



Legislation applicable to Food Contact Materials

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PRESERVE



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Contents

- Legislation applicable to Food Contact Materials
 - General requirements
 - Specific measures for plastics
 - Specific measures for coatings
- Conclusions



Materials and articles intended for Food contact, FCM

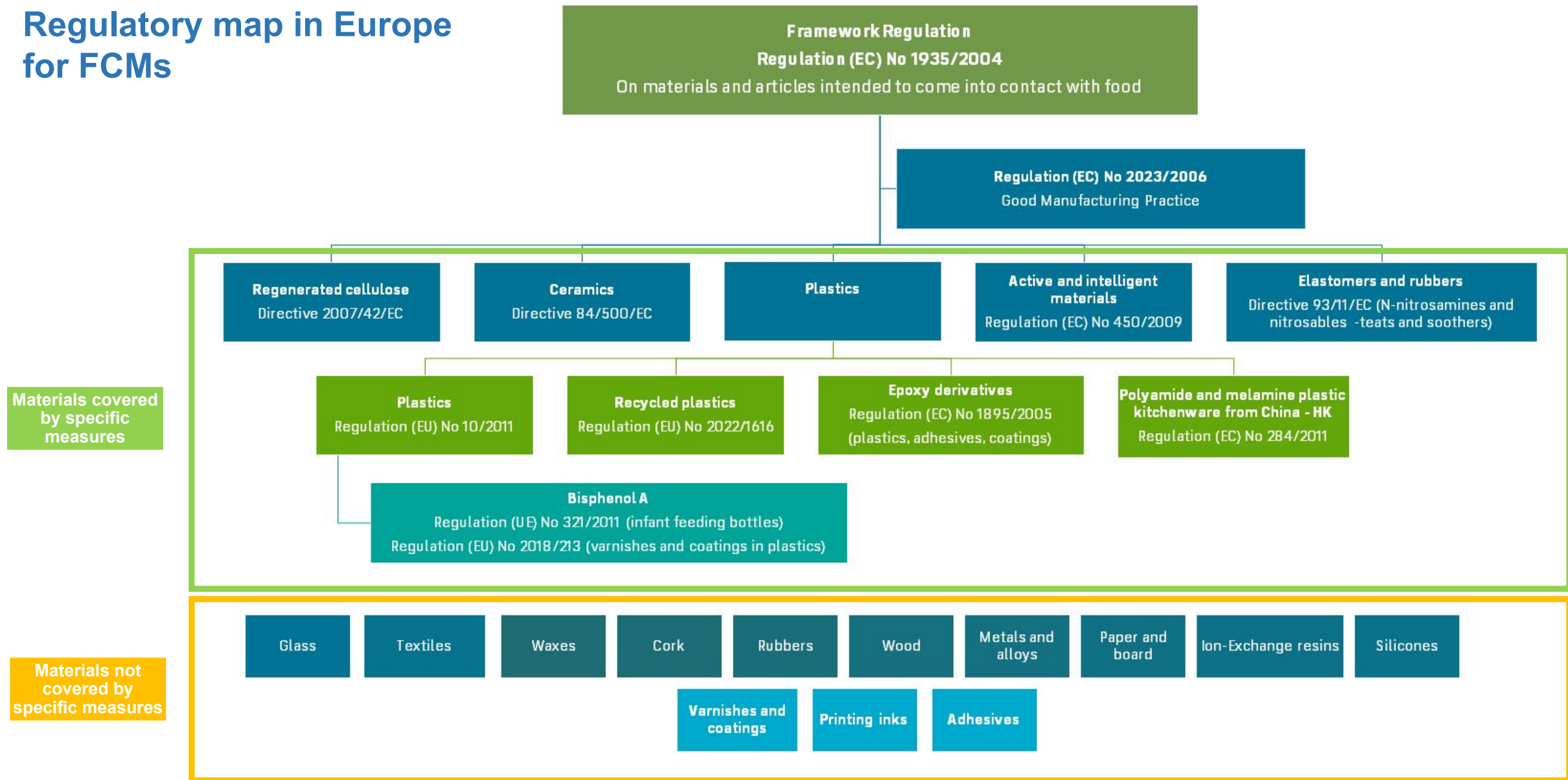
Materials which may reasonably be expected to come into direct or indirect contact with foodstuffs



FCM LEGISLATION

It aims to protect the health of consumers and the quality of food by establishing food contact suitability criteria with which FCMs must comply

Regulatory map in Europe for FCMs



Materials covered by specific measures

Materials not covered by specific measures



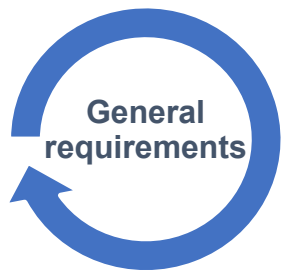
Framework Regulation (EC) No 1935/2004

Shall apply to materials which in their finished state:

- Are **intended to be into contact with food**
- Are **already in contact with food**
- Can **reasonably be expected to come into contact with food** or to **transfer** their constituents to food under normal or foreseeable conditions of use

Objective

- Ensure the effective functioning of the internal market of the FCMs in the EU
- A high level of protection of human health and the interests of consumers



- Food safety
- Labelling
- Traceability
- Declaration of compliance

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 and repealing Directives 80/590/EEC and 89/109/EEC

(OJ L 338, 13.11.2004, p. 4)



Framework Regulation (EC) No 1935/2004

Materials and articles shall be manufactured in compliance with Good Manufacturing Practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- Endanger human health
- Bring about an unacceptable change in the composition of the Food, or
- Bring about a deterioration in the organoleptic characteristics thereof



**FOOD SAFETY
PRINCIPLE**

Labelling, advertising and presentation of a material shall not mislead the consumers



- Food safety
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Good Manufacturing Practice Regulation (EC) No 2023/2006

Objective

Ensure that materials and articles are produced and controlled so that they are in conformity with:

- RULES applicable to them and
- QUALITY STANDARDS appropriate to their intended use by not:



- Endangering human health or
- Causing unacceptable changes in the composition of the food or
- Causing unacceptable changes in the organoleptic characteristics thereof.

►B

COMMISSION REGULATION (EC) No 2023/2006

of 22 December 2006

on good manufacturing practice for materials and articles intended to come into contact with food

(Text with EEA relevance)

(OJ L 384, 29.12.2006, p. 75)



Good Manufacturing Practice Regulation (EC) No 2023/2006

Scope

Shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances

General rules

- Implementation of a quality assurance system (QAS)
- Implementation of a quality control system
- Maintenance of the associated documentation

Detailed rules

- Shall apply to individually processes (Annex)
 - Printing inks
 - Recycled plastics

Sectorial industrial guidelines and standards aimed to the implementation of the GMP are available



FPE Flexible Packaging Europe



BRC GLOBAL STANDARD FOR PACKAGING & PACKAGING MATERIALS



International Confederation of Paper and Board Converters in Europe

►B

COMMISSION REGULATION (EC) No 2023/2006
of 22 December 2006

on good manufacturing practice for materials and articles intended to come into contact with food

(Text with EEA relevance)

(OJ L 384, 29.12.2006, p. 75)



Specific measures: Regulation (EU) No. 10/2011

Shall apply to:

- a) Materials and articles and parts consisting of **plastics**;
- b) **Plastic multilayer** materials and articles held together by adhesives or by other means;
- c) a) o b) printed and/or covered by a coating;
- d) Plastics layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
- e) Plastic layers in multi-material multi-layer materials and articles

APPLIES TO

Bioplastics based on:

- Synthetic polymers
- Natural polymers that have been chemically modified (e.g. modified starch)
- Polymers manufactured by microbial fermentation (e.g. polyhydroxialcanoate (PHA), polyhydroxybutyrate (PHB))

DOES NOT APPLY TO

Bioplastics based on:

- Natural polymers that not have been chemically modified (e.g. starch)

Plastic

- **POLYMER** to which additives or other substances may have been added
- Capable of functioning as a main structural component of final materials and articles

Polymer

Macromolecular substance obtained by:

- A polymerisation process such as polyaddition or polycondensation or by any other similar process of monomers and other starting substances; or
- Chemical modification of natural or synthetic macromolecules; or
- Microbial fermentation.

Regulation (EU) No 10/2011

Requirements from horizontal Regulations:

- Relevant requirements set out in Article 3 of Regulation (CE) No 1935/2004
- Labelling requirements (Article 15 of Regulation (EC) No 1935/2004)
- Traceability requirements (Article 17 of Regulation (EC) No 1935/2004)
- Manufacturing according to Good Manufacturing Practice (Regulation (EC) No 2023/2006)

Food safety principle

Requirements of the Plastics Regulation:

- Compositional requirements
- Declaration requirements

- Verification on the composition
- Verification on the restrictions and specifications
- Declaration of compliance and supporting documents

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

Amended by:

		No	page	date
► MI	Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011	L 87	1	24.4.2011
► MI	Commission Regulation (EU) No 1282/2011 of 28 November 2011	L 328	22	10.12.2011
► MI	Commission Regulation (EU) No 1183/2012 of 30 November 2012	L 338	11	12.12.2012
► MI	Commission Regulation (EU) No 202/2014 of 8 March 2014	L 62	13	4.3.2014
► MI	Commission Regulation (EU) No 865/2014 of 8 August 2014	L 238	1	9.8.2014
► MI	Commission Regulation (EU) 2015/174 of 5 February 2015	L 59	2	6.2.2015
► MI	Commission Regulation (EU) 2016/1416 of 24 August 2016	L 230	22	25.8.2016
► MI	Commission Regulation (EU) 2017/752 of 28 April 2017	L 113	18	30.4.2017
► MI	Commission Regulation (EU) 2018/79 of 18 January 2018	L 14	31	19.1.2018
► MI	Commission Regulation (EU) 2018/213 of 12 February 2018	L 41	6	14.2.2018
► MI	Commission Regulation (EU) 2018/831 of 5 June 2018	L 140	35	6.6.2018
► MI	Commission Regulation (EU) 2019/37 of 10 January 2019	L 9	88	11.1.2019
► MI	Commission Regulation (EU) 2019/988 of 17 June 2019	L 160	10	18.6.2019
► MI	Commission Regulation (EU) 2019/1338 of 8 August 2019	L 209	5	9.8.2019
► MI	Commission Regulation (EU) 2020/1245 of 2 September 2020	L 288	1	3.9.2020



Composition requirements

UNION LIST (Annex I)

- **Monomers** or other starting substances;
- **Additives**, excluding colorants;
- Polymer production aids (**PPA**) excluding solvents;
- **Macromolecules** obtained from microbial fermentation (biopolymers);
- Substances in **nanoform** (only if explicitly authorised and mentioned in the specifications in Annex I).

(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
127	26050	0000075-01-4	vinyl chloride	no	yes	no	ND		1 mg/kg in final product	
128	10060	0000075-07-0	acetaldehyde	no	yes	no		(1)		
129	17020	0000075-21-8	ethylene oxide	no	yes	no	ND		1 mg/kg in final product	(10)
130	26110	0000075-35-4	vinylidene chloride	no	yes	no	ND			(1)
131	48460	0000075-37-6	1,1-difluoroethane	yes	no	no				
132	26140	0000075-38-7	vinylidene fluoride	no	yes	no	5			

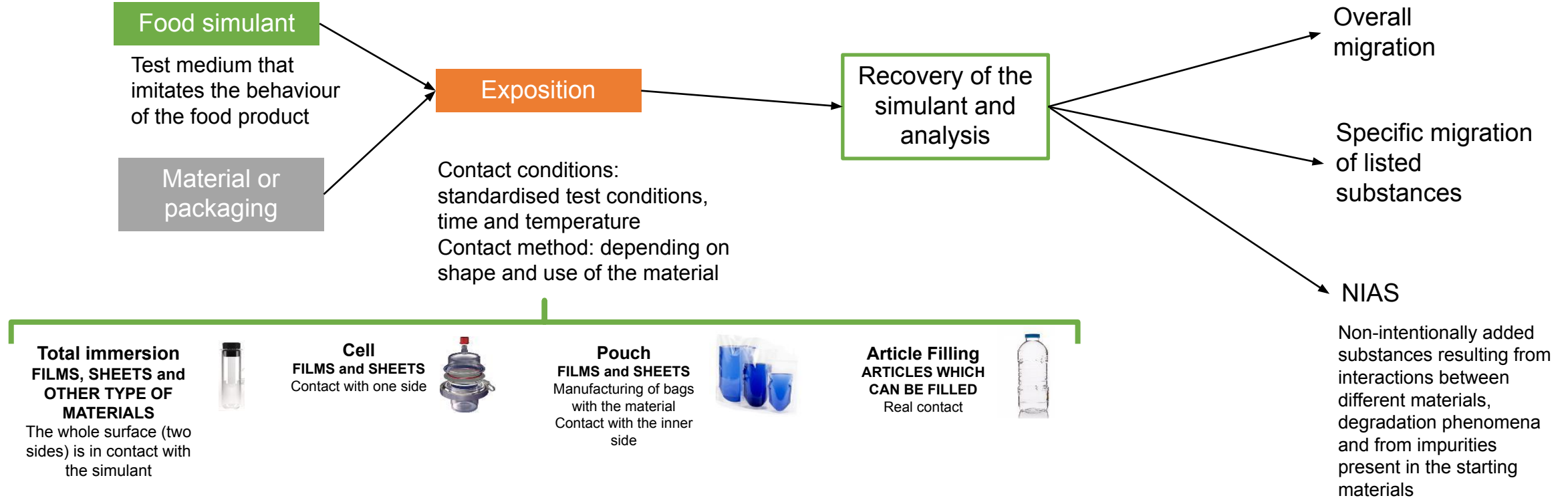
Restrictions and specifications

<p>Overall migration</p>	<p>OML 10 mg/dm² / 60 mg/kg (infants and young children) Maximum permitted amount of non-volatile substances released from a material or article into food simulants It measures the inertness of the material</p>
<p>Specific migration</p>	<p>SML X mg/kg (related to safety) Maximum permitted amount of a given substance released from a material or article into food or food simulants</p>
	<p>SML (T) X mg/kg (related to safety) Maximum permitted sum of particular substances released in food or food simulants</p>
<p>Other restrictions</p>	<p>Residual content (QMA) Maximum permitted amount of a given substance in a material</p>
	<p>Annex II: Release of certain substances (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn.....) Migration of primary aromatic amines</p>

Verifications of Restrictions and specifications: migration tests

Migration test

Basically consists of the reproduction of conditions (time, temperature and contact type) to which the material or article will be exposed when in contact with the food product (manufacturing, storage, transport, distribution and final use by the consumer)



Declaration of compliance

- Written document issued by the business operator
- At the marketing stages (except retail) for plastic materials and articles, products from intermediate stages of their manufacturing and for the substances intended for the manufacturing of those materials and articles
- Information according to Annex IV
- It shall be renewed

ANNEX IV

Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

- (1) the identity and address of the business operator issuing the declaration of compliance;
- (2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
- (3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- (4) the date of the declaration;
- (5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;
- (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,

- that are subject to restrictions in Annex II, or
- for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material 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) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
- (8) specifications on the use of the material or article, such as:
 - (i) type or types of food with which it is intended to be put in contact;
 - (ii) time and temperature of treatment and storage in contact with the food;
 - (iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;
- (9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

Supporting documents

- documents to demonstrate that the materials and articles, products from intermediate stages or their manufacturing and the substances intended for the manufacturing materials comply with the requirements of the Regulation
- available to the national competent authorities on request
- conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance

Specific measures for coatings

Lack of specific harmonised measures in Europe

- Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with Food
- Real Decreto 847/2011 (Spain), por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos
- Dutch packagings and Consumer Articles Regulation, Chapter X – Coatings
- Arrêté Royal concernant les vernis et revêtements destinés à entrer en contact avec les denrées alimentaires (Belgium)
- BfR Recommendations applicable to coatings (can be of interest BfR XIV Polymer dispersions and BfR XXV Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics)
- Framework Resolution ResAP (2004) 1 on Coatings intended to come into contact with foodstuffs and Technical document No. 1 – List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs

Regulation (EC) No 1895/2005 on epoxy derivatives

- Scope:
 - Materials and articles made of any type of plastic, those covered by coating products, and adhesives
 - It shall not apply to containers or storage tanks with a capacity exceeding 10,000 L.
- Prohibits the use of **BFDGE** and **NOGE** in FCM
- Allows the use of **BADGE** and its derivatives with migration limits
- Requires a Declaration of Compliance for the products containing **BADGE** or any of its derivatives. The presence of these substances shall be declared and comply with the established limits



Real Decreto 847/2011 on polymeric materials

- **Scope:** adhesives, natural and synthetic elastomers and rubbers, ion Exchange resins, silicones, **varnishes** and **coatings** and plastic materials as production support not listed in the Regulation (EU) No 10/2011, and waxes
- Establishes a positive list of substances for the manufacture of polymeric food contact materials and restrictions on their use (incl. SML)
- Monomers, additives and other starting substances listed in Regulation (EU) No 10/2011 may be used, subject to the restrictions specified therein
- Approved by other Member States for food contact materials
- Establishes identity and purity requirements (heavy metals and primary aromatic amines) for the dyes used in polymeric materials (Annex II)
- It sets an overall migration limit of 10 mg/dm² and 60 mg/kg for infants
- Sets specific migration limits (ANNEX 1). For unrestricted substances, generic limit of 60 mg/kg
- Test conditions according to Regulation (EU) No 10/2011 (Annexes III and V)
- Regulates dual-use additives (shall not have a technological effect on food, shall not exceed the migration limits laid down in food legislation for the food for which their use is authorized, and shall not exceed the migration limits set by food contact materials legislation)



Dutch Packaging and Consumer Articles Regulation. Chapter X – Coatings

It establishes composition requirements, monomers and additives allowed according to type of formulation

- Dispersions of macromolecular substances in water
- Dispersions of paraffin waxes and waxes in water
- Dispersions of macromolecular substances in organic liquids
- Water solutions
- Solutions in organic solvents
- Solvent-free materials consisting of waxes and wax-based products
- Other solvent-free materials
- Metallic coatings
- Polytetrafluorene (PTFE) for use as a coating for cooking and baking equipment (heating up to 140 °C or 230 °C, respectively, maximum)

Manufacturing requirements

- Base and auxiliary materials of high technical quality, in quantities strictly necessary
- Dyes and pigments (according to Chapter XI)
- Inks (Chapter XI)
- Solvents (they must comply with the safety principle of Article 3 of Regulation (EC) No 1935/2004)

Requeriments for the final article

- Overall migration limit 60 mg/kg
- Specific migration of certain listed substances, if they have been used

Arrêté royal concernant les vernis et revêtements destinés à entrer en contact avec les denrées alimentaires

- **Scope: Varnishes and coatings** for metallic materials and articles, for flexible and for high capacity agri-food applications, intended to come into contact with foodstuffs
- **Definition of varnish or coating:** Final material prepared essentially from organic substances, applied to a substrate to form a film to create a protective and/or give the substrate specific technical properties
- **Composition of monomers and additives.** The following substances can be used:
 - Listed in Annex I of Regulation (EU) No 10/2011 (applying the restrictions or specifications formulated except for mentions of specific plastics)
 - Approved by other Member States for food contact materials
 - Substances with a positive opinion of EFSA or equivalent body
 - Other substances if all the following are met:
 - They comply with Article 3 of the general requirements of Regulation (EC) No 1935/2004, and
 - Migration is not detectable ($LD = 0.01 \text{ mg/kg}$), and
 - They are not classified as CMR or Nanoform substances, and valid structure-activity relationship models do not suggest that the substance is genotoxic (provided there are no toxicological tests that invalidate this suspicion)



Arrêté royal concernant les vernis et revêtements destinés à entrer en contact avec les denrées alimentaires

Migration of substances to Food:

- An **overall migration limit** (OML) is set at 10 mg/dm² except for materials and articles intended for infants, young children, specific medical purposes or weight control treatments, in which case the OML= 60 mg/kg applies
- Coatings shall not release their components in quantities exceeding their respective **Specific Migration Limits** (SML). Where substances do not have an SML, a generic limit of 60 mg/kg shall apply
- Dual-use additives shall not have a technological effect on food, shall not exceed the migration limits laid down in food legislation for the food for which their use is authorized, and shall not exceed the migration limits set by food contact materials legislation
- Varnishes or coatings applied on metals shall not be subject to the release limits set by the CoE Resolution on metals and alloys (CM/Res (2013)9)
- The actual S/V ratio shall be used except in specific cases where legislation determines that the generic ratio of 6 dm²/kg Food shall be used

Migration tests:

- The Annex sets out requirements for carrying out migration testing, very similar to those set by Regulation (EU) No 10/2011

Documentation

Varnishes or coatings shall be accompanied by a **DoC** (except at retail) and appropriate information on compliance of the restricted substances with specific migration limits obtained by testing or theoretical calculations

BfR Recommendations

XIV. Polymer Dispersions

- Applies to coatings for applications where temperatures do not exceed 90°C
- Positive list of substances that can be used for formulation. Substances listed in Regulation (EU) No 10/2011 are allowed in addition to those proposed by the recommendation itself
 - Monomers for polymeric dispersions
 - Production aids: catalysts, polymerisation regulators, emulsifying agents, stabilisers, preservatives, anti-slip agents, defoaming agents, anti-foaming agents, anti-oxidants, anti-static agents
 - Restrictions on QMR, % use in formulation or SMLs

XXV. Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics

- Requirements regarding composition, viscosity, purity, antioxidants used, etc., for paraffin to be suitable for food contact.
- They must not be used with fats and oils or with fatty foodstuffs in which fat forms the external phase; This restriction of use also applies to such finished products for which no direct contact between food and coating is given as long as in the packaging no barrier for the transfer of substances from the coating to the food exists.

Food Contact Materials must comply with...

FCM must comply with cross-cutting regulations, compulsory for all FCM:

- Framework Regulation (EC) No 1935/2004 (safety principle)
- Good Manufacturing Practice Regulation (EC) No 2023/2006

PLASTICS

Compliance with Regulation (EU) No 10/2011:

- Composition
- Verification of restrictions
- Declaration of compliance

COATINGS

No harmonised legislation at European level



- Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with Food
- Real Decreto 847/2011 (Spain), por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos
- Dutch packagings and Consumer Articles Regulation, Chapter X – Coatings
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- Framework Resolution ResAP (2004) 1 on Coatings intended to come into contact with foodstuffs and Technical document No. 1 – List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs
- Others

Similar approach to
Plastics Regulation



Thank you
Questions?

PRESERVE



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