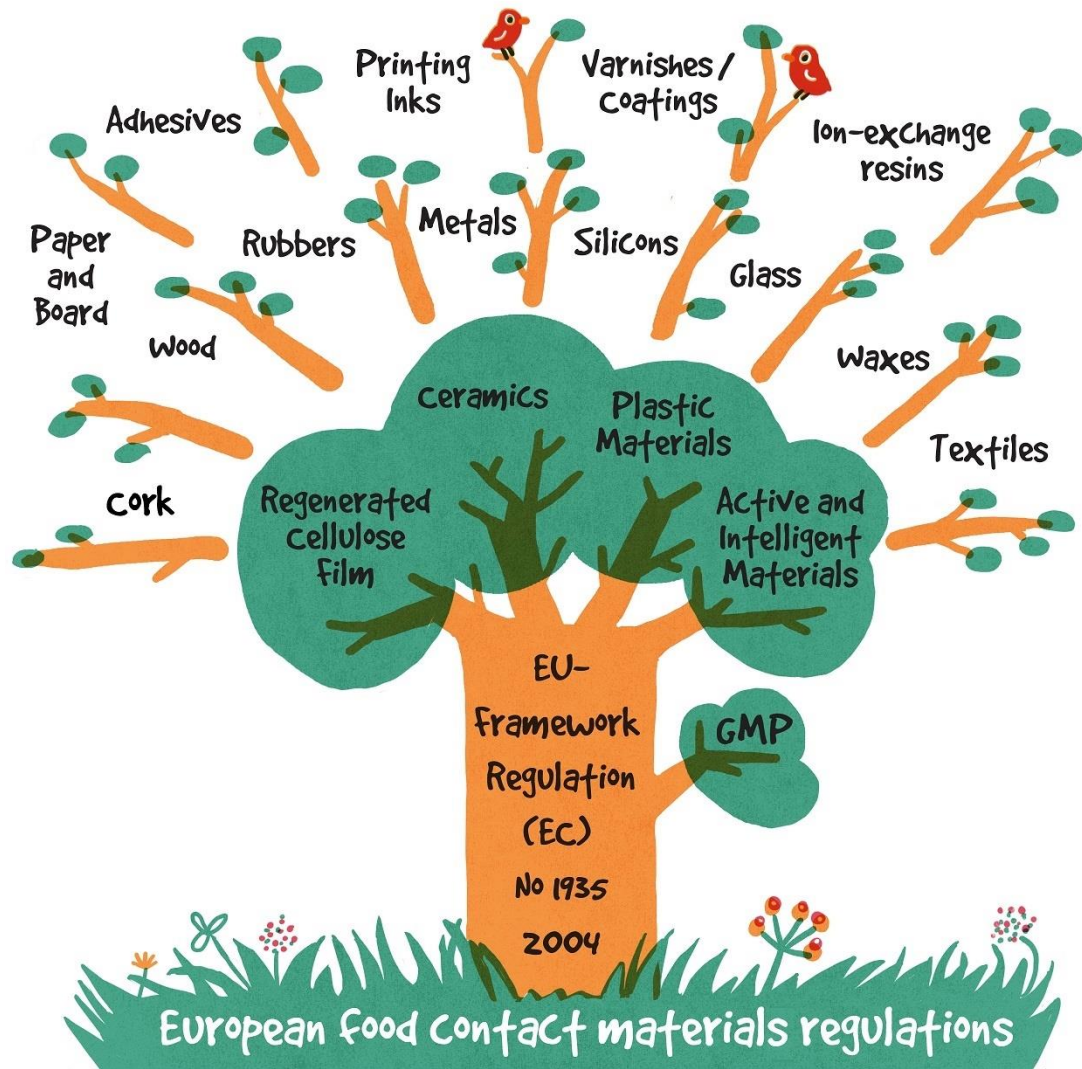


Key factors for compliance of printed Food Contact Materials



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!**





Shoots at the top:

Materials not regulated specifically 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

The Trunk of the Regulation Tree

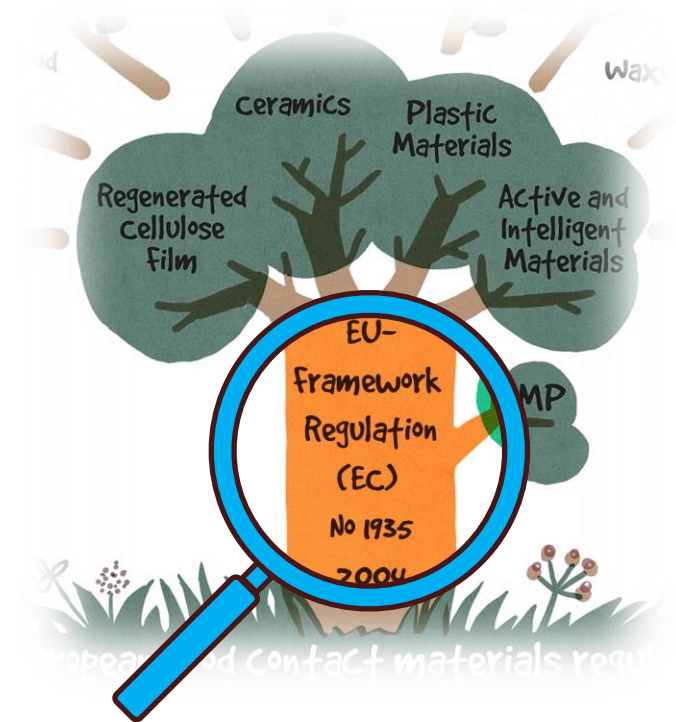
Framework regulation **(EC) No 1935/2004** for all materials in contact with food

Art. 3:

Materials shall be manufactured in compliance with GMP

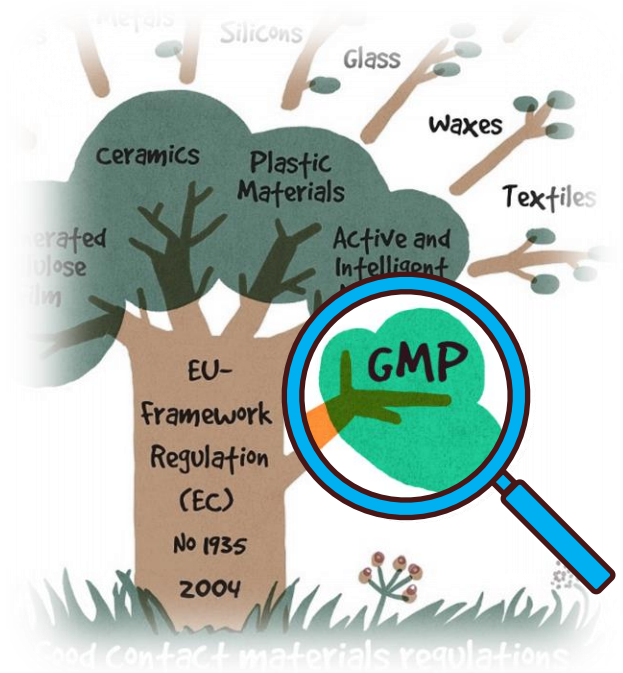
No transfer of substances to the food which could

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



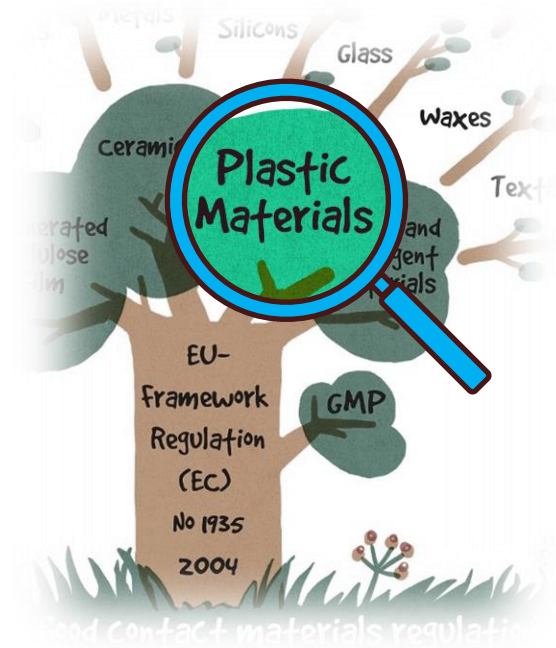
Regulation (EC) No 2023/2006 on **Good Manufacturing Practice** for materials in contact with food

- 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



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 lists 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



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.
- Inks must be manufactured and applied according to GMP.
- Revision 1.1 in force since 1st May 2017 with a transition period of four years for printing inks.
- Update of Annex 10 (Coming into force 1st December 2019 with 1 year transition period).

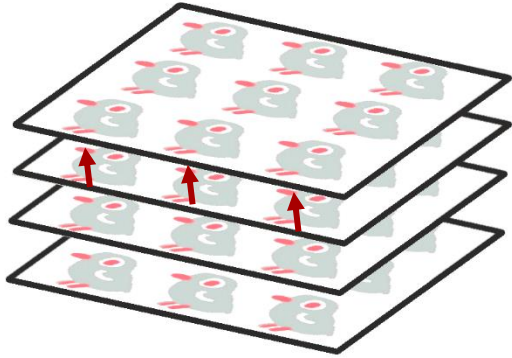
- EFSA opinions, national recommendations (e.g. of German BfR), resolutions and other documents may be relevant.
- Many customers have their own (individual) requirements.
- Some brand owners go far beyond the law with their own guidelines and questionnaires.



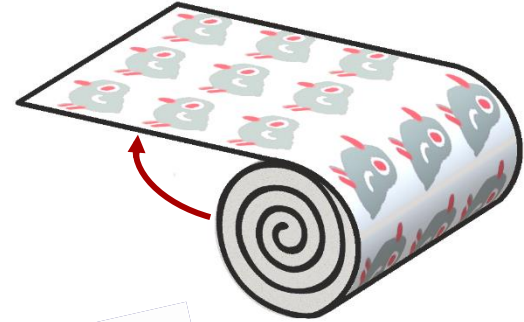
European Food Contact Material Regulations

- 1. Step: Evaluation and Fitness Check of the current status of all legislations relevant to FCM. Result: Current framework largely fit for purpose, although important materials (e.g. Paper) remain non harmonized. Enforcement is considered unsatisfactory.
- 2. Step: Based on results, derive and initiate necessary measures for harmonisation. COM is expected to communicate later in 2021 the next steps (e.g. regulation for printed food contact materials).

- Migration by Set-Off:



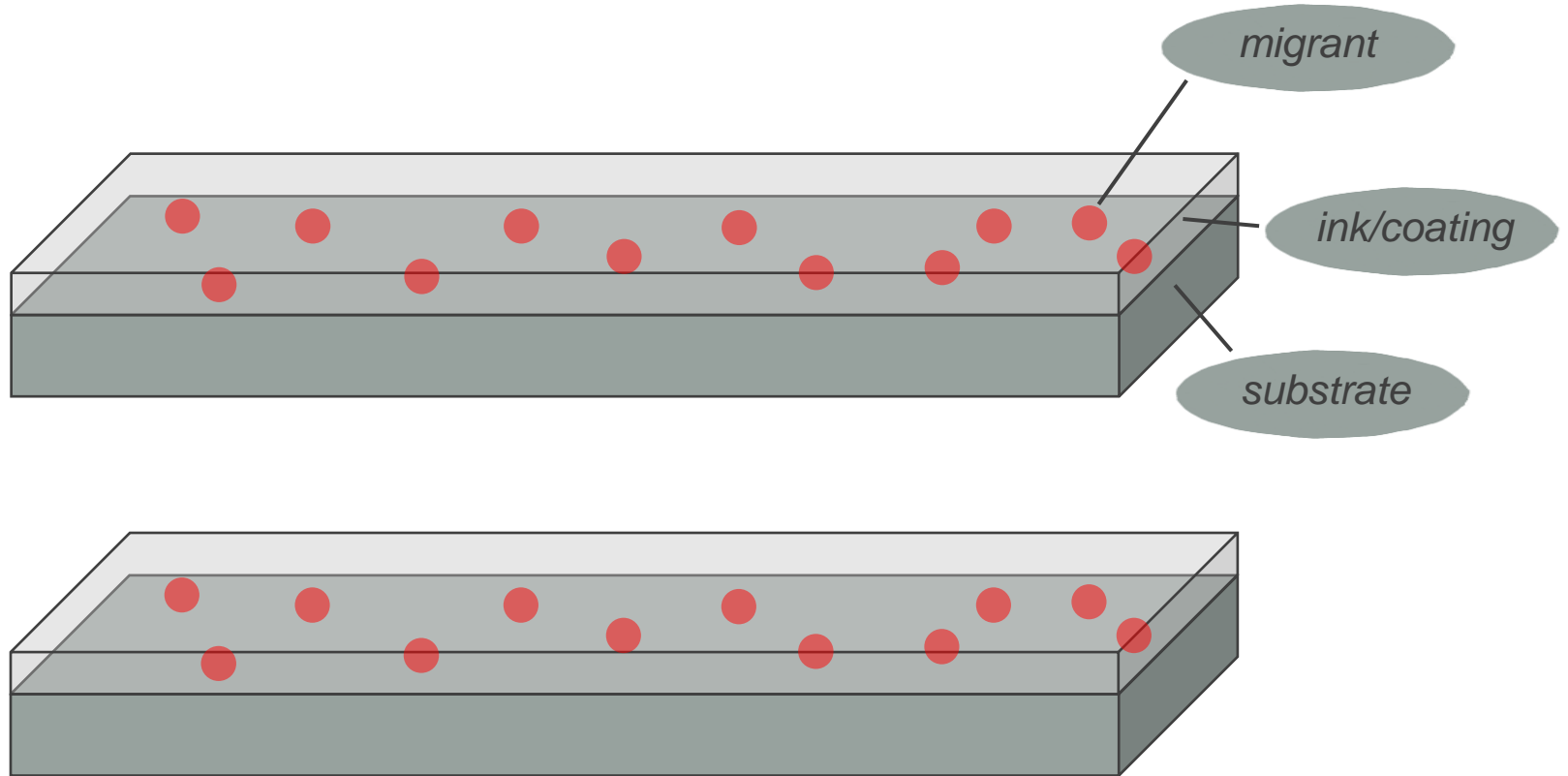
stack or reel



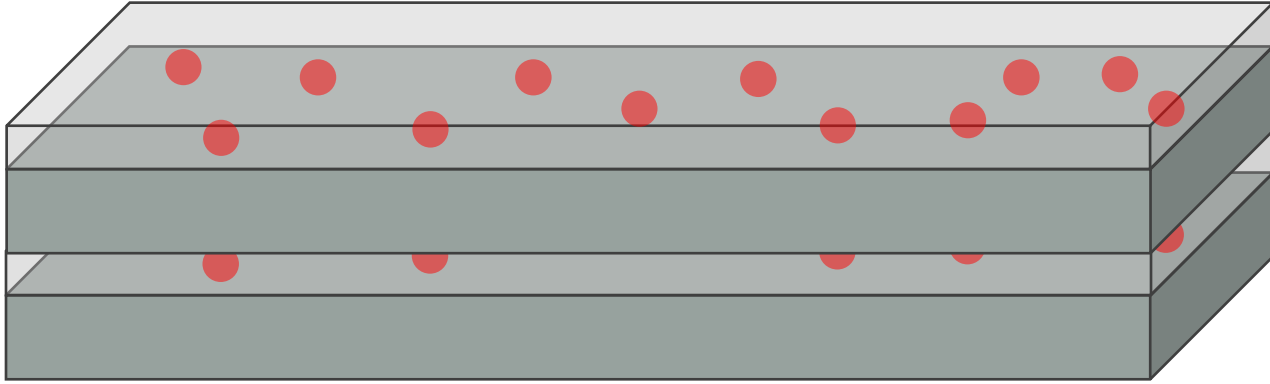
- Mass transfer within the packaging (migration) and into the packaging (diffusion):



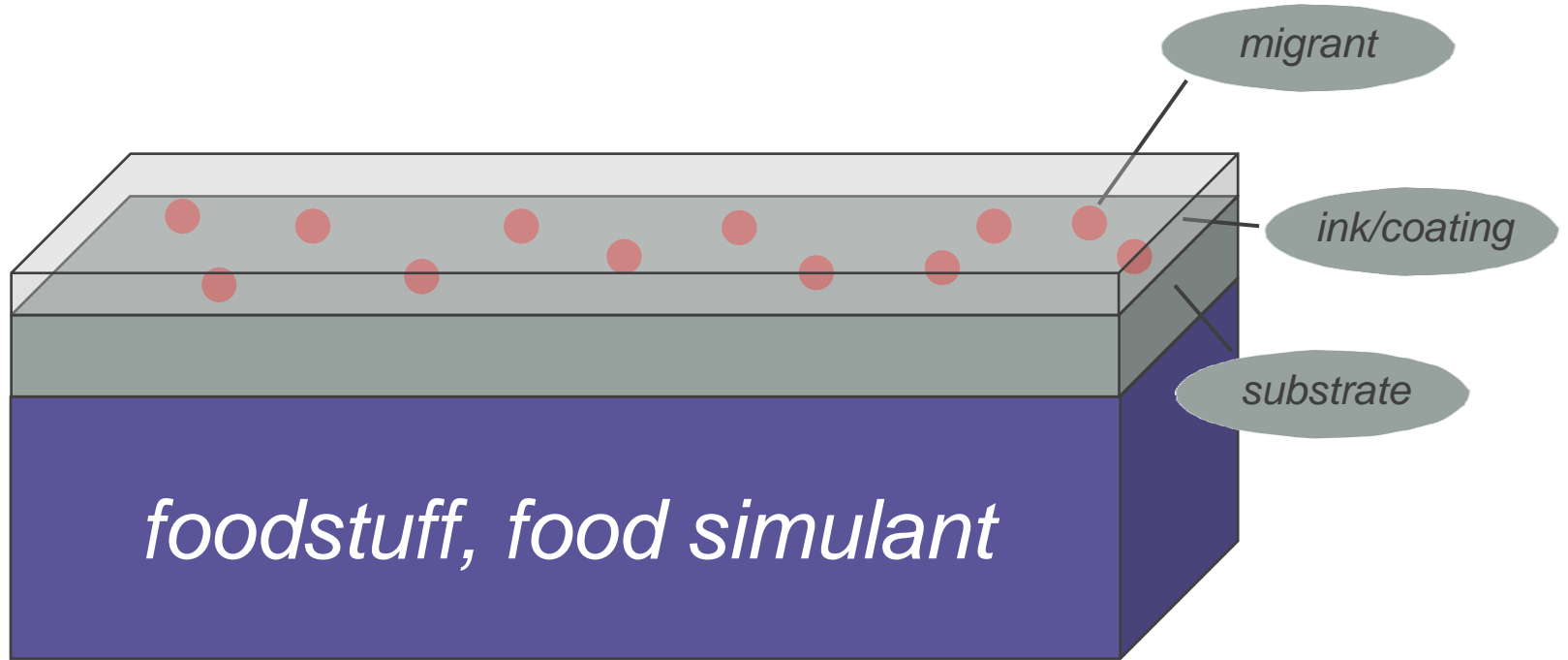
Set-Off during Production, Filling and Storage



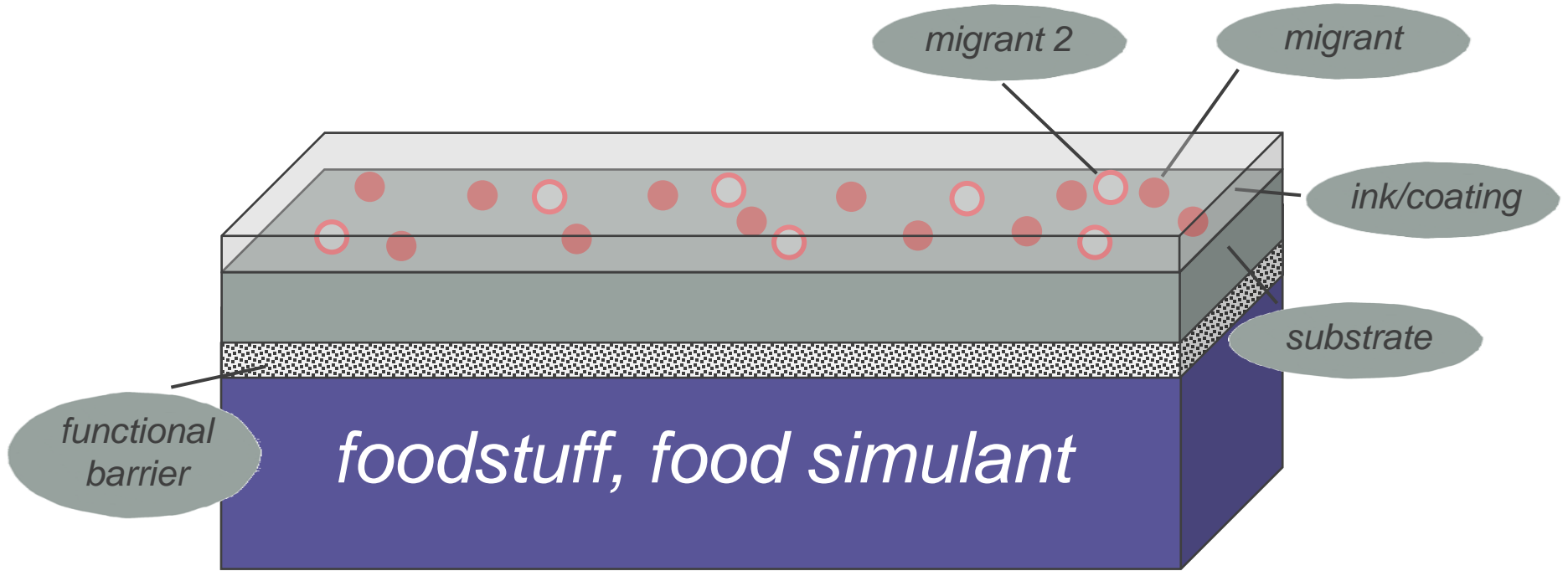
Set-Off during Production, Filling and Storage



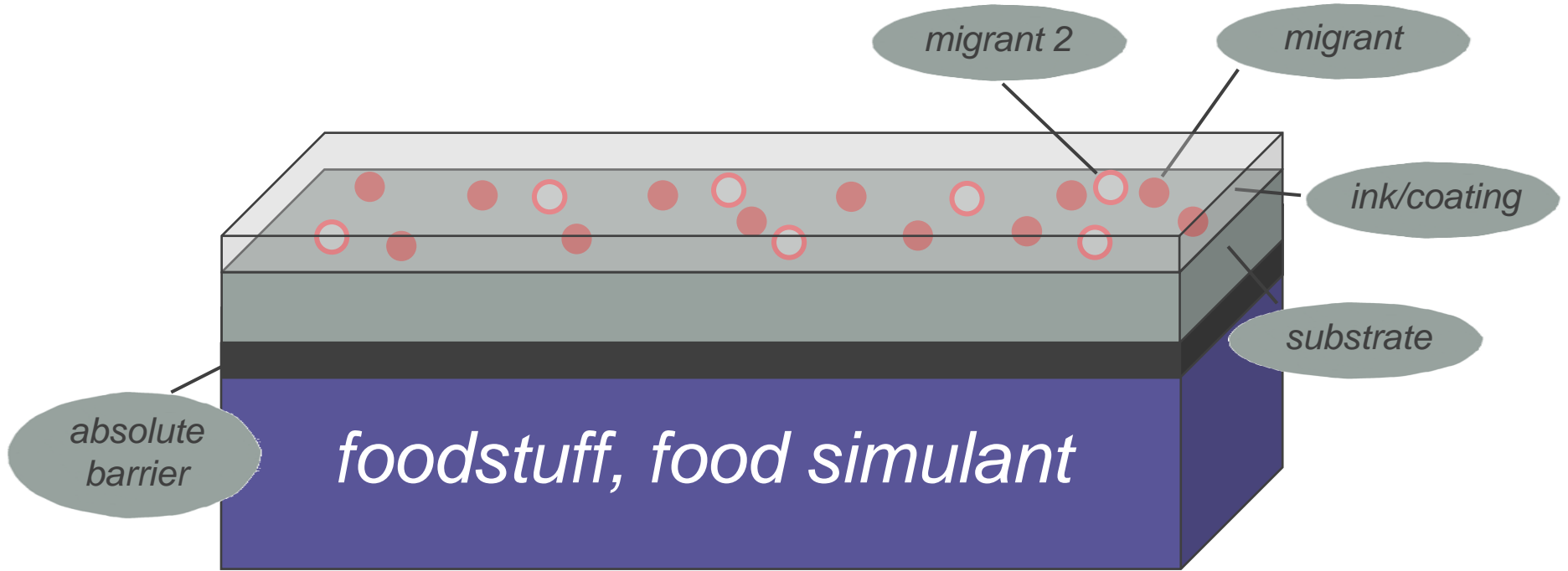
Migration – Mass Transfer inside the Packaging



Reduction of Mass Transfer - Functional Barrier



Avoidance of Mass Transfer - Absolute Barrier



Overview of statutory provisions worldwide

Food and Drug Administration (FDA)
Code of Federal Regulations (CFR) Title 21

Technical Regulations of the
Customs Union on Packaging Safety



USA

Russia

National Food
Safety Standards

China

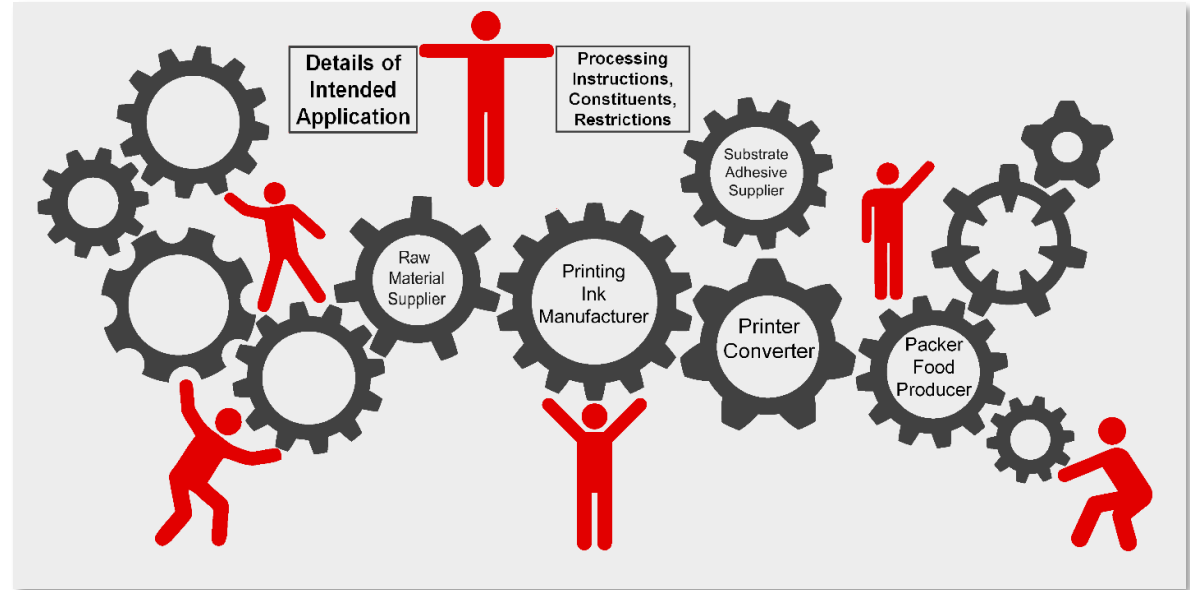
MERCOSUR
(Mercado Común Del Sur)

**South
America**

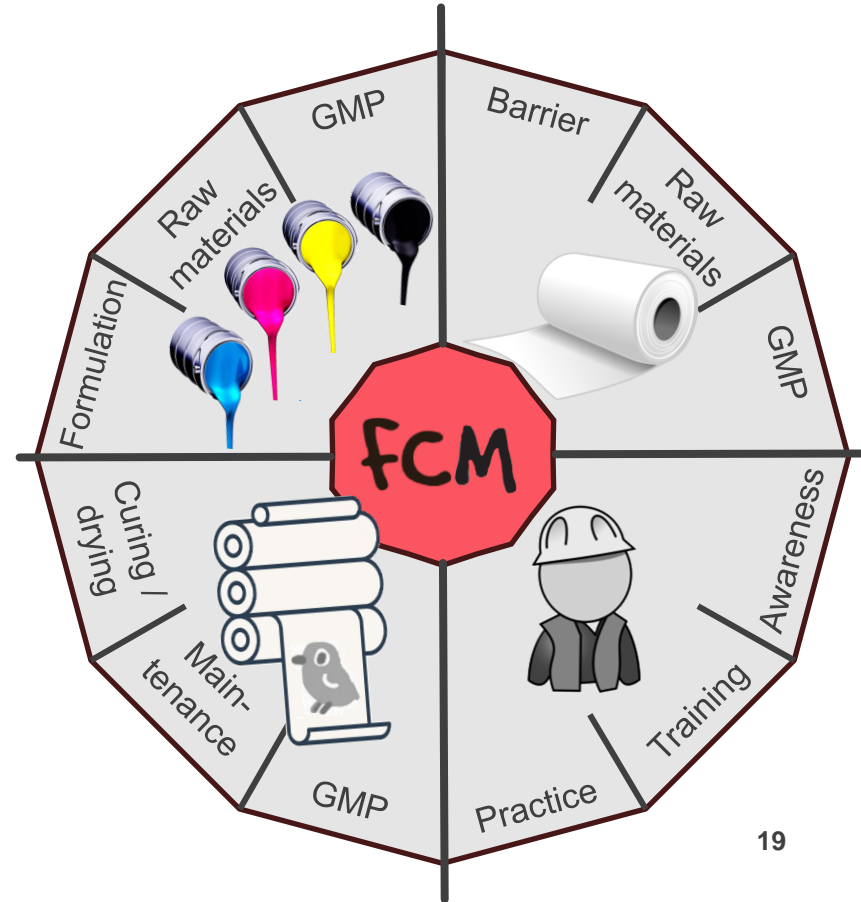
India

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

- Up stream from food manufacturer to the beginning and
- Down stream from raw material suppliers to the manufacturer of the finished article



- Printing FCM is more than using FCM inks and coatings. All materials are important for regulatory compliance.
- Materials and Processes are equally important.
- People tend to replace materials only rather than focussing on the entire process.



- ✓ The printing ink industry is able to support **consumer safety** and **regulatory compliance**.
- ✓ This can be obtained only in **cooperation** with the entire supply chain.
- ✓ **Communication** between all stakeholders involved is hereby the **core factor**.

Thank you for your attention!



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