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Key factors for compliance of printed Food Contact Materials

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Food Contact Materials ...

- Food Contact Materials (FCM) are complex high-tech products:
 - Mechanical protection
 - Product information
 - Functionality
 - Sustainability
 - Attractiveness
 - Decorative and



No negative organoleptic impact on odour / taste
during filling, storage and transport!



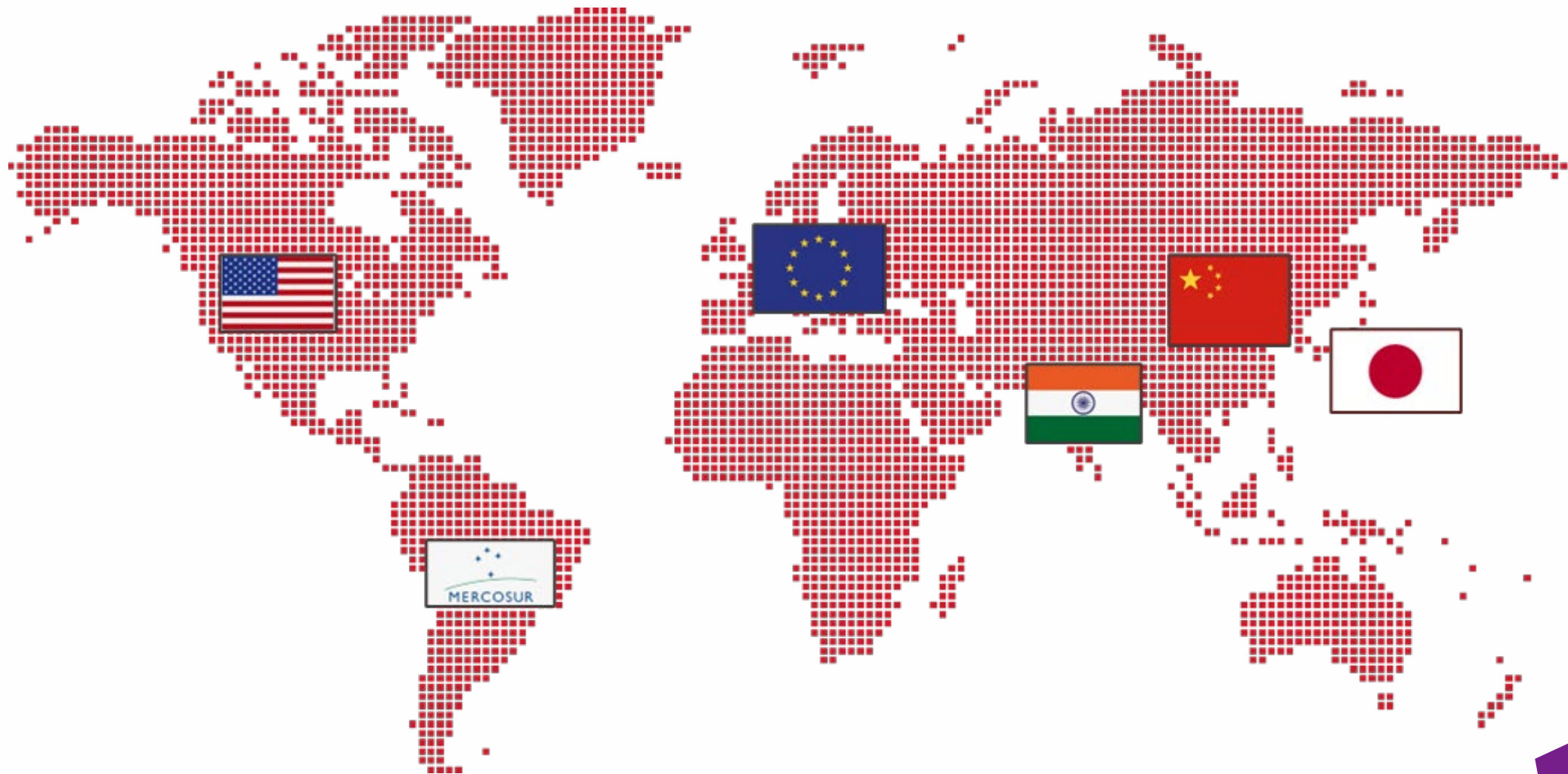
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Worldwide regulations

Overview of statutory provisions worldwide



Overview of statutory provisions worldwide: USA



- Food and Drug Administration (FDA)
Code of Federal Regulations (CFR) Title 21
- FDA section 21 CFR 110.80 "Current Good manufacturing practice in manufacturing, packing, or holding human food" requires that the **packed food must not be "adulterated"**
- Safety of substance based on **exposure** on diet, correlated to kind of packaging used and migration
- **No specific provision for inks.** Converter should evaluate impact of inks based on information provided by printing ink manufacturer

Overview of statutory provisions worldwide: South America

- Mercosur FCM regulation approach equivalent to European no-migration principle

- **Resolución GMC N° 03/92 – “Framework regulation”:**

- No transfer of harmful or toxic compounds from packaging to food
- No unacceptable change in food composition, taste or odor
- FCM’s manufactured in accordance with GMP



- **Resolución GMC N° 56/92** (last amended with No 20/21):

- OML = 60 mg/kg or 10 mg/dm
- Specific Migration Limits (SML’s) must be met

- **Resolución GMC N° 02/12 – “Plastic regulation”** (last amended with No 19/21):

- Positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic containers and equipment in contact with foodstuffs

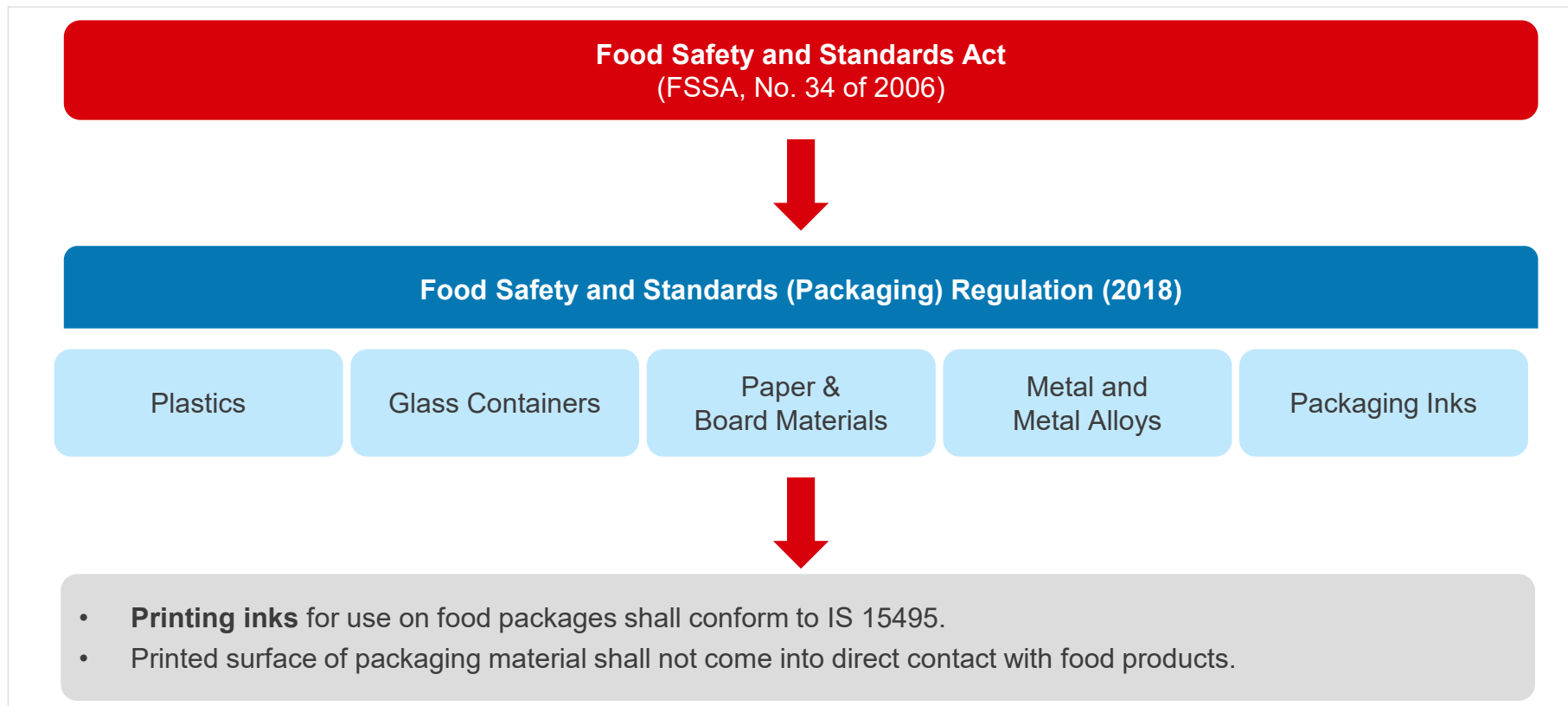
Overview of statutory provisions worldwide: China

- National Standards for Food Contact Materials & Articles
- GB 4806.1: General Safety Requirements
- GB 9685: Standard for Uses of Additives in FCMs & Articles
 - Chapter A4: Printing inks
- GB 31603: General Hygienic Standard for Production of FCMs & Art.
- GB 4806.14-2023: Inks used for FCMs and Articles
 - Come into force September 2024

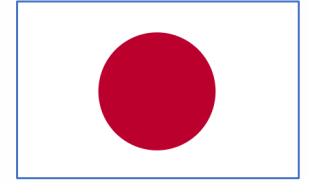


Overview of statutory provisions worldwide: India

- India: Food Safety and Standard Authority of India (FSSAI)
Food Safety and Standards (Packaging) Regulation



Overview of statutory provisions worldwide: Japan



- Japanese Positive List (April 2020)
- Covers polymers, monomers and additives used in synthetic resins which are permitted in Food Contact Materials
- Printing inks are not directly affected and rules apply to the finished packaging as a whole
- Voluntary regulation concerning printing inks issued by the Japan Printing Ink Makers Association (“JPIMA Negative List”) existing; latest version: May 2020



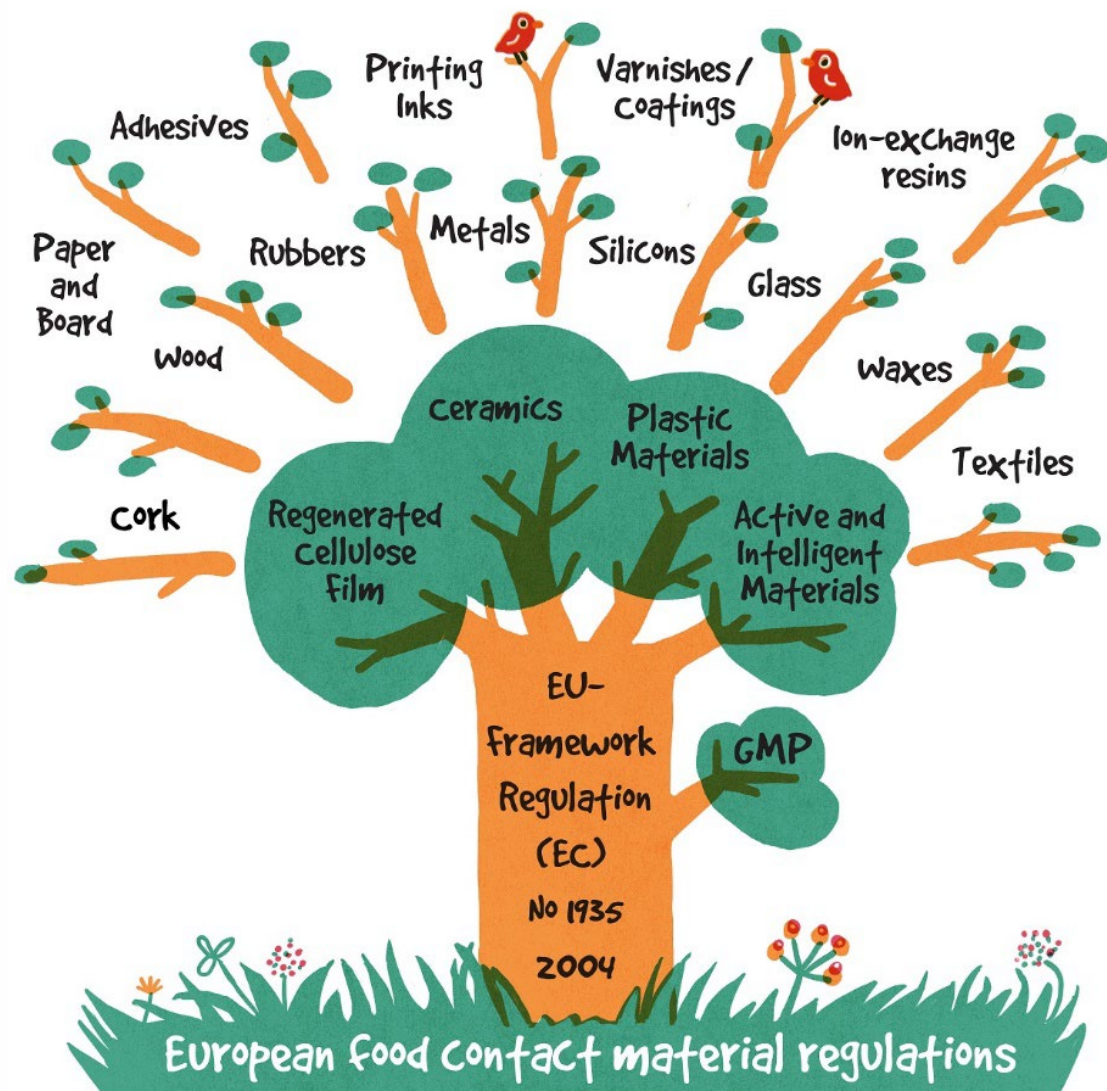
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Europe

European Food Contact Material Regulations



Shoots at the top:
Materials not regulated yet

Treetop:

Specific measures for groups of materials

- Regenerated Cellulose Film 2007/42/EC
- Plastic Materials (EU) No 10/2011
- Ceramics 84/500/EEC
- Active and Intelligent Materials (EC) No 450/2009

Trunk of the Tree:

EU-Framework Regulation
(EC) No 1935/2004

European Food Contact Material Regulations

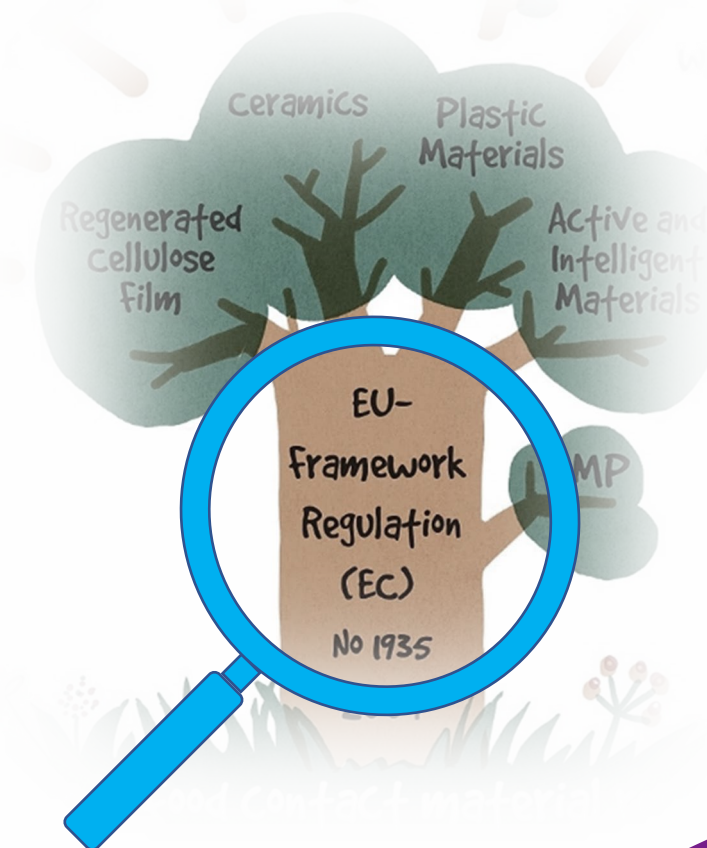
The Trunk of the Regulation Tree

Framework regulation (EC) No 1935/2004
for all materials in contact with food

Art. 3:

Materials shall be manufactured in compliance with GMP
No transfer of substances to the food which could

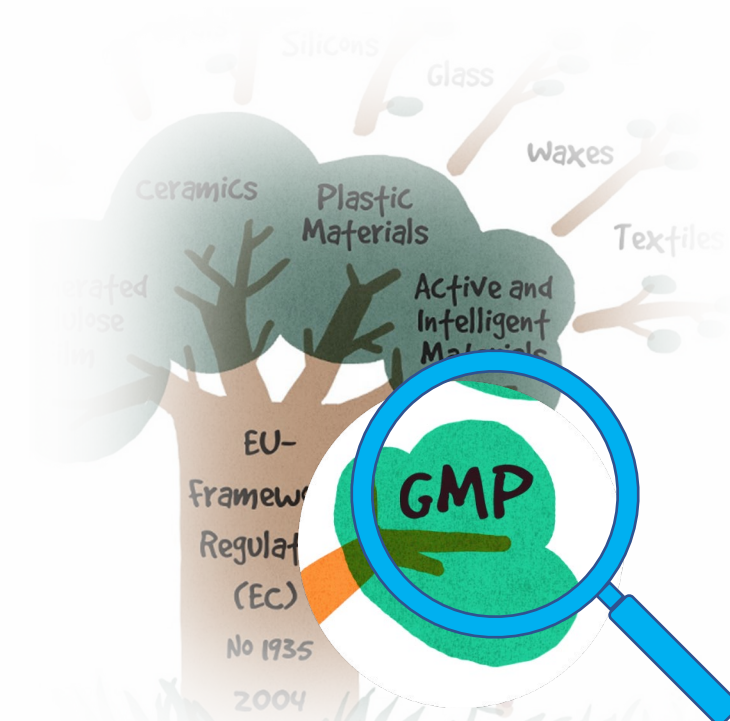
- endanger human health
- bring a change in composition of the food
- bring a deterioration in the organoleptic characteristics



European Food Contact Material Regulations

Regulation (EC) No 2023/2006 on **Good Manufacturing Practice** for materials in contact with food

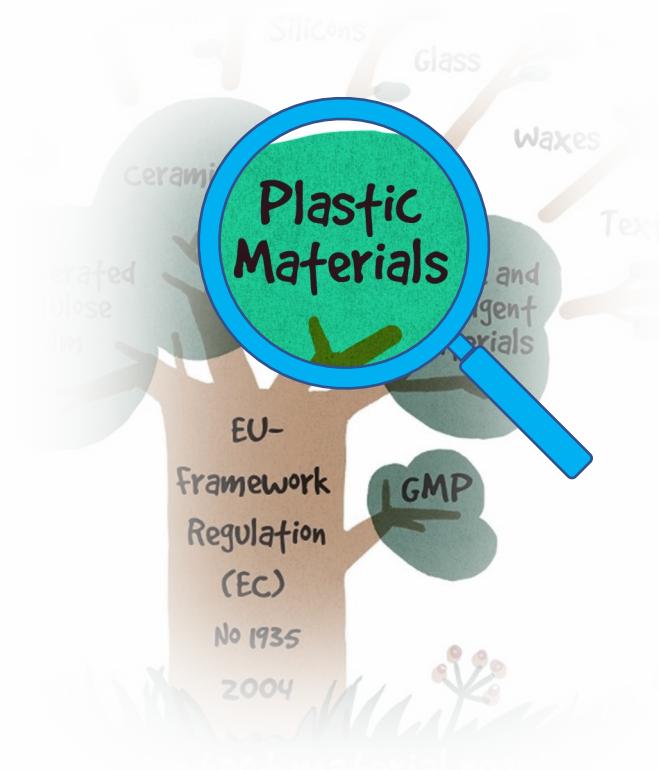
- Effective quality management system
- Material selection according to pre-established specifications
- Operations according to pre-established procedures
- The printed surface shall not come into direct contact with food
- Migration and invisible set-off below limits
- Documentation of compliance available for the authorities



European Food Contact Material Regulations

Regulation (EU) No 10/2011 on plastic materials intended for contact with food

- Only for materials made of plastic (printing inks are not in scope regarding their chemical composition)
- Positive list of evaluated substances
- Rules for migration testing
- Migration limits:
 - SML: Specific Migration Limit for single substances in mg/kg food
 - Overall Migration Limit: total migration limit for the ready material
- Risk assessment of substances not listed in Annex I (10/2011) to prove compliance with Art. 3 of Framework Regulation (EC) 1935/2004
- Declaration of compliance mandatory



European Food Contact Material Regulations

- EFSA opinions, national recommendations (e.g. of German BfR), resolutions and other documents may be relevant.
- Many converters have their own (individual) requirements.
- Some brand owners go far beyond the law with their own guidelines and questionnaires.

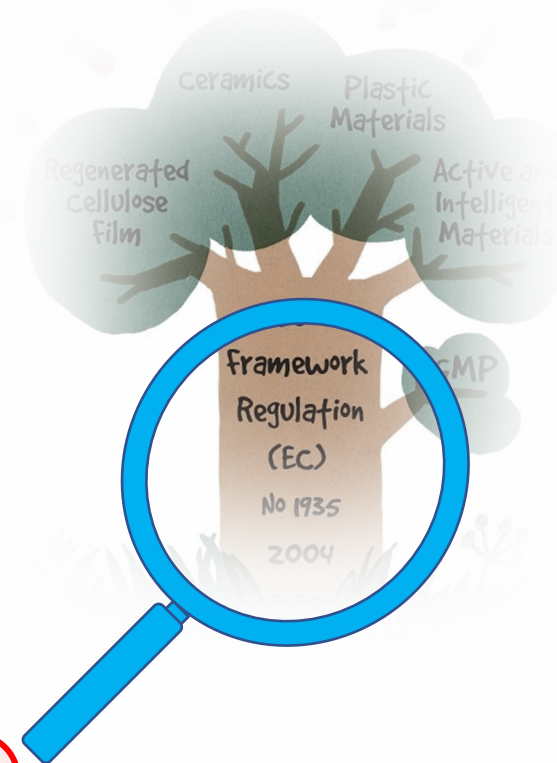


Outlook: What is happening at EU level?

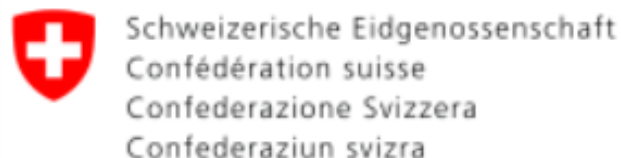
Complete revision of the Framework Regulation

- Focus on the final article
- Prioritisation of substances based on hazard (CMR, ED, etc.)
- Improving communication along the supply chain and enabling strong enforcement and high compliance
- Supporting more sustainable alternatives

Initial schedule is significantly delayed! Work on a specific measure on printed food contact materials (pFCM) is currently not in sight



Swiss Consumer Goods Ordinance



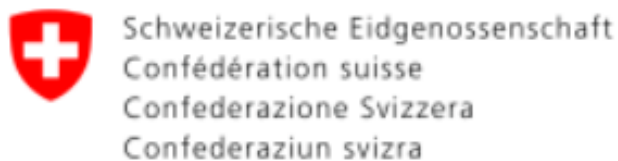
Federal Food Safety and Veterinary
Office

Swiss Ordinance on Materials and Articles In Contact with Food (SR 817.023.21)

Section 12 “Printing Inks” applied on the non-food contact surface of food contact materials (FCM)

- Printing inks shall only be formulated with substances listed in Annex 2 or Annex 10.
- The existing limits shall not be exceeded.
- *Migration of substances listed in Annex 10 Part B shall not exceed 0.01 mg/kg.*

Swiss Consumer Goods Ordinance



Federal Food Safety and Veterinary
Office

Revision 2024

- Deletion of all Part B substances
 - Non-listed substances shall only be used if
 - Migration is not detectable (detection limit: 0,01 mg/kg; if no specific detection limit applies)
 - Not classified as CMR in accordance with Swiss Chemical Ordinance
- Introduction of Declaration of Conformity (DoC) for printing inks
 - EuPIA Statement of Composition (SoC) fulfils the requirements

German Ink Ordinance (GIO) – In a Nutshell



- It is a German **national legislation** and although it is colloquially called “ink ordinance” it has **printed food contact materials** in focus
 - Printed food contact materials in direct (incl. transient) as well as indirect food contact
- Stipulates **constitutional requirements** for printing inks
- The **compliance** with the provisions **needs to be demonstrated for the final article**
- A **transition period** applies until 1st January 2026
 - During the transition period the requirements for printing inks intended for food contact materials remain unchanged

The GIO – DFC: Direct Food Contact Inks

Permitted substances for manufacture of printing inks

- **Substances listed in Table 14.1**
- **Substances from the Union List (Plastic Regulation) - if no restrictions**

DFC inks with non intended, but foreseeable food contact:
additionally pigments according table 14.2 until the end of the 5-year transition period (31.12.2026)

- e.g. Pigment Orange 34, Pigment Red 254, Pigment Yellow 174, etc.

The GIO – Non-DFC Inks

- Same rules as for DFC inks and in addition:
- **Non-listed substances** might be used if they are **not classified as CMR** (according to CLP) and a migration into food must **not be detectable**
 - Accepted non-detection limit (except for nanomaterials): **0,01 mg/kg** of food
- If substances are present as NIAS which are not listed then compliance to Art. 3 needs to be demonstrated
 - The manufacturer of the printed food contact material has to demonstrate compliance of NIAS
 - Ink manufacturers apply the EuPIA NIAS Guidance for the evaluation of NIAS and provide necessary information to assist downstream users

The GIO – Outlook

- Downside of the positive list concept: to complete the positive list, **dossiers according EFSA note for guidance need to be submitted** to the German BfR, which contain information on toxicology and worst-case migration.
- Data-owners are typically the **raw material suppliers**, hence they need to compile the dossiers
- EuPIA members and converters support the raw material suppliers as much as possible.

The GIO – Outlook

- Addition of new substances turns out to be a lengthy and uncertain process
 - extensive and unpredictable data requirements by BfR increase the expenditures for suppliers, hence only limited interest to start new processes
- No real development since the publication of the GIO, hence it can be doubted that the positive list will be significantly amended by 2026
- Although many important raw materials are still missing on the list, it should be possible for most applications to offer suitable printing inks in good time. Performance restrictions of the reformulated products cannot be ruled out.
- The regulation does not contain any requirements for the information exchange along the supply chain.

Close to the deadline, VdL will again host webinars on the status of the GIO



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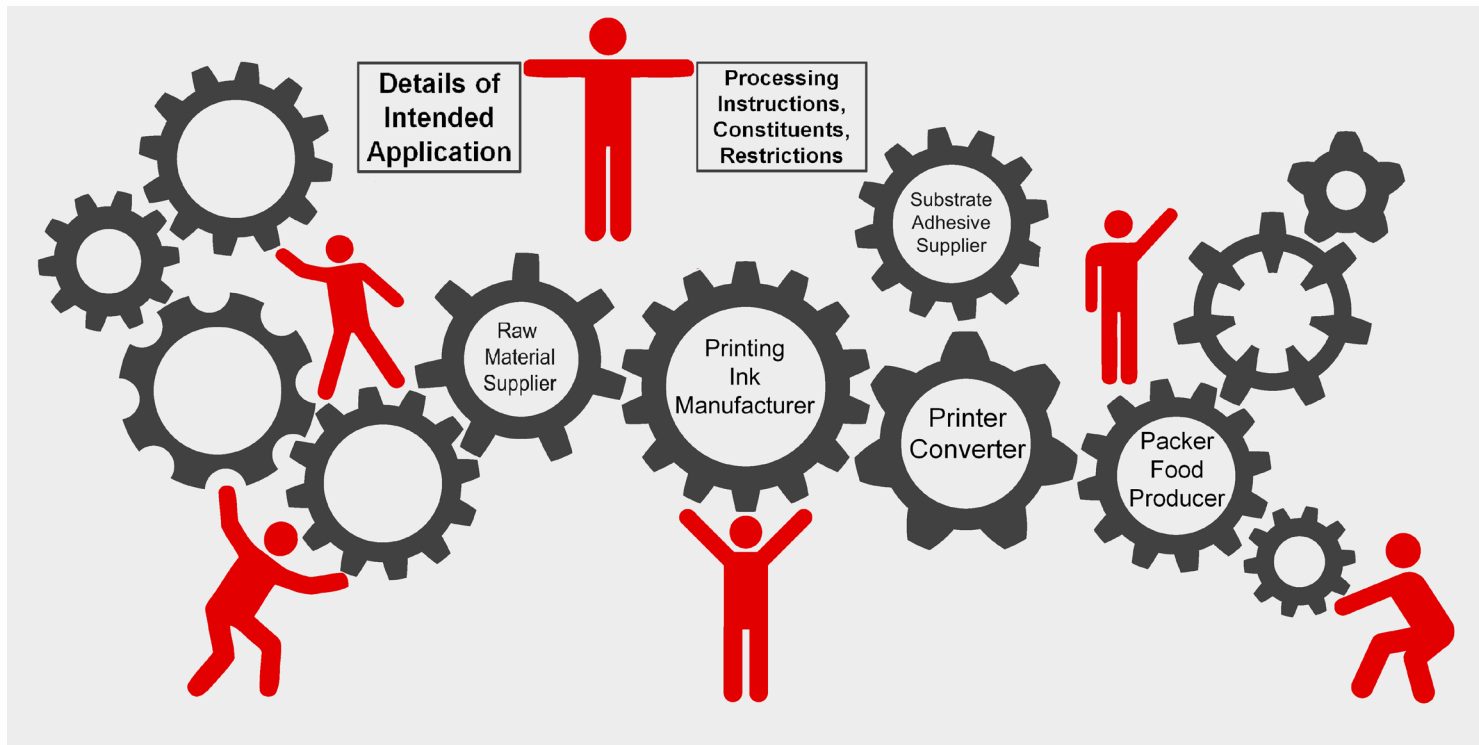
EuPIA concepts

FCM inks: The three Pillars of Compliance

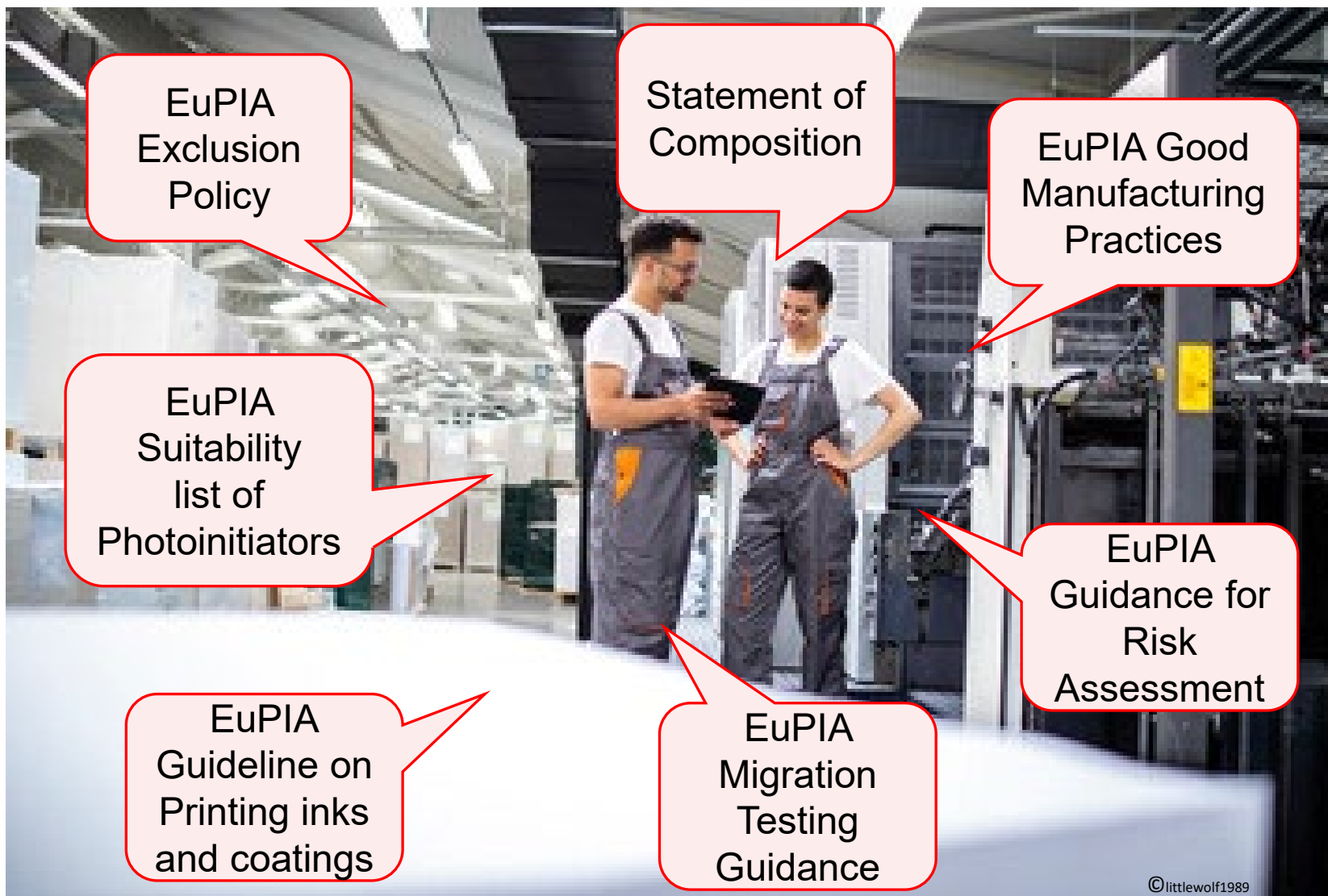


Beyond legal compliance

- As we have seen before, printing inks for food packaging are almost not regulated
- Cooperation and information sharing among all partners in the food packaging supply chain is necessary to fill the gaps



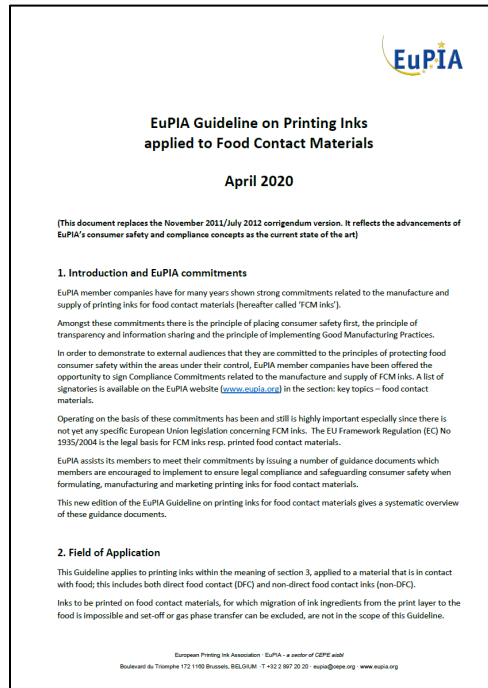
EuPIA concepts to overcome the regulatory gaps



EuPIA concepts: Printing Inks for Food packaging are safe!



EuPIA members supply their customers with all necessary data to do their compliance work for the finished food packaging



- EuPIA Exclusion Policy
- Guideline on Printing Inks applied to Food Contact Materials
- EuPIA Good Manufacturing Practice
- EuPIA Guidance on Migration Test Methods
- EuPIA Suitability List of Photo-Initiators
- EuPIA Guidance for RA of NIAS/NLS
- Statements of Composition
- ...

EuPIA Exclusion Policy for Printing Inks and Related Products

Criteria (hazard categories) for exclusion of a raw material

GROUP A

Acute Toxicity Cat. 1 & 2 [H300, H310, H330]

Acute Toxicity Cat. 3 (inhalation)
[H331]

Carcinogen or Mutagen Cat. 1A & 1B
[H350, H340]

STOT Single Exposure Cat. 1 [H370]

GROUP B

Acute Toxicity Cat. 3 (oral, dermal)
[H301, H311]

Toxic to Reproduction Cat. 1A & 1B [H360]

STOT Repeated Exposure Cat. 1 [H372]

Endocrine Disruptor for Human Health Cat. 1
[EUH380]

Valid for all printing
inks and related
products

Substitution principle by default

If substitution not possible in the short term, exemption is possible according to the clearly defined and managed procedure for a limited period of time

EuPIA Guideline on Printing Inks applied to Food Contact Materials



- **Scope**

Printing Inks and Coatings applied to a material that is in contact with food; this includes both direct food contact (DFC) and non-direct food contact inks (non-DFC).

In the absence of detailed regulations, the framework directive (EC) No. 1935/2004 is interpreted here for our products.

- **Content**

- General Requirements for FCM inks
- Selection Criteria for Raw Materials
- ...

For ink and coating manufacturers

EuPIA Good Manufacturing Practice (GMP) / 1

- **Legal background**
Regulation (EC) No 2023/2006 (does not cover DFC)
- **Scope**
Production of printing Inks and Coatings for Food Contact Materials, incl. DFC
- **Definition**
 - GMP is meant as a useful and specific extension of management system standards such as EN ISO 9001
 - GMP is not meant as an independent management system standard
- **Content**
 - Requirements and Measures to produce FCM Inks and Coatings to meet customer and applicable regulatory obligations

EuPIA Good Manufacturing Practice (GMP) / 2

- Specific Measures and Procedures are described for ...
 - General requirements (Quality Management, Equipment, ...)
 - Risk Assessment and Management (FMEA, Migration and Worst Case Calculation ...)
 - Hygiene Management
 - Identification, Traceability and Recall
 - Change Management
 - Resource Management (Raw Material Selection Scheme, ...)
 - Product Realisation (Product selector, ...)
 - Measurement, Analysis and Improvement

EuPIA Suitability List of Photoinitiators and Photosynergists for Food Contact Materials

- The Suitability List is widely referenced by the supply chain and by brand owners as a requirement for energy curing inks and coatings for their food packaging
- The list is regularly updated to reflect the current Swiss Ink Ordinance and remove materials which became subject to the EuPIA Exclusion Policy over the time

Contains a procedure how new materials can qualify for listing and the status of existing materials

EuPIA Guidance on Migration Test Methods

Specific guidance for printing inks for FCMs (non-DFC and DFC)

Recommended methods:

- Worst case calculation and migration modelling
 - Migration testing (preparation of test samples, selecting migration parameters, analytical identification and quantification)
- aimed to provide appropriate methods, conditions and parameters for indicative migration testing

EuPIA Guidance for NIAS Risk Assessment

- An IAS can become a NIAS down the packaging chain
- NIAS risk assessments are foreseen for substances which have not been officially evaluated yet
- 10 ppb limit is a detection limit not based on any hazard assessment
- Higher safety due to:
 - Identification of substances with genotoxic potential
 - Self-derived SMLs instead of detection limits
- Declaration of NIAS in the SoC



The Statement of Composition (SoC)

- Includes a table of potential migrants that are "used or known to be present", including known NIAS (non-intentionally added substances) and NLS (non-listed substances)
- Is in accordance with the "Recommendation for Adequate Information for a Non-Plastic Intermediate Material (inks, adhesives, coatings) ", from the Union Guidance to Regulation (EU) No. 10/2011
- A "Customer Guidance Note" is available from EuPIA

SoC: example Bis(2-ethylhexyl)adipat

- 1. example: Bis(2-ethylhexyl)adipate (M = 371 g/mol)
Plasticizer frequently used in printing inks

As of 2026: New column indicating listing status in the GIO.

CAS-No	PM/FCM Ref-No	Name	Restrictions and specific migration limits (SML) [mg/kg]			Regulations (EC) No 1333/2008 1334/2008 [E, FL # or No]	For non-volatile/non-reactive substances: Maximum amount in dried ink film [%]	Comments <i>[e.g. on presence of volatile/reactive substances; in this case, a footnote should be included such as "The amount of these (volatile/reactive) substances in the dried ink film and/or the final packaging is under control of converter"]</i>
			Regulation (EU) No 10/2011	GIO BedGgstV <i>[either "SML" or "<10ppb"]</i>	Swiss Ordinance 817.023.21 <i>[either "SML" or "part B."]</i>			
103-23-1	31920 / 207	Bis(2-ethylhexyl)adipat	18	18	18		5	
925246-00-0	-	2-({2-[4-(dimethylamino)benzoyloxy]ethyl}(methylamino)ethyl 4-(dimethylamino) benzoate	-	0.05	0.05		-	Reactive substance
								For NIAS: Result of NIAS-Risk Assessment

SoC: example reactive substances

- 2. example: A198 (M = 414 g/mol)
Photosynergist used in UV inks

As of 2026: New column indicating listing status in the GIO.

CAS-No	PM/FCM Ref-No	Name	Restrictions and specific migration limits (SML) [mg/kg]			Regulations (EC) No 1333/2008 [E, FL # or No]	For non-volatile/non-reactive substances: Maximum amount in dried ink film [%]	Comments [e.g. on presence of volatile/reactive substances; in this case, a footnote should be included such as "The amount of these (volatile/reactive) substances in the dried ink film and/or the final packaging is under control of converter"]
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For NIAS:
Result of NIAS-Risk Assessment

Summary

- The world is split into regions with all kinds of different regulations for food packaging compliance
- Even in Europe we have everything, from detailed regulations for plastic materials to no regulation for printing inks, plus national regulations (as an interim solution?)
- Industry, like EuPIA, tries to fill these gaps with different papers and rules on food contact materials made with inks and coatings, for their members and customers
- In the future it is planned to regulate these areas completely on an EU level. Until then, our own concepts will help the supply chain to produce safe and compliant food packaging



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