Whitepaper

Authors:
Nadine Thomis Bsc.
Intertek Chemicals & Pharmaceuticals, Geleen, Netherlands
Sonja Grosemans Bsc.
Intertek Chemicals & Pharmaceuticals, Geleen, Netherlands

Date: January 2016

Intertek

Valued Quality. Delivered.

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

Introduction

The dynamic regulatory landscape and increasing number of regulations, present a challenge for companies developing and manufacturing food packaging or other food contact materials and articles. Each company involved in the production process of a food contact substance, material or article is responsible for the compliance of his end product. For these stakeholders it is important to know their obligations and to be able to demonstrate compliance.

On European level there are general obligations for all kind of food contact materials and a general "Good Manufacturing Practice" regulation. For numerous materials and substances there are specific regulations and/or directives in place.

As of May 2011 an updated regulation (EU) 10/2011 for plastic food contact materials has become applicable. A transitional period has been provided to implement all requirements of this regulation. On January 1st of 2016 this transition period ends and the regulation fully enters into force.

For several materials, such as paper and board, colorants, pigments and inks, regulations do exist on national level. Additional to this, for numerous materials industry guidelines are available to check the safety of these materials.

In this whitepaper we cover the key elements of the most important European regulations and guidelines and will also address the different steps towards achieving compliance for food contact materials.

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 about changes in smell, composition, color or taste to the food. In addition all food contact materials should be manufactured according good manufacturing practice as regulated by Regulation (EC) 2023/2006.

The food contact regulations are not limited to packaging materials but also mandatory for materials and articles used in the food industry (machinery, storage tanks, pipes, filters, conveyor belts, etc.) and for kitchen utensils (cups, dishes, cutlery, food appliances, inner walls of a refrigerator).

For numerous materials and substances there are specific regulations and/or guidelines on how to provide evidence for 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 the following specific regulations and/or directives are in place :

- Regulation (EU) 10/2011: Plastic articles and materials
- Regulations (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014, (EU) 2015/174 amending the rules of (EU) 10/2011, adding new substances and amending restrictions and specifications of already authorized substances in the Union list
- Regulation (EU) 321/2011: Restricting use of BPA in infant bottles (amendment to (EU) 10/2011)
- Regulation (EU) 284/2011: Import procedures for polyamide and melamine kitchen from China and Hong Kong (amendment to (EU) 10/2011)
- (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
- 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, supporting valid documentation and traceability through labelling or documentation of materials and/or articles in the supply chain should be ensured. Companies should be able to identify at least one step prior and later in the supply chain.

Compliance steps

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 and/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 if the substances of your material may be used (check positive list(s)) and/or if there are any other limitations applicable
5. Identify the food contact application of your material (kind of foodstuff, time and temperature conditions)
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. Prove GMP compliance
8. Set up a Declaration of Compliance* and make sure all supporting documentation is available on request

*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.

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 quality control system, and documentation that needs to be retained.

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. For example, the Confederation of European Paper Industries (CEPI), has provided guidelines for the board and paper industry.

Commission Regulation (EU) No 10/2011

As of the 1st of 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.

This regulation applies to:

- Plastic monolayers
- Plastic multi-layer held together by adhesives
- Plastic materials and articles that are printed or covered by a coating
- Plastic layers or coatings forming gaskets in caps and closure
- Plastic layers in multi-material multi-layer materials

Ion exchange resins, rubbers and silicones are excluded from the regulation (EU) 10/2011.

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

Solvents and colorants used in the manufacturing processes are excluded from the Union list but can be used if they are in compliance with article 3 of the Framework Regulation.
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; the overall and specific migration.

Overall migration

The Overall Migration Limit (OML) of 10 mg/dm^2 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).

Samples for migration tests shall be placed in contact with the food simulant in a manner representing the worst foreseeable conditions of time and temperature of actual use. For overall migration testing , there are 7 standard test conditions and 2 alternatives for high temperatures.

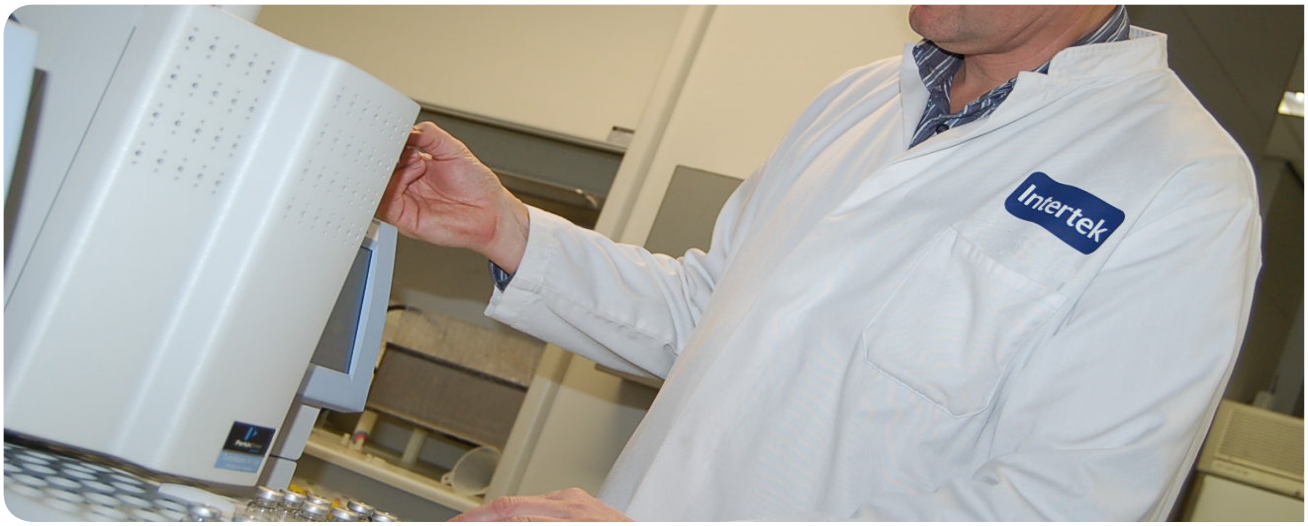
Specific migration

A Specific Migration Limit (SML) applies to individual substances and is based on toxicological assessment studies. This 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.

The plastic regulation introduces separate sets of standardized testing conditions for OML and for SML testing.

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 (with a few exceptions) for repeated use products and materials the third migration results is of relevance.



For demonstration of compliance the following food simulants are assigned:

A	10% ethanol	Aqueous food
B	3 % acetic acid	Foods that have a hydrophilic character and able to extract hydrophilic substances and which have a pH below 4.5
C	20 % ethanol	Foods with hydrophilic character and able to extract hydrophilic substances, alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic
D1	50 % ethanol	Alcoholic foods with an alcohol content of above 20 % and dairy products
D2	Vegetable oil	Fatty food and foods which contain free fats at the surface
E	Poly(2,6-diphenyl-p-phenylene oxide)	Dry foods

Screenings tests

According to the (EU) 10/2011, screening methods can be used to prove 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. Additional information needs to be available
- Replacing specific migration by overall migration
- Substitute food simulants. Clearance is expected in the Technical Guideline for migration testing on the use of substitute simulants and associated test conditions. At the time of publishing this White Paper, the technical guideline for migration testing was still under revision.

It is important to recognize that if a material fails in the screening approach, a conclusion for (non)-compliance has to be confirmed by verification tests (migration testing with regulated simulants)

NIAS, Non-intentionally Added Substances

Another topic which is implemented in this regulation is the risk assessment of Non-Intentionally Added Substances (NIAS) present in plastic materials. These substances are impurities or can be formed during the production or the decomposition process. The manufacturer should assess any safety risk associated with these substances in alignment with internationally recognized principles of risk assessment.

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-authorized 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 in 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 in the EU. The document is delivered by the supplier to his customer at marketing stages up to but excluding the retailer. It provides the customer with relevant information necessary to establish or check the compliance of his products. The content of the Declaration of Compliance depends on the position of the operator in the supply chain.

The evidence to support statements in the DoC should be traceable and available for authorities to review at any time. These are the so called "Supporting Documents" which include compositional information, manufacturing process information, migration testing results, worst case calculations, etc.

Note that the DoC needs to be renewed when significant changes in the composition or in the production process occur or when new limits are established.

A guidance document regarding information in the supply chain and the aim of the DoC was published in November 2013 and is available on the website of the European commission.

Transitional period ends December 31st 2015

Since the entry into force of the new regulation a transitional period has been introduced in order to provide a stepwise implementation of the provisions of the new regulation. As from January 1st 2016 the (EU) 10/2011 regulation shall be completely implemented. The regulation is binding in its entirety and directly applicable in the Member States of the European Union.

Amendments

Since the implementation of the (EU) 10/2011 regulation, the European Food Safety Authority issued several scientific evaluations for additional substances which need to be added to the positive list. Additional to this the restrictions and/or specifications already established need to be amended on the basis of new scientific evaluation by the Authority. At the date of publishing this White Paper, four amendments on the EU 10/2011 are already implemented.
A transitional period is in place for these amendments.

Non-plastic food contact materials

For many non-plastic materials like paper and board, printing inks, adhesives and colorants, no harmonized European regulation exist, outside of the overall Framework regulation EC 1935/2004.

These materials need to be in compliance with the 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).

Although these guidelines are legally binding, they are very useful to assess the safety of materials are articles and to make sure they are compliant with the European Framework regulation. In case no European regulation exists national regulations are binding above the guidelines written by the CoE or industry associations.

Paper/board - Printing inks

In the following paragraphs guidance is provided for paper/board, printing inks and metals & alloys. 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 Article 3 of (EC) 1935/2004:

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

References

- European Union web site: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm
- European Framework Regulation 1935/2004, commission regulation (EU) No 10/2011 and directive (EC) 2023/2006
- EuPIA Guideline on printing inks: http://www.eupia.org/index.php?id=29
- Swiss Ordinance (SR 817.023.21)
- Metals & Alloys used in food contact materials and articles, EDQM, 2013

Printing Inks

Printing inks applied to the non-food contact side of materials are regulated in the Annex of GMP regulation EU2023/2006. Substances from the printed surface may not transfer to the food contact side through the substrate or by set-off in the stack or the reel.

In the absence of specific EU legislation for food packaging inks, the EuPIA association has developed a guideline setting out a mechanism for the selection of raw materials for printing inks intended to be applied on the non-food contact surface of food packaging.

The Swiss Ordinance for printing inks (SR 817.023.21) is only mandatory in Switzerland, but many companies do perform a risk assessment on the use of printing inks on packaging materials according to the rules as lays down in this ordinance. The Swiss ordinance is accompanied by lists of permitted substances (set out in annex 1 and annex 6). List A of annex 6 includes evaluated substances subject to the requirements set out therein. List B includes non-evaluated substances which are permitted if no transfer (below 10 ppb) of these substances to food or food simulants can be detected.

In the absence of specific EU legislation for food packaging inks, the EuPIA association has developed a guideline setting out a mechanism for the selection of raw materials for printing inks intended to be applied on the non-food contact surface of food packaging.

Metals and alloys

Many national regulations are in place for metals & alloys intended to come into contact with food but no harmonized regulation on EU level is in place. In 2013 the European Directorate for the Quality of Medicines & Healthcare (EDQM) published a practical guide to support the industry with ensuring compliance with the provisions of the framework regulation for these materials. The recommendations as set out in this guidance are intended also to assist national policy makers and to enhance a harmonized approach within Europe. A list of specific release limits for metals and alloy components and for metals as contaminates and impurities is included in the guidance.

Conclusion

Understanding the food contact regulations is key to successful compliance and risk management for all companies involved in the development, manufacturing or selling food contact materials. On January 1st of 2016 the transition period to implement all requirements for the plastic regulation (EU) 10/2011 ends and the regulation fully enters into force, which means the deadline is very close.

Intertek

Valued Quality. Delivered.

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 38,000 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
- NIAS studies
- Food contact notification of new substances
- Toxicological evaluation of substances
- Standardized and customized training programs

For more information visit:

http://www.intertek.com or contact eufoodcontact@intertek.com