Seminar: Current trends regarding food safety and food security in Romania

Legislation on packaging at national and international level

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Overview

https://www.foodpackagingforum.org/

Food packaging is highly essential for protecting and handling food *from farm to fork*. However, packaging is also a source of chemical contamination of food.

Overview

https://www.foodpackagingforum.org/

Food packaging consists of many different materials and combinations thereof, e.g., plastics, paper and board, metals, glass, adhesives, coatings, printing inks.

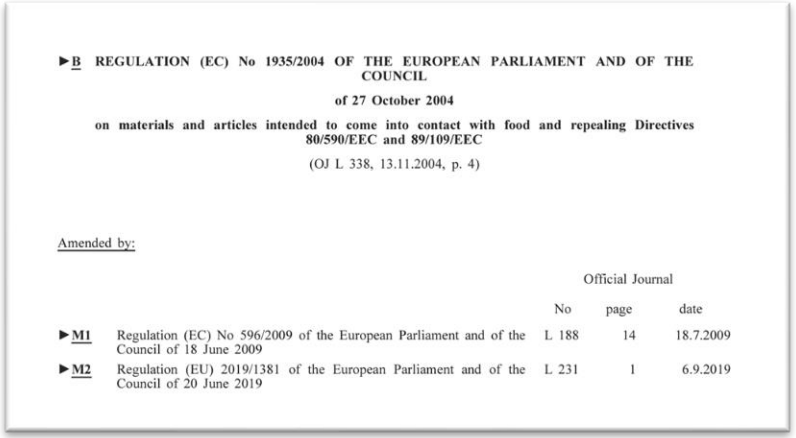
Not only packaging, but also other items contact food – collectively they are known as food contact materials (FCMs).

General regulation(s)

To ensure a high level of food safety, all food contact materials must comply with ***Regulation (EC) No 1935/2004*** ***on materials and articles intended to come into contact with food*** when placed on the European market.

All FCMs must be manufactured in accordance with Good Manufacturing Practices (GMP) - ***Commission Regulation (EC) No 2023/2006***.

Regulation (EC) No 1935/2004



►B 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)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009	L 188	14	18.7.2009
►M2	Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019	L 231	1	6.9.2019

All FCMs should be manufactured in compliance with GMP, so that, under normal and foreseeable conditions of use, they do not transfer their constituents to food in quantities that could endanger human health, bring about an unacceptable change in the composition of the food, or a deterioration of its organoleptic characteristics.

Types of FCMs

1. Active and intelligent materials and articles

https://www.interempresas.net/

2. Adhesives

https://blog.lddavis.com/what-exactly-is-a-food-safe-adhesive

3. Ceramics

https://www.etsy.com/

4. Cork

https://www.masilva.pt/en/cork-stoppers/

5. Rubbers

https://www.dongjuesilicone.com/

Types of FCMs

6. Glass

https://www.diffpack.com/beer-bottle/

7. Ion-exchange resins

http://bsrresin.com/

8. Metals and alloys

https://new-box.com/en/products/food-cans

9. Paper and board

https://www.welmpacking.com/

Types of FCMs

10. Plastics

https://www.michaelpackage.com/

https://www.amazon.com/

11. Printing inks

12. Regenerated cellulose

https://www.aboutmechanics.com/

https://www.risingsunmembranes.com/

13. Silicones

Types of FCMs

14. Textiles

https://m.indiamart.com/

15. Varnishes and coatings

https://www.vectornator.io/blog/beer-labels/

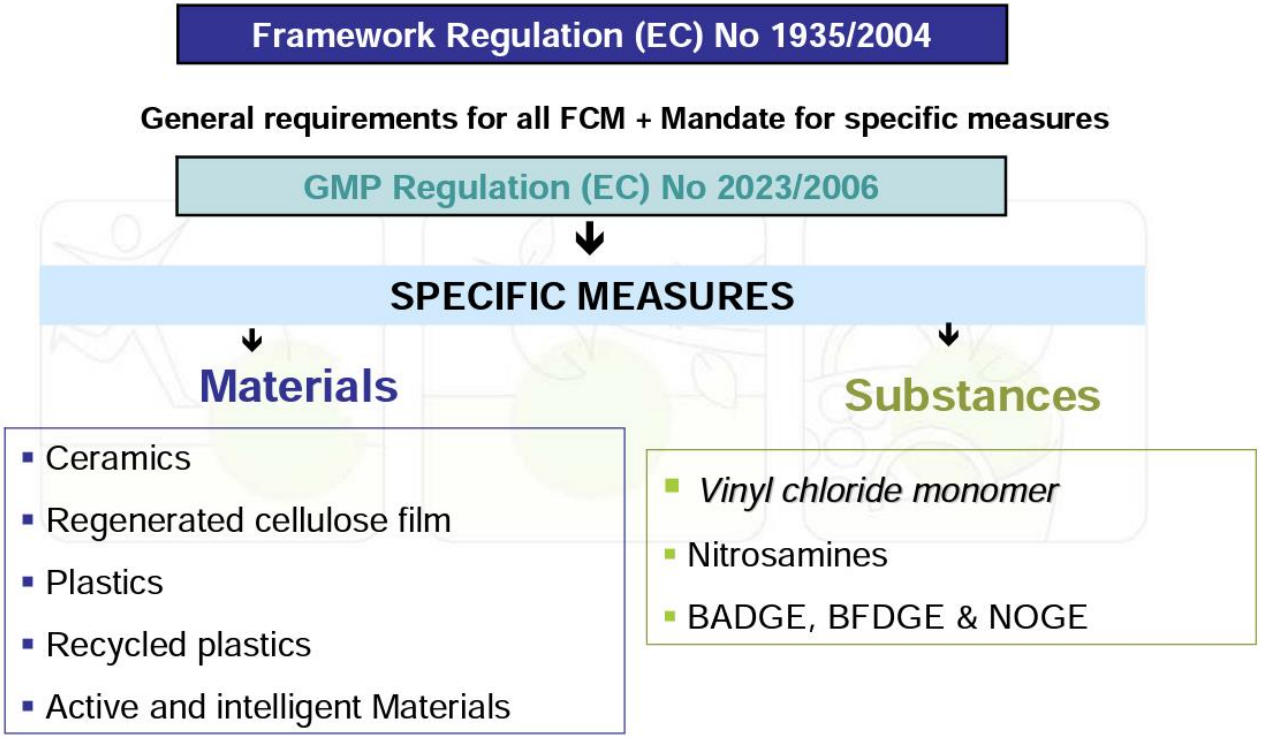
16. Waxes

https://fr.wessling-group.com/

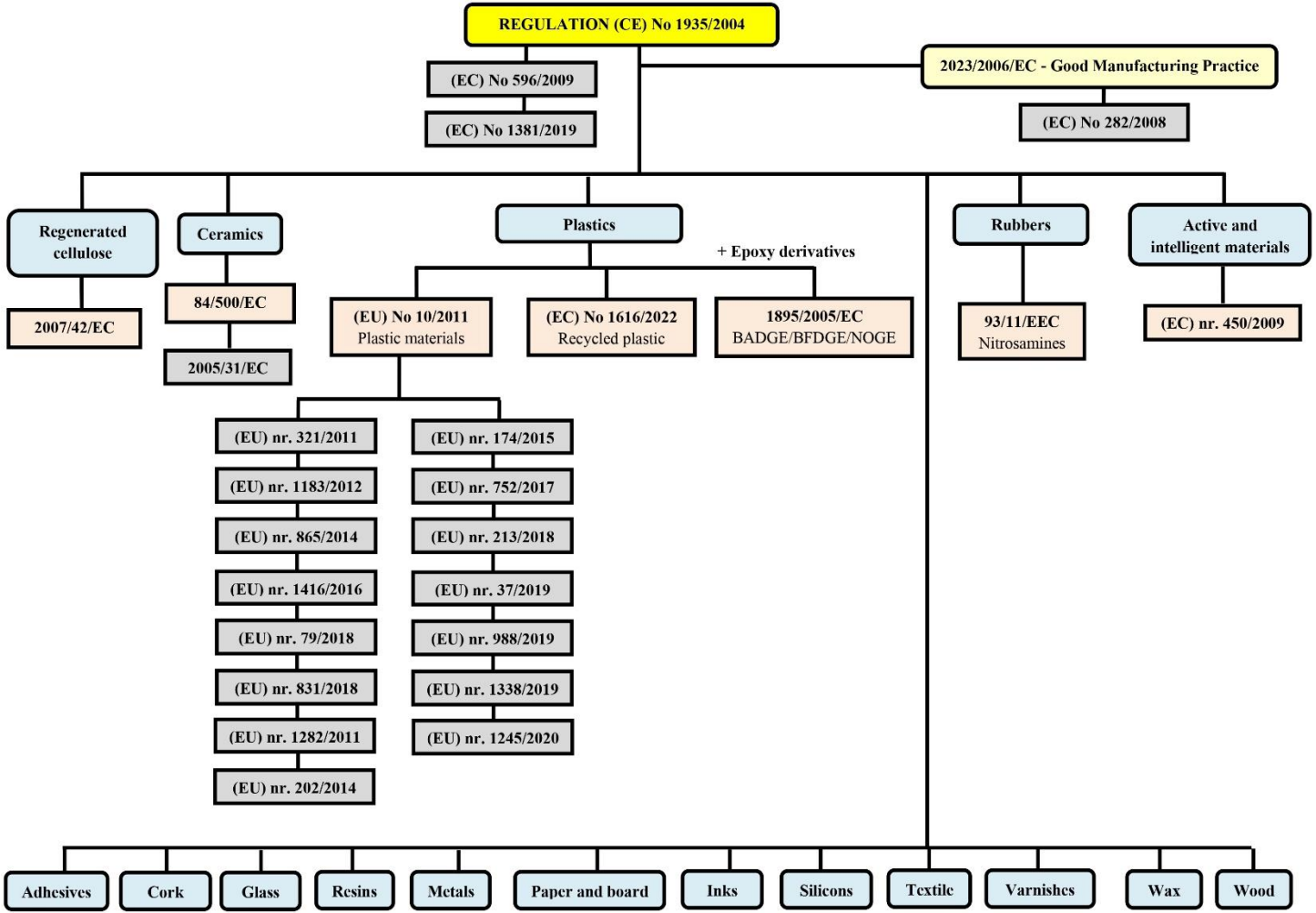
https://serowar.eu/

17. Wood

Legislation overview



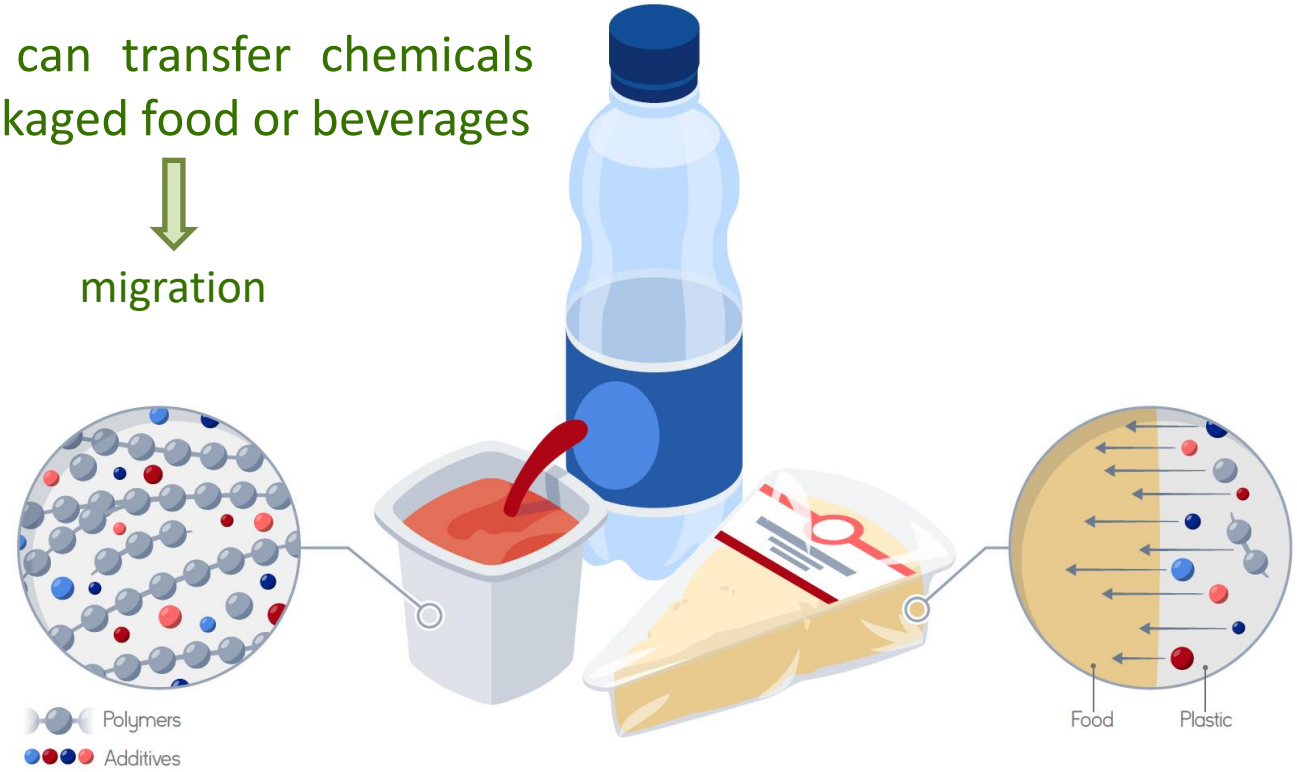
Source: Annette Schäfer, DG Health & Consumer Protection, European Commission


REGULATION (CE) No 1935/2004
(EC) No 596/2009
(EC) No 1381/2019
2023/2006/EC - Good Manufacturing Practice
(EC) No 282/2008
Regenerated cellulose
2007/42/EC
Ceramics
84/500/EC
2005/31/EC
Plastics
+ Epoxy derivatives
(EU) No 10/2011 Plastic materials
(EC) No 1616/2022 Recycled plastic
1895/2005/EC BADGE/BFDGE/NOGE
(EU) nr. 321/2011
(EU) nr. 1183/2012
(EU) nr. 865/2014
(EU) nr. 1416/2016
(EU) nr. 79/2018
(EU) nr. 831/2018
(EU) nr. 1282/2011
(EU) nr. 202/2014
(EU) nr. 174/2015
(EU) nr. 752/2017
(EU) nr. 213/2018
(EU) nr. 37/2019
(EU) nr. 988/2019
(EU) nr. 1338/2019
(EU) nr. 1245/2020
Rubbers
93/11/EEC Nitrosamines
Active and intelligent materials
(EC) nr. 450/2009
Adhesives
Cork
Glass
Resins
Metals
Paper and board
Inks
Silicons
Textile
Varnishes
Wax
Wood

Plastics

Plastics can transfer chemicals into packaged food or beverages

migration



https://www.foodpackagingforum.org/

Regulation (EU) No 10/2011

Reg. 10/2011 sets out safety requirements for **plastic** materials and articles intended to come into contact with food. This regulation is a specific measure for plastic food contact materials as mentioned in the Reg. 1935/2004 and applies to:

- Materials and articles and parts thereof, consisting exclusively of plastics
- Plastic multi-layer materials and articles held together by adhesives
- Materials that can be printed or covered by a coating
- Plastic layers or plastic coatings, forming gaskets in caps and closures
- Plastic layers in multi-material and multi-layer materials and articles

Key requirements

Only authorised substances that are positive-listed in Annex I of the Regulation may be intentionally used in the manufacture of plastic materials and articles

Declaration of Compliance (DoC) – is required at all stages of production and marketing (excluding the retail stage) and it needs to be supported by appropriate underlying documentation.

Testing requirements - Requirements for testing of overall and specific migration, including comprehensive guidance on selecting simulants and conditions for testing

Risk Assessment Requirements - Assessment of Non-Intentionally Added Substances (NIAS) and their risk, by the manufacturer of plastic food contact materials and articles.

Annex I – Regulation 10/2011

(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 applica-ble (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restricti-on No)	Restrictions and specifications	Notes on verification of compliance
1	12310	0266309-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formal-dehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethyl-hexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C_5-C_{15})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_7-C_{17}), 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)		

Overall migration

List of food simulants

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
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

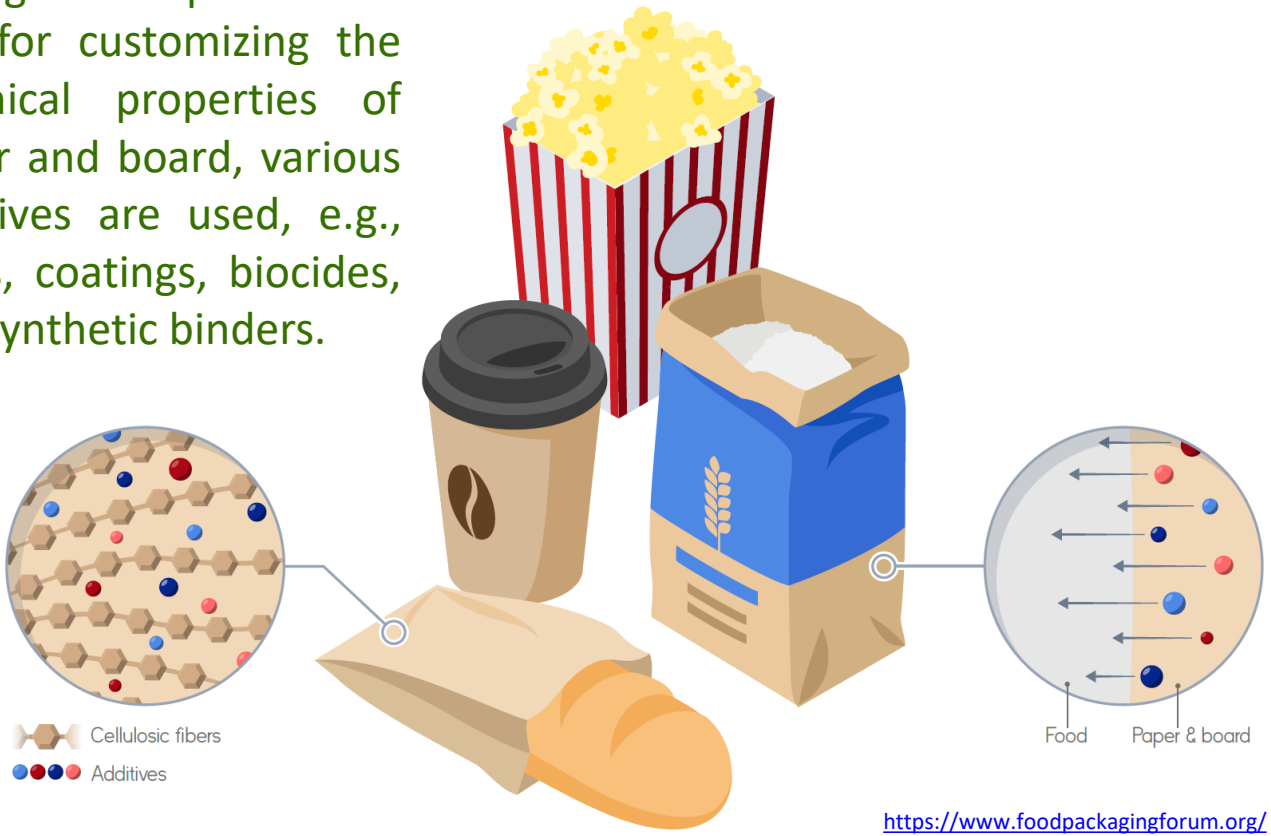
Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 shall be used for foods which contain free fats at the surface.

Food simulant E is assigned for testing specific migration into dry foods.

Paper and board

During the production and for customizing the technical properties of paper and board, various additives are used, e.g., fillers, coatings, biocides, and synthetic binders.



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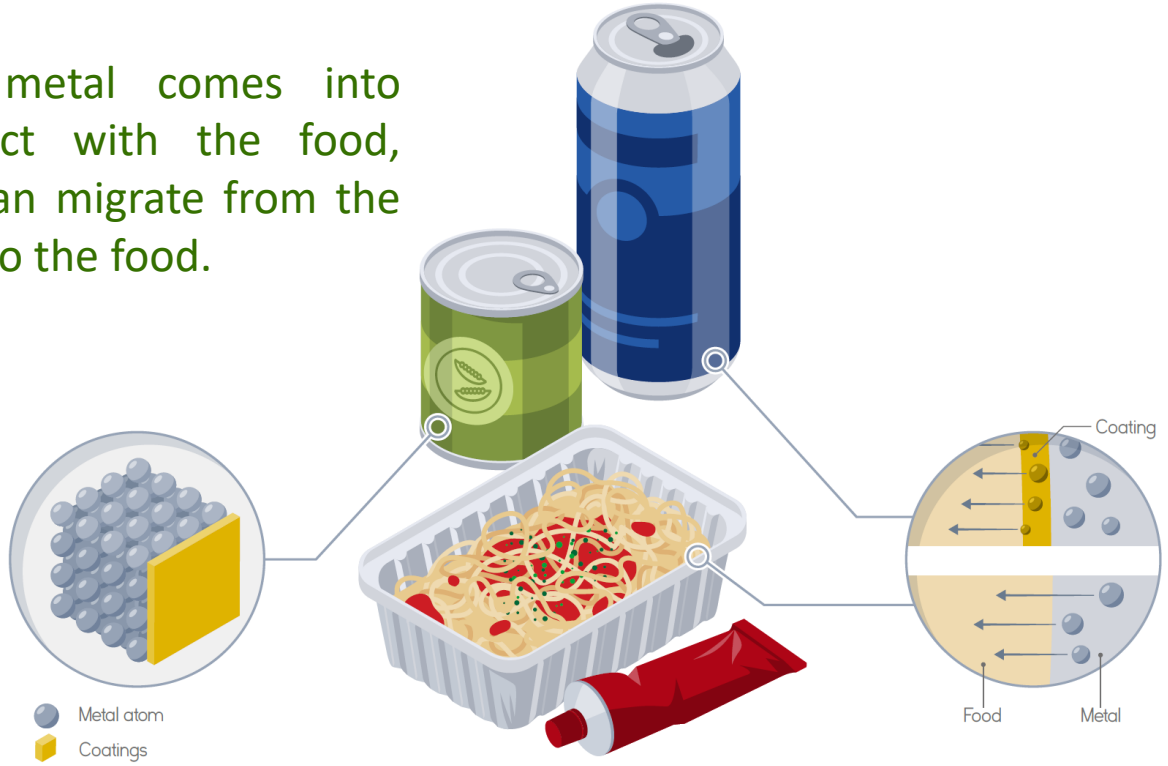
Metals

When the metal comes into direct contact with the food, metal ions can migrate from the packaging into the food.



https://www.foodpackagingforum.org/

Glass

The transfer of glass constituents into food is of low concern due to its structural properties.

https://www.foodpackagingforum.org/

Multimaterial

When addressing chemical migration from multimaterial food and beverage packaging, the primary focus should be placed on the material that is in direct contact with the food.

https://www.foodpackagingforum.org/

Directive 2007/42/EC

DIRECTIVES

COMMISSION DIRECTIVE 2007/42/EC

of 29 June 2007

relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

(Text with EEA relevance)

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 5 thereof,

Whereas:

(5) The method for determining the absence of migration of colouring matters should be established at a later stage.

(6) Until criteria of purity and methods of analysis have been drawn up, national provisions should remain in force.

(7) The establishment of a list of approved substances, accompanied by limits to the quantities to be used, is sufficient in principle in this specific case to achieve the objective laid down in Article 3(1) of Regulation (EC) No 1935/2004.

Directive 84/500/EEC

	Pb	*Cd*
— Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm	0,8 mg/dm^2	0,07 mg/dm^2
— Category 2: All other articles which can be filled	4,0 mg/l	0,3 mg/l
— Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three litres	1,5 mg/l	0,1 mg/l

Regulation (EC) 450/2009

COMMISSION REGULATION (EC) No 450/2009

of 29 May 2009

on active and intelligent materials and articles intended to come into contact with food

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 5(1) (h), (i), (l), (m) and (n) thereof,

substances that have to comply with Community and national provisions applicable to food and labelling rules. Specific rules should be laid down in a specific measure.

(4) This Regulation is a specific measure within the meaning of Article 5(1)(b) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.

Directive 94/62/EC

►B **EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC**

of 20 December 1994

on packaging and packaging waste

(OJ L 365, 31.12.1994, p. 10)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
►M2	Directive 2004/12/EC of the European Parliament and of the Council of 11 February 2004	L 47	26	18.2.2004
►M3	Directive 2005/20/EC of the European Parliament and of the Council of 9 March 2005	L 70	17	16.3.2005
►M4	Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009	L 87	109	31.3.2009
►M5	Commission Directive 2013/2/EU of 7 February 2013	L 37	10	8.2.2013
►M6	Directive (EU) 2015/720 of the European Parliament and of the Council of 29 April 2015	L 115	11	6.5.2015
►M7	Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018	L 150	141	14.6.2018

Directive 94/62/EC

Covers all packaging placed on the market in the EU and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used.

Member States shall ensure that the sum of concentration levels of **lead**, **cadmium**, **mercury** and **hexavalent chromium** present in packaging or packaging components shall not exceed **100 ppm** by weight.

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