

November 2011

## Explanatory views on Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food

### Table of contents

Disclaimer:.....	2
1. General introduction: .....	2
2. Regulatory background: .....	2
3. General provisions (Chapter I): .....	4
3.1. Subject matter and Scope (article 2): .....	4
3.2. Definitions (article 3):.....	5
3.3. General conditions for placing on the market plastic materials and articles (article 4):	6
4. Compositional requirements (Chapter II):.....	7
4.1. Authorised substances: .....	7
4.1.1. Union list:.....	7
4.1.2. Derogations: .....	8
4.2. General requirements, restrictions and specifications.....	9
4.3. Generic specific Migration: .....	10
5. Compliance (Chapter V):.....	10
5.1. Rules for assessing Compliance .....	10
5.1.1. Fat Reduction Factors for lipophilic substances .....	11
5.1.2. Correction factors of migration into food stimulant .....	11
5.2. New testing Conditions.....	12
5.2.1. OML testing: .....	12
5.2.2. SML testing.....	12
5.2.3. Repeated use: .....	13
6. Declaration of compliance and documentation (DoC) (Chapter IV): .....	14
7. Transitional provision (Chapter VI):.....	14
7.1. Provisions for testing: .....	14
7.2. Other provisions: .....	14
8. Bibliography:.....	14

## **Disclaimer:**

This document is a technical paper which has been developed as a support to Regulation (EU) No. 10/2011. It does not replace its legal text. PlasticsEurope and CEFIC FCA advise the reader to refer to the original Regulation available on the EU DG Health and Consumer Protection website

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm) and to comply with the requirements of the Regulation for which he/she is responsible.

### **1. General introduction:**

EU food contact legislation covers general rules applicable to all materials and articles intended to come into contact with foodstuffs (Regulation (EC) No. 1935/2004). For specific materials such as plastics, more detailed legislation has been additionally in place for several years.

Following the publication of Regulation (EU) No 10/2011, PlasticsEurope and CEFIC FCA produced this document in order to assist and provide guidance to the polymer producers and to explain their position in the supply chain regarding the interpretation of Regulation (EU) No 10/2011, on plastic materials and articles intended to come into contact with food.

Additionally the Commission announced in Member States Meetings in 2010-2011 to publish a guidance document, which would replace the old document entitled "Practical Guide" to assist us in ensuring compliance and gives technical explanations for specific requirements.

### **2. Regulatory background:**

Food contact materials are regulated by the so-called Framework Regulation (EC) No. 1935/2004 of 27 October 2004. This Framework sets out basic rules for all materials in contact with food, thus removing differences which existed at the time between national legislations. Attached to the framework Regulation, the Good Manufacturing Practice Regulation (EC) No 2023/2006 set down the requirements/principles of good manufacturing practices for all food contact materials and articles.

The Framework Regulation also allows the development of implementing measures for specific materials. Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food is such an implementing measure (so-called "PIM" or Plastics Implementation Measure) addressing Plastics specifically.

The food contact legislation can be summarized as follows:



27.04.2011

PlasticsEurope, Brussels

Annette Schäfer

Source: Annette Schäfer, DG Health & Consumer Protection, European Commission

Where no EU measures are available for specific materials (for example: paper, inks, coatings...), National provisions such as the Swiss Ordinance on Printing Inks, International recommendations such as Council of Europe Resolutions may be taken into account and Best Practices proposed by associations could help the industry to implement these specific requirements. The Regulation (EU) No 10/2011 consists of a consolidation of existing Directive 2002/72/EC, Directives related to migration tests conditions, food simulants and specific measures concerning vinyl chloride into a single Regulation.

This Regulation is constituted of 6 chapters and 6 annexes as following:

- Chapter I dedicated to general provisions including Subject matter, Scope, Definitions, placing on the market (articles 1 to 4).
- Chapter II on Compositional requirements (articles 5 to 12).
- Chapter III on Specific provisions for certain materials and articles (articles 13 and 14).
- Chapter IV dedicated to Declaration of compliance and documentation (articles 15 and 16).
- Chapter V on Compliance (articles 17 to 19).
- Chapter VI on Final provisions including repeal of EU acts, transitional provisions and entry in force (articles 20 to 23).
- Annexes:
  - o Annex I being dedicated to the list of authorised substances
  - o Annex II concerning restrictions for specific elements on final materials and articles
  - o Annex III for food simulants
  - o Annex IV on declaration of compliance
  - o Annex V describing the testing conditions to verify the compliance
  - o Annex VI relating correlation tables

This document should not be used as a substitute for professional legal advice

This new Regulation entered into force on 1<sup>st</sup> May 2011 and foresees transitional provisions up to 1<sup>st</sup> January 2016 (see article 22). According to article 22.5 and «whereas» 46 all materials and articles that have been lawfully placed on the market before 1 May 2011 may continue to be placed on the market until 31 December 2012.

According to article 21 the following Directives are repealed from 1<sup>st</sup> May 2011:

- Directives 80/766/EEC, 81/432/EEC
- Directives 2002/72/EC and its amendments,

The annex to Directive 85/572/EEC on food simulants is replaced by Annex III point 3 of Regulation (EU) No 10/2011, the remaining part of Directive 85/572/EEC will remain in force. Directive 82/711/EEC (migration testing) will remain valid as long as testing can still be done according to the old test regime (expiration date 1 January 2016) – see paragraph 7.1 provisions for testing

Please note that this Regulation contains significant changes with respect to:

- Scope
- Definitions
- Test methods
- Food simulants
- ...

These changes will be explained further in this document.

### **3. General provisions (Chapter I):**

#### **3.1. Subject matter and Scope (article 2):**

The subject matter is given in article 1.

This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles:

- (a) Intended to come into contact with food; or
- (b) Already in contact with food; or
- (c) Which can reasonably be expected to come into contact with food.

This Regulation is a specific measure which deals exclusively with monolayer plastics and multi-layer plastic bound by adhesives which could be printed or coated, plastic layers or coatings forming gaskets and plastic layers in multi-material multi-layer materials and articles

Compared to the previous Directive 2002/72/EC and its amendments the scope of this Regulation has been enlarged and now also addresses plastic layers which are part of multi-material multi-layer materials and articles (MMML) (for example liquid beverages cartons...). In the multi-material multilayer materials and articles, only the plastic layers are subject to Regulation as far as the composition is concerned. Details could be found later (see comments on article 14).

This Regulation applies not only to plastics food contact packaging but also to e.g. all plastic materials and articles used in the Food Industry (food storage tanks, pipes, pumps, containers, conveyer belts, ...) and to kitchen utensils (such as cups, dishes, cutlery, table surfaces in food preparation areas, inner walls and shelves of a refrigerator...).

This document should not be used as a substitute for professional legal advice

Please note that the Regulation gives a clarification on the plastic materials and articles that are printed and/or covered by a coating. The plastics layer is in the scope of this Regulation whereas the coating and printing inks shall comply with the Framework Regulation (Regulation (EC) No 1935/2004) and specific national provisions if existing (see article 2.3). However obligation exists, that if the printing inks and/or coatings contain substances which are on the European positive list with a restriction under the PIM, adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance («whereas» 30). The same rules apply for adhesives between two plastics layers or between the packaging and label.

This Regulation shall not apply to the following materials and articles which are placed on the EU market (article 2.2):

- Ion exchange resins
- Rubbers
- Silicones.

This is explained in the «whereas» 7 of the Regulation. Although these materials are macromolecular substances obtained by polymerisation processes, they are composed of different substances than plastics and have different physical and chemical properties. Consequently specific rules (for examples national Regulations for rubbers, Resolutions of Council of Europe or French legal texts on ion exchange resins, on silicones...) for these need to apply and it should be emphasised that they are not within the scope of this Regulation.

National measures for these materials could be found using the following URL:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg\\_20091026.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg_20091026.pdf)  
[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum\\_nat\\_legis\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf)

### **3.2. Definitions (article 3):**

This Regulation contains 18 definitions providing a better understanding compared to the previous legislation.

We focus our comments only on specific definitions which need more explanations.

The «whereas» 8 of the Regulation (EU) No 10/2011, explains clearly that plastics are made of monomers and other starting substances which chemically react in order to form a macromolecular structure referred to as the polymer, which forms the main structural component of the plastics. To the polymer, additives are added to achieve defined technological effects. The polymer as such is an inert high molecular weight structure. These plastics are further processed in order to form the plastic materials and articles (see figure 1).

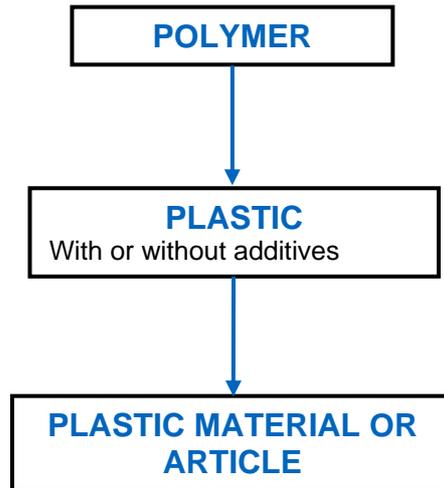


Figure N°1: Scheme related to important definitions.

Please note that in the definition of additive, the “technical effect” used in the old legal texts has been changed by “physical or chemical effect” in PIM (see Article 3, definition number 7).

The PIM makes now a clear distinction between Additives and Polymer Production Aids (PPAs: see Article 3, definition number 8).

The Polymer Production Aids wording replaces the former terminology “Polymerisation Production Aids”. This means that Polymer Production Aids include substances used in post polymerisation steps. It is important to keep in mind that PPAs are not intended to be present in the final material or article.

There is now a clear definition of Aids to Polymerisation (AP: see article 3 definition number 10) while in the previous Directive 2002/72/EC you could only find a description in annex III as follows: “...the substances which directly influence the formation of polymers...”

This Regulation gives a clear definition for Non Intentionally Added Substances (NIAS) that means any impurity in the substances used or reaction intermediates formed during the production process or a decomposition or reaction products. Now the “«whereas»” 18, 20 and article 19 apply to these substances

### **3.3. General conditions for placing on the market plastic materials and articles (article 4):**

- Reference to the general conditions of inertia, composition, labelling, traceability and good manufacturing practice
  - As this specific measure is a daughter Regulation of the so-called “Framework” Regulation (EC) No. 1935/2004, this new Regulation automatically refers to the general conditions of the Framework Regulation for materials and articles to come into contact with food. This means that plastic articles and materials (for food contact) can be put on the market only if they
    - (a) Comply with Article 3 (of the Framework Regulation) in compliance with good manufacturing practice (GMP) so that, they do not transfer chemical substances to food in quantities which could harm the consumer or affect the composition of the food or deteriorate the organoleptic characteristics of the food (i.e. affect the smell and the taste). The general condition of inertia deals

This document should not be used as a substitute for professional legal advice

with two main aspects in food hygiene, i.e. control food safety and preserve the characteristics of the food

(b) Comply with the requirements for labelling, which are set out in Article 15 of (EC) No. 1935/2004. The labelling of the end product (= what is put on the market) has to have the words “for food contact or a specific phrase referring to their use, such as soup spoon, salad cutlery, water bottle or the symbol



(c) Comply with the rules on traceability according to Article 17 of Regulation (EC) No. 1935/2004. Traceability should allow withdrawing defective products with the obligation to inform the consumer as well as to identify those responsible.

This Regulation describes in detail the procedures to follow for authorizing substances at EU level if/when a Union list of Substances is foreseen in one of the specific measures. This is the case for plastics where an EU list of Substances is part of the measure.

d) Comply with the obligations of “Good Manufacturing Principles” according to Regulation (EC) No. 2023/2006. This Regulation is aimed at manufacturers of food contact materials and articles (not only plastics), excluding the producers of starting substances, but not at the users of these materials except if they manufacture their own packaging from for instance a compound.

#### **4. Compositional requirements (Chapter II):**

Chapter II of the Regulation (EU) No 10/2011 outlines the requirements on the composition of the plastics materials and articles intended to come into contact with foodstuffs. Article 5 defines the contents of the Union list of authorised substances.

##### **4.1. Authorised substances:**

###### **4.1.1. Union list:**

The Union list in annex I of the Regulation (EU) No. 10/2011 replaces annex II and annex III of Directive 2002/72/EC as amended. Although we now have only one list, the differences between an authorised use as a monomer or other starting substance versus an additive (and/or PPA) remain. Please note that an additive can not be used as a monomer and vice versa. If the intention is to use a listed monomer as an additive, a new petition must be made.

Remark: Please note that some substances are today authorised for use as an additive and a monomer and or starting substance.

The Union list contains substances used as:

- Monomers and other starting materials (see definition number 6 in article 3)
- Additives excluding colorants
- Polymer Production Aids excluding solvents (non exhaustive list)
- Macromolecules obtained by microbial fermentation.

*NB Please note that solvents and colorants are excluded from the Union Lists but could be used and should be in compliance with article 3 of the Framework Regulation*

*Note that for substances for which the restriction is expressed as ND = non detectable, the detection limit of 0.01 mg substance per kg food is applicable unless specified differently for*

This document should not be used as a substitute for professional legal advice

*an individual substance. Although the principle of analytical tolerance is not specifically mentioned in the regulation, it is our understanding that the ND of 0.01 mg/kg excludes the analytical tolerance.*

A new substance could be added to this list according to the procedure defined by Regulation (EC) No. 1935/2004 (articles 8 to 12) which implements an authorisation request for a new chemical. The rules to prepare a petition dossier are described in the "Note for Guidance" (<http://www.efsa.europa.eu/en/scdocs/doc/21r.pdf>) and submitted through one of the national authorities to EFSA which undertakes a risk assessment of the substance and publishes an opinion, which the EU Commission will use as a basis for risk management and subsequently may authorize the substance by including it in the Union list.

#### **4.1.2. Derogations:**

Article 6 addresses derogations for substances not covered by the Union list (article 5 and article 6.3), which could be used if these are approved by national laws or subject to risk assessment according to article 19 of PIM. These substances belong to one of the following categories: Polymer Production Aids (Art 6.1), solvents, colorants (Art 6.2), Non Intentionally Added Substances, Aids to Polymerisation (Art 6.4), additives being on the provisional list (Art 6.5).

Considered authorised and covered by the Union list are the cases described under Article 6.3 with respect of the conditions described in the article: salts, mixtures, additives being polymers for which monomers are listed, pre-polymers. We would like to highlight some special cases here:

a) Article 6.3 (a) introduces an extension of the salts that are authorised by the parent acid or phenol or alcohol entry. The extension includes now the salts of barium, cobalt, copper, lithium and manganese. Additionally in Annex II point 1 you will find the restrictions for the counter-ions. For example the reference 92000 which represented barium sulphate has been withdrawn from the list as the barium sulphate is now authorised by the entry of the parent acid, "sulphuric acid" with reference number 91920. The restriction for barium, being 1 mg/kg food or food simulants remains.

b) The «whereas» 15 and article 6.3(c) introduce the notion of polymeric additive and makes the distinction between additives which are either polymers being able to function as a main structural component as defined in this Regulation or polymers being considered as polymeric additives. Both are macromolecular substances obtained by polymerisation process or any other process. If the molecular weight of the macromolecular substance is high enough and the fraction below 1000 Da low enough in order not to endanger human health and the polymer would allow to prepare a plastic material or article (sheets, films...), this macromolecular substance could be considered as a structural polymer and consequently is covered by its monomers, provided that these are authorised. There is no need here for a petitioning of the polymer as an additive. Polymeric additives that cannot be used as a main structural component in plastics and macromolecules obtained from microbial fermentation do require petitioning.

c) As from 31<sup>st</sup> of December 2015, the list of additives others than plasticizers<sup>1</sup>, used in plastic layers or plastic coatings in caps and closures becomes a positive list. Please note that the plasticizers used in this application are already today subject to authorisation (see article 23).

---

<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:164:0012:0013:EN:PDF>

d) Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19 (see article 22.4. After that day, this list of additives is also becoming a positive list.

To ensure compliance with article 3 of the Framework Regulation (EC) No 1935/2004, article 19 allows industry to conduct self assessments following the internationally recognised scientific principles for risk assessment of substances used in Plastic materials and articles, exempt from authorisation in this Regulation (colorants, solvents, PPAs, APs and NIAS),

In summary, for non listed substances which do not need to be authorized, the following methodology could be used:

- Verify if the substance is authorized by international recommendations or at national level or:
- Do a risk assessment on the basis of internationally recognised scientific principles according to Article 19

Monomers and additives must explicitly be authorized, except behind a functional barrier with specific restrictions.

Thus it is mandatory to submit a petition dossier to EFSA for new monomers, starting substances and additives (including polymeric additives) or when there is a change in use for these existing authorised substances.

#### **4.2. General requirements, restrictions and specifications**

Article 8 is dedicated to general requirements on substances. This is not a new requirement. This was highlighted in both annex II and Annex III of Directive 2002/72/EC and amendments as follows: "*Substances shall be of good technical quality as regards the purity criteria.*" Now the requirement appears in the basic text of the Regulation, under article 8. It clarifies the legal obligations of the supplier to allow the customer to meet its own regulatory obligations.

Definition 18 in Article 3 on specifications is to be looked at in the context of this Regulation. We are not referring to the technical performance of the substance like for instance anti-oxidant or rheology modifier properties, but to the specifications needed to ensure consumer safety. Dialogue between customer and supplier could include:

- Physico-chemical properties like solubility in several solvents/simulants are important to evaluate the potential to migrate
- Purity profile and the manufacturing of the substance, to ensure consistency of this purity profile, are important
- Changes of the purity profile should be subject to management of change.

Article 9.2 only authorizes the use of a nano form substance if it is explicitly listed in the Union List with the specifications indicated in column 10. Even behind a functional barrier, substances in nano form need to be authorized. This is based on the principle of Responsible Care due to the fact that there are concerns about the way to determine the migration limits for substances in nano form. All other non-authorized substances (articles 13 and 14), with the exception of substances classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR's) , could be used behind a function barrier if the migration should be below the detection limit of 0.01 mg/kg.

This document should not be used as a substitute for professional legal advice

### **4.3. Generic specific Migration:**

Article 11.2 introduces the notion "Generic Specific Migration" for substances for which no specific migration limit or other restrictions exist. This was already written in Directive 2002/72/EC: Annex I, *Special provisions relating to overall migration, point 8, paragraph 2*. It is not the intention of this article to imply that those substances need to be disclosed in the declaration of compliance (DoC). Only the substances with restrictions mentioned in annex I and Annex II need to be disclosed.

## **5. Compliance (Chapter V):**

Producers of polymer resins are required to pay attention to NIAS and the use restrictions applicable to their resins. However it is the responsibility of the downstream users to check compliance of the final article.

### **5.1. Rules for assessing Compliance**

Article 17 gives rules on the expression of migration test results and article 18 gives the rules for assessing compliance with the migration limits.

Screening methods including residual content, other simulants use or extraction tests, OML for non volatiles, migration modelling, are normally quoted as more severe as they are giving overestimates. If all previous mentioned methods failed, then real migration testing results will prevail to confirm (or not) the compliance.

The following hierarchy of tests results should also be considered:

- a) If compliant in screening but non-compliant in verification with simulant then non-compliant
- b) If compliant in verification with simulant but non-compliant in verification with food then non-compliant

Compliance in food prevails over compliance in food simulants, which prevails over screening methods.

Article 18.4 explains that migration can be measured by using food simulants. New simulants have been introduced in annex III. Please note that water is considered now as a food and not as a food simulant. However testing can be performed into water only for plastic materials intended to come into contact with water. Additional changes are highlighted here:

- Simulant A: 10% EtOH (was: distilled water)
- Simulant C: 20% EtOH (was: 10% EtOH)
- Simulant D2: all vegetable oils (see specifications in annex III table 1)
- Simulant E: Tenax for dry food (new)

Ref.	Food simulant	Food types
A	10% ethanol	Aqueous Food
B	3% acetic acid	Foods that have a hydrophilic character and are able to extract hydrophilic substances and which have a pH below 4.5
C	20% ethanol	Foods that have a hydrophilic character and are 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

\* Particle size 60-80 mesh, pore size 200 nm

#### 5.1.1. Fat Reduction Factors (FRF) for lipophilic substances

The lipophilic substances submitted to fat reduction factor are indicated in the column 7 of the union list. Fat Reduction Factors (FRF) applies for the specific migration of lipophilic substances into foods containing more than 20% of fat. (See chapter 4.1. of annex V):

- The FRF shall not lead to a specific migration exceeding the overall migration limits
- The FRF is not applicable to material or article intended to come into contact with foodstuffs for infants and young children according to the directives 2006/141/EC and 2006/125/EC
- The FRF is not applicable for material and articles for which it is not possible to estimate the relationship between surface area and the quantity of food in contact therewith.

#### 5.1.2. Correction factors of migration into food stimulant

Table 2 of annex III gives the food category specific assignment of food simulants. Please note that the correction factors for migration into food simulant D2 to calculate the migration into food have been reviewed (e.g. factor 3 instead of 5 for chocolate).

The correction is not applicable to the specific migration for substances in the Union list in Annex I for which the specific migration limit in column 8 is 'not detectable' and for non-listed substances used behind a plastic functional barrier covered by the rules of Article 13(2)(b) which should not migrate in detectable amounts.

## 5.2. New testing Conditions

The Regulation introduces separate sets of standardized testing conditions for OML and for SML, while in past the same conditions covered both. Additional information could be found in annex III and V.

There is still an acceptance of a hierarchy related to the **choice of simulants** and test conditions, but these might be different from the previous situation:

- a) An example for the demonstration of compliance with the OML for all food types: the tests need to be performed with either distilled water or simulant A (10% ethanol) and simulant B (3% acetic acid) and simulant D2 (vegetable oils). For more details please consult Annex III point 4
- b) An example for demonstration of compliance with SML for all food types: the tests need to be performed with simulant A, B, D2. For more details please consult the Annex V, chapter 2, section 2.1.2

### 5.2.1. OML testing:

The test conditions (contact times and temperatures) for overall migrations are set out in Annex V, chapter 3, table 3. Most of the testing conditions for OM are the same as previously mentioned in Directive 97/48/EEC, with the exception of the following situations:

- a) Introduction of OM1: 10 days at 20°C to cover any food contact at frozen and refrigerated conditions
- b) Introduction of substitute test for OM7 with food simulant D2: In case it is technically NOT feasible to perform OM7 with food simulant D2, the test can be replaced by test OM 8 or OM9.

Here also a hierarchy of the test conditions is described, like e.g.: Test OM 2 covers also food contact conditions described for OM1 and OM3.

Please read carefully the notes in the paragraph 3.1 of the chapter 3 of the annex V that give an explanation of the hierarchy of the Overall Migration testing conditions.

Additionally please note that the OML test results are now expressed in mg/dm<sup>2</sup> with the exception of infant food where the units remain mg/kg food or food simulant which is more stringent for small packs with higher surface to volume ratio.

### 5.2.2. SML testing

The test conditions (contact time and temperature) for the specific migrations are set out in Annex V chapters 1 and 2. Some examples of significant changes are highlighted here:

- a) Change of contact time up to 4h to up to 6h.
- b) Introduction of time from 1 day till 3 days, to be tested at 3 days.
- c) Specific rules are given for long term storage at room temperature. These changes reflect the changes in storage conditions in the market.
  - For storage times up to 6 months at room temperature, testing need to be done at 50°C for 10 days.
  - For storage times above 6 months at room temperature, the test conditions have been defined as 10 days at 60°C.

- Derogation from these conditions is possible if the former 10 days at 40°C can be used, provided that there is scientific evidence that migration of the respective substance in the polymer has reached equilibrium under this test condition.
- Additionally for contact times above 30 days at room temperature and below, there is the possibility to use an accelerated test at elevated temperature for a maximum of 10 days at 60 °C (i.e. simulating worst case conditions of 10 days at 60°C).

Testing time and temperature conditions shall be based on the following formula:

$$t_2 = t_1 * \text{Exp} ((-E_a/R) * (1/ (T_1-1/T_2)))$$

$E_a$  is the worst case activation energy 80kJ/mol

$R$  is a factor 8, 31 J/Kelvin/mol

$t_1$  is the contact time

$t_2$  is the testing time

$T_1$  is the contact temperature in Kelvin. For room temperature storage this is set at 298 K (25 °C). For refrigerated and frozen conditions it is set at 278 K (5 °C).

$T_2$  is the testing temperature in Kelvin.

- d) Following the principle that the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place, a change in temperature was introduced:
- For  $T > 175^\circ\text{C}$ , it is recommended to adjust the temperature to the real temperature at the interface with the food. Attention has to be given to the footnote, telling us that this temperature shall be used for food simulant D2 and E.
    - For simulant A, B, C and D1, the test may be replaced by a test at  $100^\circ\text{C}$  or at reflux temperature for duration of 4 times the time selected in table 1.
    - For applications heated under pressure, migration testing under pressure may be performed at the relevant temperature.
- e) Contrary to the applications done at room temperature or below with different contact times, there are no worst cases testing conditions presented for high temperature applications covering the contact with all types of food.
- f) Modelling: According to «whereas» 32, article 16 and section 2.2.3 of the chapter II of annex V, modelling could be used as screening test to check compliance.

As a result of discussion and decision of the Plastics Implementing Measure (PIM) Technical Meeting a contact time of 10 days maximum still can be applied until more realistic  $D_p$ s and  $K_{p,F}$  are determined, knowing that the model currently overestimate migration.

For more information on modelling consult:

[http://ihcp.jrc.ec.europa.eu/our\\_labs/eurl\\_food\\_c\\_m/resource-centre-legislative-docs](http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/resource-centre-legislative-docs)

### 5.2.3. Repeated use:

For repeated use articles the migration test(s) shall be carried out three times and its compliance shall be checked on the basis of the level of migration found in the third test, provided that the third result is lower than the previous ones. Annex V Chapter 2 point 2.1.6 has introduced a requirement that for substances for which the specific migration should be non-detectable and for non-listed substances behind a plastic functional barrier, the compliance should be checked based on the first migration test.

This document should not be used as a substitute for professional legal advice

## **6. Declaration of compliance and documentation (DoC) (Chapter IV):**

The DoC has to be understood as a method to pass on information for compliance of the final article along the manufacturing chain.

The content of the written DoC to be delivered to customers is depending on the position of the company in the supply chain. The Commission announced that this will be explained in more details in the chapter of the Guidance Document dealing with the DoC.

Note that this DoC needs to be renewed when significant changes in the production or composition occur and/or when new scientific data are available.

Supporting documentation are all in-house documents; It consists in the basic information for establishing the DoC which covers the food contact products, materials, articles. It includes composition information, manufacturing information, analytical information, testing results and so on.

Supporting documentation needs to be available **only** to enforcement authorities and there is no legal obligation to transmit this to the downstream users.

## **7. Transitional provision (Chapter VI):**

### **7.1. Provisions for testing:**

From the 1<sup>st</sup> of May 2011 until 31<sup>st</sup> of December 2012: the old testing regime applies. However the new testing regimes can be used by industry if convenient.

From 1<sup>st</sup> of January 2013 until 31<sup>st</sup> of December 2015: the supporting document can be based on one of the two testing regimes, old and new ones.

After 1<sup>st</sup> of January 2016: Only new testing regime is applicable.

Therefore industry should need to adapt to the new regime and become familiar with the above mentioned deadlines.

### **7.2. Other provisions:**

Materials and articles lawfully placed on the market before 1st of May 2011 may continue to be placed on the market until 31<sup>st</sup> December 2012. Additionally this means that the declaration of compliance documents referring to Directive 2002/72/EC and amendments for those materials and articles are still valid until 31<sup>st</sup> December 2012, provided that there have been no changes.

The list of additives used in plastics and coatings forming gaskets in lids and additives in film formers for glass fibre reinforced plastics becomes a positive list from 1<sup>st</sup> of January 2016.

## **8. Bibliography:**

- 1: « Les matériaux en plastique au contact des aliments : nouveau règlement communautaire (1<sup>er</sup> partie), A. SOROSTE, Option Qualité, mars 2011, n° 302, p. 21-25.
- 2: « Les matériaux en plastique au contact des aliments : nouveau règlement communautaire (2<sup>ème</sup> partie), A. SOROSTE, Option Qualité, avril 2011, n° 303, p. 17-23.
3. Presentation of Annette Schaefer on PIM at PIRA, Cefic-FCA conferences and PlasticsEurope meetings

This document should not be used as a substitute for professional legal advice