

The present work, produced by the [ECOSIGN Consortium](#), is licensed under a [Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License](#).

# Ecodesign In Food Packaging

## UNIT 12: Testing of Food Packaging

Gabriel Laslu, Dipl. Eng. (IDT1), [gabriel.laslu@gmail.com](mailto:gabriel.laslu@gmail.com)

Gabriel Mustatea, Ph. D. [gabi.mustatea@bioresurse.ro](mailto:gabi.mustatea@bioresurse.ro)

12.1 Overview.....	2
12.2 Laws and rules for food contact materials.....	2
12.3 Types of tests for materials that come in contact with food products.....	5
12.4 Migration tests .....	6
12.5 Physical properties testing of food packaging .....	9

After learning this unit, the student will be able to:

- Know the main requirements imposed on the packaging materials
- Be informed about the main testing methods of the materials for food packaging



## 12.1 Overview

In the practice of food packaging, a wide variety of materials are used, including glass, paper, metal and plastics, as well as a wide variety of packaging technologies.

The properties of materials such as mechanical properties and other physical properties, permeability, sealing and migration of substances in contact with food are determinants of food quality, shelf-life and food safety.

Therefore, food packaging materials should be tested to ensure that they have the right properties in terms of gas permeability, water vapor and contaminants; mechanical properties and other physical properties; and the thickness of the main components and coating layers.

Food categories, such as fresh produce, frozen foods, irradiated foods, fresh fish, cans, etc., have regulatory requirements and special packaging requirements. Packet testing can take into account:

- Food safety,
- Packaging compatibility with food,
- Migration of material from packaging to food, shelf life,
- Barrier properties, porosity, package atmosphere, etc
- Special requirements for quality assurance, good manufacturing practice, HACCP<sup>1</sup> , validation protocols, etc .

In view of the wide variety of testing practices, some EU regulations and some test methods and principles for food packaging will be presented below. The main packet testing technologies are presented in Annex 1, Table A1.4

## 12.2 Laws and rules for food contact materials

---

<sup>1</sup> What is HACCP? <http://proalimente.com/este-haccp-proiectarea-implementarea-unui-sistem-haccp/>

- it represents a series of measures to ensure food safety from harvesting to consumption.
- it is a key tool of quality management to ensure food innocuity, based on risk identification, assessment, prevention and surveillance.
- it is integrated into the General Principles of Food Hygiene and it is applied with other codes of hygiene practice.
- it is based on a system of preventive actions in all processes in the food chain: supply, reception, storage, production and delivery.
- as a food quality assurance system it can be on its own implemented in an organization or on the structure of a SMC ISO 9001: 2008 correlated with the ISO 151161 guideline.



The general legislation on all food contact materials is ensured by:

- COUNCIL REGULATION (EC) REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food

EU Regulation on Good Manufacturing Practices for materials and objects that come in contact with food products (CE) 2023/2006

- REGULATION (EU) NO. COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food products  
EU laws and regulations exist only for 5 out of 17 packaging materials that may come into contact with food products.

- 

Annex 1 presents a graph indicating EU normative acts.

Annex 1 to EC Regulation 1935/2004 includes the following materials that can come into contact with food:

- |                               |                           |   |
|-------------------------------|---------------------------|---|
| 1. Active and smart materials | 7. Ion exchange resins    | 14. Textiles                            |
| 2. Adhesives                  | 8. Metals and alloys      | 15. Varnishes and film-forming products |
| 3. Ceramics                   | 9. Paper and cardboard    | 16. Wax                                 |
| 4. Cork                       | 10. Plastics              | 17. Wood                                |
| 5. Rubber                     | 11. Typographical inks    |   |
| 6. Glass                      | 12. Regenerated cellulose |   |
|                               | 13. Silicon               |   |

### Declaration of Conformity

Framework Directive 1935/2004 Article 6 (5) provides: "Specific Directives require these materials and articles to be accompanied by a written declaration that they comply with the rules applicable to them".

EU legislation and EFSA<sup>2</sup> guidance documents detail how to compile dossier for food contact applications and what type of scientific data and other information should be included. EFSA updates the guidance documents on a regular basis.

Minimum requirements in the declaration of conformity for the chemical substances of food contact materials:

- (A) EFSA opinion on chemicals (if available)  
(B) Self-assessment of manufacturers and declaration of compliance and documentation on toxicological tests (in vitro and in vivo) in accordance with EFSA requirements for FCM

---

<sup>2</sup> <http://www.efsa.europa.eu/en/applications/foodcontactmaterials/regulationsandguidance>



- (C) Assessment of compliance risk from other countries according to the guidelines and required data equivalent to EFSA requirements such as BfR (Germany) or FDA (USA).
- (D) Restrictions in other legislation, eg. whether chemicals are regulated as food additives, including purity and identity requirements.


Reg 10/2011 se aplică materialelor și obiectelor introduse pe piața UE și care intră în următoarele categorii:

- (A) material objects and parts thereof consisting exclusively of plastics;
- (B) materials and the objects made up of several layers of plastic bonded with adhesives or by other means;
- (C) materials and objects referred to in (a) or (b) printed and / or coated with a coating;
- (D) plastic layers and coatings of plastic caps forming gaskets and closures which, together with covers and closures that make up a set of two or more layers of different types of materials;
- (E) plastic layers in multilayer materials and articles multimaterial.

Regulation shall not apply to materials and articles placed on the EU market and are intended to be covered by other regulations:

- (A) ion exchange resins;
- (B) rubber;
- (C) silicones.

Reg. 10/2011, provides plastics migration limits such as:

 The global migration limit (Overall Migration Limits - OMLs):

- Plastic materials and objects shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm<sup>2</sup> of contact surface (mg/dm<sup>2</sup>).
- By way of derogation from the previous paragraph, the plastic materials and articles intended to come into contact with food intended for infants and young children, shall not transfer their components into food simulants in quantities exceeding 60 milligrams/kg (simulant).

 The limit of specific migration (Specific Migration Limits - SMLs):

- Plastic materials and objects shall not transfer their constituents to foods in quantities exceeding the specific migration limits set out in annex I. Those specific migration limits expressed in mg of substance per kg of food (mg/kg).
- For substances that do not set a specific migration limit or other restrictions in annex I, shall apply to a generic specific migration limit of 60 mg/kg

Annex I can be consulted at:

<http://eur-lex.europa.eu/legalcontent/RO/ALL/?uri=celex:32011R0010>



Reg. 10/2011, annex V, also regulates the general rules for testing compliance of migration from plastic materials and objects in contact with food, namely:

- Testing for specific migration of materials and objects already in contact with food, with the following steps:
  - Preparation of a sample
  - Analysis of the migrated substances
  - Special Cases (e.g., phthalates)
- Testing for specific migration of materials and objects not yet in contact with food

### 12.3 Types of tests for materials that come in contact with food products<sup>3</sup>

The principles of the main tests that are performed for materials that come in contact with food will be presented.

Migration is determined on the material or object or, if this determination presents practical difficulties, on a specimen taken from the material or object or a specimen representative of this material or object. For each food simulant or food type, a new test specimen is used. Only those parts of the sample intended to come into contact with food products in actual use shall be placed in contact with the food simulant or the food product.

Sample preparation must follow a certain protocol which must indicate the date and place where the sample was taken, type of sample (material, object, intermediate product , etc.), the label information , the number of samples taken, the volume and the dimensions of each sample, the detailed description of the sample (ex. type of material/materials etc.), transport and storage conditions of the sample, the reason of sampling, the person responsible.

Migration tests can be carried out in four ways: using a cell test for the migration, through the preparation of handbags, by total immersion and by filling the package. Depending on the shape and dimensions of the material or the object to be tested, one of the methods is chosen.

#### **Testing by total immersion**

Through this method samples are cut to obtain specimens of 1 dm<sup>2</sup> which are immersed in the simulant. With a test of immersion, both sides of the sample are in contact with the simulant.

---

<sup>3</sup> <http://ukp.vscht.cz/files/uzel/0009413/Testing%20of%20food%20contact%20materials.pdf?redirected>



### **Testing on a single part using a migration cell**

When testing uses a cell, only a surface of the material is in contact with the simulant. This is particularly important for materials with multiple layers.

### **Testing on a single part using a purse**

For flat items which have a sufficient resistance to sealing to form durable bags, unique testing side in a bag may be preferred, as this does not require a specialization, and allows a more efficient use of the oven space. As to the cell migration only one of the surfaces is in contact with the food simulant. The surface to volume ratio in a bag is conventionally 2 dm<sup>2</sup> of the material to 100 ml of food simulant.

### **Testing on a single side by filling**

For articles in the form of containers, it is usually most convenient to test them by filling with food simulant. For very large containers, testing by filling may not be possible and may be necessary to fabricate specimens for testing smaller representing the article that will be tested.

## 12.4 Migration tests

The migration of the components or combinations of materials which come into contact with food products in the packaged food depends on the properties of materials on the safety and stability of the materials.

The migration of the compounds is a two-way process, i.e., the compounds or the components of these materials that come in contact with food can migrate from the materials into food, and in equal measure compounds from food may migrate into the packaging material.

Many types of food materials are complex matrices, and the determination of the substance migrants is very complicated. The best method is to determine the migration of compounds through the use of food simulants. There are four basic simulants for food:

- A - Distilled water (substituting neutral foods)
- B - solution of diluted acid (e.g., acetic acid solution 3% (weight / volume), substitution of acidic foods)
- C - Mixtures of ethanol / water (for example ethanol solution 10% (v / v), the substitution of alcoholic foods)
- D - olive Oil or isooctane (replacement of fatty foods) and 50% ethanol with 50% water mixture (v /v) (substituting milk products)



**Tab.2 Food simulants according to Annex III, reg. 10/2011**

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Vegetable oil (*)	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

In general, there are two kinds of migration tests:

- Global migration (the level of transmission of all the compounds is monitored / components polymers in food/food simulants)

#### **The overall migration (OM)**

- All substances that can migrate (gravimetric analysis)
- Unit: mg / dm<sup>2</sup> (with the exception of the FCM for infants and children mg/kg food/simulant).

The overall limit has been imposed to ensure that materials don't transfer large amounts of undesirable substances in the food that would cause about an unacceptable change in it. The overall limit is 10 mg/dm<sup>2</sup> or 60 mg/kg. The error of measurement is 2 mg/dm<sup>2</sup> or 12 mg/kg for food simulants A, B, C, D1 (see tab 2) and 3 mg/dm<sup>2</sup> or 20 mg/kg for simulants of fatty foods D2. These methods are described in detail in tab A1.1 of annex 1. They do not apply to volatile substances. Also in annex 1 the recommended methods for other materials are presented outside the plastic as they are for example, paper and cardboard tab A1.2<sup>4</sup>.

Specific migration (the level of transmission of the compounds / of the specific components (for example primary aromatic amines) of the polymers in food/food simulant / food is monitored).

<sup>4</sup> Catherine Simoneau Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) a CRL-NRL-FCM Publication, JRC, 1st Edition [2009]



## The specific migration (SM)

- The amount of a specific substance which migrates
- Unit: mg / kg

There are several ways to demonstrate compliance with migration-specific Limits (SMLs) set in EU legislation on food products. Following the exposure phase, substance (s) in question must be extracted/e of adequate simulant food or from the food product and then identified and quantified/e using a method of analysis. The analytical approach will depend on:

- the volatility of the substance (s)
- the polarity of the substance (s)
- the nature of the food product or of the food simulant (for example, aqueous or fat)- the level of determination (e.g., high or low)
- the functional groups of the substance (s) (considered to define the method of detection).

Specific migration limits for some substances are defined as being undetectable at a detection limit of 10 µg substance / kg food (or food simulant).

The analytical determination of migrants includes three main steps: extraction, sample clean-up if necessary and determination (mainly by chromatography). The type of extraction and sample clean-up used depends on how much substance is expected to be present and the characteristics of the substance and the matrix from which it is extracted. The purpose of this phase of cleaning is the removal of any substance from food that might interfere or that would prevent the signal investigation.

Another purpose is the elimination of the major components of food such as proteins, carbohydrates or fats, which is able to upload and disturb analytical equipment. General information about the mode of determination of the specific migration from plastic are available in the CEN EN 13130-1: 2004, Materials and objects in contact with foods products - Plastic Substances (see table A1.3 , annex 1)<sup>5</sup> document.

There are standards for the determination of specific migration and for the other packaging materials that come in contact with food: paper, cardboard, ceramic, coatings, varnishes, baking trays made of metal, glass.

**Example 1:** *Determination of the migration of the primary aromatic amine from the materials that come into contact with food.*

---

<sup>5</sup> Catherine Simoneau Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) a CRL-NRL-FCM Publication, JRC, 1st Edition [2009]





**Principle:** The aromatic Amines in the test samples extract (extract = specific volume of the food simulant which is in contact with the tested material, specific time and specific temperature) react in the presence of hydrochloric acid (HCl) of sodium nitrite (NaNO<sub>2</sub>) and a herbicide (sulfamat ammonium) with a reagent (n-naphthyl-ethylene diamine) into a purple product whose intensity is measured with a spectrophotometer at 550 nm wavelength .

**Example 2: Method of test for consumption of potassium permanganate<sup>6</sup>**

**Principle:** The Method determines the volume of total oxidizable organic material of potassium permanganate after dissolving a sample in water. The value determined is known as the value of the permanganate. Also, the permanganate potassium can be used as absorbent of ethylene, for example, it prolongs the storage time of bananas even at high temperatures. This effect can be exploited by packing bananas in polyethylene with potassium permanganate. By removing the ethylene by oxidation, permanganate delays ripening, increasing shelf life of fruits up to 4 weeks without requiring refrigeration<sup>7</sup>.

In Romania, the IBA Lab, holds RENAR accreditation (in accordance with standard SR EN ISO/CEI 17025:2005) for testing the hygienic and sanitary packaging materials. It can perform tests of overall migration into food simulants (A, B, C, D1, D2) as well as tests of specific migration of metals in accordance with EC Regulation 10/2011 and subsequent amendments for the packaging materials of plastics. Tests for overall migration and specific migration of components (formaldehyde, heavy metals) from the packaging materials of paper and cardboard can be performed. Tests of specific migration of heavy metals from the materials and articles of glass and ceramics can be performed.

## 12.5 Physical properties testing of food packaging

Testing of the food packaging shall be in accordance with the conditions of standard ISO 2206 , complete Packaging and filled with content, Packaging, Transport of goods, sample Preparation, testing Equipment, humidity measuring, performance testing. The standard conditions for probation: 23 OC, 50%RH.

- **Thicknesses.** The thickness of a material is the perpendicular distance between the two surfaces of the material. There are many physical properties of the packaging material depending on the thickness, ex. The rate of water vapor transmission (Water Vapour Transmission Rate - WVTR) and the transmission Rate of gas (Gas Transmission Rate GTR) of a film is inversely proportional to the thickness (decreases with increasing thickness). Measuring instruments used for thickness measurement: micrometers, calipers or electronic devices of high precision (especially for films). Paper thickness is measured in inches, points of inches or in mm (1 point = 1/1000 of an inch); For films, the thickness is measured in microns, mils, or in the gauge (25 microns = 1 mil = 1/1000 of an inch = 100 gauge = 0.25 mm).

- **The paper density:** the paper density (also known as basic weight or grammage) is a term used in the pulp and paper industry to denote a measure of the mass of the product per

---

<sup>6</sup> Permanganatul de potasiu este un [compus anorganic](#), [sarea acidului permanganic](#) cu [potasiul](#), cu formula KMnO<sub>4</sub>, fiind un [agent oxidant](#) extrem de puternic, adeseori folosit în laborator

<sup>7</sup> [https://en.wikipedia.org/wiki/Potassium\\_permanganate](https://en.wikipedia.org/wiki/Potassium_permanganate)



unit of area for a type of paper or cardboard. The term "density" is not used in its traditional sense of mass per unit of volume."The paper density ", rather, it is a measure of the density of the surfaces thereof. The paper density can also be used to distinguish paper from cardboard as the cardboard usually has a grammage greater than 224 g / m<sup>2</sup>.

Normally two ways of expressing the density of the paper is used:

- Expressed in grams per square meter (g / m<sup>2</sup>), the paper density is, also, known as weight. This is the measure used in most parts of the world.
- Expressed in terms of mass / weight on the number of sheets, it is known as the base weight. The convention used in the United States and several other countries using the paper sizes in the U.S. are the mass in pounds of 500 or in some cases 1000 sheets of paper (pounds of a ream 500 or in some cases 1000 sheets) from a certain size of the basic (raw, still uncut). The Japanese paper is expressed as weight in kg of 1000 sheets.

- **Breaking strength:** the Test measures the ability of a sample of paper, cardboard, foil, film, laminate plastic, to withstand the pneumatic or hydraulic shock. For films, foils, laminates and papers, the pneumatic test is used. Heavy paper and cardboard are tested hydraulically (kgf/cm<sup>2</sup> or lbs /sq. inch). In many cases, it serves as a good index of the quality of manufacturing of packaging materials.

- **Resistance to tearing:** the Paper is tested for the properties of resistance to tearing in two ways: internal laceration: the force required to propagate a internal breaking is measured. Laceration edges: measure the force required to initiate a rupture. The test is done in both directions of the paper. Unit of measurement [mN (mili Newton)]. The factor of rupture is calculated as tear strength per unit of the basis weight of the paper and expressed in mN / g / m<sup>2</sup> or dm<sup>2</sup>. The factor of breaking = breaking strength / weight. If the resistance to tearing = x [m], weight of base = y [gf / m<sup>2</sup>]. Then the factor of breaking = x / y [mN \* m<sup>2</sup> / gf] or 100 \* x / y [dm<sup>2</sup>]. It has taken into account that 1 m = 1gf.

- **Tensile strength:** the testing Process involves placing the sample test in the testing machine and then slowly extend it until breaking. During this process, it is recorded the elongation of the sample function of the applied force. The data is handled so as not to be specific to the geometry of the test sample.

Measurement of elongation is used to calculate the elongation of the specific (modulus of elasticity),  $\epsilon$ , using the following equation:

$$\epsilon = \Delta L / L_0 = (L - L_0) / L_0$$

where  $\Delta L$  is the change in length of the sample,  $L_0$  is the original length of the sample and  $L$  is the final length. Force measurement is used to calculate the tensile stress,  $\sigma$ , using the following equation:

$$\sigma = F / A$$



Where **F** is the tensile force and **A** is the section of the nominal sample size. The machine does these calculations as the force, so that the data points can be included in a curve  $\sigma = f(\epsilon)$ . The tensile strength of a paper is defined as the force applied parallel to the plane of the sample with width and length specified, which is loaded with a force in standard conditions. The test indicates the durability and usefulness of the paper in the packaging operations, such as, packaging, printing etc. Plastic films are tested normally at higher speeds of loading due to the higher extensibility.

The curve of loading helps in locating the area of productivity of maximum packaging. It is measured in both directions: - the direction of the processing on the machine (MD – machine direction) and perpendicular to it (CD – cross direction). The unit of measurement is the [N. m – newton meter].

The index of paper tensile strength (tensile index) is defined as the tensile strength relative to the basis weight of the paper  $[(N/m)/gf/m^2] = [Nm/gf]$ .

- **Resistance to fat:** Resistance to fats is measured by exposing a sample crisped in the fat that contains red dye. The time required for the red spot to appear on the unexposed side is a measure of this property. For films of plastic, the test can be carried out directly in the bags using peanut oil colored with red paint of the Sudan.

- **The rate of gas transmission (GTR):** The transmission rate of the gas is determined normally by measuring the variation of pressure at constant volume. The amount of gas that flows through the film is calculated as the volume at NTP (temperature and normal pressure). GTR is an important property to estimate the efficiency of the packaging material or the resistance of the pack to the flow of gas and helps in selecting the materials of the barrier, mainly for foods sensitive to oxygen.

- **The rate of water vapor transmission (WVTR):** WVTR is a measurement of the amount of water vapor in grams which will permeate from one side of the film with a surface of one square meter in 24 hours, when the difference of relative humidity between the two sides is maintained at 90% and 37.8 ° C. this Property is important for estimating the efficiency of the packaging material or a packaging for the resistance to water vapour and is useful in the consideration of the selection of the materials of the barrier for the food hygroscopic. Example: Determining the permeability to water vapour, Principle: Determining the permeability of water vapor is a gravimetric analysis. Dried Silica gel placed in cans with tight-fitting lid made from the packaging material, change the weight of the box, because the silica gel absorbs the water vapor through the packaging material, in the environment whose relative humidity and temperature are known.

- **Resistance to shock:** These tests are designed to measure the ability of plastics to resist breakage by shock.



- **Resistance to abrasion:** This test is designed to measure the ability to resist surface wear by friction. The procedure consists in grinding the sample with a wheel of abrasion standard for a determined number of revolutions and measuring the loss of weight of a sample.

The equipment used in the tests of the materials of packing food products is very diverse, and the presentation and knowledge of this is beyond the framework of the course. Information on this can be found in the catalogues of the various manufacturing firms ex.

<http://www.worldoftest.com/packaging-testing> or

[http://www.zwick.com.tw/zwick-tw/pdf/brochures/99\\_269\\_Kunststoffe\\_FP\\_E.pdf](http://www.zwick.com.tw/zwick-tw/pdf/brochures/99_269_Kunststoffe_FP_E.pdf) etc.



**Table A1.1.** Laws and regulations of the EU only 5 of the 17 packaging materials can come into contact with food products

Regulated	Not regulated	Not regulated, high priority
Ceramics	Cork	Paper and cardboard
Regenerated Cellulose Film	Adhesives	Varnishes & Coatings
Active & Intelligent Materials	Silicones	Printing Inks
Plastics	Elastomers & Rubbers	
Recycled Plastics	Glass	
Ion Exchange Resins	Metal & Alloys	
Wood		
Textiles		
Waxes		

### The framework Regulation

[Regulation \(EC\) No 1935/2004](#) provides a harmonised legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- Release their constituents into food at levels harmful to human health;
- Change food composition, taste and odour in an unacceptable way.

Moreover, the framework provides:

- for special rules on active and intelligent materials (they are by their design not inert);
- powers to enact additional EU measures for specific materials (e.g. for plastics);
- the procedure to perform safety assessments of substances used to manufacture FCMs involving the [European Food Safety Authority](#);
- rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol. For more information, please refer to the following document on [Symbols for labelling food contact materials](#);
- for compliance documentation and traceability.



## **Regulation on Good Manufacturing Practices**

[Regulation \(EC\) No 2023/2006](#) ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- premises fit for purpose and staff awareness of critical production stages;
- documented quality assurance and quality control systems maintained at the premises;
- selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles.

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

## **II. EU legislation on specific materials**

In addition to the general legislation, certain FCMs — ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials — are covered by specific EU measures. There are also specific rules on some starting substances used to produce FCMs.

[\[Collapse All\]](#)

### **Plastic Materials**

The most comprehensive specific EU measure is [Regulation \(EU\) No 10/2011](#) on plastic materials and articles. It sets out rules on the composition of plastic FCMs, and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles.

This Regulation is regularly amended, please consider the consolidated version as a tool for your convenience.

### **Consolidated version of Regulation (EU) No 10/2011**

The consolidated version however is not legally binding, and a list of specific amendments is given below. In particular, there are amendments to the plastics Regulation that will only enter into force in September 2018, on limits for metals and to food groups 04.01 and 04.04, which are included in the amending [Regulation \(EU\) 2016/1416](#).



Relation between the present Regulation and [earlier Directives](#).

An important mechanism to ensure the safety of plastic materials is the use of migration limits. These limits specify the maximum amount of substances allowed to migrate to food. For the substances on the Union list the Regulation sets out '**Specific Migration Limits**' (SML). These are established by EFSA on the basis of toxicity data of each specific substance. To ensure the overall quality of the plastic, the overall migration to a food of all substances together may not exceed the **Overall Migration Limit** (OML) of 60mg/kg food, or 10 mg/dm<sup>2</sup> of the contact material.

The Regulation sets out detailed migration testing rules. Although migration testing in the food prevails, migration is usually tested using '**simulants**'. These simulants are representative for a food category, e.g. Acetic acid 3 % (w/v) is assigned for acidic foods. The migration testing is done under standardised time/temperature conditions, representative for a certain food use, and covers the maximum shelf life of packed food.

To ensure the safety, quality and compliance of plastic materials, adequate data on the composition of (intermediate) materials has to be communicated via the manufacturing chain, up to but not including the retail stage. For this purpose a '**Declaration of Compliance**' (DoC) needs to be provided. The DoC is based on supporting documentation which documents the reasoning on the safety of a plastic food contact material, and which must be provided to enforcement Authorities on their request. The supporting documentation also provides an important link to the manufacturer's responsibility under GMP ([Regulation \(EC\) No 2023/2006](#)).

### Guidance on plastic materials:

- [EU Guidance](#)Search for available translations of the preceding linkEN\*\*\* **on Regulation (EU) No 10/2011 (click on the white balloon for more languages)**

– in support of the implementation of the general requirements of Commission Regulation (EU) 10/2011 on plastic food contact materials and articles

- [EU Guidance](#)Search for available translations of the preceding linkEN\*\*\* **on information in the plastics supply chain (click on the white balloon for more languages)**

– in support of the implementation of Commission Regulation (EU) 10/2011 on plastic food contact materials as regards the declaration of compliance



### Amendments to Regulation (EU) No 10/2011

- [Regulation \(EU\) 2017/752](#)- amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- [Regulation \(EU\) 2016/1416](#)- amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

The amendments below only amend Annex I of [Regulation \(EU\) No 10/2011](#), thus changing the Union list of authorised substances.

- [Regulation EU 2015/174](#) - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- [Regulation EU 202/2014](#) - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- [Regulation EU 1183/2012](#) - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- [Corrigendum to Regulation EU 1183/2012](#) - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011.
- [Regulation EU 1282/2011](#) - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- [Regulation EU 321/2011](#) - restricting Bisphenol A use in plastic infant feeding bottles

### Register and Lists

- [Provisional list of additives](#) for use in plastic food contact materials

### Active and Intelligent Materials

Active and intelligent materials extend the shelf-life by maintaining or improving the condition of packaged food, by releasing or absorbing substances to or from the food or its surrounding environment.

As a result they are exempted from the general inertness rule in Regulation (EC) No 1935/2004. The specific rules in [Regulation \(EC\) No 450/2009](#) apply to address their specific purpose, e.g.:

- absorption of substances from food packaging interior such as liquid and oxygen;
- release of substances into the food such as preservatives;





- indicate expiry of food through labelling that changes colour when maximum shelf life or storage temperature is exceeded.

Active materials do not include systems that absorb substances entering from the atmosphere, such as active oxygen barriers.

Regulation (EC) No 450/2009 foresees the establishment of a Union list of substances permitted for the manufacture of active and intelligent materials.

- [EU Guidance on active and intelligent materials and articles](#) intended to come into contact with food - in support of the implementation of Commission Regulation (EC) No 450/2009 of 29 May 2009
- [Register of substances with a valid application for authorisation](#) (Regulation (EC) No 450/2009 - active and intelligent materials and articles)

### Recycled Plastic Materials

[Regulation \(EU\) No 10/2011](#) sets out criteria for the composition of new plastic materials. However after these materials have been used, they do not comply anymore to the plastic Regulation, as they may have been contaminated with other substances. Therefore, a separate Regulation exists to control the recycling processes: [Regulation \(EC\) No 282/2008](#) on recycled plastic materials and articles intended to come into contact with foods

- [Explanatory note](#) concerning authorisation of "old" and "new" recycling processes;
- [Questions and answers](#) - Regulation EC 282/2008 - recycling processes to produce recycled plastic materials and articles intended to come into contact with foods;
- [Valid applications for authorisation of recycling processes](#) to produce recycled plastic materials and articles intended to come into contact with foods.

### Ceramics

- [Directive 84/500/EEC](#) – approximating EU countries' laws on ceramic articles intended to come into contact with foods.

### Regenerated Cellulose Film

- [Directive 2007/42/EC](#) - materials and articles made of regenerated cellulose film intended to come into contact with foods.



### III. Other Legislation

#### Legislation on Specific Substances

- [Regulation 1895/2005/EC](#) - restricting use of certain epoxy derivatives in materials and articles intended to come into contact with food
- [Directive 93/11/EEC](#) - release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers.

#### Products originating or consigned from China or Hong Kong

From 1 July 2011 kitchenware made of melamine or polyamide originating or consigned from China or Hong Kong must comply with the import rules of [Regulation EU No 284/2011](#):

- Consignments must be notified to the competent authorities at the [entry points](#) at least 2 working days before arrival
  - Consignments must have [a declaration](#) and a laboratory report on the analysis of primary aromatic amines (for polyamide) and formaldehyde (for melamine).
- [Guidance](#)
  - [EU guidelines for the import of polyamide and melamine kitchenware](#) from China and Hong Kong
  - [Technical Guidelines concerning polyamide and melamine kitchenware](#) including sampling and analytical methods

#### Other documents

- [Declaration of compliance under Commission Regulation \(EU\) No 284/2011](#) - on import of polyamide and melamine plastic kitchenware from China and Hong Kong - Template



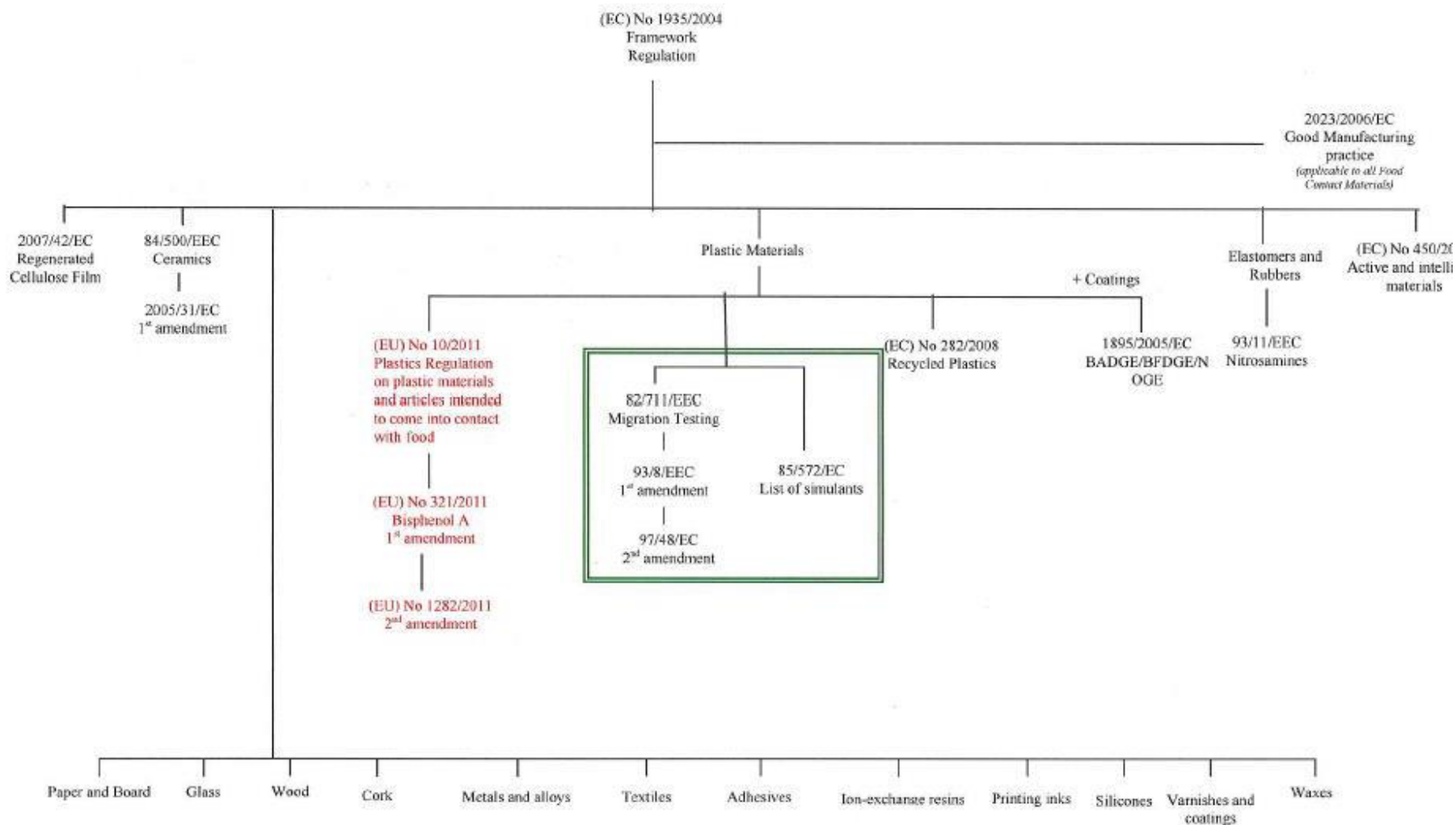


Fig. A1.1 BRC/FDF and Campden BRI Guidance on migration from packaging materials into food, Consultation Draft Only, 2015



**Tab.A1.2 Test methods for global migration for plastics:** series EN-1186, after Catherine Simoneau Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) a CRL-NRL-FCM Publication, JRC, 1st Edition [2009]

<i>Plastics Materials and articles in contact with foodstuffs /</i>
EN 1186-1:2002 Part 1: Guide to the selection of conditions and test methods for overall migration
EN 1186-2:2002 Part 2: Test methods for overall migration into olive oil by total immersion
EN 1186-3:2002 Part 3: Test methods for overall migration into aqueous food simulants by total immersion
EN 1186-4:2002 Part 4: Test methods for overall migration into olive oil by cell EN 1186-5:2002 Part 5: Test methods for overall migration into aqueous food simulants by cell
EN 1186-6:2002 Part 6: Test methods for overall migration into olive oil using a pouch
EN 1186-7:2002 Part 7: Test methods for overall migration into aqueous food simulants using a pouch
EN 1186-8:2002 Part 8: Test methods for overall migration into olive oil by article filling
EN 1186-9:2002 Part 9: Test methods for overall migration into aqueous food simulants by article filling
EN 1186-10:2002 Part 10: Test methods for overall migration into olive oil (modified method for use in cases where incomplete extraction of olive oil occurs)
EN 1186-11:2002 Part 11: Test methods for overall migration into mixtures of C-labelled synthetic triglycerides
EN 1186-12:2002 Part 12: Test methods for overall migration at low temperatures
EN 1186-13:2002 Part 13: Test methods for overall migration at high temperatures
EN 1186-14:2002 Part 14: Test methods for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol
EN 1186-15:2002 Part 15: Alternative test methods to migration into fatty food simulants by rapid extraction into iso-octane and/or 95 % ethanol



**Tab A1.3 Global test methods for paper and cardboard**, after Catherine Simoneau Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) a CRL-NRL-FCM Publication, JRC, 1st Edition [2009]

<b><i>Paper &amp; board Paper and board intended to come into contact with foodstuffs</i></b>
EN 1104:2005 Determination of the transfer of antimicrobial constituents
EN 1230-1:2001 Sensory analysis - Part 1: Odour
EN 1230-2:2001 Sensory analysis - Part 2: Off-flavour (taint)
EN 13676:2001 Polymer coated paper and board intended for food contact - Detection of pinholes
EN 14338:2003 Conditions for determination of migration from paper and board using modified polyphenylene oxide (MPPO) as a simulant
EN 20187:1993 Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187:1990) EN 645:1993 Preparation of a cold water extract
EN 646:2006 Determination of colour fastness of dyed paper and board EN 647:1993 Preparation of a hot water extract EN 648:2006 Determination of the fastness of fluorescent whitened paper and board
EN 920:2000 Determination of dry matter content in an aqueous extract



**Tab. A1.4 Examples of standards for determination of the specific migration to plastics**

<b><i>Plastics Materials and articles in contact with foodstuffs - Plastics substances subject to limitation</i></b>
EN 13130-1:2004 Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants
EN 13130-2:2004 Part 2: Determination of terephthalic acid in food simulants
EN 13130-3:2004 Part 3: Determination of acrylonitrile in food and food simulants
EN 13130-4:2004 * Part 4: Determination of 1,3-butadiene in plastics
EN 13130-5:2004 Part 5: Determination of vinylidene chloride in food simulants
EN 13130-6:2004 * Part 6: Determination of vinylidene chloride in plastics
EN 13130-7:2004 Part 7: Determination of monoethylene glycol and diethylene glycol in food simulants
EN 13130-8:2004 * Part 8: Determination of isocyanates in plastics
CEN/TS 13130-9:2005 Part 9: Determination of acetic acid, vinyl ester in food simulants
CEN/TS 13130-10:2005 Part 10: Determination of acrylamide in food simulants
CEN/TS 13130-11:2005 Part 11: Determination of 11-aminoundecanoic acid in food simulants
CEN/TS 13130-12:2005 Part 12: Determination of 1,3-benzenedimethanamine in food simulants
CEN/TS 13130-13:2005 Part 13: Determination of 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) in food simulants
CEN/TS 13130-14:2005 Part 14: Determination of 3,3-bis(3-methyl-4-hydroxyphenyl)-2-indoline in food simulants
CEN/TS 13130-15:2005 Part 15: Determination of 1,3-butadiene in food simulants
CEN/TS 13130-16:2005 Part 16: Determination of caprolactam and caprolactam salt in food simulants
CEN/TS 13130-17:2005 * Part 17: Determination of carbonyl chloride in plastics



CEN/TS 13130-18:2005 Part 18: Determination of 1,2-dihydroxybenzene, 1,3-dihydroxybenzene, 1,4-dihydroxybenzene, 4,4'-dihydroxybenzophenone and 4,4'-dihydroxybiphenyl in food simulants
CEN/TS 13130-19:2005 Part 19: Determination of dimethylaminoethanol in food simulants
CEN/TS 13130-20:2005 * Part 20: Determination of epichlorohydrin in plastics
CEN/TS 13130-21:2005 Part 21: Determination of ethylenediamine and hexamethylenediamine in food simulants
CEN/TS 13130-22:2005 * Part 22: Determination of ethylene oxide and propylene oxide in plastics
CEN/TS 13130-23:2005 Part 23: Determination of formaldehyde and hexamethylenetetramine in food simulants
CEN/TS 13130-24:2005 Part 24: Determination of maleic acid and maleic anhydride in food simulants
CEN/TS 13130-25:2005 Part 25: Determination of 4-methyl-1-pentene in food simulants
CEN/TS 13130-26:2005 Part 26: Determination of 1-octene and tetrahydrofuran in food simulants
CEN/TS 13130-27:2005 Part 27: Determination of 2,4,6-triamino-1,3,5-triazine in food simulants
CEN/TS 13130-28:2005 Part 28: Determination of 1,1,1-trimethylolpropane in food simulants



Tabel A1.5 A few of the testing technologies of food packaging materials according to

<http://www.worldoftest.com/packaging-testing>

<b>Nr. crt</b>	<b>The testing technology</b>	<b>The executed tests</b>	<b>Features</b>
1	Universal Testing Machines	Resistance to stretch and elasticity, resistance to compression, for various materials including the packaging	Load 2-3000 kN (approx. 200 – 300000 kgf) and race from 400 to 1200 mm.
2	Universal Force Test Systems	Tester operated by the computer, with quality control software for automatic calculation and graphical display of the resistance to breaking, elongation, modulus of elasticity and other information about the stretching force and the compression for extruded, rolled films, paper, and fabrics	
3	Box Compression Tester /Tester de rezistență la compresiune of packing boxes, packages and containers.	The resistance to compression is one of the used properties to evaluate the ability of the packages, boxes and containers to successfully resist the forces of compression to which they are subjected during storage and distribution. The test provides a clear understanding of the deformation under the compression force	ASTM D 642, ASTM D 4169, TAPPI T804, ISO 2872, ISO 12048, JIS Z0212
4	Plastic Film Permeability Tester	This tool is generally used for measuring the speed of oxygen transmission (O <sub>2</sub> ), nitrogen (N <sub>2</sub> ), carbon dioxide (CO <sub>2</sub> ) and other non-flammable gases by the packaging container and thus to ensure that the food inside the packaging is maintained according to the requirements. Also, for the packaging permeability measurement to water vapour	ASTM D1434, ISO 15105-1, ISO 2556, JIS K7126-A and for the water vapor, ASTM D3985, ASTM F1927, ASTM F1307, ASTM F2622, ISO 15105-2, DIN 53380-3, JIS K7126-B
5	Adhesion Testers	This tool is used to apply a layer of ink from the tape to test the sample by pressing it and the printed adhesive along, which are	JIS C2107, JIS Z0237





		then separated by the Peeling Disk tester to determine the optimum conditions for the ink transfer from the tape to the sample. This operation is carried out under controlled conditions of load , running speed, running time etc.,	
6	Leak Tester	Testing to leakage of packaging under pressure is a very important part of the product manufacture and preservation to maintain its quality and quantity up to the consumer for food packaging, beverages, pharmaceuticals etc. used to test the sealing quality and the packaging performance such as bags, bottles, cans, boxes, etc. Also, it can be used to test the samples sealing performance after the compression tests, free-fall tests and other destructive testing methods.	ASTM D 3078
7	Digital Elmendorf Tearing Tester	It uses the method of Elmendorf and it is used to determine the resistance properties to tearing the films, sheets, pliable PVC, PVDC, waterproof films, woven materials, polypropylene, polyester, paper, cardboard, textiles, etc.	ASTM D1922, ASTM D1424, ASTM D689, ISO 13937-1, ISO 6383, ISO 1974, GB/T16578.2-2009, GB/T 455, TAPPI T414
8	Hot Tack Tester to determine the resistance of joints by hot-gluing.	Hot Tack Tester is used to test the adhesive resistance or the peeling resistance <sup>9</sup> of the packaging films used for sealing by hot-gluing. This device is compatible with testing various types of thermoplastic sealing foils at different temperatures, pressure and at a controlled speed in order to assess the different criteria of application for the packing materials taking into consideration the environmental conditions for the effective application. Hot Tack Tester measures the strength of the thermally bonded sealing, immediately after the seal realization and before its cooling to room temperature. It simulates the packaging and sealing and it allows the analysis of its effects on the seals.	ASTM F1921, ASTM F2029



9	Torque testers - Tester to determine the time retention of assembly	The torque tester of the tightening moment is a special tool designed for effective measurement of the torque retention of the containers covers. It is the most suitable method for the technical evaluation of the different projects and models of packing containers and to their quality control. For example, the zero value of torque retention means that the bolts have lost all clamping force and it didn't compresses the gasket and, thus, the screws fall out and the assembly has failed.	ASTM D2063, ASTM D3198, ASTM D3474
10	Impact Tester	It determines the required energy for the plastic films and sheets to break under the impact of a free-falling of a body in specific conditions. This energy is expressed in terms of the body weight which falls from a specified height which leads to a malfunction of 50% of the tested samples.	ASTM D1709, ISO 7765-1, JIS K7124
11	Ink Rub Tester	The frictional resistance describes the printed material ability to withstand the marking, breaking or soiling during packaging handling, distribution transport and use. It simulates the real working environment of the product and it helps to identify the quality and printing method which must be used for the label printing based on the mode of product use and its environment of work.	ASTM D5264, TAPPI T830



12	Coefficient of Friction Tester	The friction properties testing of the materials is very important to evaluate the techniques indices that meet the requirements for obtaining the product quality. The friction coefficient is determined by the ease with which two surfaces slide one over the other. The dimensionless value of the friction coefficient is the ratio of the required force for the surfaces sliding and the perpendicular force on the surfaces. A lower friction coefficient indicates that the surfaces are smoother - they have a lower resistance to the sliding movement.	ASTM D1894-01, ISO 8295, TAPPI 816
13	Specific Gravity Tester – Densimeter	The measurement of the materials density	Examples: Resolution 0.001 g/cm <sup>3</sup> Capacity 0.01-300g The type of the sample Solid, Liquid
14	Film and Paper Thickness Gauges	High precision electronic tester is a suitable tool to perform the thickness measurement or the comparative analysis of the measurements of the thin films with thickness from 0 to 1.5 mm with a high accuracy of $\pm 0.1 \mu\text{m}$	

<sup>9</sup>The peel strength is the average force measure to split two glued materials such as banlie, labels, textiles or plastic.

The zero torque retention value means that the screws have lost all their load and they do not compress the gasket, and thus, the screws fall and the joint has failed.

