



GLOBAL FOOD REGULATORY SCIENCE SOCIETY

*GFORSS is a Disciplinary Organization of IUFOST, devoted to Food Regulatory Science*



GFORSS Capacity Building Program

**Food Contact Materials: International Regulatory Framework**

**Overview of Regulatory Management Approaches for Food Contact Materials  
USA & EU**

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- Introduction
- United States Food Contact Regulations
- European Union Regulations on Food Contact Materials
- Conclusion



# Introduction

## Food Contact Articles



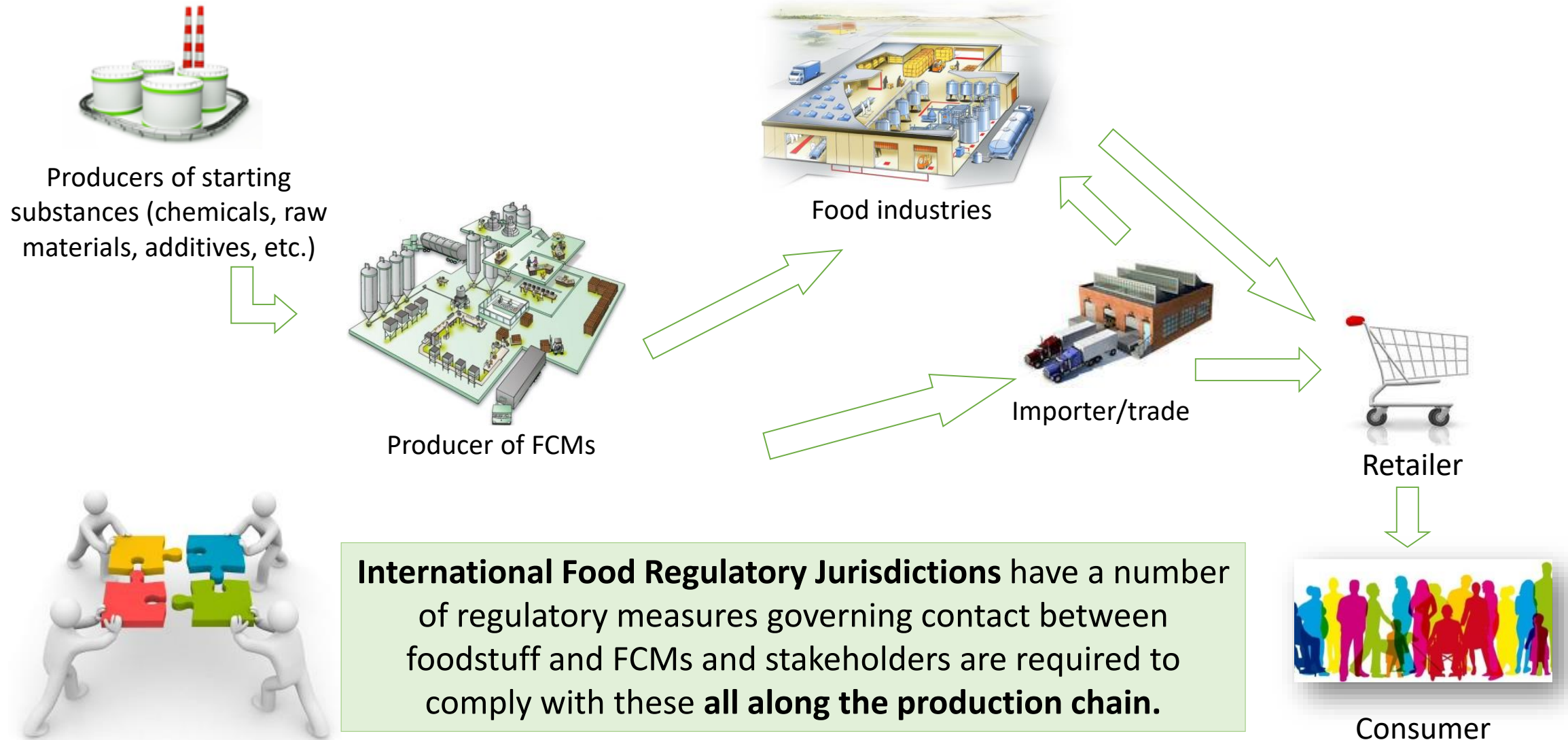
## Food Contact Materials (FCMs)

- Plastics
- Metals & Alloys
- Paperboard
- Glass
- Varnishes
- Coatings
- Adhesives
- ....

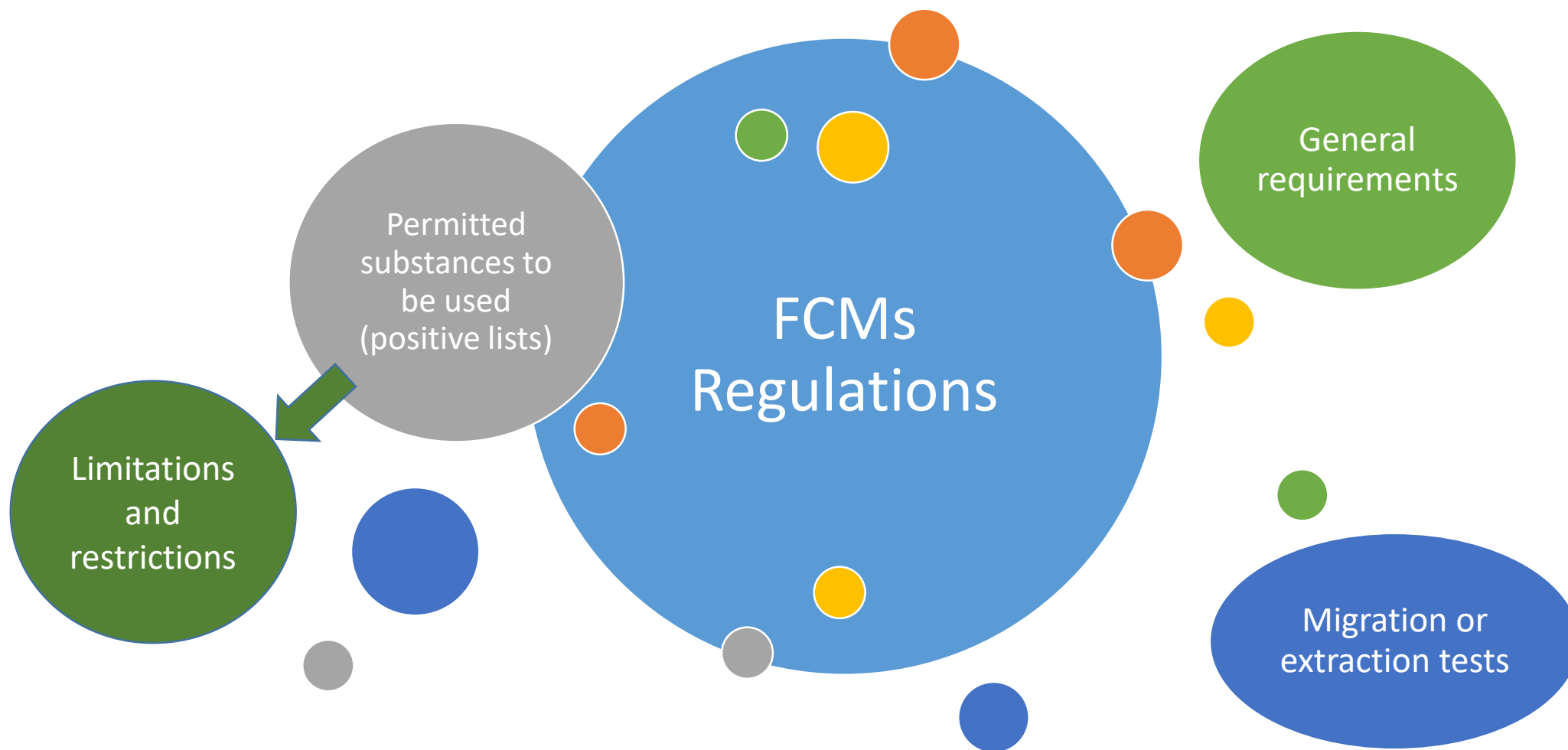
## Food Contact Chemicals (FCCs)

- Polymers
- Oligomers
- Residual Monomers
- Intentionally Added Substances (IAS)
  - Additives
  - Pigments
  - Starting Substances
  - Production Aids
- Non-Intentionally Added Substances (NIAS)
  - Impurities
  - Reaction and Degradation Products
- ...

# FCMs Production Chain



# FCMs Regulations - Background



# Food Contact Materials Legislation in the United States of America



*<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B>*

# USA Food Contact Regulations

The **US-FDA** defines the following, and in a **hierarchical manner**:



**Food Contact Substance (FCS)** is any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food.



**Food Contact Material (FCM)** is made with the FCS and (usually) other substances. It is often (but not necessarily) a mixture, such as an antioxidant in a polymer.



**Food Contact Article** is the finished film, bottle, dough hook, tray, etc. that is formed out of the FCM.



*FDA, “Food Ingredient & Packaging Terms.” <https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms> (accessed Dec. 09, 2021).*

# Food and Drug Administration (FDA) Food Contact Regulations

- All relevant provisions for FCMs are published in **title 21 of the Code of Federal regulations (CFR), Chapter I (Food and Drug Administration, Department of Health and Human Services), subchapter B (Food for Human Consumption), parts:**
  - **109:** Unavoidable contaminants in food for human consumption and food-packaging material.
  - **170:** Food additives
  - **174:** Indirect food additives - General
  - **175:** Adhesives and components of coatings
  - **176:** Indirect food additives: Paper and paperboard components
  - **177:** Indirect food additives: Polymers
  - **178:** Indirect food additives: Adjuvants, production aids and sanitizers
  - **180:** Food additives permitted in food or in contact with food on an interim basis pending further study
  - **181:** Prior-sanctioned food ingredients
  - **182:** Substances generally recognized as safe
  - **184:** Direct food substances affirmed as generally recognized as safe
  - **186:** Indirect food substances affirmed as generally recognized as safe
  - **189:** Substances prohibited from use in human food



# Food and Drug Administration (FDA) Food Contact Regulations

- The precise requirements of the FDA are very **material-specific**. The fundamental assumption is that all components of a material can migrate into food. Plastics, additives and other FCMs are thus considered as **“indirect food additive”**.
  
- **Three general types of regulations:**
  - **Those covering specific materials**, e.g. 176 on Paper and Paperboard; 177 on Polymers. These contain:
    - Lists of permitted additives and maximum levels of use where not covered by general lists.
    - Specifications such as density and melting point.
    - End-test extractable limits and sometimes test methods for these.
  - **Those covering substances by use** e.g. 178.2010 on antioxidants/stabilizers for polymers. These contain lists of permitted substances and maximum levels of use.
  - **Those listing substances used in specific types of packaging** e.g. 175.105 on adhesives, 177.300 on can coatings. These contain:
    - Lists of starting components and intermediates that react together in the curing reaction.
    - Permitted curing reactions for can coatings.
    - Restriction on adhesives such that they can only be used when a functional barrier is present or for very low exposure at seams and edges.

# Food and Drug Administration (FDA) Food Contact Regulations

## ➤ Part 170.39 - Threshold of regulation for substances used in food-contact articles

A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food **will be exempted from regulation as a food additive** because it becomes a component of food at levels that are below the threshold of regulation if:

- ✓ The substance has not been shown to be a carcinogen in humans or animals, and there is no reason, based on the chemical structure of the substance, to suspect that the substance is a carcinogen;
- ✓ The substance presents no other health or safety concerns because the use in question has been shown to result in or may be expected to result in dietary concentrations at or below 0.5 ppb, corresponding to dietary exposure levels at or below 1.5 µg/person/day (based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day);
- ✓ The substance has no technical effect in or on the food to which it migrates; and
- ✓ The substance use has no significant adverse impact on the environment.

# Food and Drug Administration (FDA) Food Contact Regulations

## ➤ Part 174: Indirect food additives - General

- The quantity of any food additive substance that **may be added to food as a result of use in articles that contact food** shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; **shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself**, except as such may be permitted by regulations in parts 170 through 189 of this chapter.
- Any substance used as a component of **articles that contact food** shall be of a **purity suitable for its intended use**.

# Food and Drug Administration (FDA) Food Contact Regulations

## ➤ Part 174: Indirect food additives - General

- Substances, that under conditions of **good manufacturing practice**, may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:
  1. Substances **generally recognized as safe** in or on food.
  2. Substances **generally recognized as safe** for their intended use in food packaging.
  3. Substances used in accordance with a prior sanction or approval.
  4. Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and § 179.45.
  5. Food contact substances used in accordance with an effective premarket **notification for a food contact substance (FCN)** submitted under section 409(h) of the act.

# Food and Drug Administration (FDA) Food Contact Regulations

**Part 176-Indirect Food Additives: paper and paperboard components**

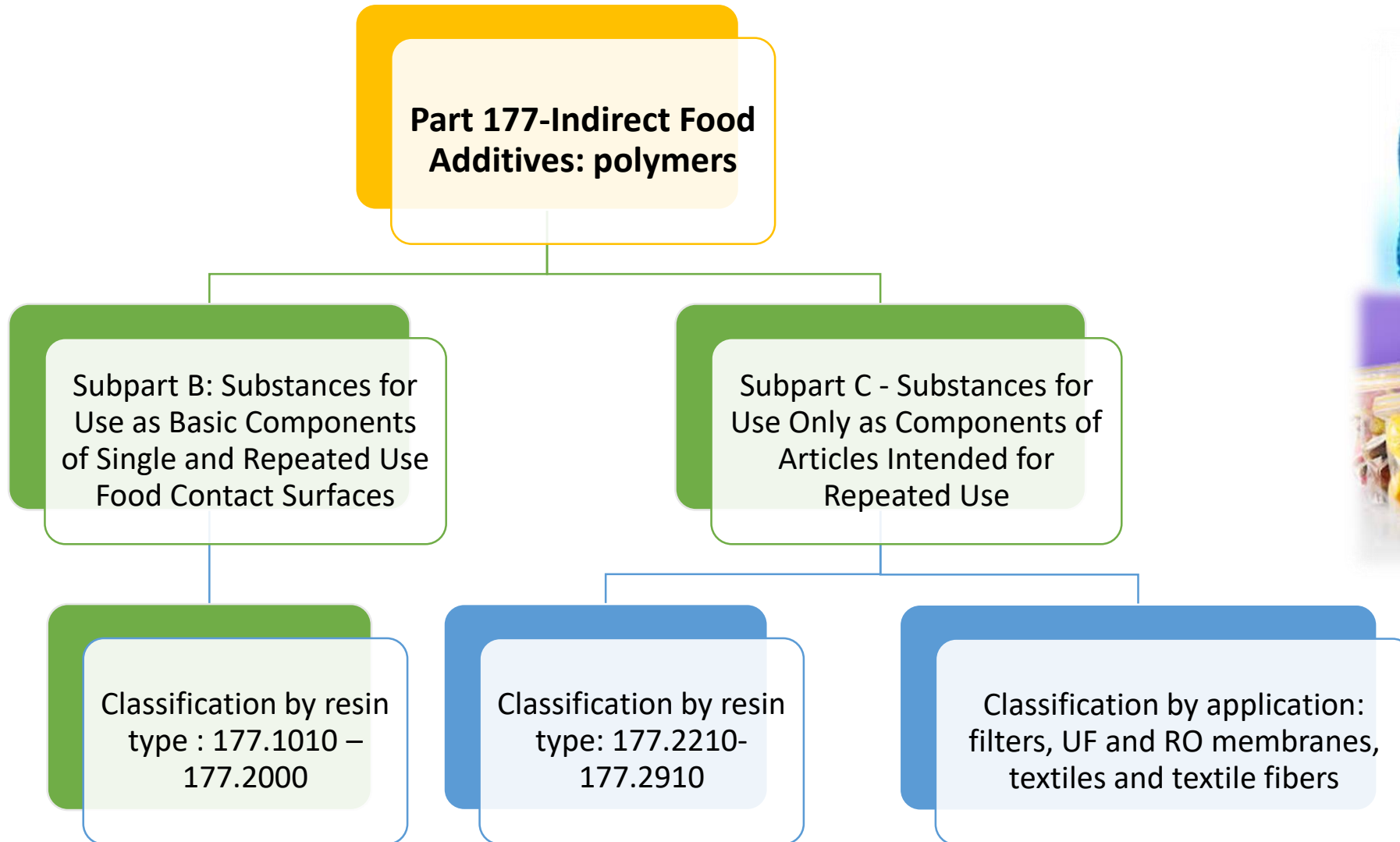
Subpart B - Substances for Use Only as Components of paper and paperboard components

Classification by substance: 176.110-176.350

Paragraph c: food simulating solvents, time-temperature conditions for migration tests



# Food and Drug Administration (FDA) Food Contact Regulations



# Food and Drug Administration (FDA) Food Contact Regulations

Part 176 - Indirect food additives: Paper and paperboard components

Part 177-Indirect Food Additives: polymers, ...

Part 176: classification by substances for use only

Part 177: classification by resin type (Polyethylene phthalate polymers, Olefin polymers, etc.)

Chemical definition  
(monomers, co-polymers)

Permitted additives and production aids

Migration tests conditions and Analytical methods

Limitations (use only as, levels not to exceed)

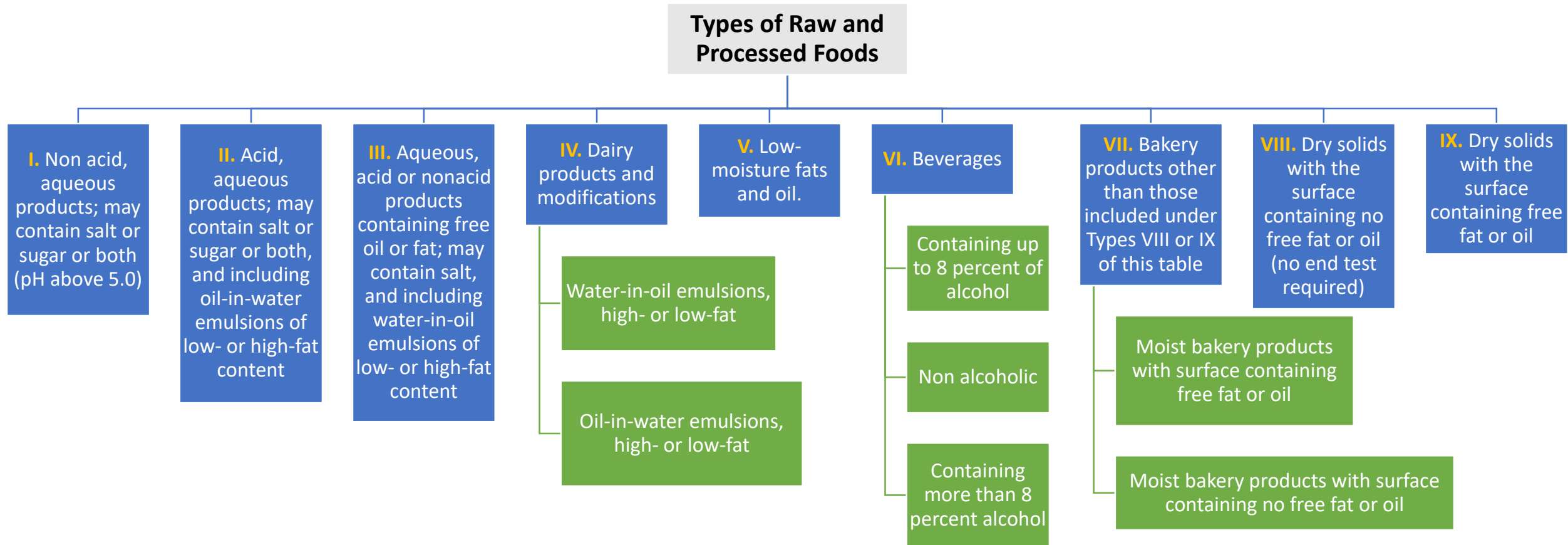
Physical properties (density, melting point, etc.)

Total nonvolatile extractives

Other solvent extractable fractions

# Food and Drug Administration (FDA) Food Contact Regulations

**Part 176.170:** Test conditions for extraction with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of intended use





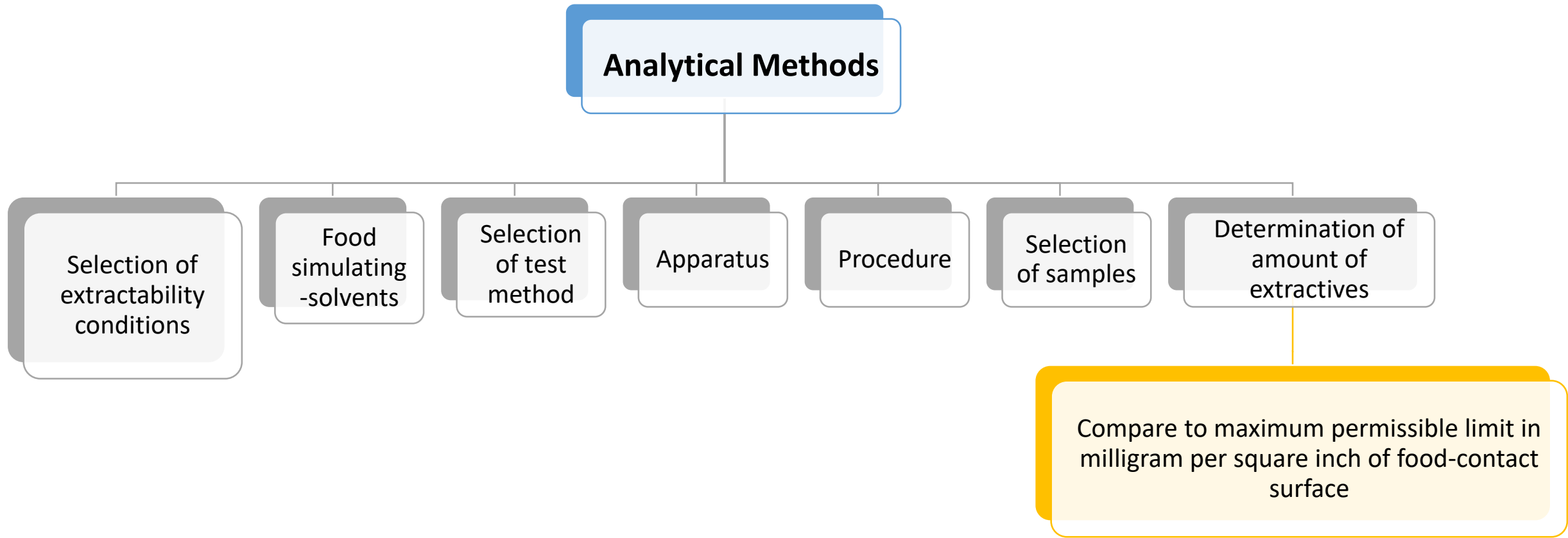
# Food and Drug Administration (FDA) Food Contact Regulations

**Part 176.170:** Test conditions for extraction with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of intended use

Solvents Simulating Types of Foods and Beverages					
Condition of use	Types of food (see table 1)	Food-simulating solvents			
		Water	Heptane <sup>1</sup>	8 percent alcohol	50 percent alcohol
		Time and temperature	Time and temperature	Time and temperature	Time and temperature
A. High temperature heat-sterilized (e.g., over 212 °F)	I, IV-B, VII-B	250 °F, 2 hr			
	III, IV-A, VII-A	.....do	150 °F, 2 hr		
B. Boiling water sterilized	II, VII-B	212 °F, 30 min			
	III, VII-A	.....do	120 °F, 30 min		
C. Hot filled or pasteurized above 150 °F	II, IV-B, VII-B	Fill boiling, cool to 100 °F			

# Food and Drug Administration (FDA) Food Contact Regulations

**Part 176.170:** Test conditions for extraction with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of intended use



# European Regulations on FCMs



# EU Food Contact Regulations

Food Contact Materials (FCMs) are any **materials** or **articles** intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use.



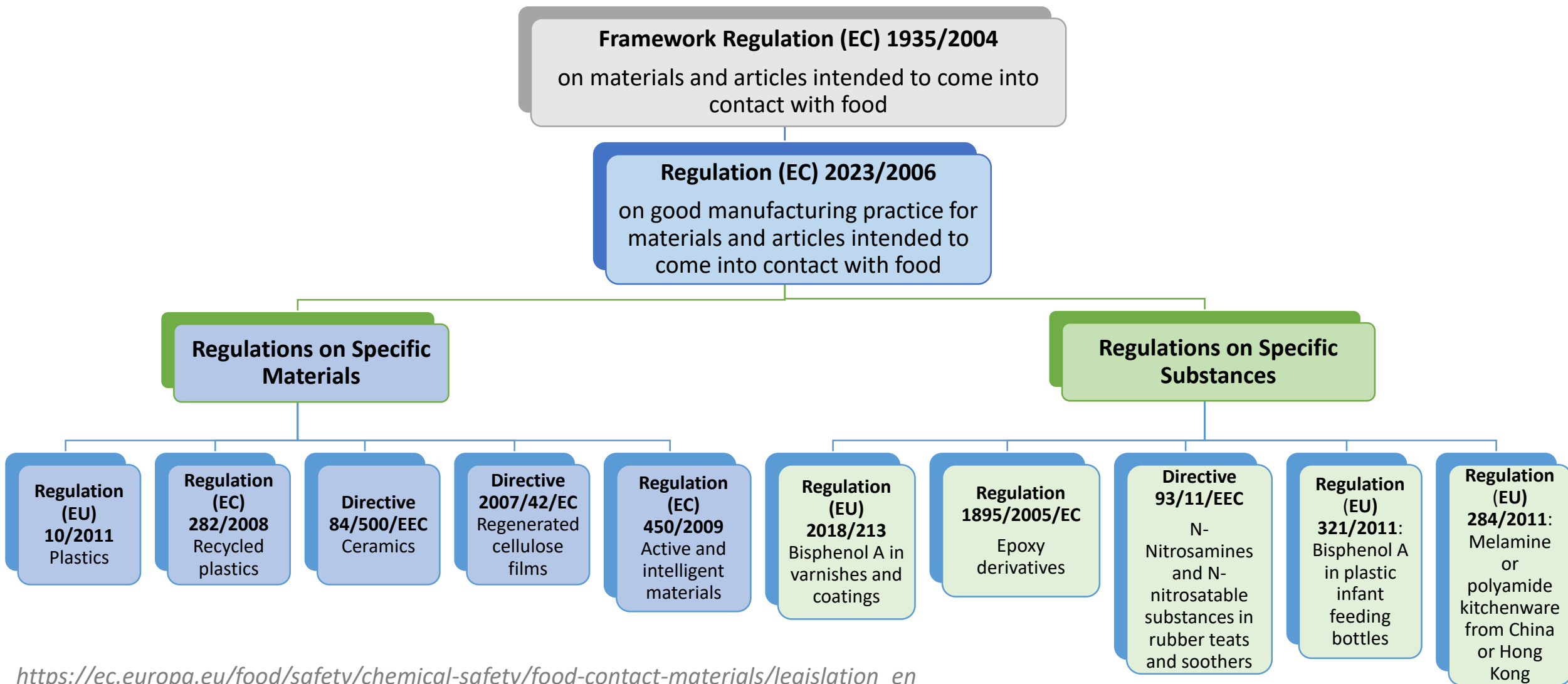
This potential contact may occur during food's production, processing, storage, preparation and serving, before its eventual consumption



*European Commission, "Food Contact Materials."*

*[https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials\\_en](https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials_en)*


# EU Food Contact Regulations



[https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/legislation\\_en](https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/legislation_en)

# EU Food Contact Regulations

## ➤ Framework Regulation (EC) 1935/2004

- The primary European regulatory measure related to FCMs.
  - Applies to all food contact articles and materials.
  - **Article 3:** general requirements that should be fulfilled by any FCM.
  - In the absence of European specific measures, **article 6** urges member states to maintain and adopt **national legislations**.
  - **Articles 8 & 9:** procedure for notifying new substances.
  - **Article 15:** labelling “for Food Contact”.
- 
- **Article 16:** declaration of compliance and supporting documentation.
  - **Article 17:** importance of traceability.

### Article 3

#### General requirements

1. Materials and articles, including active and intelligent 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:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

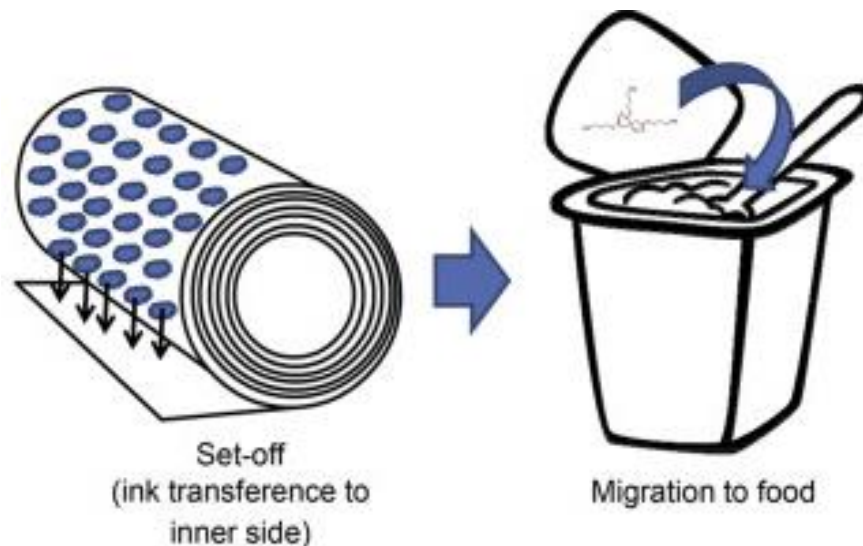
or

(c) bring about a deterioration in the organoleptic characteristics thereof.

# EU Food Contact Regulations

## ➤ Regulation (EC) 2023/2006 on Good Manufacturing Practice (GMP)

- Companies that make FCMs must establish and maintain:
  - A quality assurance system (**article 5**)
  - A quality control system (**article 6**)
  - A documentation in accordance with good manufacturing practice guidelines (**article 7**)
  - **Annex X:** Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied /handled and stored in such a manner that substances from the printed surface are not transferred to the food-contact side.



Aznar, M., Domeño, C., Nerín, C., & Bosetti, O. (2015). Dyes and Pigments, 114(C), 85–92. <https://doi.org/10.1016/j.dyepig.2014.10.019>

# EU Food Contact Regulations

## ➤ The Plastic Regulation (EU) 10/2011

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)

- In order to satisfy the requirements of **framework regulation (EC) 1935/2004**, stakeholders must also observe other regulations specific to the type of material.
- For plastic FCMs, this is **regulation 10/2011** and **its amendments**. It consolidates and extends the previous directive 2002/72/EC.
- The most important sections of regulation (EU) 10/2011 are:
  - The union list of authorized substances or the positive list
  - Migration tests (overall and specific)
  - Declaration of compliance



# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

- **Annex I: Union list of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives (excluding colorants) and polymer production aids (excluding solvents).**

(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(I) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance

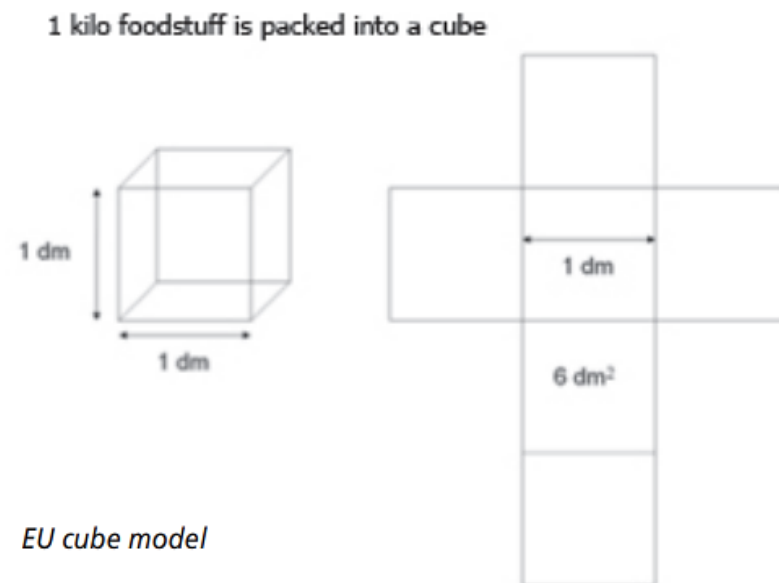
- Only the substances listed in the “Union list” may be used in the manufacture of plastics. This is a positive list with originally 885 substances which is updated regularly.

# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

### ○ Overall migration limit (OML)

- Total amount of **non-volatile** substances that migrate from the material into the food or food simulants.
- Determined by gravimetric analysis.
- Plastic materials and articles shall not transfer their constituents to food or food simulants in quantities exceeding **10 milligrams of total constituents released per  $\text{dm}^2$**  of food contact surface ( $\text{mg}/\text{dm}^2$ ) or exceeding **60 milligrams of total of constituents released per kg of food or food simulant**.
- The OML applies equally to all plastic FCMs.



# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

### ○ Specific Migration Limit (SML)

- Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the **specific migration limits (SML)** set out in the “Union list”. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).
- For substances for which no specific migration limit or other restrictions are provided in the positive list, a generic specific migration limit of **60 mg/kg of food** shall apply.

# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

- **Food simulants:** to determine the extent of chemical transfer from packaging into food, migrants are measured in food simulants, not actual foodstuffs.
- Food simulants are used as substitutes for food in order to simplify the analytical procedure.

Table 1  
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
Vegetable oil (*)	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

(\*) This may be any vegetable oil with a fatty acid distribution of

No of carbon atoms in fatty acid chain: No of unsaturation	6-12	14	16	18:0	18:1	18:2	18:3
Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography	< 1	< 1	1,5-20	< 7	15-85	5-70	< 1,5

# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

### ○ Food simulants:

Table 2

food category specific assignment of food simulants

(1) Reference number	(2) Description of food	(3) Food simulants					
		A	B	C	D1	D2	E
01	<b>Beverages</b>						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:  A. Clear drinks:		X(*)	X			

Correction factors

- **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 E** is assigned for testing specific migration into dry foods.

# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

- Compliance testing
  - Testing for **specific migration** of materials and articles **not yet in contact with food**.

Contact time

Contact time in worst foreseeable use	Test time
$t \leq 5 \text{ min}$	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

Contact temperature

Conditions of contact in worst foreseeable use	Test conditions
Contact temperature	Test temperature
$T \leq 5 \text{ °C}$	5 °C
$5 \text{ °C} < T \leq 20 \text{ °C}$	20 °C
$20 \text{ °C} < T \leq 40 \text{ °C}$	40 °C
$40 \text{ °C} < T \leq 70 \text{ °C}$	70 °C
$70 \text{ °C} < T \leq 100 \text{ °C}$	100 °C or reflux temperature
$100 \text{ °C} < T \leq 121 \text{ °C}$	121 °C (*)
$121 \text{ °C} < T \leq 130 \text{ °C}$	130 °C (*)
$130 \text{ °C} < T \leq 150 \text{ °C}$	150 °C (*)
$150 \text{ °C} < T < 175 \text{ °C}$	175 °C (*)
$T > 175 \text{ °C}$	Adjust the temperature to the real temperature at the interface with the food (*)

For contact times above 30 days at room temperature and below, the specimen shall be tested in an accelerated test at elevated temperature for a maximum of **10 days at 60 °C**.

# EU Food Contact Regulations

## ➤ Regulation (EU) 10/2011

- Compliance testing
  - Testing for **overall migration** of materials and articles **not yet in contact with food**.

Standardised testing conditions

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C]	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
OM3	2 h at 70 °C	Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM4	1 h at 100 °C	High temperature applications for all food simulants at temperature up to 100 °C.

OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

# EU Food Contact Regulations - What You Need to Know/Check

## ➤ Regulation (EU) 10/2011

- What do you need to check and measure to prove the compliance of a plastic FCM with EU regulations?
  - Ensure that all your monomers and additives are listed either in Regulation 10/2011 or on the provisional positive list.
  - Show compliance with the overall migration limit by migration testing.
  - Show compliance with specific migration limits, or residual quantity limits, for monomers listed with these restrictions in Regulation 10/2011. This involves experimental testing.
  - Show compliance with specific migration limits for additives either by calculation of 100% migration (worst case scenario), or, by diffusion rate calculations (mathematical modelling), or, by experimental migration measurements.



# EU Food Contact Regulations - What You Need to Know/Check

## ➤ Regulation (EU) 10/2011

- What do you need to check and measure to prove the compliance of a plastic FCM with EU regulations- **Problem of NIAS.**
  - As far as they are relevant for the risk assessment, the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance.
  - Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognized scientific principles on risk assessment.
  - **Potential Solution:** untargeted analytical approaches – analytical fingerprints coupled to chemometrics.

# EU Food Contact Regulations – Recycled Plastics

## ➤ Regulation (EC) 282/2008

- Plastic packaging waste may contain residues from previous use, contaminants from misuse and contaminants from non-authorized substances.
- Therefore, it is necessary to lay down special requirements to ensure that materials and articles produced from recycled plastics and intended for food contact respect the requirements of Article 3 of Regulation (EC) No 1935/2004.
- Recycled plastic used behind a plastic **functional barrier** are regarded as sufficient to ensure the safety.
- Certain types of materials and articles manufactured with recycled plastics may only be suitable for contact with specified types of food under certain conditions.
- **Article 4:** conditions for the authorization of recycling processes (mechanical and chemical depolymerization), which must demonstrate that it can efficiently reduce potential contamination to a level that does not pose a risk to human health.

# Conclusion



A heterogeneous regulatory environment related to food contact materials internationally.

Some regulatory measures are highly explicit (EU, FDA), where others remain brief, placing responsibility on food industries.

This remains a challenging area to regulate for developing countries.

