

What is a food contact material (FCM)?

- Intended to be brought into contact with food
- Already in contact with food and intended for that purpose
- Can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or foreseeable conditions of use
- Examples:
 - food packaging, kitchenware and tableware, processing equipment, work surfaces, ...



What is a food contact material? (continued)

FCM legislation:

- **covers chemical risks of substances** migrating from the contact material to the food,
- **it does not cover other risks** for instance hygiene, risks due to foreign bodies (glass splinters),...
- states that materials and articles, shall be manufactured so that, under normal or foreseeable conditions, they do **not transfer their constituents to food in quantities which could endanger human health**
- **does not require direct food contact**, it is the potential transfer which is important → Contact can be direct or indirect

EU Framework legislation:

Regulation (EC) No 1935/2004

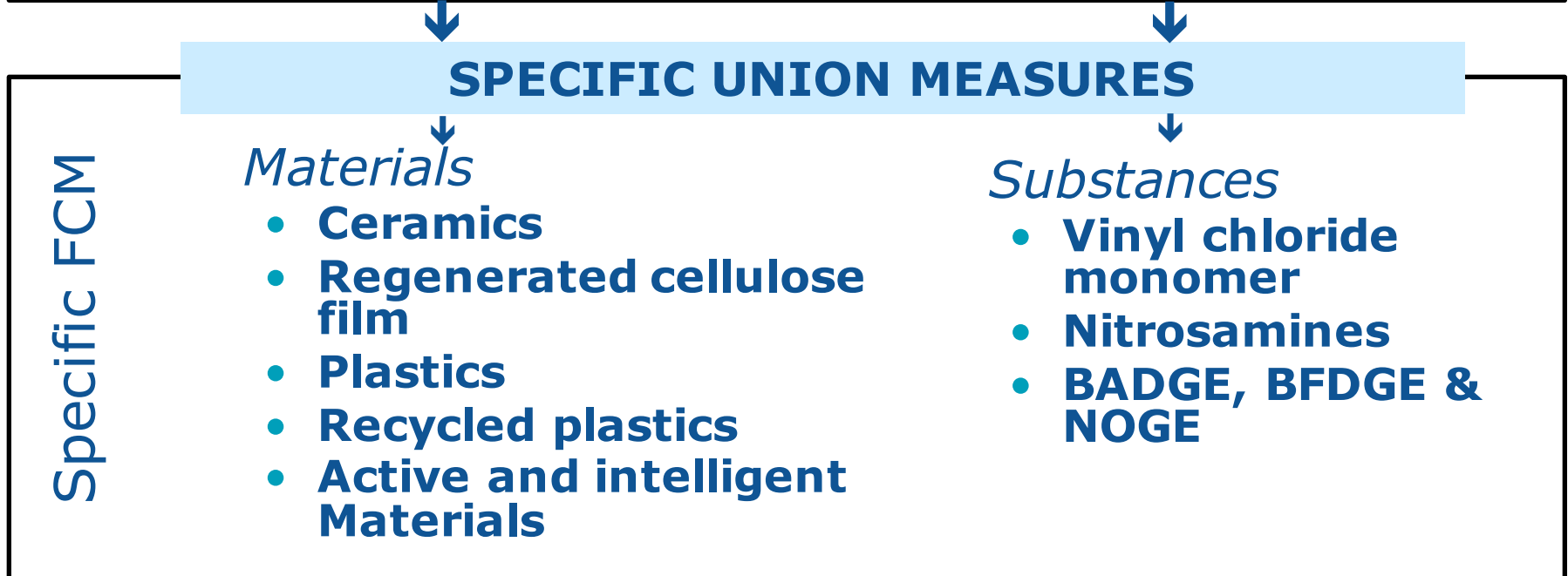
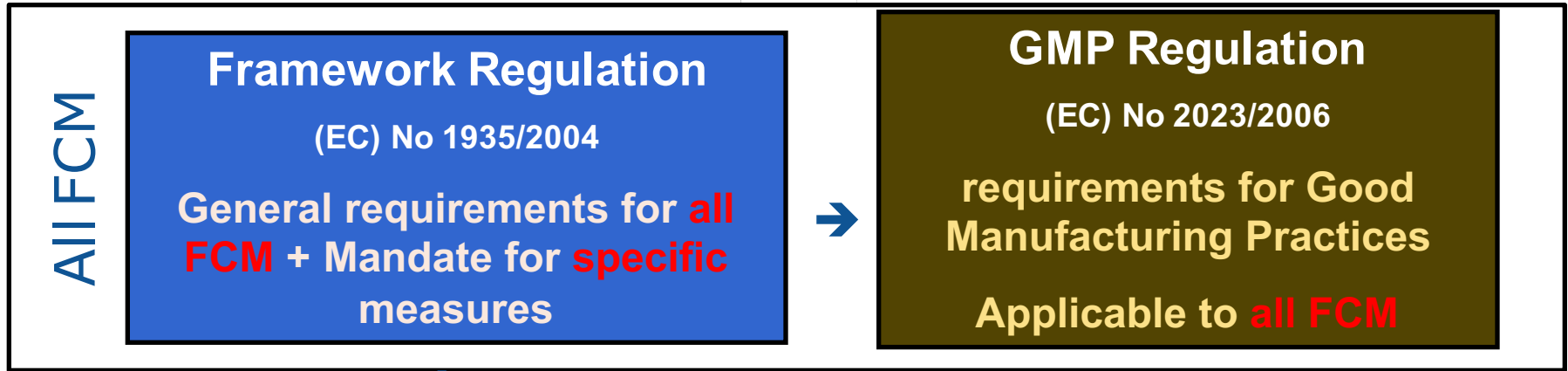
Food contact materials must not:

- **Endanger human health**
- **Bring about an unacceptable change in the composition of the food**
- **Bring about a deterioration in the organoleptic characteristics**

Definitions, specific measures, role of EFSA and authorisation procedure, labelling, traceability, declaration of compliance (DoC)



legislative overview



(national legislation, if existing, applies to materials for which no specific Union measures exist)



Framework Regulation (EC) No 1935/2004

SPECIFIC MEASURES – 'toolkit' provided by the FWR

POSITIVE LISTS

(referred to as '*Union Lists*' in legislation)

- Positive list of plastic monomers and additives
- Positive list of substances in regenerated cellulose film (cellophane)
- List of active and intelligent substances (Future)

individual decisions, registry

Authorization of plastic recycling processes (Future)

RESTRICTIONS OF USE

- Migration limits in plastics
- Leaching limits for cadmium and lead ceramics
- Nitrosamines limits in rubber teats and soothers
- BADGE limits in plastics, coatings and adhesives
- Residual content of substances in plastics or cellophane

PROHIBITION OF USE

- BFDGE and NOGE in plastics, coatings and adhesives
- Bisphenol A in infant feeding bottles
- Certain Phthalates in FCM intended for infants & young children
- **Substances which are not on a Positive list that are not covered by a derogation**



specific measure for plastics

- covers exclusively plastics
- plastic multilayers bound by adhesives
- Plastic layers, coatings forming gaskets
- Plastic layers in multi-materials

All plastics can be coated and/or printed

covered by national legislation

- Adhesives
- Printing Inks
- Coatings



Only substances in Union list can be used to manufacture plastic FCM

- listing only after Safety evaluation by the European Food Safety Authority
- Evaluates the use of the substance in the food contact material
- Non-tox evaluation: focus on use of substance in FCM
- tox evaluation: focus on the toxicity, basis for migration limit
- Evaluation on-going for over 30 years.

Union list



European
Commission

(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 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-trimethylhexane-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.	



Other important provisions of the plastics regulation:

- suitability
- compositional requirements (including migration limits)
- derogations (some substances subject to national law)
- testing procedures
- declaration of compliance + supporting documentation

Plastic recycling

Why regulate recycled plastics?

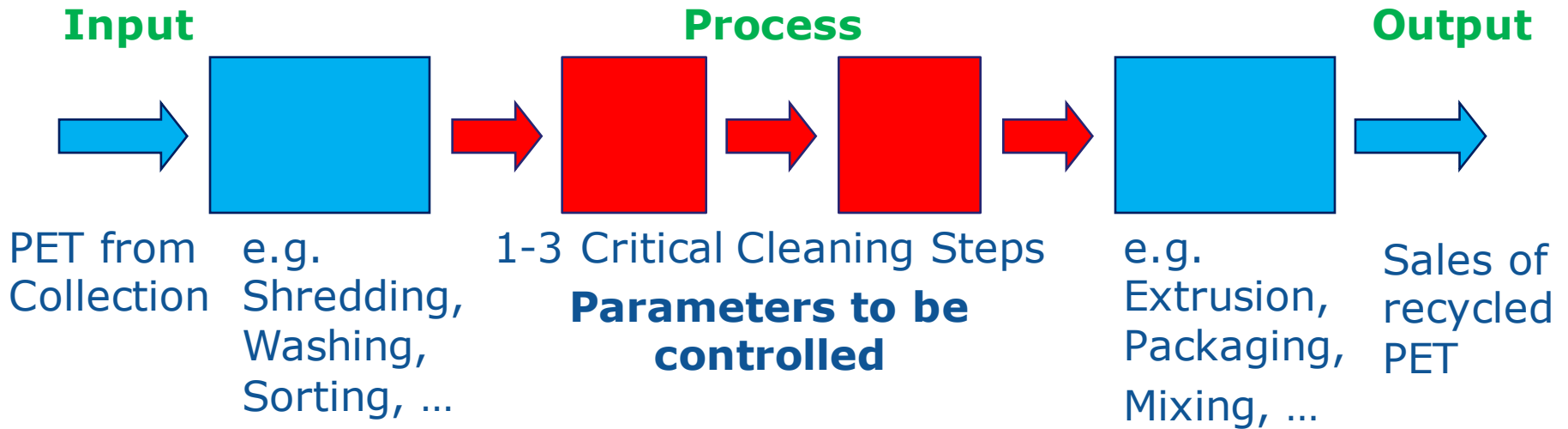
Virgin plastic regulated by 10/2011

However: Plastic packaging waste may contain residues from previous use, contaminants from misuse and contaminants from non-authorised substances



Chemical recycling and recycled plastic behind functional barrier outside the scope of this Regulation

Recycling Process



Critical cleaning steps subject to EFSA evaluation