



# EU-Asia Cooperation on (Phyto-) Sanitary and Food Safety Regulation

## Commission Regulation (EU) No 10/2011 on plastic food contact materials and articles

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Regional seminar on FCM, Bangkok (Thailand),  
26-27 June 2023



Contracting Authority  
**Regional Team FPI**

Contract Number  
**PI/2019/409-971**

Contractor





# Overview

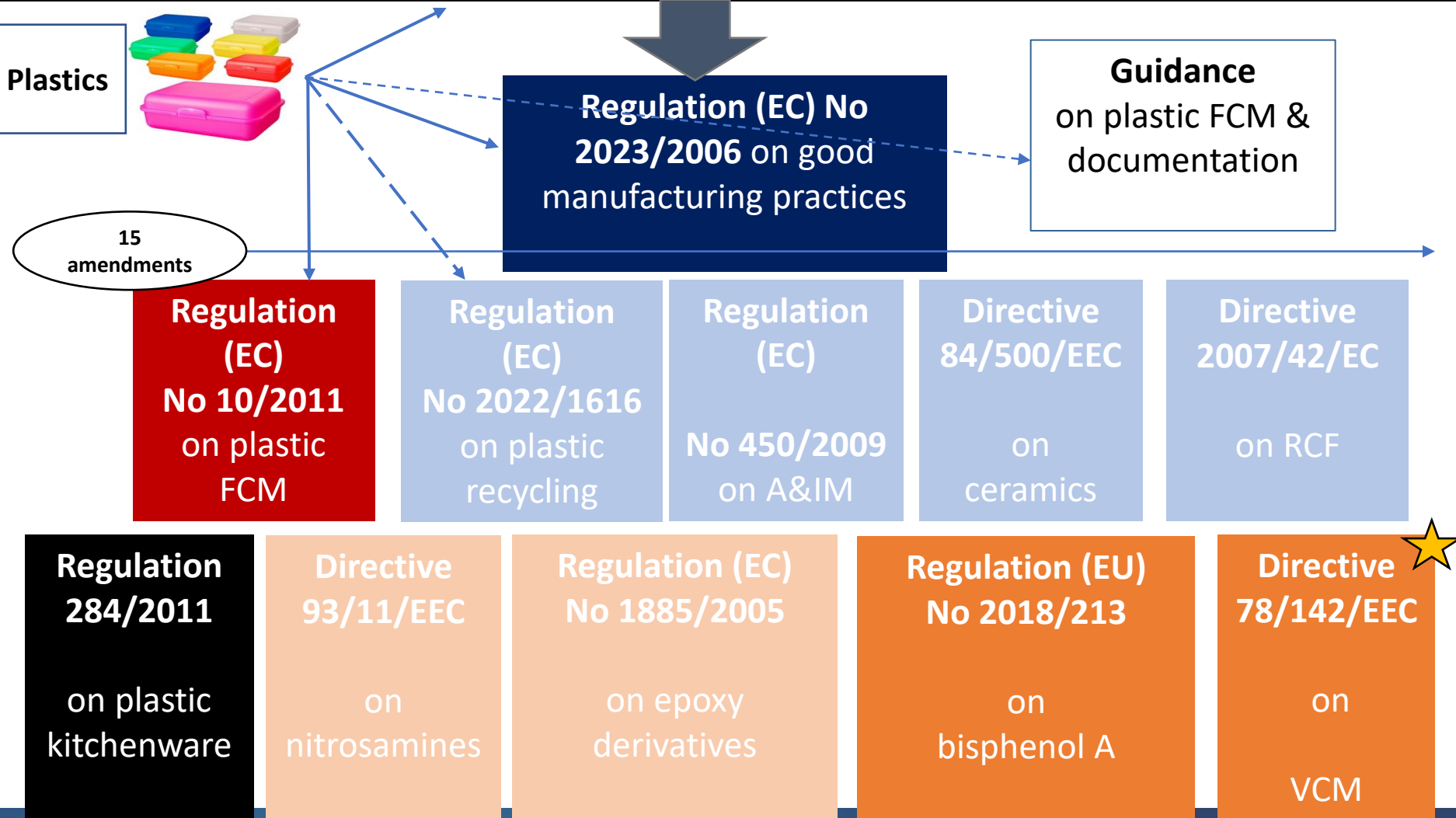
- **Introduction specific measures for plastics**
- **Structure and scope of the EU Plastic Regulation**
- **Compliance requirements and testing**
- **Conclusions**





# Regulation EP and Council (EC) No 1935/2004 (objectives: human health and functioning of EU market)

Basic rules on safety, labelling, traceability, inspection and control, authorisation process





## Key Points

### Regulation (EU) 10/2011 :

**Specific measures for plastics**, more detailed than other FCMs  
(with 15 amendments)

#### Positive list of:

- Monomers & starting substances
- Additives

Requirements include restrictions on uses & migration of substances

Specifies how testing should be carried out

Specific format for 'Declaration of compliance'





## EU legislation

(Directives and Regulations)  
**can be revised and updated by amendments**  
 and they follow the same numbering system as Directives or Regulations.

When reference is made to a Directive or Regulation, the last amendment is always included.

**The consolidated versions are very useful** → **they are usually made available on the Commission website EURLEX**

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► **B** COMMISSION REGULATION (EU) No 10/2011  
 of 14 January 2011  
 on plastic materials and articles intended to come into contact with food  
 (Text with EEA relevance)  
 (OJ L 12, 15.1.2011, p. 1)

Amended by:

		Official Journal		
		No	page	date
► <b>M1</b>	Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011	L 87	1	2.4.2011
► <b>M2</b>	Commission Regulation (EU) No 1282/2011 of 28 November 2011	L 328	22	10.12.2011
► <b>M3</b>	Commission Regulation (EU) No 1183/2012 of 30 November 2012	L 338	11	12.12.2012
► <b>M4</b>	Commission Regulation (EU) No 202/2014 of 3 March 2014	L 62	13	4.3.2014
► <b>M5</b>	Commission Regulation (EU) No 865/2014 of 8 August 2014	L 238	1	9.8.2014
► <b>M6</b>	Commission Regulation (EU) 2015/174 of 5 February 2015	L 30	2	6.2.2015
► <b>M7</b>	Commission Regulation (EU) 2016/1416 of 24 August 2016	L 230	22	25.8.2016
► <b>M8</b>	Commission Regulation (EU) 2017/752 of 28 April 2017	L 113	18	29.4.2017
► <b>M9</b>	Commission Regulation (EU) 2018/79 of 18 January 2018	L 14	31	19.1.2018
► <b>M10</b>	Commission Regulation (EU) 2018/213 of 12 February 2018	L 41	6	14.2.2018
► <b>M11</b>	Commission Regulation (EU) 2018/831 of 5 June 2018	L 140	35	6.6.2018
► <b>M12</b>	Commission Regulation (EU) 2019/37 of 10 January 2019	L 9	88	11.1.2019
► <b>M13</b>	Commission Regulation (EU) 2019/988 of 17 June 2019	L 160	10	18.6.2019
► <b>M14</b>	Commission Regulation (EU) 2019/1338 of 8 August 2019	L 209	5	9.8.2019
► <b>M15</b>	Commission Regulation (EU) 2020/1245 of 2 September 2020	L 288	1	3.9.2020

Corrected by:

► **C1** Corrigendum, OJ L 349, 19.12.2012, p. 77 (1183/2012)

Indication of the changes introduced



## Countinous amendments (1)

- ***M1 Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 [L 87, 1, 2.4.2011]***
- ***M2 Commission Regulation (EU) No 1282/2011 of 28 November 2011 [L 328, 22, 10.12.2011]***
- ***M3 Commission Regulation (EU) No 1183/2012 of 30 November 2012 [L 338, 11,12.12.2012]***
- ***M4 Commission Regulation (EU) No 202/2014 of 3 March 2014 [L 62, 13, 4.3.2014]***
- ***M5 Commission Regulation (EU) No 865/2014 of 8 August 2014 [L 238, 1, 9.8.2014]***
- ***M6 Commission Regulation (EU) 2015/174 of 5 February 2015 [L 30, 2, 6.2.2015]***
- ***M7 Commission Regulation (EU) 2016/1416 of 24 August 2016 [L 230, 22, 25.8.2016]***
- ***M8 Commission Regulation (EU) 2017/752 of 28 April 2017 [L 113, 18, 29.4.2017]***



## Countinous amendments (1)

- ***M9 Commission Regulation (EU) 2018/79 of 18 January 2018 [L 14, 31, 19.1.2018]***
- ***M10 Commission Regulation (EU) 2018/213 of 12 February 2018 [L 41, 6, 14.2.2018]***
- ***M11 Commission Regulation (EU) 2018/831 of 5 June 2018 [L 140, 35, 6.6.2018]***
- ***M12: Commission Regulation (EU) 2019/37 of 10 January 2019 [L 9, 88, 11.1.2019]***
- ***M13: Commission Regulation (EU) 2019/988 of 17 June 2019 [L 160, 10, 18.6.2019]***
- ***M14: Commission Regulation (EU) 2019/1338 of 8 August 2019 [L 209, 5, 9.8.2019]***
- ***M15: Commission Regulation (EU) 2020/1245 of 2 September 2020 [L 288, 3.9.2020]***

**More to follow... (16<sup>th</sup> will be issued soon,... 17<sup>th</sup>, 18<sup>th</sup>...)**



## Structure of Regulation 10/2011 (1)

Chapter	Section	Article	Related Annex
<b>I – GENERAL PROVISIONS</b>		<b>1. Subject matter</b> <b>2. Scope</b> <b>3. Definitions</b> <b>4. Placing on the market of plastic materials and articles</b>	
<b>II – COMPOSITIONAL REQUIREMENTS</b>	<b>1. Authorised substances</b>	<b>5. Union list of authorised substances</b> <b>6. Derogations for substances not included in the Union list</b> <b>7. Establishment and management of the provisional list</b>	<b>Annex I</b>
	<b>2. General requirements, restrictions and specifications</b>	<b>8. General requirement on substances</b> <b>9. Specific requirements on substances</b> <b>10. General restrictions on plastic materials and articles</b> <b>11. Specific migration limits</b> <b>12. Overall migration limit</b>	<b>Annex II</b>





## Structure of Regulation 10/2011 (2)

Chapter	Section	Article	Related Annex
<b>III – SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES</b>		<b>13. Plastic multi-layer materials and articles</b> <b>14. Multi-material multi-layer materials and articles</b>	
<b>IV – DECLARATION OF COMPLIANCE AND DOCUMENTATION</b>		<b>15. Declaration of compliance</b> <b>16. Supporting documents</b>	<b>Annex IV</b>
<b>V – COMPLIANCE</b>		<b>17. Expression of migration test results</b> <b>18. Rules for assessing compliance with migration limits</b> <b>19. Assessment of substances not included in the Union list</b>	<b>Annex III, V</b>
<b>VI – FINAL PROVISIONS</b>		<b>20. Amendments of EU acts</b> <b>21. Repeal of EU acts</b> <b>22. Transitional provisions</b> <b>23. Entry into force and application</b>	<b>Annex VI</b>



# Scope of Regulation 10/2011 – what's in? (Article 2)

- Materials and articles consisting exclusively of plastics
- Plastic multi-layer materials and articles (joined using adhesives or other means)
- Plastic layers in multi-material multi-layer materials and articles
- Plastic layers or coatings forming gaskets in caps / closures
- Printed or coated plastic materials and articles



# And what's not?

## **Regulation 10/2011 does not apply to:**

- Adhesives, coatings and printing inks
- Ion exchange resins, rubbers and silicones
- Colours and solvents used in plastics production

(although they do need to comply with requirements of Article 3 of Framework Regulation 1935/2004)



# Use of Substances

**Only listed starting substances and additives can be used to manufacture a plastic material**

- Subject to restrictions

## **Typical restrictions:**

- limitation to a certain kind of plastic or food
- Specific Migration Limit (SML)
- QM, maximum quantity in the material

## **Derogations in Article 6**

- polymer production aids, solvents, salts, some polymeric additives, aids to polymerisation
- not intentionally added substances
- Subject to rules on verification of compliance
  - Overall Migration Limit does not directly ensure safety  
(It indicates inertness of plastic)



## **Union List of Authorised Substances (Article 5 + Annex I)**

- **One single positive list including:**
  - *Monomers and other starting materials*
  - *Additives (excluding colours)*
  - *Some 'polymer production aids' (excluding solvents)*
  
- **Only use those substances on the list (over 900)**
  
- *Specific Migration Limits (SMLs) in mg/kg food, restrictions of use, and specifications set out in Annex I*
  
- *Article 12 sets on Overall Migration Limit (OML) of 10 mg/dm<sup>2</sup> (as inertness)*



# Union List of Authorised Substances (Article 5 + Annex I)

▼B

Table 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
1	12310	0266309-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C <sub>4</sub> -C <sub>22</sub> )	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C <sub>5</sub> -C <sub>13</sub> )acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C <sub>7</sub> -C <sub>17</sub> ), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		



## Examples of restrictions

FCM No*	Substance	Restriction*
76	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	Only for use in PET
381	Cyclooctene	Only to be used in polymers contacting foods for which simulant A is laid down [ <i>in Annex III</i> ]
728	phthalic acid, diesters with primary, saturated C <sub>8</sub> -C <sub>10</sub> branched alcohols, more than 60 % C <sub>9</sub>  [ <i>alias: Di-Iso-Nonyl Phthalate</i> ]	Only to be used as:  (a) <b>plasticiser</b> in repeated use materials and articles;  (b) <b>plasticiser</b> in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae ... or processed cereal-based foods and baby foods for infants and young children ...;  (c) <b>technical support agent</b> in concentrations up to 0,1 % in the final product.

\*FCM substance No - in the Plastics Regulation (EU) No. 10/2011, Annex I



## Examples of restrictions for nanoparticles

Nr*	Substance	Restriction*
807	titanium nitride, <b>nanoparticles</b>	No migration of titanium nitride nanoparticles. Only to be used in polyethylene terephthalate (PET) up to 20 mg/ kg. In the PET, the agglomerates have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm.
859	(butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in <b>nanofom</b>	Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. ... The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm.
1050	zinc oxide, <b>nanoparticles</b> , uncoated	Only to be used in unplasticised polymers.

\*In the Plastics Regulation (EU) No. 10/2011, Annex I





## **General Requirements: Article 8**

- *Substances must be of suitable technical quality and purity*
- *Composition known to manufacturer of the substance*
- *Information on composition available to competent authority on request*

## **General Restrictions: Article 10, Annex II**

- **Maximum levels set for migration of certain metals** from all plastic materials and articles, including heavy metals (likely impurities) and lanthanides
- **Primary aromatic amines ("PAAs"):**
  - **listed in REACH regulation**<sup>\*</sup>, no migration limit in Reg (EU) No 10/2011 Table 1 of Annex I - shall not be detectable using analytical equipment **with a new LOD of 2 ppm** applied to each individual PAA
  - **not listed in REACH regulation**<sup>\*</sup>, no specific migration limit specified in Reg (EU) No 10/2011 Annex I. **The sum of those PAAs shall not exceed 10 ppb.**
- <sup>\*</sup>in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006



## Annex II: Restrictions on plastic materials and articles

Name	Salts allowed in accordance with Article 6(3)(a)	SML [mg/kg food or food simulant]	Name	Salts allowed in accordance with Article 6(3)(a)	SML [mg/kg food or food simulant]
Aluminium	yes	1	Iron	yes	48
Ammonium	yes	-	Lanthanum	yes	0,05
Antimony	no	0,04	Lead	no	ND
Arsenic	no	ND	Lithium	yes	0,6
Barium	yes	1	Magnesium	yes	-
Cadmium	no	ND (LOD 0,002)	Manganese	yes	0,6
Calcium	yes	-	Mercury	no	ND
Chromium	no	ND	Nickel	no	0,02
Cobalt	yes	0,05	Potassium	yes	-
Copper	yes	5	Sodium	yes	-
Europium	yes	0,05	Terbium	yes	0,05
Gadolinium	yes	0,05	Zinc	yes	5



## Rules on verification of compliance

- Regulation „only“ includes
  - starting substances + additives → authorisations
  - general requirements + rules for verification of compliance
- Article 19 – assessment of non-listed substances
  - derogations under Article 6 + 14 (NLS + MMMLs)
  - not intentionally added substances (‘NIAS’)
  - impurities, reaction + decomposition products, includes oligomers

### **FINAL Material must be safe!**

- intended and foreseeable use (Article 4(a))

### **Business operators needs to know**

- which substances migrate
- in what amount
- whether that is acceptable
- According to internationally recognised principles

**Risk  
assessment**



## Verification of compliance :

### **IAS + NLS + NIAS**

The „plastics“ REG (EU) No 10/2011 requires the evaluation of the presence and amount (quantity of substances in material or level of migration into food simulant or into food) falling into categories:

**IAS - intentionally added substances:** SMLs +restrictions

**NLS - non-listed substances:** aids to polymerisation, solvents, colorants, etc.

**NIAS - non-intentionally added substances:** as impurities, reaction or decomposition products, by products

Article 19 – assessment of non-listed substances (NLS + NIAS)



## **General rules for testing compliance of migration from plastic food contact materials and articles are specified in the Annex V of the Regulation EU No. 10/2011**

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/recommended by EFSA on the basis of toxicity data of each specific substance.



## Rules on verification of compliance

### **Overall migration limit (OML):**

10 mg/dm<sup>2</sup>

maximum permitted amount of non-volatile substances released from a material or article into food simulants

(60 mg/kg FCMs for infants and young children)

### **Specific migration limit (SML):**

maximum permitted amount of a substance released from a material or article into food or food simulants

Unit: mg/kg



# What methods are needed for testing of compliance

- 1. Methods for to confirm the identity of the polymers (e.g. FTIR)**
- 2. Methods for the analysis of the substance or migrant:**
  - a. The determination of the residual concentration of the migrant in a material or article
  - b. The determination of the migrant concentration in a food or a food simulant after a migration experiment
  - c. The determination of the migrant concentration in a packaged food that has been sampled on the market.
- 3. Methods for sensory analysis on organoleptic evaluation of the samples (basic requirements according to article 3 Framework regulation No 1935/2004)**



## New rules for Compliance of repeated use of FCM articles

**Section 2.1.6. of Annex V** of Regulation (EU) No 10/2011 on plastic food contact materials (in 15th amendment - REG (EU) 1245/2019):

“If the material or article is intended to come into repeated contact with foods, the migration test(s) **shall be carried out three times on a single sample** using another portion of food simulant on each occasion.

The specific **migration** in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

$$SM1 \geq SM2 \geq SM3 \text{ (similar for OM)}$$

Compliance of the material or article shall than be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test.

**In case of insufficient stability, compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.**





## Food simulants (Annex III)

Food simulant	food
<b>Food simulant A</b>	foods that have a hydrophilic character and are able to extract hydrophilic substances pH >4.5 (aqueous food) - <b>ethanol 10% (v/v)</b> or distilled water
<b>Food simulant B</b>	foods that have a hydrophilic character and are able to extract hydrophilic substances; pH < 4.5 (acidic food) – <b>acetic acid 3% (w/v)</b>
<b>Food simulant C</b>	alcoholic foods with an alcohol content of up to 20 % - <b>ethanol 20% (v/v)</b> those foods which contain a relevant amount of organic ingredients that render the food more lipophilic
<b>Food simulant D1</b>	foods that have a lipophilic character and are able to extract lipophilic substances. Alcoholic foods with an alcohol content of above 20 % and oil in water emulsions (milk products) – <b>ethanol 50% (v/v)</b>
<b>Food simulant D2</b>	foods that have a lipophilic character and are able to extract lipophilic substances. Foods which contain free fats at the surface (fatty food) – <b>any vegetable oil</b>
<b>Food simulant E</b>	testing specific migration into dry foods - <b>poly(2,6-diphenyl-p-phenylene oxide)</b> , known as TENAX



## Annex III, Table 2 - food category specific assignment of food simulants

02011R0010 — EN — 23.09.2020 — 015.001 — 121

▼ B

(1) Reference number	(2) Description of food	(3) Food simulants					
		A	B	C	D1	D2	E
		03.02	Confectionery products: A. In solid form: I. With fatty substances on the surface II. Other B. In paste form: I. With fatty substances on the surface II. Moist				
03.03	Sugar and sugar products A. In solid form: crystal or powder B. Molasses, sugar syrups, honey and the like	X				X/2	X
04	<b>Fruit, vegetables and products thereof</b>						
04.01	Fruit, fresh or chilled: A. unpeeled and uncut B. peeled and/or cut	X	X (*)				X/10

▼ M7



# Migration test conditions - time

## Selection of test time

Contact time in worst foreseeable use	► <u>M7</u> Time to be selected for testing ◀
$t \leq 5 \text{ min}$	5 min
$5 \text{ min} < t \leq 0,5 \text{ hour}$	0,5 hour
$0,5 \text{ hours} < t \leq 1 \text{ hour}$	1 hour
$1 \text{ hour} < t \leq 2 \text{ hours}$	2 hours
$2 \text{ hours} < t \leq 6 \text{ hours}$	6 hours
$6 \text{ hours} < t \leq 24 \text{ hours}$	24 hours
$1 \text{ day} < t \leq 3 \text{ days}$	3 days
$3 \text{ days} < t \leq 30 \text{ days}$	10 days
Above 30 days	See specific conditions

worst case scenario



# Migration test conditions - temperature

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5 \text{ }^{\circ}\text{C}$	5 $^{\circ}\text{C}$
$5 \text{ }^{\circ}\text{C} < T \leq 20 \text{ }^{\circ}\text{C}$	20 $^{\circ}\text{C}$
$20 \text{ }^{\circ}\text{C} < T \leq 40 \text{ }^{\circ}\text{C}$	40 $^{\circ}\text{C}$
$40 \text{ }^{\circ}\text{C} < T \leq 70 \text{ }^{\circ}\text{C}$	70 $^{\circ}\text{C}$
$70 \text{ }^{\circ}\text{C} < T \leq 100 \text{ }^{\circ}\text{C}$	100 $^{\circ}\text{C}$ or reflux temperature
$100 \text{ }^{\circ}\text{C} < T \leq 121 \text{ }^{\circ}\text{C}$	121 $^{\circ}\text{C}$ (*)
$121 \text{ }^{\circ}\text{C} < T \leq 130 \text{ }^{\circ}\text{C}$	130 $^{\circ}\text{C}$ (*)
$130 \text{ }^{\circ}\text{C} < T \leq 150 \text{ }^{\circ}\text{C}$	150 $^{\circ}\text{C}$ (*)
$150 \text{ }^{\circ}\text{C} < T < 175 \text{ }^{\circ}\text{C}$	175 $^{\circ}\text{C}$ (*)
$175 \text{ }^{\circ}\text{C} < T \leq 200 \text{ }^{\circ}\text{C}$	200 $^{\circ}\text{C}$ (*)
$T > 200 \text{ }^{\circ}\text{C}$	225 $^{\circ}\text{C}$ (*)

**worst case scenario**



**Cca 900 substances – only for cca 300 are commercial standard and methods available**



**Concept of generic SML (60 mg/kg)**



**For substances without SML  
Risk assessment according  
art. 19 regulation 10/2011**



# Technical Guidelines of EURL FCM

JRC Scientific and Technical Reports



## Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware

1<sup>st</sup> edition 2011

[in support of Commission Regulation 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China]



C. Simoneau (EURL), E. Hoekstra (EURL), E. Bradley (NRL-UK), J. Bustos (NRL-ES), V. Golje (NRL-SI), O. Kappenstein (NRL-DE), D. Kalsbeek (NRL-NL), J. Keegan (NRL-IE), M.R. Milana (NRL-IT), K. Cwiak-Ludwicka (NRL-PL), J. Petersen (NRL-DK), M. Polz (NRL-AT), P. Sauvagnin (NRL-FR), F. Vanhee (DG-SANCO)

C. Simoneau, ed.



EUR 24815 EN 2011

JRC Scientific and Technical Reports



## Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials

Stefanka Bratinova, Barbara Raffael, Catherine Simoneau



EUR 24105 EN - 1<sup>st</sup> edition 2009



## Declaration of compliance for plastics: Annex IV

1. Name & address of the business operator issuing declaration
2. **Name and address** of EU manufacturer or importer of food contact material, or FCM substances
3. **Identity** of the plastic material or substances
4. **Date** of declaration
5. Confirm that FCM **complies with** Reg 10/2011 & **Reg 1935/2004** (Articles 3, 11(5), 15, 17)
6. Information on any substances used or products of degradation thereof for which there are **restrictions under Reg 10/2011** to allow users to comply. At intermediate stages, this information shall include the identification and amount of substances in the intermediate material (subject to restrictions in Annex II, or for which genotoxicity has not been ruled out,.. and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant)
7. Information on any substances used for which there are restrictions under **food law**, to allow users to comply
8. **Specifications** for safe use (foods, time/temp, S/V)
9. For plastic multi-layer materials using '**functional barrier**' layers, *confirmation that finished FCM complies with relevant parts of Reg 10/2011*



## Guidances on plastic materials:

- EU Guidance on Regulation (EU) No 10/2011 – in support of the implementation of the general requirements of Commission Regulation (EU) 10/2011 on plastic food contact materials and articles
- EU Guidance on information in the plastic supply chain – in support of the implementation of Commission Regulation (EU) 10/2011 on plastic food contact materials as regards the declaration of compliance





EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain  
Innovation and sustainability

Brussels, 21.02.2014

## **Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food**

### **Version History**

<b>Version</b>	<b>Date</b>	<b>Change</b>
1.0	28.11.2013	original version
1.1*	12.01.2016	information update on this title page

\* Translated versions have not been updated



**EUROPEAN COMMISSION**  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain  
Innovation and sustainability

Brussels, 28.11.2013

# **Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain**

## **Version History**

<b>Version</b>	<b>Date</b>	<b>Change</b>
1.0	28.11.2013	original version
1.1*	12.01.2016	information update on this title page



## ***Guidelines on information in the supply chain***

- **Information to be generated and exchanged in the supply chain within scope of Regulation 10/2011**
- **Specifically addresses:**
  - Aim of the DoC
  - Roles and obligations in the supply chain
    - Role of business operator and obligations of different operator roles
  - Principles for sharing compliance work throughout the supply chain
  - Content of the DoC and what constitutes “adequate information”
    - Substances for manufacture of plastics
    - Substances for the manufacture of non-plastic intermediates: adhesives, coatings or printing inks
    - Intermediate and final materials



# Addition of new substances to the Union list – procedure laid down in Framework Regulation ( in Articles 8 to 12)



Guidance |  Open Access |   

## Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel ... [See all authors](#) 

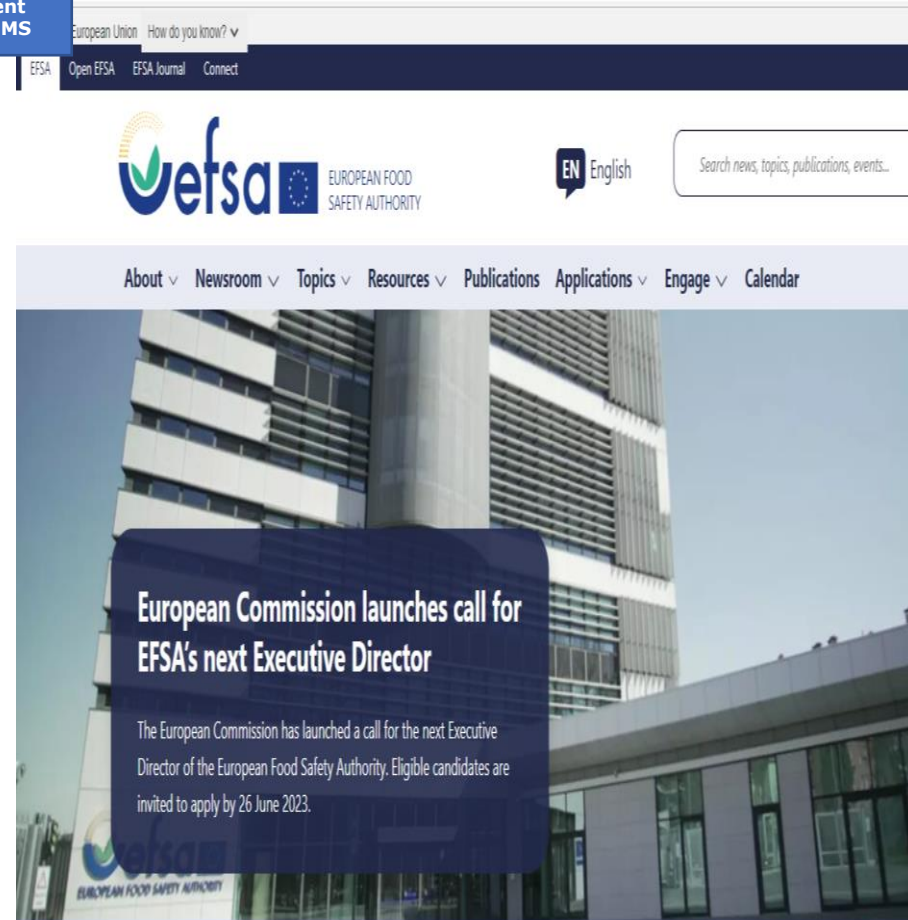
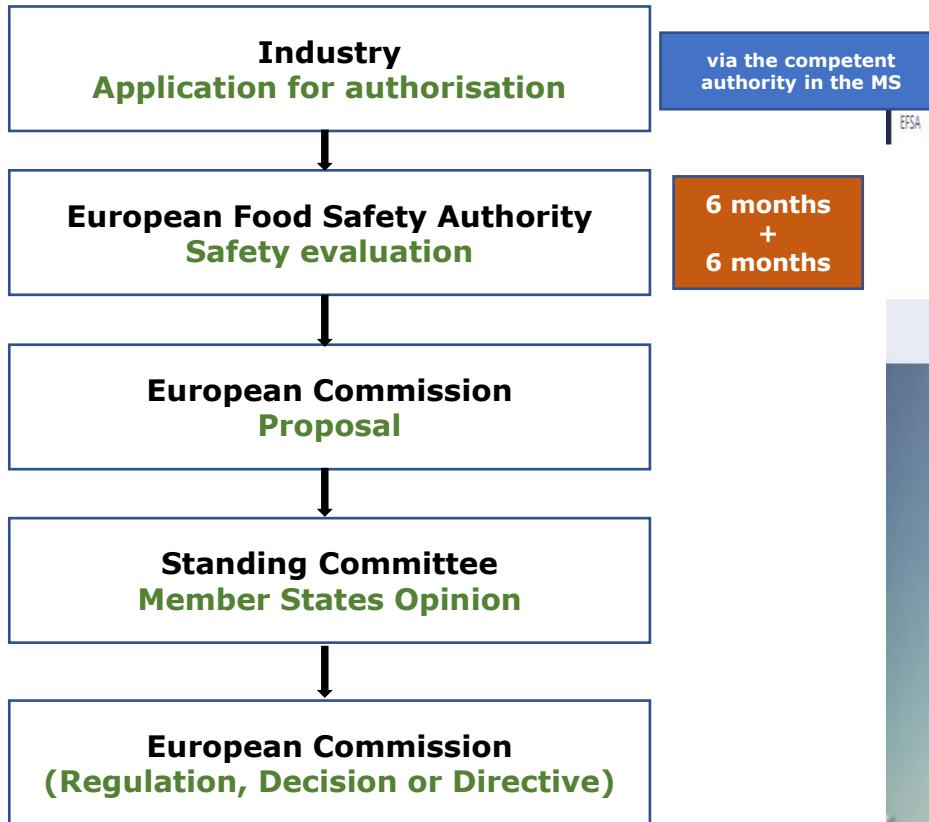
First published: 31 July 2008 | <https://doi.org/10.2903/j.efsa.2008.21r> | Citations: 11

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**Question number:** EFSA-Q-2006-00327

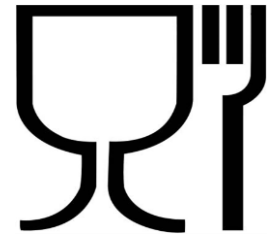
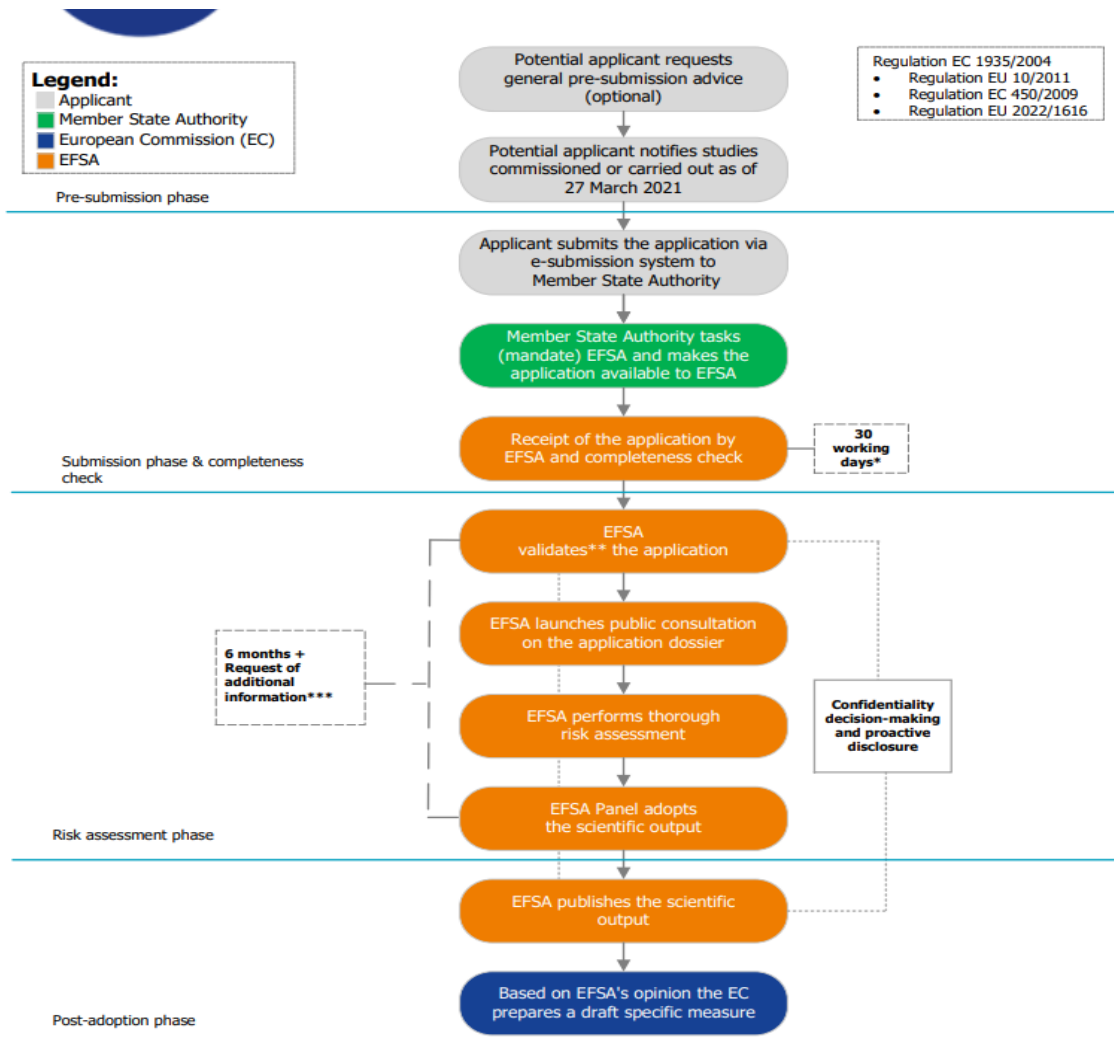


## Authorisation procedure for the inclusion of a substance or recycling process in Union list or Register





[apdeskapplworkflowcm.pdf \(europa.eu\)](http://apdeskapplworkflowcm.pdf)



\* EFSA aims at providing its 1st feedback on Completeness check within 30 working days after receipt of the application. In case certain parts of the application need modification or completion in order to be considered valid, EFSA requests the missing information to the applicant.

\*\* In certain cases, the application might be declared as non-valid (see EFSA administrative guidance for further information).

\*\*\* In case of a request of additional information, the scientific risk assessment process is put on hold until the requested additional information





## Problems/difficulties and challenges in carrying out FCM official controls in EU (MSs)

This information is **often missing in the declaration of conformity and SD is not adequate** :

- Information on substances with restrictions (SML, SML (T),...)**
- If the list of used substances with restrictions (SML) in the DoC exists,**
  - in the documentation, only compliance verification is based on overall migration, specific migration tests are missing or incomplete
- in general, the scale of specific migrations is very narrow
- Information on dual-use additives** - very important for the food industry, especially organic production – very often missing
- No information about NIAS** (degradation or reaction products or impurities)
- the amount and quality of information passed down the supply chain decreases (from the polymer manufacturer to the intermediate manufacturer to the final product trader or distributor)



# Thank you for your attention!



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**For more information on the project activities:**



<https://eu-asia-sps.com/>  
[www.aets-consultants.com](http://www.aets-consultants.com)