



## An overview of the 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

3

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## Why food contact legislation?

- Food contact legislation is prepared to ensure:
  - o Free circulation of goods
  - o Protection of human health

4

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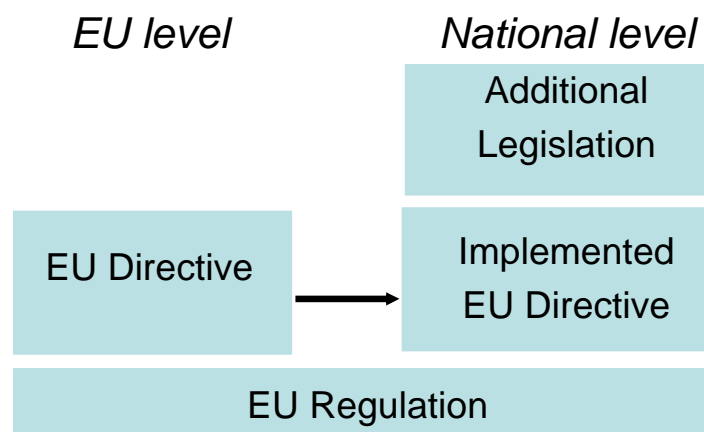
## What are food contact materials?

Materials and articles which in their finished state:  
(a) are intended to be brought into contact with food;  
or  
(b) are already in contact with food and were intended for that purpose;  
or  
(c) 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.

This includes:

packaging, conveyor belts, food processing machinery, food utensils etc

## EU & national legislation



# Overview of the EU food contact legislation

## EU directives & Regulations

### General measures

- Framework Regulation (EC)1935/2004
- GMP Regulation (EC) 2023/2006

### Measures defining testing conditions

Directive 85/572/EEC, 82/711/EEC and amendments

### Measures for specific group(s)

Applies to one or few groups of materials: example plastics are covered by Directive 2002/72/EC

## 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

9

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## Framework Regulation (EC)1935/2004

### Article 4 Active and Intelligent materials may be used if....

- o Allows release of ingredients if authorized food additives
- o Not misleading the consumer (masking)
- o Intelligent system should provide reliable information
- o Labeling of non-edible part
- o Labeling as active or intelligent

*Specific EU regulation is in preparation*

10

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## Framework Regulation (EC)1935/2004

### Article 15 Labeling for materials

not yet in contact with food

- o Text or symbol
- o Instructions for manufacturer or trader



### Article 17 traceability

- o Traceability = ability to trace and follow a material or article through all stages of manufacture, processing and distribution
- o One step forward & one step back
- o Must be made available within 4 hours
- o Came into force 27 October 2006

## Legislative status of Coatings

- Only specific EU measure present is concerning the use of BADGE and the prohibition of BFDGE/NOGE (Regulation (EC) 1895/2005).
- Coating on plastic covered by EU plastic regulation
- Legislation present in some member states
- Many countries accept compliance with plastic regulation
- Must comply with art. 3 of Regulation (EC) 1935/2004

## Plastic regulation

- Regulated in EU directive 2002/72/EC and amendments
- Plastics are defined as

*“the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds.”*

## Plastic regulation

### Legislative definition of plastic

Materials and articles which, in the finished product state covered by:

- a) materials and articles consisting exclusively of plastics;
- b) plastic multi-layer materials and articles;
- c) plastic layers/coatings, forming gaskets in lids

## Plastic regulation

The following shall not be regarded as “plastics”:

- (a) varnished or unvarnished regenerated cellulose film;
- (b) elastomers and natural and synthetic rubber;
- (c) paper and paperboard, whether modified or not by the addition of plastics;
- (d) **surface coatings obtained from:**
  - **paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,**
  - **mixtures of the waxes listed in the first indent with each other and/or with plastics,**
- (e) ion-exchange resins;
- (f) silicones.

## Plastic regulation

The positive lists of monomers and additives, do **not yet** include monomers and other starting substances and additives used only in the manufacture of:

- surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
- epoxy resins,
- adhesives and adhesion promoters,
- printing inks.

## What are additives?

### Legislative definition on additives in plastic

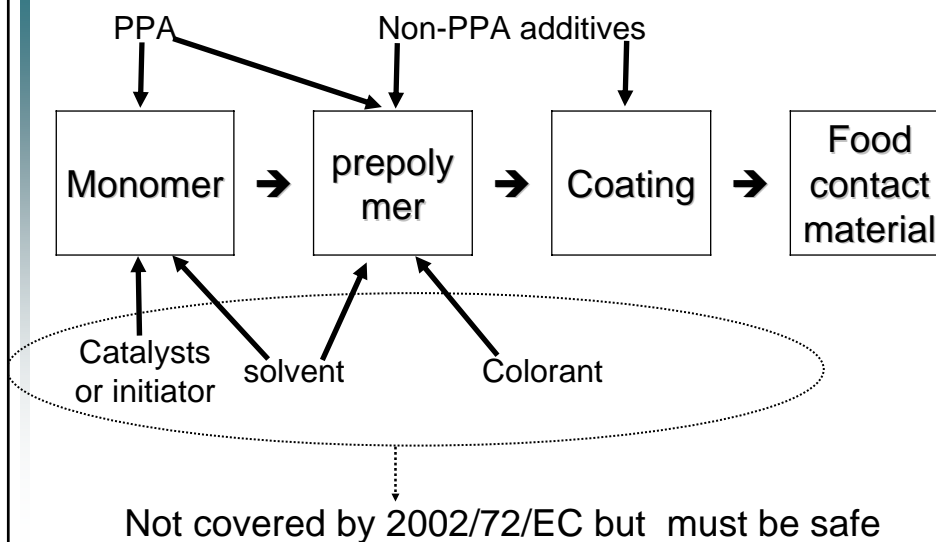
#### Additive:

- Substances which are incorporated into plastics to achieve a technical effect in the finished product, including “polymeric additives”. They are intended to be present in the finished articles.
- Substances used to provide a suitable medium in which polymerization occurs. Polymerization production aids (PPAs) are not intended to remain in the finished article

#### The additive list does not include:

- (a) Aids to polymerization: the substances which directly influence the formation of polymers (catalysts, initiators etc);
- (b) colorants;
- (c) solvents.’;

## What are additives?



## Legislative status of Plastics

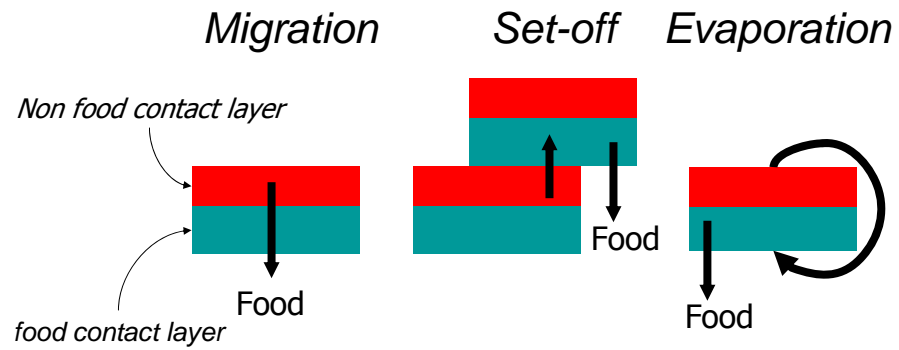
- Monomers completely harmonized
- (non PPA) additive list incomplete. Will be considered complete at 1/1/2010
  - List of approved additives
  - List of temporary approved additives (new)
- Some member states do have additional national legislation (mutual recognition can be used)
- Restrictions on composition and migration and purity
- Barrier concept (10ppb)

## Legislative status of Inks

- No specific inks legislation in the EU is available
- No legislation in member states present
- Covered by the plastic legislation, but positive list not yet established
- Expert judgment needed to state the use is safe
- Migration depends on composition of inks, curing, substrate and much more
- Mentioned in GMP Regulation
- Must comply with art. 3 of Regulation (EC) 1935/2004

## How can components migrate

Components may migrate in different ways to the food:



21

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## Demonstrating compliance

22

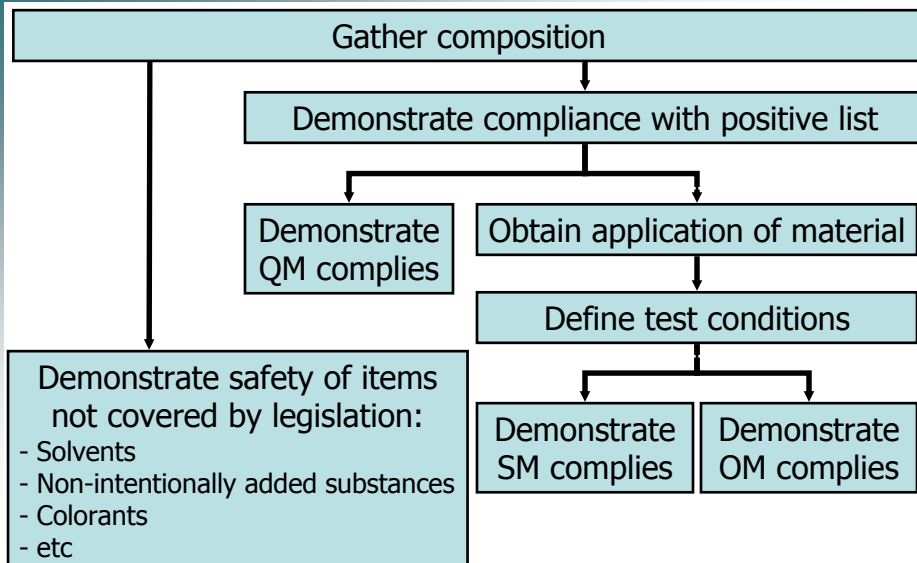
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## Route for lawful marketing?

- 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

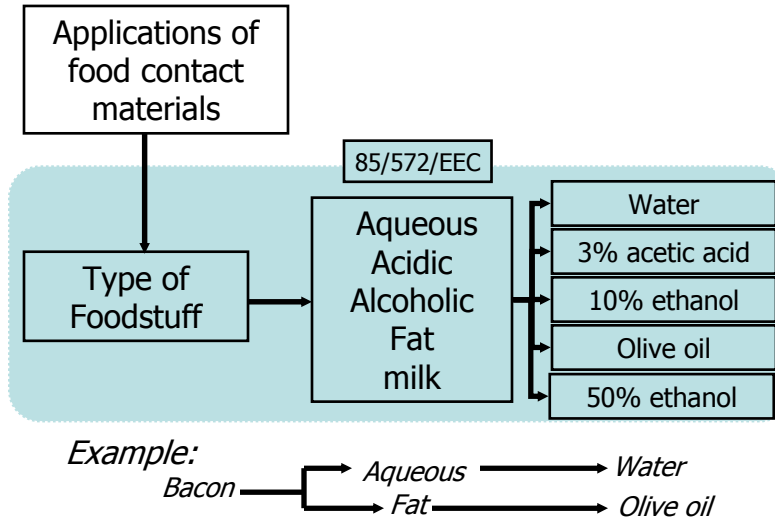
### Residual content

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

## Demonstrating compliance

	Analytical determination	Worst-case calculation	Mathematic modeling
Overall migration			
Residual content			
Specific migration			

## Selection of test simulants



## Selection of test time & temperature

82/711/EEC and amendments

Contact time	Test time
< 5min	Actual use
5min-0.5h	0.5h
0.5h-1h	1h
1h-2h	2h
2h-4h	4h
4h-24h	24h
>24h	10d

Contact temp	Test temp
<5°C	5°C
5°C-20°C	20°C
20°C-40°C	40°C
40°C-70°C	70°C
70°C-100°C	100°C
100°C-121°C	121°C
121°C-130°C	130°C
130°C-150°C	150°C
>150°C	175°C

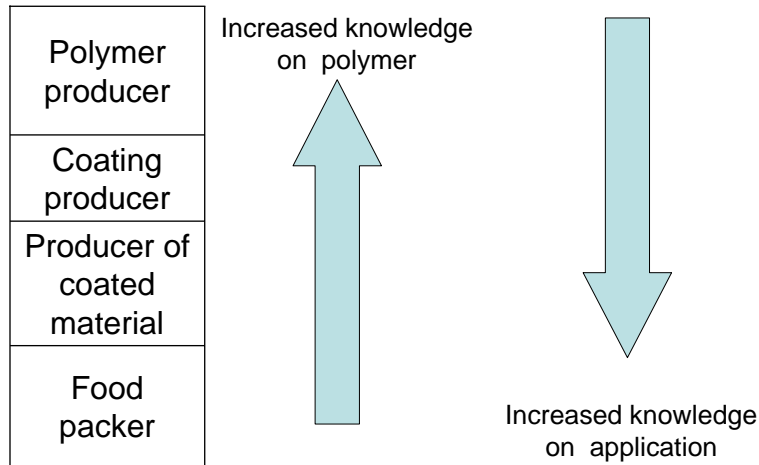
*Example:* Storage for 3 months at room temperature:  
Test conditions: 10 days at 40°C

## Who needs to do what?

## Distinguish:

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

## Distribution of information



## Sharing information

Polymer producer	<ul style="list-style-type: none"> <li>•State that composition complies</li> <li>•Specify which specific migration determinations have to be made in FP</li> <li>•Test residual content</li> </ul>
Coating producer	<ul style="list-style-type: none"> <li>•State that composition complies</li> <li>•Specify which specific migration determinations have to be made in FP</li> </ul>
Producer of coated material	<ul style="list-style-type: none"> <li>•State that composition complies</li> <li>•Test specific migration</li> <li>•Test overall migration</li> </ul>
Food packer	<ul style="list-style-type: none"> <li>•Make sure that food packaging can be used for the purpose (contact time, contact temperature and food types)</li> </ul>

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 provided according to art. 16 or (EC) 1935/2004

## 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) 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)  
(Plastics)

## 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.'

## FDA legislation

- Different system compared with EU  
(not more or less strict)
- Many ways to clear ingredient/material
  - o Listed in the Code of Federal Regulation (CFR);  
warning relevant section depends on substrate!!!
  - o Food contact notifications (FCN)
  - o GRAS (Generally recognized as safe)
  - o Threshold of Regulation
  - o Prior Sanctioned
  - o No migration position
  - o And more....

37

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## Council of Europe Resolutions

- Resolutions submitted on many materials which are not included in the EU
- Drafted by non-EU body consisting of countries that include both EU members and non-EU members
- Often referred to and used
- **BUT**, no legal status!!!

38

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## Summary of evaluation

- How is the coating application considered in the legislation
- Is the application covered by EU measures?
- Is the substance covered by EU measures?
- If no (implemented) EU measures do apply, do National legislations exist?
- If restrictions do apply, must they be determined analytically? who has to this?
- What information should I put in the declaration of conformity?
- Do I have supporting documentation for this?

## Conclusions

- Determine how your coating is covered in the legislation: as a plastic, coating, paper, or ..
- Some EU legislation exists for coating used as food contact materials
- Member states of the EU can have additional legislation, mutual recognition may be useful
- Information has to be and is shared by documents throughout the supply chain
- Documents issued also results in legal liability
- FDA compliance ≠ EU compliance
- Council of Europe resolutions have no legal status



# Thank you!

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