



Responsibilities throughout the multi-layer supply chain and food contact legislation

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Who is Keller and Heckman?

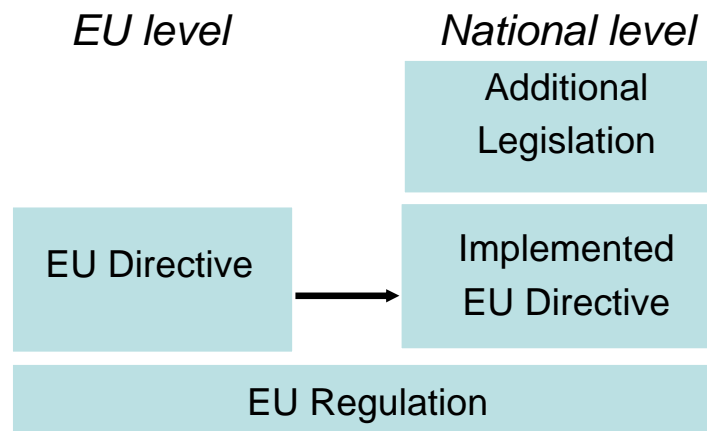
- Founded in 1962
- Located in Washington DC, San Francisco, Brussels and Shanghai
- Broad practice in the areas of regulatory law, litigation, and business transactions
- A pioneer in the use of interdisciplinary approaches to problem-solving.
- In-house scientific staff that works closely with the firm's attorneys on matters of technical complexity.
- Many of our attorneys also have experience with food and food packaging governmental agencies.

Outline

- Introduction
- EU legislation
- Demonstrating compliance
- Who needs to do what?
- Conclusions

Overview of the EU food contact legislation

EU & national legislation



Framework Regulation (EC)1935/2004

Article 3 General safety requirements

- o Not endanger public health
- o No unacceptable change in composition
- o No deterioration of the organoleptic characteristics

Legislative Status of Plastics

- Regulated in EU directive 2002/72/EC and amendments
- Applies to materials only made from plastic (or with adhesives)
- Monomers completely harmonized
- (Non-PPA) additive list incomplete. Will be considered complete at 1/1/2010
 - List of approved additives
 - List of temporary approved additives (new)

Legislative Status of Plastics

- Solvents, polymerization production aids and colorants not covered by the legislation
- Some member states do have additional national legislation
- Restrictions on composition, overall migration, specific migration and purity
- Barrier concept (10 ppb)

Legislative Status of Coatings

- 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 present in some member states
- Many countries accept compliance with plastic regulation
- Must comply with art. 3 of (EC) 1935/2004

Legislative Status of Adhesives

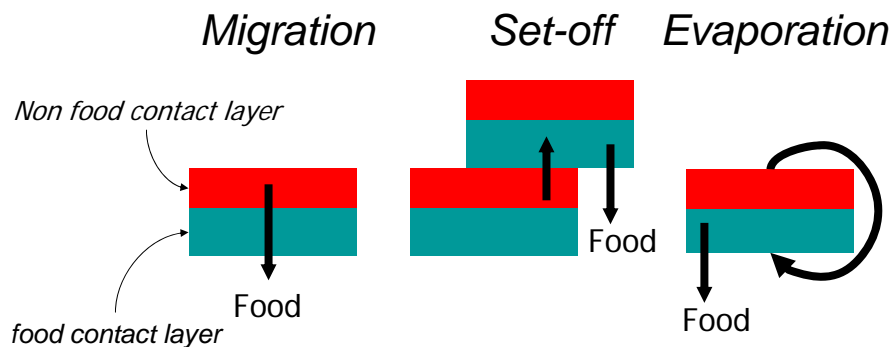
- Only specific EU measure present is concerning the use of BADGE and the prohibition of BFDGE/NOGE (Regulation (EC) no. 1895/2005).
- Adhesives on plastic covered by EU plastic regulation, no positive list established yet
- Legislation present in some member states
- Many countries accept compliance with plastic regulation
- Must comply with art. 3 of (EC) no.1935/2004

Legislative Status of Inks

- 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
- Guidelines (EUPIA) available
- Must comply with art. 3 of (EC) 1935/2004

How Can Components Migrate?

Components may migrate in different ways to the food:

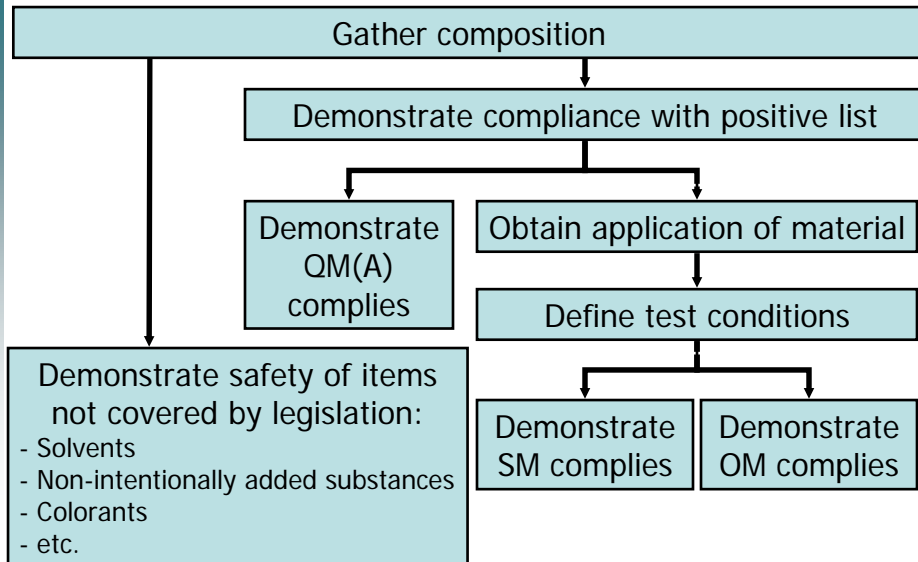


Demonstrating compliance

Route for Lawful Marketing

- How is my material/application defined in the European legislation?
- If a EU measure is not available, is a legislation present at member state level?
- Do I comply with these member state legislations?
- If not can I use other legal vehicles to market lawfully (mutual recognition)?

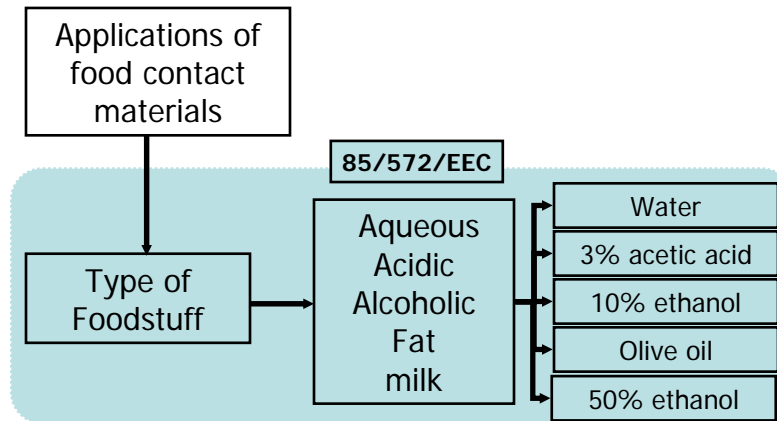
Demonstrating Compliance



Specific Migration vs Residual Content

Specific migration	Residual content
Depends on contact time and temperature	Independent of food contact time and temperature
Depends on food type	Independent of food type
Actual migration is determined	Actual amount in polymer is determined
Expressed in mg/kg food or mg/6 dm ²	Expressed in mg/kg finished product or mg/6 dm ²

Selection of Test Simulants



Example:
 Bacon → Aqueous → Water
 Bacon → Fat → Olive oil

Selection of Test Time & Temperature

82/711/EEC and amendments		Contact temp	Test temp
Contact time	Test time	<5°C	5°C
< 5min	Actual use	5°C-20°C	20°C
5min-0.5h	0.5h	20°C-40°C	40°C
0.5h-1h	1h	40°C-70°C	70°C
1h-2h	2h	70°C-100°C	100°C
2h-4h	4h	100°C-121°C	121°C
4h-24h	24h	121°C-130°C	130°C
>24h	10d	130°C-150°C	150°C
		>150°C	175°C

Example: Storage for 3 months at room temperature:
 Test conditions: 10 days at 40°C

Who needs to do what?

Distinguish:

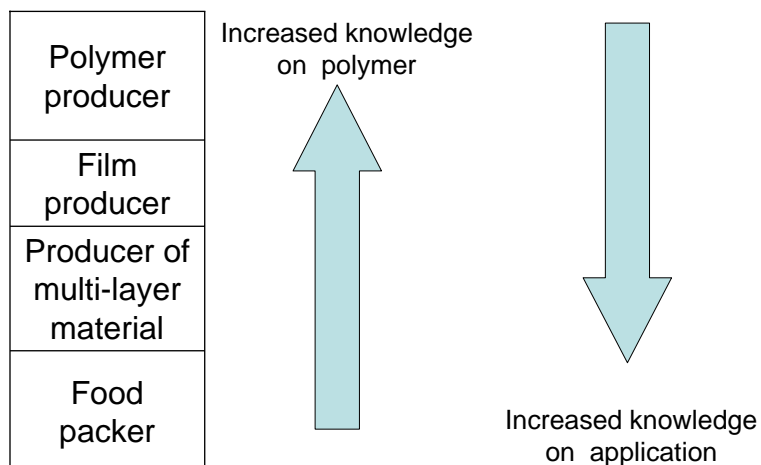
- Legislative requirements
What needs to be done!
- Client requirements, service, marketing
What does your client want (to see)?

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
- Latex
- BPA
- Endocrine Disruptor
- Organotins
- Melamine
- And much more.....

Distribution of Information



Sharing Information

Polymer producer	<ul style="list-style-type: none"> •State that composition complies •Specify which specific migration determinations have to be made in FP •Test residual content
Film producer	<ul style="list-style-type: none"> •State that composition complies •Specify which specific migration determinations have to be made in FP
Producer of multi-layer material	<ul style="list-style-type: none"> •State that composition complies •Test specific migration •Test overall migration <p>The final article must have a statement that it 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)



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

2002/72/EC Art. 9

1. At the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles, shall be accompanied by a written declaration
2. The declaration referred to in paragraph 1 shall be issued by the business operator and shall contain specified information

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 (Dual use additives)
- 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)

2002/72/EC Art. 9

3. Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Directive shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.'

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 (not for FP)
- Make your customers aware of any applicable limitations, but do no testing and make no statements of migration compliance (not for FP)

Voluntary Submission of DoC

Even in cases where a DoC is not legally required, suppliers often must provide their customers assurance as to the regulatory status and safety of their material

Largely a customer assurance statement should contain the same information as a DoC

Incoming Certificates

- Request Certificate of Compliance from all (raw) material suppliers
 - Carefully review to ensure completeness
 - Is the certificate adequate?
 - Was the certificate authorized?
 - (Watch out for: “Tell me what you need and I’ll sign it.”)
 - Is testing required to ensure compliance?
 - Controlled at central office or at local plants?

Incoming Certificates

- Does certificate apply to use or can it be extended to cover intended use(s)?
 - Statement that material complies with 2002/72/EC may be sufficient even if not used in entirely plastic article
- Compliance with single member state adequate?
 - Mutual recognition
 - How are limits communicated to your customers?

Submitting Documentation

- 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

Summary of Evaluation

- How is the material/application considered in the legislation
- Is the application covered by EU measures?
- Is the substance covered by EU measures?
- If no (implemented) EU measures apply, does National legislation exist?
- If restrictions apply, must they be determined analytically? Who has to confirm this?
- Which requirements can be covered by documents from suppliers?
- What information should I put in the declaration of conformity?
- Do I have supporting documentation?
- Documents issued also results in legal liability



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