Intertek Compliance Program for Packaging to:

Framework Regulation 1935/2004 (EC)

European Commission Regulation (EU) 10/2011 for plastics
Resolution ResAP (2002)1 for paper and board
and others
# Table of contents

Table of contents ...................................................................................................................... 2  
Introduction ................................................................................................................................ 3  
How do manufactures and retailers benefit from the compliance confirmation? ............ 3  
How does the Compliance Program benefit buyers? ................................................................. 4

1. Description of the Intertek’s Compliance Program to Framework Regulation 1935/2004 (EC) .......................................................................................................................... 5
3. Framework, Directives and Amendments for food contact materials .......................... 7
5. Good Manufacturing Practice (GMP) .................................................................................. 8
7. Basics of migration testing ................................................................................................. 9
   7.1. Overall migration testing ............................................................................................... 10
   7.2. Specific migration testing ............................................................................................ 10
   7.3 Maximum permitted Quantity (QM limit) ..................................................................... 11
8. Paper and cardboard ........................................................................................................ 11
9. Other food contact materials ............................................................................................ 12
10. Compliance to national legislation .................................................................................. 12
11. Organoleptic/ Olfactory testing ....................................................................................... 12
12. Declaration of Compliance ............................................................................................... 12
12.1. Specimen ‘Declaration of Compliance’ : ...................................................................... 13
13. News from the EU and Updates to previous versions ..................................................... 15
Appendix I: Schematically overview Framework Regulation No 1935/2004 (EC) (dated valid as of 1 May 2011) ............................................................................................................. 17
Introduction

Intertek’s voluntary EU 1935/2004 (EC) Compliance Program is intended to ease and verify company’s obligation and compliance towards this regulation.

Within the European Union, the Framework Regulation 1935/2004 (EC) lays down stipulations for materials and articles which are intended to come into contact with foodstuffs. Those materials shall be manufactured in compliance with good manufacturing practice and they shall not transfer their components into the food in quantities that could endanger human health, change the composition of the food in an unacceptably way or deteriorate the taste and odor of foodstuffs.

Articles on the European market intended to come in contact with foodstuff need to be accompanied with a Declaration of Compliance in all marketing stages other than the retail stage.

Packaging materials which are approved by Intertek’s voluntary new Compliance Program to 1935/2004 (EC) ensures that the packaging materials, which are intended to come into contact with food or beverage, are in compliance with the Framework Regulation 1935/2004 (EC).

The Program is modularly designed to suit our clients’ needs. Program elements can be selected, from a simplified screening program up to a full style program which is inclusive assessment of materials and substances against legislation and overall and specific migration testing, guidance in setting up of a Declaration of Compliance and screening of results.

This document is intended to provide you with the necessary tools, resources and information to gain a better understanding of the process and requirement of an obligatory compliance certificate declaring that your packaging materials comply with Framework Regulation 1935/2004 (EC).

How do manufactures and retailers benefit from the compliance confirmation?

Confirmation with Intertek’s voluntary compliance program against the 1935/2004 (EC) provides a tangible measure of assurance to packaging manufactures, retailers and retail-buyers that products or materials they source meet applicable regulatory requirements.

Participation into Compliance Program will mitigate liability and assure that user brand image is protected. Compliance to documentation and traceability requirements of the 1935/2004 (EC) forms part of this program.
Intertek’s voluntary Compliance Program also assists companies to comply with the requirements on packaging (materials) for quality standards in the food production e.g. BRC Packaging standard or International Food Services (IFS).

**How does the Compliance Program benefit buyers?**

While the system cannot guarantee that products confirmed are, in all instances ‘safe’, it does provide a tangible measure of assurance for buyers and their customers that products meet standards and legislation.
1. Description of the Intertek’s Compliance Program to Framework Regulation 1935/2004 (EC)

This voluntary compliance program is designed to provide a tangible measure of assurance to manufacturers, retailers and retail-buyers that products they source meet applicable regulatory requirements. The program is mainly based on the most common packaging materials; plastic, paper and board. But the program is also applicable to all other types of food contact materials.

Companies manufacturing materials intended to come in contact with food and who wish to sell and supply materials to ……….[insert company name] can voluntary candidate for the program by submitting information and/or samples of their materials to Intertek.

Intertek is an independent certification company and manages this voluntary program which is modularly designed to suit our clients’ needs. Program elements can be selected, from a simplified screening up to a full style program which is inclusive; assessment of materials and substances against legislation, guidance on GMP, overall and specific migration testing, organoleptic testing, screening of results, guidance in setting up of a Declaration of Compliance.

The program is staggered into six (6) stages. Each stage includes a pass / fails decision for the material. If the 5th stage is successfully passed a Declaration of Compliance is supplied.

This staged process allows early identification of non-compliant materials and quick implementation of material/ process improvement actions so as to reduce lead-time. In the 6th stage Intertek can also handle maintenance of the program; this includes storage of results in databases, auditing and inspection.

A Declaration of Compliance needs to be renewed when a change has been made in the supply chain or production process, which can have effected the composition of the food contact material. When no changes have been made Intertek is recommending a screening and renewing of a Declaration of Compliance after 2 year. These 2 years are based on market demands.

The above program is schematically worked out on the next page.

Intertek can manage on behalf of its customers a supplier’s evaluation program. The program can be designed to our customers’ preferences with the intention that it assures that products and materials they source meet the appropriate regulatory requirements so that it provides a tangible measure of assurance and brand image protection.

Our dedicated experts can easy be contacted on telephone number +31 (0)88 126 8888 or via eufoodcontact@intertek.com for questions or remarks related to the program or parts of the program.

Intertek information package on the Program describing the program to all suppliers.

Intertek or Suppliers gather a complete list of substances used in the production of their food contact product(s) and proof of GMP Compliance.

Intertek identifies presence of substances with restrictions according the EU Positive list of additives and monomers or list of substances to be used in manufacturing of paper/board.

Reporting of non-listed substances → non Compliance for plastics!

Test program proposal set-up by Intertek.

Execution of overall migration test(s) for plastics (advisable paper/board)

If necessary modelling or execution of specific migration and/or QM test(s)

Execution of olfactory testing.

A set-up of a Declaration of Compliance based on all documentation, "positive" test results and information on GMP compliance.

Supplier become company name approved for a period of 2 years, Intertek send Declaration of Compliance to company name and supplier.

Intertek maintenance of the program, screening outcome, perform audits and inspection where relevant.

Reporting of non-listed substances → non Compliance for plastics!

Phase 1

Phase 2

Phase 3

Phase 4

Phase 5

Phase 6
3. Framework, Directives and Amendments for food contact materials

All materials on the European market intended to come in contact with food need to comply with the Framework Regulation 1935/2004 (EC). The Intertek voluntarily compliance program towards Framework Regulation 1935/2004 (EC) is intended as an easy tool to verify company’s obligation and compliance towards this regulation.

For several different types of food contact materials, like plastics and regenerated cellulose, specific requirements are set- out in EC Directives and their amendments (See appendix I).

4. 1935/2004 (EC) Legislation

Within the European Union, the Framework Regulation 1935/2004 (EC) lays down stipulations for materials and articles which are 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. Although the Intertek voluntary Compliance Program can be used for all types of food contact materials its main focus is on packaging materials made of plastics, paper and board.

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

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

The traceability of materials and articles shall be ensured at all stages of the marketing process, with exception of the retail stage, through labeling or documentation.

In practice: The Framework Regulation 1935/2004 (EC) states that:

- Product(s) need to be produced according Good Manufacturing Practice (GMP) 2023/2006 (EC).
- Materials intended to come into contact with foodstuffs are not allowed to do any harm to people.
- Products may not create any olfactory changes to the foodstuffs, like smell or taste.

The rules set- out in the Framework regulation are very general and do apply to all food contact materials.
5. Good Manufacturing Practice (GMP)

Materials and articles intended to come into contact with food need to be manufactured in compliance with general and detailed rules on Good Manufacturing Practice (European Directive 2002/72/EC).

This Directive describes requirements for the quality assurance and control system, and documentation that need to be retained.

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

Some sectors did establish specific GMP guidelines while others have not.

For example; for paper and board specific the CEPI (guide for good manufacturing of paper and board for food contact).

Intertek provides expertise and training to educate companies in order to fulfill quality standards.


As of 1 May 2011 a new regulation on plastic food-contact materials is applicable. Regulation (EU) 10/2011 on Plastics Materials and Articles intended to come into contact with foodstuff will replace the Plastics Directive 2002/72 and its amendments as well as directives on migration testing. It covers specific measures for plastic monolayers, plastic multi-layers and plastic layers in multi-material multi-layer materials.

A first amendment on Regulation (EU) 10/2011 concerning the restriction of use of Bisphenol A in plastic infant feeding bottles (Commission Implementing Regulation (EU) No 321/2011) is also applicable as of 1 May 2011.

To establish compliance under the (EU) Regulation (EU) 10/2011 implementation of the migration testing requirements is spread out over several years. At this moment, rules on overall and specific migration testing are laid down in Directive 82/711/EEC and amendments 93/8/EEC and 97/48/EEC and Directive 85/572/EC. They still apply until 31 December 2012.

As of 1 January 2013 the rules provided by the legislations 82/711/EEC and amendments 93/8/EEC and 97/48/EEC and Directive 85/572/EC will be replaced by the provisions on migration testing and simulants in (EU) No 10/2011.
As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:
(a) the rules for migration testing set out in Regulation (EU) 10/2011 or (b) the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

As from 1 January 2016, the supporting documents shall be based on the rules for migration testing set out in Regulation (EU) 10/2011

7. Basics of migration testing

The transfer of constituents 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.

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:

a. **Overall Migration Limit** (OML) of 60 mg (of substances)/kg (of foodstuff or food simulants) or 10 mg/ dm² (of surface area of material or article) applies to all substances that can migrate from food contact materials to foodstuffs;

b. **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).

**Simulants**

As testing in food is not practical simulants are used instead. There are several simulants which are used for testing the materials.

At this moment, the four main simulants are water, 3% acetic acid, 10 % ethanol and olive oil. For dairy products the simulant 50% ethanol must be used. Substitute simulants are e.g. MPPO, Iso-octane and 95 % ethanol; these substitutes are used when the migration test with the fatty food simulant is not feasible for technical reasons connected with the method of analysis.

The new (E) 10/2011 replaces the simulant water by 10% ethanol, 10% ethanol by 20% ethanol and instead of olive oil vegetable oil may be used. In addition MPPO or Tenax must be used as simulant for dry food.
The simulant to be used for testing depends on the characteristics of the foodstuff for which
the food contact material (packaging) is intended. E.g. chocolate consists mostly of fat, so
therefore olive oil should be used. Depending on use the material needs to be tested with
more then one simulant.

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

The migration test condition most commonly used for overall migration testing 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.

In the new Regulation (EU) 10/2011 separate sets of testing conditions apply for overall
migration and specific migration testing. Especially for long time storage more severe test
conditions for specific migration testing are obligatorily.

7.1. Overall migration testing

For ‘Overall Migration Testing’ the packaging material is tested for the sum of all
components that migrates from the food contact material into the simulant. There are several
simulants which are used for testing the materials. The result for the Overall Migration test is
a measure of how much of the packaging material migrates into the simulant. It does not
specify the type of component migrating from the food contact material.

7.2. Specific migration testing

The second type of migration testing is ‘Specific Migration Testing’. This is where traces of
toxic substances are quantified in the sample. Therefore it is essential that before testing is
conducted; it is known what substances are added to the packaging material at every level of
manufacturing and if any of those substances have a specific migration limit (SML).

Specific migration testing can be avoided when the assumed/calculated migration is smaller
than the SML. Generally recognized mathematical modeling can be applied.

European Commission Regulation (EU)10/2011 consists of a Union list of monomers,
additives and other starting substances that may be used for the manufacture of plastic
materials and articles, with the restrictions set out therein.
7.3. Maximum permitted Quantity (QM limit)

For the QM limit not the migration but the residual content of the component in the food contact material is relevant.

To comply with the European Commission Regulation (EU) 10/2011 it is necessary to ensure that all requirements are met.

8. Paper and cardboard

For paper and board guidelines are set- out in Resolution ResAP (2002)1. Materials should not transfer their constituents to foodstuff in quantities that could endanger human health; therefore it is advisable to perform overall migration testing.

According EU guidelines there are no overall migration limits for paper and board, but there are restrictions on the levels of pentachlorophenol, cadmium, lead and mercury in the food contact material. A technical document contains a list of additives which may be used in the manufacture of paper and board materials in contact with foodstuffs.

The basic principal of migration testing is similar with migration testing for plastics. Simulant used for uncoated paper and board is MPPO (Tenax).
9. Other food contact materials

In some cases guidelines are set out for other food contact materials. Although the voluntary compliance program is initially set-up for the most common used food contact materials paper, board and plastics, Intertek experts can assist companies in selecting the right settings and assist in designing an appropriate test program for other food contact materials.

10. Compliance to national legislation

All food contact materials intended for the European market need to comply with Framework Regulation 1935/2004 (EC). EU Member states have the right, if appropriate, to include a number of additional subjects into their national legislation. Intertek advises companies with the testing of all types of materials according the EU legislation and consults companies to comply with member state specific legislation.

11. Organoleptic/ Olfactory testing

According to the 1935/2004 (EC) food contact materials may not cause any organoleptic changes to the foodstuff like smell or taste.

Off-flavour or off-taste depends on the food contact material in relation to the contact time and temperature, foodstuff and the assessor. Most common used is the triangle test in which a sample together with two “blanc” samples are tasted or smelled anonymously by a trained test panel. They have to pick out the sample with an off-odour or off-taste. Another test method used is quantitative descriptive analyses (QDA); this test method includes appearance, aroma, taste, texture and the after-taste in the analyses.

12. Declaration of Compliance

According to European Commission Regulation (EU)10/2011 (Article 15) plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles at the marketing stages other than the retail stage, shall be accompanied by a written declaration (Declaration of Compliance or DoC) in accordance with Article 16 of the Regulation 1935/2004 (EC).

There are also specific measures on the DoC for ceramics, regenerated cellulose, active and intelligent packaging and materials and articles containing BADGE and derivates.

Intertek can support companies in establishing this Declaration of Compliance.
12.1. Specimen ‘Declaration of Compliance’:

Declaration of Compliance

based on the regulations concerning materials and articles intended to come into contact with foodstuffs.

Certificate nr. : Date :

Company: Manufacturer/Importer : full address

Product: product name, brand, type base materials etc.

Conditions of use:
- type of food intended to come in contact with:
- time and temperature of treatment and storage in contact with the food:
- surface/volume ratio:

Information on all substances for which there are restrictions and/or specifications in place in the EU as well as at the National level. (In the absence of any national or European legislation, all information on international restrictions, norms or guides has to be provided (i.e. council of Europe)

Monomers:
Additives:
Dual use additives
Other substances used in the formulation:

Migration tests of the above-mentioned product(s) is/are performed according to directive 97/48/EC and directive 85/572/EEC.
Name manufacturer/retailer/authorized representative: ........................................
declares that the product prescribed:
- complies with the requirements of the Framework Regulation 1935/2004 (EC).
- complies with the relevant restrictions of European Commission (EU)10/2011 (for plastics)
- is manufactured according to Good Manufacturing Practices and complies with Regulation 2023/2006.

Optional:
- complies with National Legislation:
  - Netherlands
    Regeling Verpakkingen- en gebruiksartikelen (Warenwet)
  - Germany
    “Bedarfsgegenständeverordnung” of 10 april 1992 as well as “bR Recommendations “, part X, date X.
  - complies with the restrictions of a functional barrier conform Article 14 of European Commission (EU)10/2011
  - complies with ResAP (2002)1 (for paper and board)

This Declaration of Compliance relies on the product recipe disclosed to Intertek Polychemlab, the performed migration tests and the compliance statements submitted by the raw material producers. This Declaration of Compliance and the above mentioned test report are limited to the tested samples and do not represent a generally applicable statement on the quality of the continuous production. Any change in the recipe, the raw materials, the production process or the intended use of the above mentioned product can have an impact on the food contact compliance. This Declaration of Compliance is valid as long as no changes in the relevant regulations occur.

Done at,

Date :

Signature:

Name and function (of the signatory who is authorized to represent the manufacturer)
13. News from the EU and Updates to previous versions

13.1 A Commission Decision (2010/169/EU) has been released on 19 March 2010 concerning the non-inclusion of 2,4,4’-trichloro-2’-hydroxyphenyl ether in the Union list of additives which may be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs under Directive 2002/72/EC.

13.2 A food contact materials database has been released by DG Sanco. This database is a tool to inform about the substances to be used in materials and articles intended to come into contact with food. This database can be found on: https://webgate.ec.europa.eu/sanco_foods/main/?sector=FCM&auth=SANCAS

13.3 The European paper and board food packaging chain (CEFIC, CEPI, CITPA and FPE) released an Industry Guideline for the Compliance of Paper and Board Materials and Articles for Food Contact. This Guideline provides a methodology for establishing the suitability of paper and board for food contact applications. http://www.nvc.nl/files_content/PDF(1).pdf

13.4 In January 2011 a new regulation, referred to as the Plastics Implementing Measure (PIM), is expected to be adopted. This new Regulation combines the 2002/72/Ec and amendments, the migration directives and the vinyl chloride directive. The most important changes that are introduced:
- measures for plastic layers in multi-layer materials
- changes in the simulants used for migration testing
- standardized testing conditions for migration testing
Ultimately 5 years after adoption all supporting documents shall be based on the rules set out in the new regulation.

13.5 As of 1 May 2011 a new regulation on plastic food-contact materials is applicable. Regulation (EU) 10/2011 on Plastics Materials and Articles intended to come into contact with foodstuffs will replace the Plastics Directive 2002/72 and its amendments as well as directives on migration testing.
Intertek Polychemlab BV

Koolwaterstofstraat 1
6161 RA Geleen
Netherlands

Tel: +31 (0)88 126 8888
Fax: + 31 (0)88 126 8876

Email: eufoodcontact@intertek.com

Internet: www.intertek.com/packaging

KvK nr. 24 39 55 64
BTW no. NL 815792401.B01

All contents in this article are protected by copyright and other protective laws. The information may only be copied, reused or redirected with written permission given by Intertek Polychemlab. Intertek Polychemlab carefully compiled the contents of the program\(^1\) in accordance with their current state of knowledge; the program will be reviewed and when applicable updated every 1\(^{st}\) working day of the month, based upon information provided by the European Commission.

Damage and claims arising from missing, incompleteness, exactitude, topicality or incorrect information are excluded. Intertek Polychemlab takes no responsibility or liability for damage of any kind, also for indirect or consequential damages resulting from using this information. Please contact Intertek Polychemlab for more information on “the program” or any other related information in order to comply with your specific request.

\(^{1}\) The Intertek voluntarily compliance program towards 1935/2004 (EC)
As of 1 January 2013 the rules provided by the legislations in the right green frame will be replaced by the provisions on migration testing and simulants in (eU) No 10/2011