarding food safety can be found at the following link: www.ec.europa.eu/food/food/chemicaلسafety/foodcontact
All information on food contact material regulations and food contact testing can be obtained through our customer service centre phone +31 (0)46 47 62713 or groupeurope.packaging@intertek.com. We will bring you in direct contact with one of our regulatory experts.

For more information on packaging testing and aspects of quality, speed and pricing: www.intertek.com/packaging

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