European Food Contact Regulations - Guidance towards Compliance of Materials and Articles

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European Food Contact Regulations

European Framework Regulation EC 1935/2004

Within the European Union all materials and articles intended to come into contact with food need to comply with the European Framework Regulation EC 1935/2004. This regulation states that food contact materials may not threaten human health or bring changes in smell, composition, color or taste to the food. In addition, all food contact materials should be manufactured according to good manufacturing practice - Directive EC 2023/2006. For numerous materials and substances there are specific regulations and/or guidelines on how to provide evidence for safety and compliance.

The harmonization of European food contact materials legislation fulfils two essential goals:

- Securing a high level of health protection
- Remove technical barriers to trade

To date there are specific regulations and/or directives for:

- EU 10/2011: Plastic articles and materials
- (EC) 450/2009: Active and intelligent materials
- 2007/42/EC: Regenerated cellulose film
- 84/500/EEC: Ceramics
- (EC) 282/2008: Recycled plastics and materials
- 93/11/EEC: Nitrosamines in elastomers and rubbers
- EU 321/2011: Restricting use BPA in infant bottles (amendment to EU 10/2011)
- 1895/2005/EC: Restricting use of certain epoxy derivates

All materials covered by these measures need to be accompanied by a written declaration stating that they comply with the rules applicable to them. In addition, valid documentation and traceability through labelling or documentation of materials and/or products in the supply chain should be ensured. Companies should be able to identify at least one step prior and later in the supply chain. Some situations do require a broader scope of traceability. This rule also concerns importers of food contact materials/products.
Steps towards achieving compliance:

1. Gather a complete list of all materials and substances used in the production of your food contact material/product.

2. Verify which regulations (in addition to the EU 1935/2004) are in place for your products to fulfil compliance for global or local markets.

3. Verify if industry guidelines or resolutions are available to support you with establishing the safety of your materials (risk management)

4. Identify the food contact application of your material (kind of foodstuff, time and temperature conditions)

5. Identify if the substances of your material may be used (check positive list(s)) and/or if there are any other limitations applicable

6. Set up a compliance scheme for your product/material. This may include: migration tests, worst case calculation/modelling, screening tests, NIAS studies/toxicological risk assessment

7. Proof GMP compliance

8. Set up a Declaration of Compliance* and make sure all supporting documentation is available on request

Good Manufacturing Practice

Materials and articles intended to come into contact with food should be manufactured in compliance with general and detailed rules on Good Manufacturing Practice (GMP).

The principles for GMP for food contact materials are covered in the European Regulation (EC) No. 2023/2006. This regulation is applicable in all stages of the production process and distribution of food contact materials, up to but excluding the production of the raw materials.

The European Regulation (EC) No. 2023/2006 describes requirements for the quality assurance, the control system, and documentation that needs to be retained.

A company’s quality management system should include production processes and cover quality assurance, quality control and documentation.

Elements to verify your GMP compliance could or should include:

- Risk assessment
- Traceability
- Training
- Documentation
- Internal audits

Some related industry sectors have established specific GMP guidelines for food contact materials while others have not. An example is the Confederation of European Paper Industries (CEPI), who provided guidelines for the board and paper industry.


As of the 1 May 2011 a new regulation for plastics intended to come into contact with food has become applicable. Regulation (EU) No. 10/2011 has replaced the Plastics Directive 2002/72/EC and its amendments as well as the specific directives on migration testing.

The difference between the most recent regulation and the old Directive is the immediate activity status. The old Directive had an introduction phase on member state levels of 18 months. Many European member states did have their own translation of the Directive.

*This is not an obligation for all food contact materials. However to ease and verify obligations in the supply chain Intertek advises to set-up a similar document for all food contact materials.
In addition, specific measures for plastic mono-layers, plastic multi-layers and plastic layers in multi-material multi-layer materials are covered.

Some types of materials are excluded from the regulation EU 10/2011, these are:

- Ion exchange resins
- Rubber
- Silicones

**Union List**

The positive list (called the Union list) of authorized substances is set out in Annex I of the regulation. Only monomers and additives included in the Union list may be used in the manufacturing process of plastic food contact materials.

The Union list contains:

- Monomers or other starting substances
- Additives excluding colorants
- Polymer production aids excluding solvents
- Macromolecules obtained from microbial fermentation

If a substance is not listed, a notification process for listing by EFSA can be initiated. Relevant actions would involve migration studies and toxicological evaluation among others.

**Migration testing**

The transfer of substances from food contact materials into food is called migration. Migration limits have been set because food contact materials should not transfer their components into the foodstuff in unacceptable quantities.

Two types of migration limits have been established for plastic materials being the overall and specific migration.

**Overall migration**

The Overall Migration Limit (OML) of 10 mg/dm² applies to the sum of all substances that can migrate from the food contact material to the food. The overall migration limit is of relevance for all simulants, except simulant E - MPPO powder.

There are 7 standard test conditions and 2 alternatives for high temperatures.

**Specific migration**

A Specific Migration Limit (SML) applies to individual substances and is formed on toxicological assessment studies, and is generally based on the Acceptable Daily Intake (ADI) or the Tolerable Daily Intake (TDI) as provided by the Scientific Committee on Food (SCF). Analytical techniques are used to identify the presence of these substances.

Test conditions for specific migration testing are a combination of contact time and temperature, which are based on the actual condition of use.
It is important to know that in general for repeated use products and materials the third migration result (with a few exceptions) is of relevance.

### Simulants EU 10/2011 versus the old Directive EC 2002/72

<table>
<thead>
<tr>
<th>Food type</th>
<th>Old directive 2002/72/EC</th>
<th>New regulation EU 10/2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous food</td>
<td>Distilled water (simulant A)</td>
<td>10% Ethanol (simulant A)</td>
</tr>
<tr>
<td>Acidic food</td>
<td>3% Acetic acid (simulant B)</td>
<td>3% Acetic acid (simulant B)</td>
</tr>
<tr>
<td>Alcoholic food</td>
<td>10% Ethanol (simulant C)</td>
<td>20% Ethanol (simulant C)</td>
</tr>
<tr>
<td>Semi-fatty food</td>
<td>50% Ethanol (simulant D (b))</td>
<td>50% Ethanol (simulant D1)</td>
</tr>
<tr>
<td>Fatty food</td>
<td>Olive oil (simulant D)</td>
<td>Vegetable oil (simulant D2)</td>
</tr>
<tr>
<td>Dry food</td>
<td>No simulant assigned</td>
<td>MPPO (Tenax) (simulant E)</td>
</tr>
</tbody>
</table>

### Transition period

This transitional period has started with the actual launch of the new regulation and should be completely implemented by the end of December 2015. These transition periods include:

**As from 1 January 2013:**
- Migration testing conditions based on rules 82/711/EEC or based on (EU) 10/2011
- Food simulants to be used according to (EU) 10/2011

**As from 1 January 2016:**
All migration testing based on (EU) 10/2011

Note: Materials and articles that have been lawfully placed on the market before May 1st 2011 may be placed on the market until 1 January 2014 (amendment EU No 1183/2012).

### Screenings tests

According to the EU 10/2011, screening methods can be used to proof compliance, and can limit the number of migration tests. The following screening methods are included:
- Residual content determination
- Migration modelling: applying generally recognized diffusion models. But information needs to be available
  - Replacing specific migration by overall migration
  - Substitute food simulants. Clearance is expected in the Guidance document of the European commission

### NIAS, Non-intentionally Added Substances

Another topic which requires attention is the presence of Non-Intentionally Added Substances (NIAS) in plastic materials. These substances are impurities or can be formed during the production or the decomposition process.

The manufacturer should assess any health or safety risk associated with these substances in alignment with internationally recognized principles of risk assessment.

One approach which is often used for assessing the risk of a chemical exposure to human health, is the Threshold of Toxicological Concern (TTC approach). It establishes generic exposure thresholds based on chemical structure, below which, chemicals are assumed to be used safely.

### Functional barrier

One of the other significant changes in the EU 10/2011 compared to the old directive is the specific reference to the application of a functional barrier. A functional barrier is a layer preventing the migration of substances from behind that barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided that they are not mutagenic, carcinogenic or toxic to reproduction and that their maximum level of migration through the functional barrier layer is 0.01 mg/kg in food.

### Declaration of Compliance (DoC)

Plastic food contact materials imported and/or sold into the European Union should be accomplished by a so called Declaration of Compliance. This is a written paper stating that the food contact materials/products comply with relevant regulations inside the EU. Specific requirements on parts to cover are included in the EU 10/2011.*

The evidence to support statements in this document should be traceable and available for authorities to review at any time. These are the so called “Supporting Documents”.

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* Intertek has drafted a template Declaration of Compliance as a guidance document. Contact us via the details in this White Paper for a copy.
Other non-plastic food contact materials

For many non-plastic materials like paper and board, printing inks, adhesives and colorants, no European regulation exist, outside of the overall Framework regulation EU 1935/2004. These materials need to be handled via regulations on European member state level. There is a list on the European Commission web site that details all national regulations.

The "mutual recognition" principle makes it possible to use the compliance report of one member state in another European country.

Additional to the national regulations, there are guidelines available written by the Council of Europe (CoE)* and guidelines written by industry associations (e.g. for inks, paper, adhesives).

Notwithstanding these are not mandatory, they are very useful on how to deal with your materials and make sure they are compliant. (In case no European regulation exists national regulations are binding above the guidelines written by the CoE or industry associations)

Risk management

In general risk management procedures are being used to provide guidance for completing a test strategy for non-specific regulated products or materials. We need to keep in mind that all food contact materials within Europe need to fulfil the European Framework regulation 1935/2004/EC.

For a general approach we would like to refer to the compliance steps listed on page 2 of this document.

Paper/board - Printing inks

In the following paragraphs there is some guidance provided for paper/board and printing inks. How to handle your specific case will depend on different aspects of the products or materials and so should be approached case-by-case.

Paper/board

In general the legislations/guidelines listed below are applicable or can be used to demonstrate compliance with Art 3 of 1935/2004:

- Resolution ResAP(2002)1, Council of Europe
- German recommendation BfR - general accepted by the industry
- National legislations, e.g. The Netherlands, Belgium, France, Italy, which are binding at national level
- Industry Guideline by Confederation of European Paper Industries (CEPI)

Printing Inks

For printing inks the Swiss Ordinance (SR 817.023.21) accompanied by a positive list is often being used as a guideline. It is expected that in 2014 a German ordinance on printing inks will be published.

CoE Resolution (2005)2 on packaging inks applied to the non-food contact surface:

- Applies to printing inks and varnishes
- Requirements according to Art 3 of 1935/2004

The guideline published by the industry association EuPIA on Printing Inks also applies to the non-food contact surface of food packaging materials and articles.

Note: Directive 2007/42/EC for regenerated cellulose film does include a comment on printing inks. Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs

* Activities of the Council of Europe (CoE) have been transferred to the European Directorate for the Quality of Medicines & Healthcare (EDQM)

References

- Guidelines by industry associations CEPI and EuPIA
- Swiss Ordinance (SR 817.023.21)
- Directive 2007/42/EC
Intertek is the leading quality solutions provider to industries worldwide. From auditing and inspection, to testing, training, advisory, quality assurance and certification, Intertek adds value to customers’ products, processes and assets. With a network of more than 1,000 laboratories and offices and over 36,000 people in more than 100 countries, Intertek supports companies’ success in a global marketplace. Intertek helps its customers to meet end users’ expectations for safety, sustainability, performance, integrity and desirability in virtually any market worldwide.

Intertek services in food contact materials safety, include:

- Risk assessment and management
- Set- up of migration testing programs for all types of food contact materials
- Mathematical modelling for SML components
- Overall and specific migration testing
- Analytical method development
- Screening methods (e.g. on NIAS)
- Complex formulation identification
- Food contact notification of new substances
- Toxicological evaluation of substances
- A commitment to achieve the broadest clearance for new substances globally
- Assistance in the set- up of guidance documents
- Standardized and customized training programs

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