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Materials and Articles in Contact with Food - Regulations

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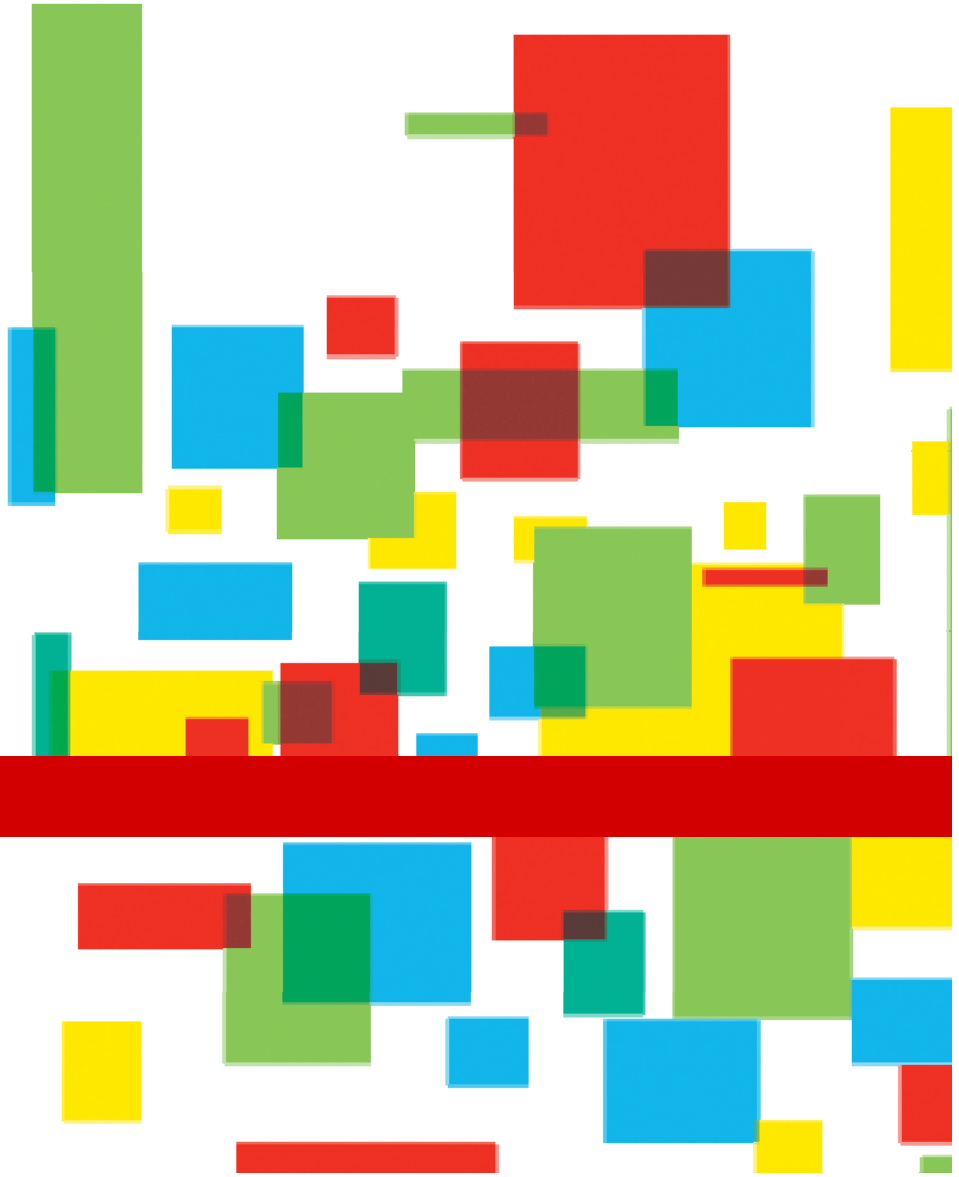
working for you.



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- Working together in the Supply Chain

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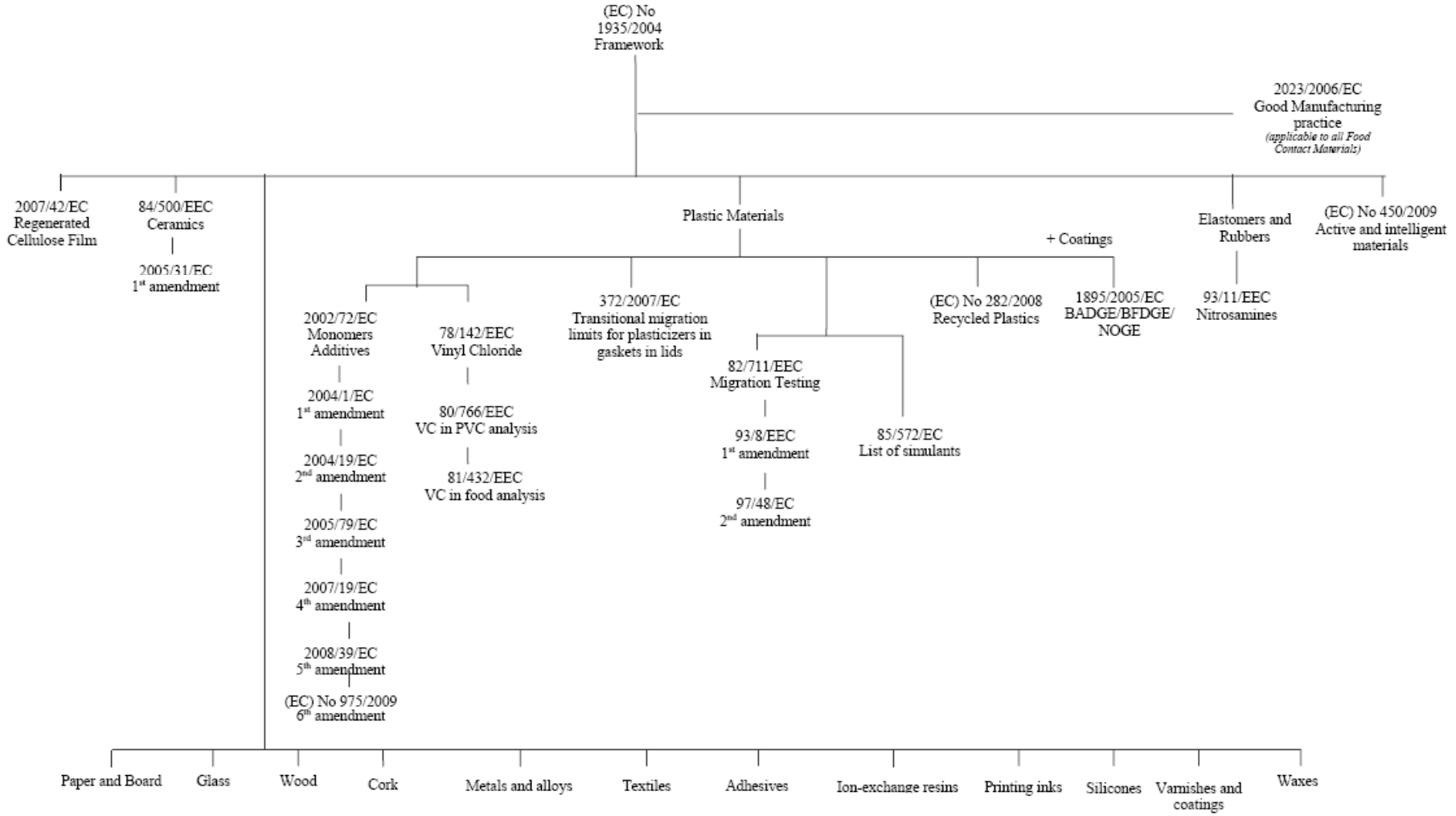
European Regulatory landscape

European Food Contact Materials Legislation



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Framework Directive – General Requirements – Article 3

Materials and Articles must be manufactured in accordance with GMP so that they do not transfer constituents to food in quantities that could:

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

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Scope of the Framework Directive 1935/2004

Materials and Articles which in their finished state:

- Are intended to be brought into contact with food.

Or

- Are already in contact with food and were intended for that purpose.

Or

- Can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

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This would also cover utensils, food machinery…

Framework Directive – Declaration of Compliance – Article 16

- Specific measures must require materials and articles to be accompanied by declaration of compliance.
- Appropriate documentation of such compliance must be available, and must be provided to authorities on demand.
- In the absence of specific measures, national legislation may regulate this.

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Scope of the Framework Directive 1935/2004

Traceability is a key element of the Framework Directive (and GMP), for any given Food Contact Article an inspector should be able to see:

Where? Products are at all stages of production and distribution

Who? Which business operators are involved at all stages

What? From who and to who materials or articles are supplied (may also apply to substances or products) – full supply chain detail

For? Should be available to competent authorities on demand

How? Use an appropriate system to allow traceability across supply chain

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Framework Directive – Specific Measures

Materials

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

Substances

- Nitrosamines
- BADGE, BFDGE & NOGE

In the absence of specific measures Member States can adopt National provisions, but must notify the Commission before adopting

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European Regulatory Landscape

There are other food packaging components that could be regulated at a European Union level, but so far this has not happened.

- Paper and Board
- Glass
- Wood
- Cork
- Metals and alloys
- Textiles
- Adhesives
- Ion exchange resins
- Printing inks
- Silicones
- Varnishes and coatings
- Waxes

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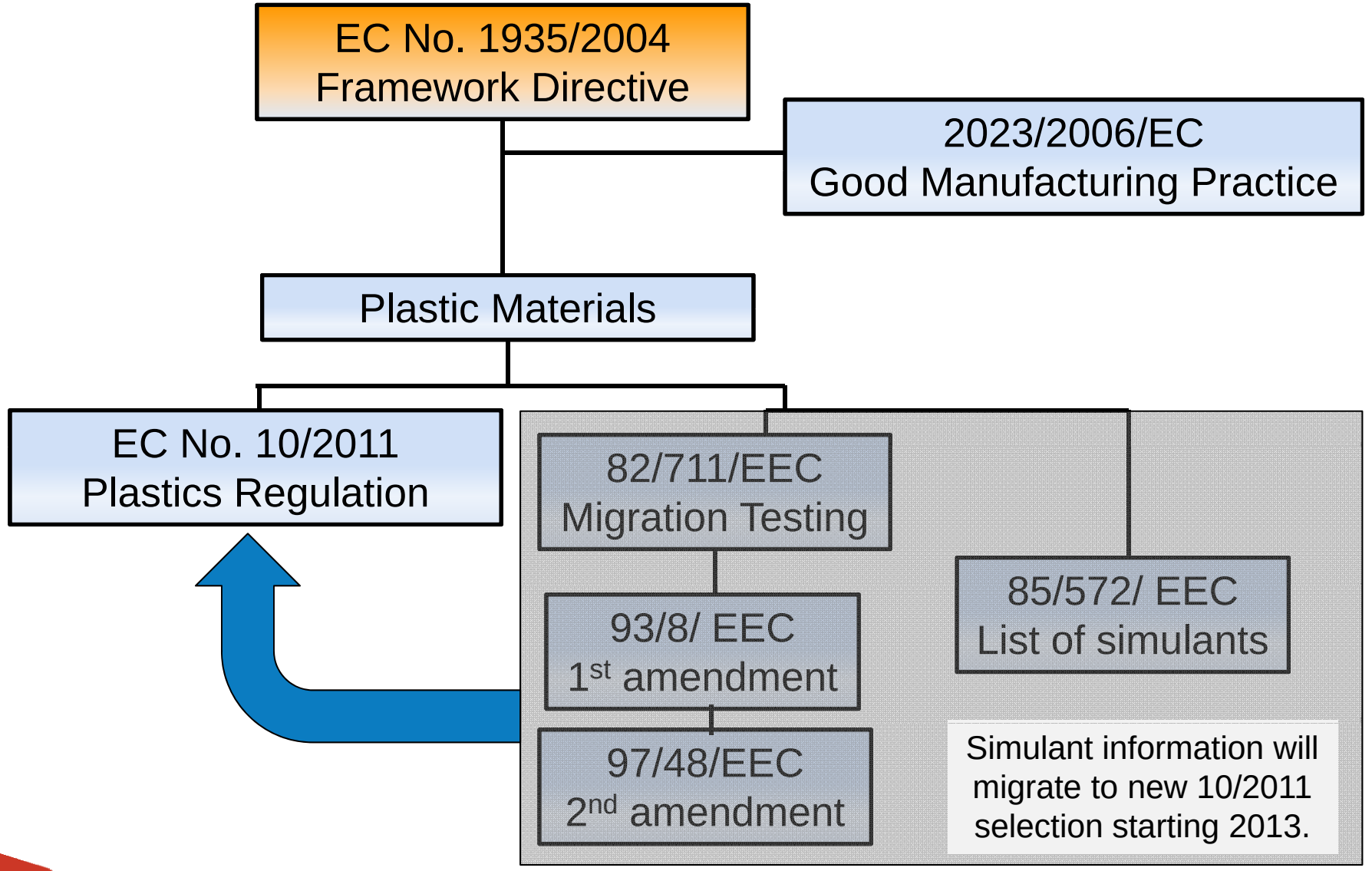
Plastics Focus

Plastic Materials - European Regulatory Landscape



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2023/2006/EC - Good Manufacturing Practice

- Applies to all food-contact materials and applies at all stages of production.
- General requirement to implement a system of quality assurance, quality control, and maintain supporting documentation.
- Provides some specific rules for printing inks applied on the non-food contact side of M&A.
  - Must not transfer by off set in the stack or roll up at unsafe levels.
  - Must not transfer through the substrate.
- Industry guides exist, EUPIA members of code of practice.

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Plastics Regulation

- Plastics Regulation 10/2011 came into force May 2011, replacing Plastics Directive 2002/72.
- Updated definitions, updates to migration limits. Changes to food simulants, temperatures & times (with 3 year transition)

Contact time	Dir. 82/711	New Regulation
Aqueous food	Water (Simulant A)	10% ethanol (simulant A)
Acidic food (pH <4.5)	3% acidic acid (Simulant B)	3% acidic acid (Simulant B)
"Ethanolic" food	10% ethanol (simulant C)	20% ethanol (simulant C)
Semi fatty food products	50% ethanol (Simulant D)	50% ethanol (simulant D1)
Fatty food	Olive oil (Simulant D)	Vegetable oil (simulant D2)
Dry foods	No simulant assigned	TENAX (simulant E)

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Plastics Regulation - Scope

- Materials and Articles and parts thereof consisting exclusively of plastics;
- Plastic multi-layer materials and articles held together by adhesives or by other means;
- Materials and Articles referred to above that are printed and/or covered by a coating;
- Plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
- Plastic layers in multi-material multi-layer materials and articles

- "**Plastic**" means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles:
  - Not applicable to printing inks, coatings & adhesives.

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Inks & Coatings – where are we going?

National Printing ink regulations – Swiss Ordinance

- **There are no European Regulations regarding printing inks.**
- The Swiss Federal Department of Home Affairs (FDHA) adopted an amendment to their Ordinance of 23/11/05 on Materials and Articles (SR 817.023.21) detailing certain provisions relating to packaging inks.
- Within this amendment, introduced 07/0308 enforced 01/04/10, Article 26g details the requirement that only permitted substances should be used in the manufacture of Packaging Inks.
- Permitted Substances are defined as those which are listed in Annex 1 Lists I and II and in Annex 6.
- Annex 6 substances listed as List A status either had quoted specific migration limit (SML) or defaulted to a global migration limit - 60 mg/Kg (60 ppm).
- Substances listed with List B status (unevaluated) have a default migration limit of 0.01 mg/Kg (10 ppb).

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Any migrating substance must be listed and meet the migration limits set to 'comply'

National Printing ink regulations – draft German Ordinance

Comparing Swiss Ordinance with the recent draft of the German Ordinance on Food Packaging Inks and Varnishes:

- **Switzerland:** Food packaging inks may only be manufactured from listed substances (only covers inks printed on outside of packs)
- **Germany:** Printed food contact materials may be manufactured using only printing inks composed of listed substances (inside & outside print!)

	evaluated substances	non-evaluated substances (10 ppb)
Switzerland	Annex 6, part A	Annex 6, part B
Germany	Annex 14 (“positive list”)	Inventory list (not part of the Ordinance)

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Migration limits in Swiss & German Ordinance are likely to be very similar as both are based on the same scientific opinion.
Disclosures of migrating substances are demanded under both

Plastics and Printing ink regulations – summary

- The Framework Directive covers all Materials and Articles intended for food packaging, and gives overall direction but not specific instructions.
- The Plastics Regulation includes printed food packaging but is not applicable directly to printing inks.
- The Swiss Ordinance is a regulation that is only in force in Switzerland but does impact on inks printed on the outside of food packaging.
- The draft German Ordinance is set to impact on inks and coatings printed on both inside/outside of food packaging
- It may change the way in which the supply chain has to work together.

Ink makers must communicate up the supply chain on whether the inks and coatings they supply, when printed onto food packaging, will meet the requirements of the Framework Directive.

- To do this they must use information from the Plastics Regulation & Swiss Ordinance, even if those regulations do not specifically apply.

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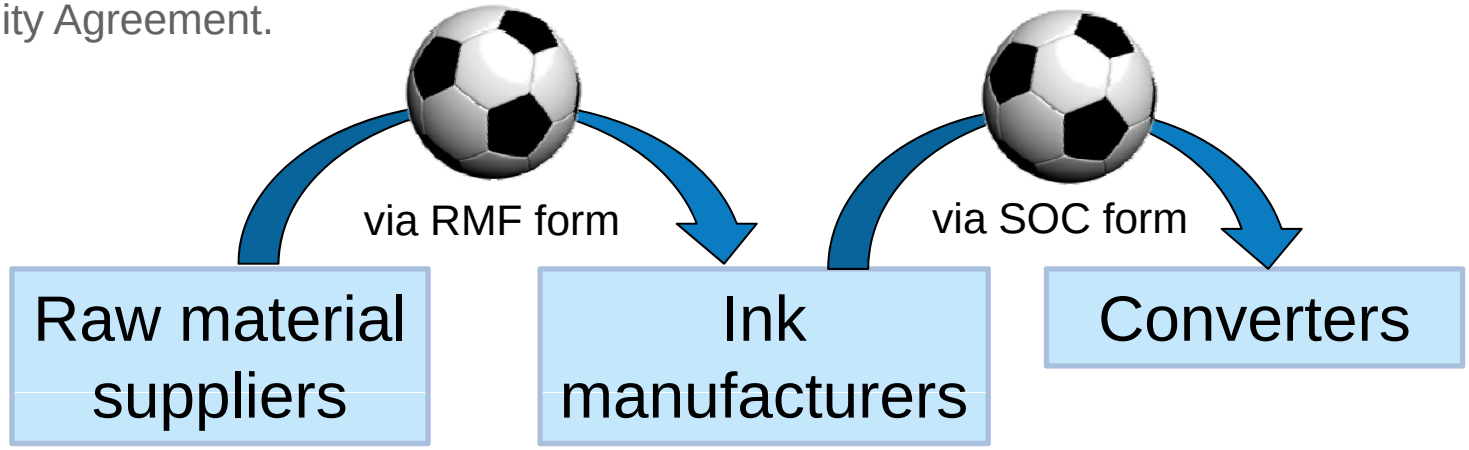
Working together in the supply chain

Packaging Declaration of Compliance

- Our customers would like their packaging to comply with regulations:
- We pass to our customer information about the potentially migrating substances in our inks, also the SML for these substances, and how much is present, this allows them to calculate whether their food packaging is compliant through a ‘Worst Case Calculation’.
- The mechanism that we use to supply this ‘adequate information’ is called a “Statement of Composition” (SOC).
- As we are passing detailed information about substances in our inks the preference is for a Confidentiality Agreement.



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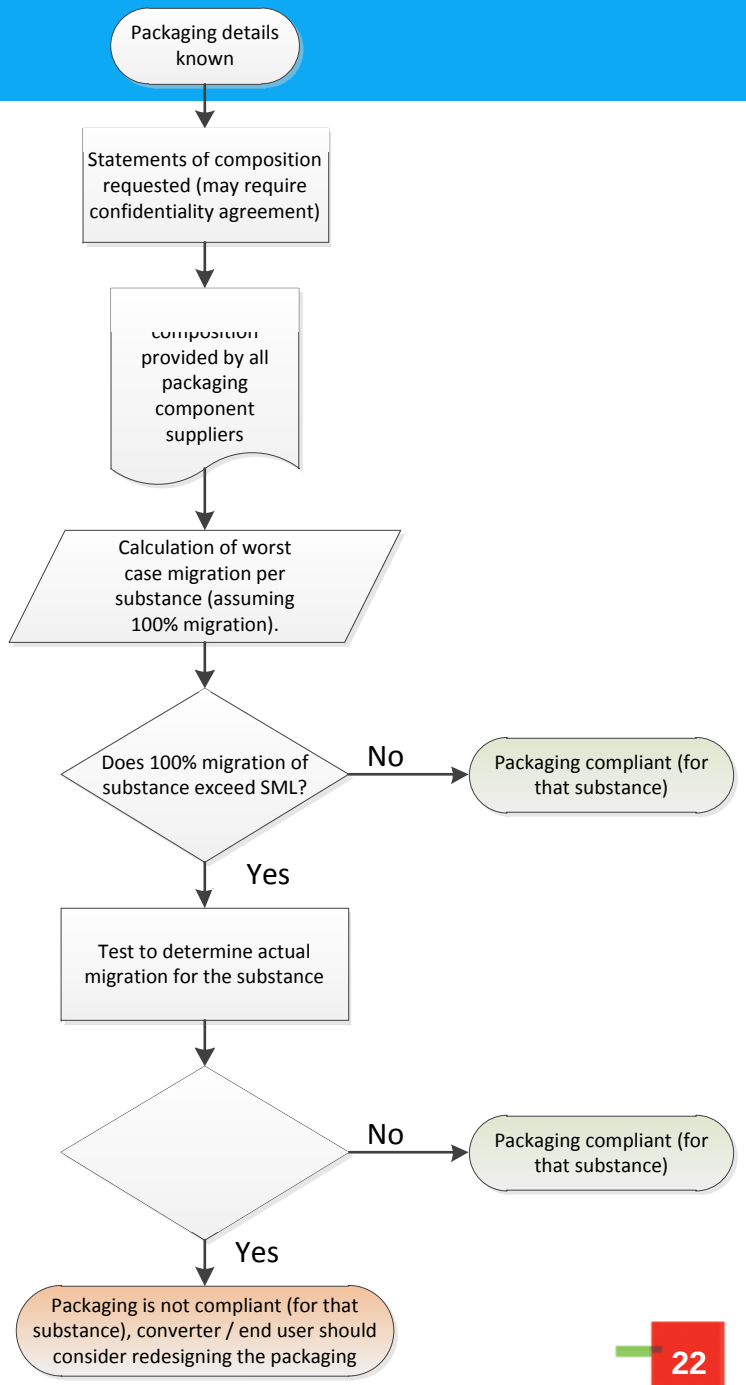
Using a Statement of Composition

- What converters do with SOC's…...
  - Get data on potentially migrating components from all of the package component suppliers (substrate, adhesive, coatings, inks…).
  - Work out how much of each substance is actually there, for inks this is based on:
    - The actual applied coating weight & % coverage.
    - How well the ink is dried (residual solvent (mg/m^2).
    - The actual package surface area and weight of food.
  - If in a worst case calculation even if all of the substance migrates, if this does not exceed the SML then the packaging is compliant. If not then migration testing*.



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*Note: may be able to model migration. May be able to test migration into food rather than more aggressive food simulant

Testing migration

- If after doing these calculations, including information from all of the components in the packaging (ink, adhesive, plastics), the customer / End User finds that for his packaging, even if all of the substance(s) were to migrate, then it would still not exceed the migration limits, then they can be confident of compliance.

- If after doing these calculations the customer / End User finds that for his packaging, if all of the substance were to migrate, then the substance will exceed the migration limits, then he needs to establish how much of the substance actually migrates. (Migration testing).

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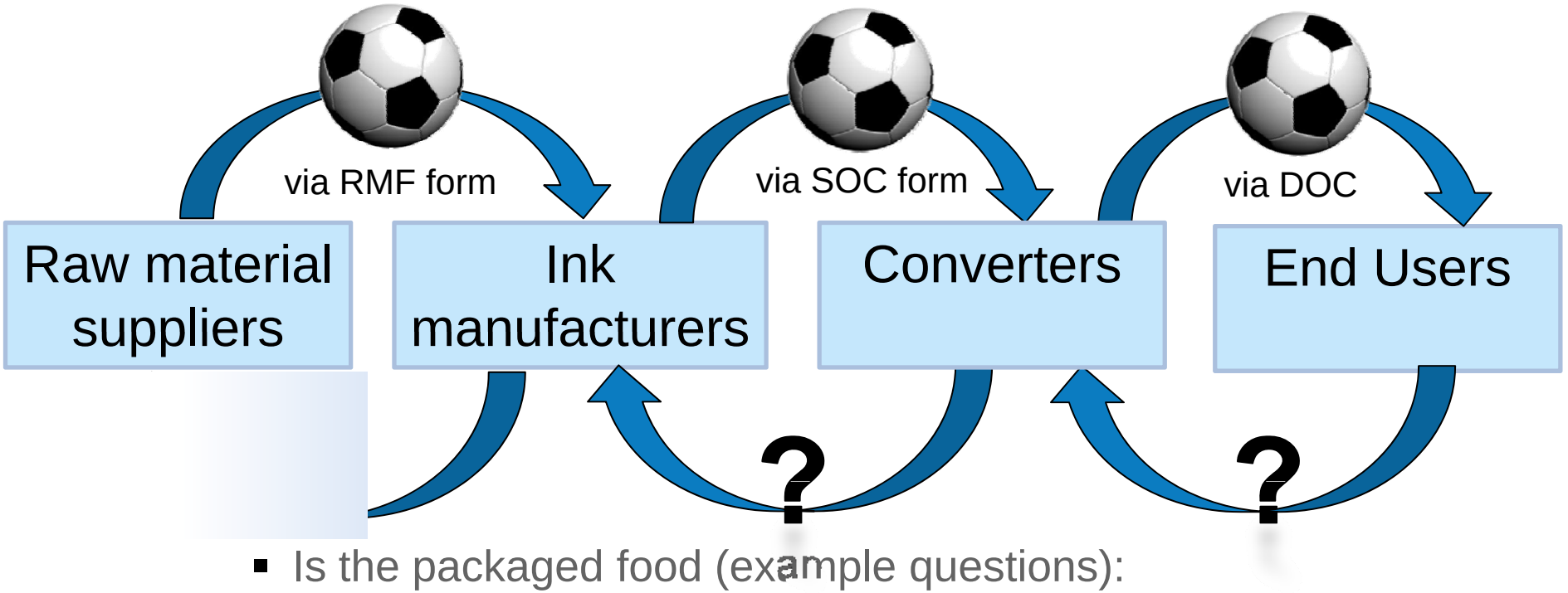
Working with the supply chain

- Where there are new regulatory requirements please help communicate these back down the supply chain.



- Is the packaged food (example questions):
  - Intended for children / babies.
  - Particularly high fat content.
  - Particularly high temperatures at some point in packaging life-time (retort, microwave ….).

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Finish

- If you have regulatory / product stewardship questions, I'm here for the rest of the day, or please feel free to e-mail me.

Thank you

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