



Food Contact Legislation of Coatings and Inks in the EU

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Who is Keller and Heckman?



- Broad practice in the areas of regulatory law, litigation, and business transactions
- A pioneer in use of interdisciplinary approaches to problem-solving
- In-house scientific staff that works closely with attorneys on matters of technical complexity
- Assists in petitioning, issuing opinion letters regarding legal status, GMP auditing

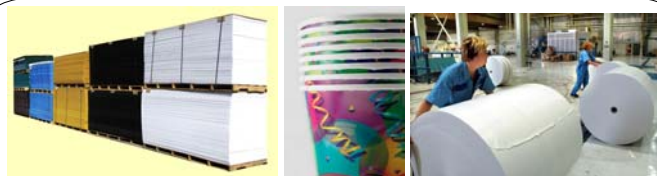
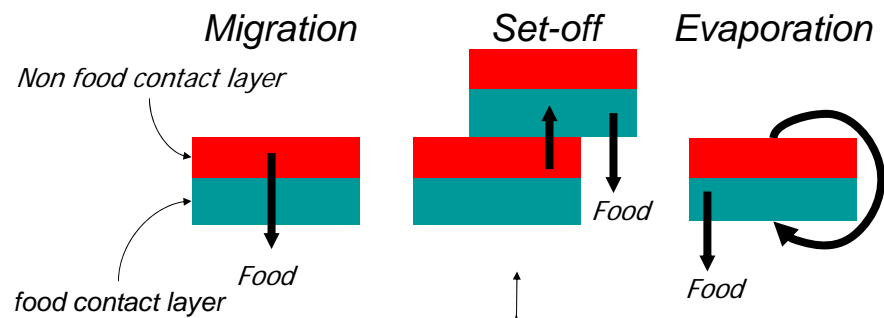
Agenda

- Introduction
- Food contact legislation in the EU
- Who needs to do what?
- Incoming and outgoing certificates

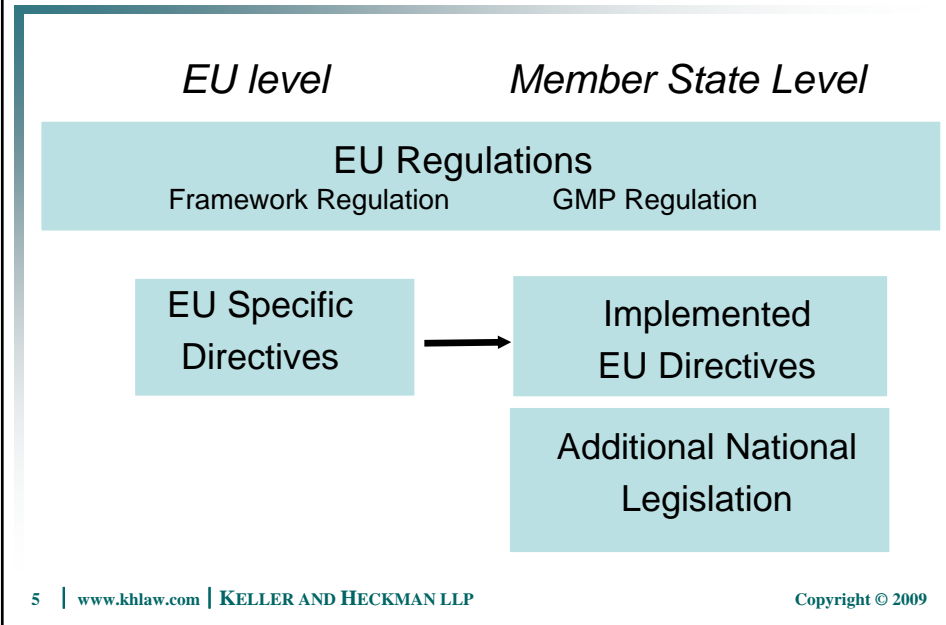


How Can Components Migrate?

Components may migrate in different ways to the food:



Food Contact Legislation



Food contact legislation in the EU



Regulation 1935/2004

- Applies to materials and articles which in 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

General Requirements (Article 3)

- **Must not**, under normal or foreseeable conditions of use, **transfer constituents to food in quantities**, that could:
 - Endanger human health; or
 - Bring about an unacceptable change in the composition of the food; or
 - Deteriorate the organoleptic characteristics (taste/odor) of the food

Definition of GMP

- **Regulation (EC) 2023/2006** (as amended)
 - Came into force 1st August 2008
- **GMP** = those aspects of quality assurance which ensure that:
 - Materials & articles are **consistently produced**
 - **controlled** to ensure conformity with
 - the rules applicable to them
 - the quality standards appropriate to their intended use by:
 - Not endangering human health
 - Not causing an unacceptable change in the composition of the food
 - Not causing a deterioration in the organoleptic characteristics

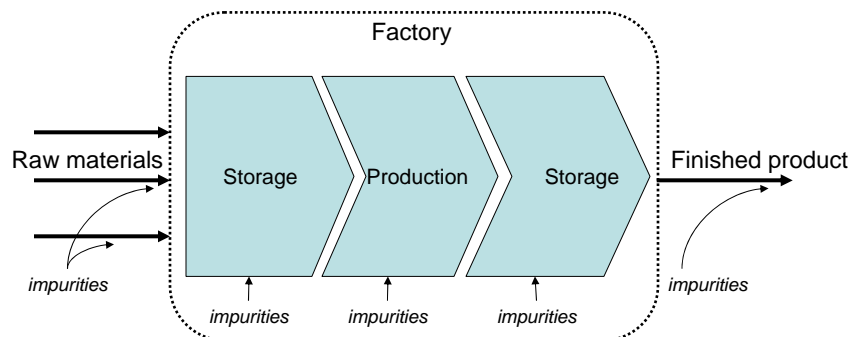
GMP

- **GMP = ISO 9001 + more**
- Only general requirements
- All food contact materials
- All stages of manufacture, processing and distribution of materials & articles :
 - « **Up to but excluding the production of starting substances** »
 - Problem of interpretation of this exclusion in the absence of definition in that Regulation of « starting substances », e.g., are additives excluded?

GMP implementation requires

- **Quality assurance system**
 - Specification of starting materials must be established
 - Adequacy of personnel, equipment and premises
- **Quality control system**
 - Monitor GMP implementation
 - Identification of corrective measures to correct failures
- **Documentation**
 - Includes specifications, manufacturing formulae etc
 - Must be kept available to competent authorities upon request

Impurities needs to be addressed under GMP



Evaluate effect when a impurity enters the product/process:

- Will it be noticed (testing, specification, etc.)?
- If not, what will be the effect of the presence of the impurity in the final application?

Items that need to be addressed in GMP plan/audit

- Organization and personnel
- Buildings and facilities
- Equipment
- Raw materials
- Manufacturing procedures
- Testing and labeling of finished products
- Packing and loading procedures
- Legal status of products
- Record keeping and product removal/correctional procedures
- Internal auditing procedures
- Hazard assessment of critical control points (HACCP)

Legal status of coatings in the EU

- Only specific EU measure present is concerning the use of BADGE and the prohibition of BFDGE/NOGE (Regulation (EC) no. 1895/2005).
- Coating on plastic covered by EU plastic regulation, no positive list established yet
- Legislation exists in some Member States
- Many countries accept compliance with plastic legislation
- Compliance with art. 3 of (EC) 1935/2004 is required
- Compliance with general requirements of GMP Regulation is required

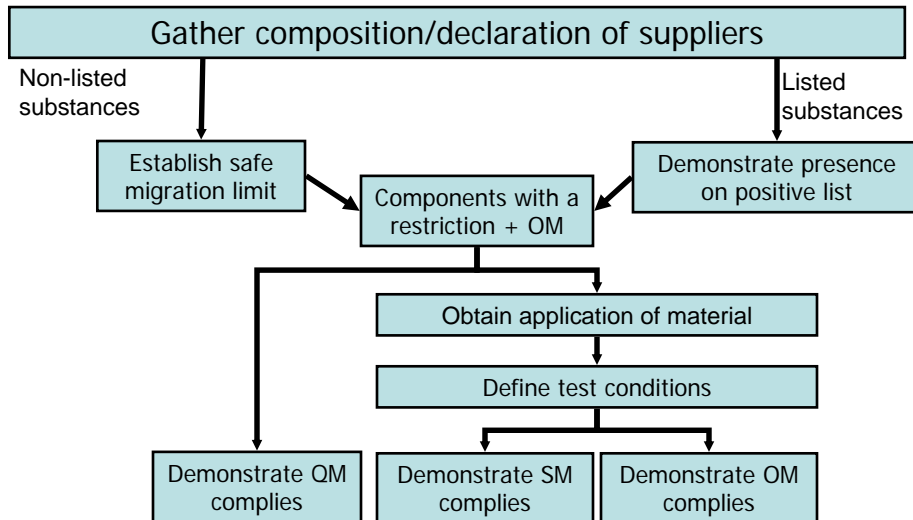
Legal status of printing inks in the EU

- No specific ink legislation in the EU exists
- No specific ink legislation in member states
- Covered by the plastic legislation, but positive list not yet established
- Expert judgment needed to establish safe use
- Migration depends on composition of inks, curing, substrate and other factors
- Specific rules in GMP Regulation
- Compliance with art. 3 of (EC) 1935/2004 required
- Non legal guidance documents:
 - EUPIA exclusion list
 - Council of Europes Resolution

Restrictions

- Restrictions mentioned in plastics directive
 - Ingredients
 - Purity requirements
 - Application
 - e.g. only for certain food types
 - Final article
 - overall migration (OM)
 - Amount of single/group components
 - specific migration (SM or SM(A))
 - residual amount (QM or QM(A))

Approach of Demonstrating Compliance



How Much of a non-regulated component may migrate?

- Depends on toxicity
- Depends on toxicity information available
- Depends on level found in the migration
- Depends on consumption of the food in the packaging

Solution

- Use a tiered approach: the more favorable toxicological information is available the higher the exposure can be
- Different approaches are published:
 - Cheeseman et al.
 - Kroes et al.
 - Sue Barlow et al.
 - ILSI

Who needs to do what?

Distinguish:

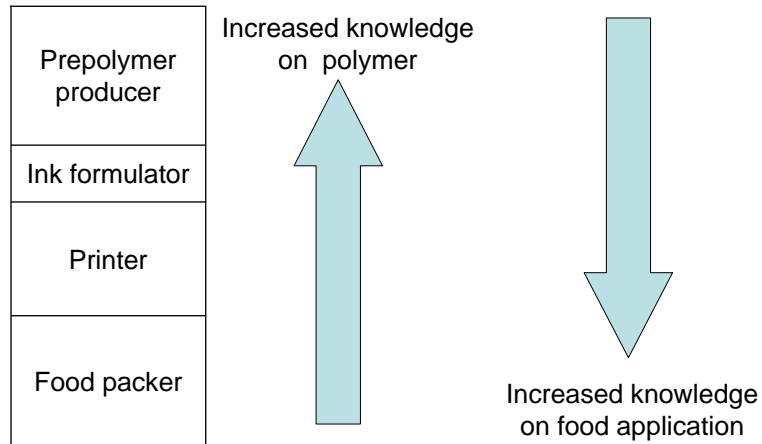
- Legislative requirements
What needs to be done!
- Customer requirements, service, marketing
What does your customer want (to see)?

Bad Components List

Assurance requests often go well beyond food-contact and are not always related to the composition of the material

- Heavy Metals
- BSE
- PFOA
- Kosher, Halal
- Phthalates
- GMOs
- ITX
- Latex
- BPA
- Endocrine Disruptor
- Organotins
- Melamine
- And much more.....

Distribution of Information



Sharing Information

Prepolymer producer	<ul style="list-style-type: none"> •State that composition complies •Specify which specific migration determinations have to be made in finished product (FP) •Test residual content
Ink formulator	<ul style="list-style-type: none"> •State that composition complies •Specify which specific migration determinations have to be made in FP
Printer	<ul style="list-style-type: none"> •State that composition complies •Test specific migration •Test overall migration <p>The final article must be statement that final material complies for which intended purposes!</p>
Food packer	<ul style="list-style-type: none"> •Make sure that food packaging can be used for the purpose (contact time, contact temperature and food types)

Information & documentation

Sharing Information

- Suppliers in the beginning of the chain want to provide as little information as possible
- Users at the end of the chain wants to have as much information as possible
- Information can be delivered under confidentiality agreements, different approaches possible
- Documentation is important and will become more important over the years
- Declaration of compliance must be submitted for some materials

Declaration of Compliance

- Identity and address of business operator
- Identity of the materials/articles
- Date of declaration
- Confirmation compliance with (EC) no. 1935/2004
- Adequate information regarding migration restriction/specifications of substances
- Adequate information regarding substances with food additive restrictions
- Specification regarding use of material (types of food, temperature, time, min food/area ratio)
- Conformity of barrier with requirements (if used)
- Presence of recycled plastic (registration number)

Different Approaches

Information on compliance with limitations – your choice:

- Do testing yourself to assure your customers that limitations will be met
- Do testing yourself and suggest that the limitations will be met, but state that it is the customer's responsibility to comply
- Make your customers aware of any applicable limitations, but do no testing and make no statements of migration compliance (not for FP)

Incoming and outgoing certificates?



Outgoing certificate

- Be specific, describe detailedly:
 - identity of the material (name of product, from which plant)
 - Use restrictions (time/temperature/food types, use-level etc)
 - What the responsibility of the purchaser
- Be sure that the statement is supported by supporting documentation
- Keep track of documents issued
- Limit and specify the people who can change and sign documents
- Issuing of statement results in liability

Conclusions

- Specific legislation in EU and Member States on inks/coatings intended for food contact is limited
- However horizontal legislation exists: Framework Regulation (1935/2004) & GMP (2023/2006)
- Implementation of GMP seems not to be easy for food contact material producing companies
- Information and responsibility should be shared through the chain to ensure safety of the final article
- Incoming certificates are an important source of information
- Outgoing certificates needs to be clear, complete and state which responsibility is and which responsibility is not taken by your company (liability)



THANK
YOU!

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