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:


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

All FCM

Framework Regulation
(EC) No 1935/2004
General requirements for all FCM + Mandate for specific measures

SPECIFIC UNION MEASURES

Materials
- Ceramics
- Regenerated cellulose film
- Plastics
- Recycled plastics
- Active and intelligent Materials

Substances
- Vinyl chloride monomer
- Nitrosamines
- BADGE, BFDGE & NOGE

Specific FCM

GMP Regulation
(EC) No 2023/2006
requirements for Good Manufacturing Practices
Applicable to all FCM

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

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)

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

Individual decisions, registry
Authorization of plastic recycling processes (Future)
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

<table>
<thead>
<tr>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
<th>(7)</th>
<th>(8)</th>
<th>(9)</th>
<th>(10)</th>
<th>(11)</th>
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<tbody>
<tr>
<td>FCM substance No</td>
<td>Ref. No</td>
<td>CAS No</td>
<td>Substance name</td>
<td>Use as additive or polymer production aid (yes/no)</td>
<td>Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)</td>
<td>FRF applicable (yes/no)</td>
<td>SML [mg/kg]</td>
<td>SML(T) [mg/kg]</td>
<td>Group restriction No</td>
<td>Notes on verification of compliance</td>
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<tr>
<td>1</td>
<td>12310</td>
<td>0266309-43-7</td>
<td>albumin</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>12340</td>
<td>—</td>
<td>albumin, coagulated by formaldehyde</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>3</td>
<td>12375</td>
<td>—</td>
<td>alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_22)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>22332</td>
<td>—</td>
<td>mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>(17)</td>
<td>1 mg/kg in final product expressed as isocyanate moiety.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>25360</td>
<td>—</td>
<td>trialkyl(C_2-C_15)acetic acid, 2,3-epoxypropyl ester</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>ND</td>
<td>1 mg/kg in final product expressed as epoxycation. Molecular weight is 43 Da.</td>
<td></td>
<td></td>
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</tbody>
</table>
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
Critical cleaning steps subject to EFSA evaluation