



EU Food-Contact Regulation of Multilayer materials

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Rob Veraart

Keller and Heckman LLP
Brussels Belgium
Tel: +32 2 6455083
Fax: +32 2 6455050
veraart@khlaw.com

www.khlaw.com
www.packaginglaw.com
www.foodcontactmaterials.com

Washington, D.C. • Brussels • San Francisco • Shanghai

Outline

- Introduction
- EU legislation
- Overview of legislative status of materials
- Demonstrating compliance
- Mutual recognition
- Future legislative developments
- Conclusions

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.

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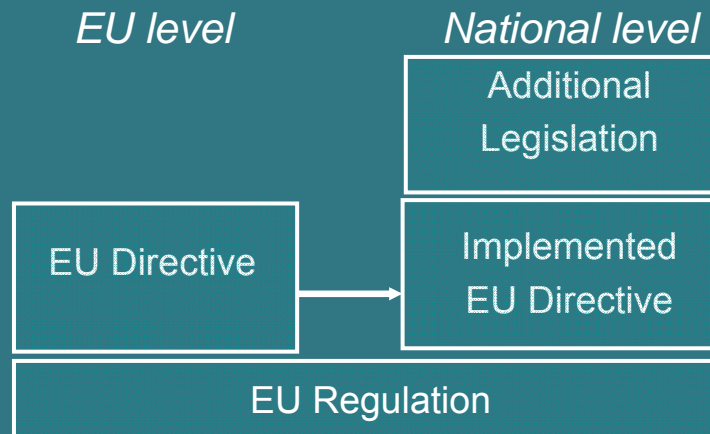
Why food contact legislation?

- Food contact legislation is prepared to ensure:
 - Free circulation of goods
 - Protection of human health
- What is covered:
Everything that can be in contact with food contact materials: obviously packaging, but also conveyor belts, industrial food processing machinery, food utensils etc

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EU & national legislation



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EU directives & Regulations

General

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

Testing conditions

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

Specific measures

Applies to one or few groups of materials

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Framework Regulation (EC)1935/2004

Article 1 + 2 purpose & definitions

Article 3 General safety requirements

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

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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

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Framework Regulation (EC)1935/2004

Article 5 Specific regulation for groups of food contact materials

Article 6-14

- o Member states may maintain or adopt national provisions
- o Free trade
- o Role of EFSA (European food and safety authority)
- o Authorization procedure

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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 16 Declaration of compliance

- o Appropriate documentation shall be made available to competent authorities
- o Only after published of special measure. For now only a measure has been published for plastics/ceramics/badge containing materials

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Framework Regulation (EC)1935/2004

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

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Multilayer packaging



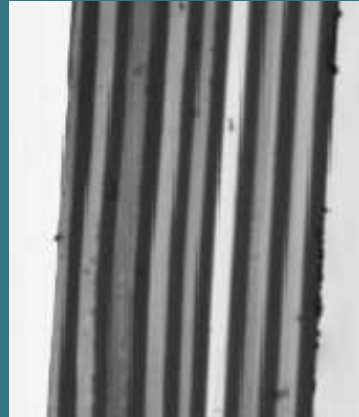
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Materials used for multilayers

The following materials are used in multilayer materials

- Plastics
- Metal
- Coatings
- Adhesives
- Inks
- Regenerated cellulose
- Paper



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Legislative status of Plastics

- Plastic include multilayers of plastic (with or without adhesive)
- Monomers completely harmonized
- Additive list incomplete. Will be considered complete soon (1/1/2008?)
- Catalysts and aid to polymerization and polymerization production aids not harmonized by EU
- Some member states do have additional national legislation
- Barrier concept (10ppb)
- Supporting documentation is needed within 1 year
- Requirements on composition, migration and purity

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Legislative status of Metal

- No EU legislation present
- Some member states do have national legislation
- In multilayers mainly aluminum is used
- No limit is present for aluminum

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Legislative status of Coatings

- Only EU legislation is available concerning the use of BADGE and the prohibition of BFDGE/NOGE (Regulation (EC) 1895/2005).
- Legislation present in some member states
- But must always comply with article 3 of Regulation (EC) 1935/2004

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Legislative status of Adhesives

- Only EU legislation is available concerning the use of BADGE and the prohibition of BFDGE/NOGE (Regulation (EC) 1895/2005).
- No national legislation present
- Expert judgment needed to state the use is safe
- But must always comply with article 3 of Regulation (EC) 1935/2004

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Legislative status of Inks

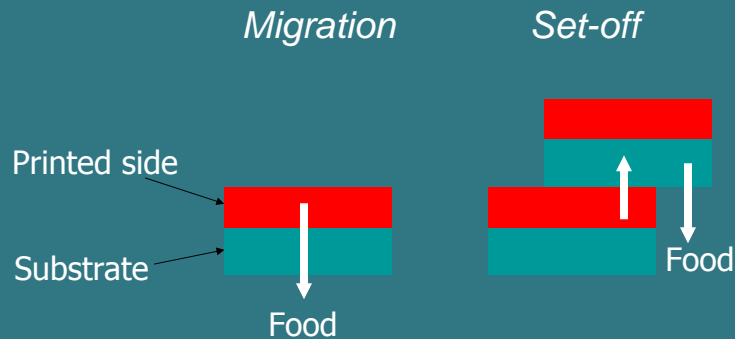
- No EU legislation is available
- No legislation in member states present
- Expert judgment needed to state the use is safe
- Migration depends on composition of inks, curing, substrate and much more
- Mentioned in GMP Regulation
- But must always comply with article 3 of Regulation (EC) 1935/2004

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Legislative status of Inks

Components may migrate in two ways to the food:



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Legislative status of Regenerated Cellulose

- Regulated at EU level for use (Directive 93/10/EEC, 93/111/EEC and 2004/14/EC)
- Positive list of additives + maximum amounts to be used
- Use of regenerated cellulose as casings excluded from the above legislation (but regulated in plastic directive)

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Legislative status of Paper

- No EU regulation present
- Some countries do have national legislation on paper (Czech Republic, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Poland, Slovakia, Slovenia)
- But must always comply with article 3 of Regulation (EC) 1935/2004

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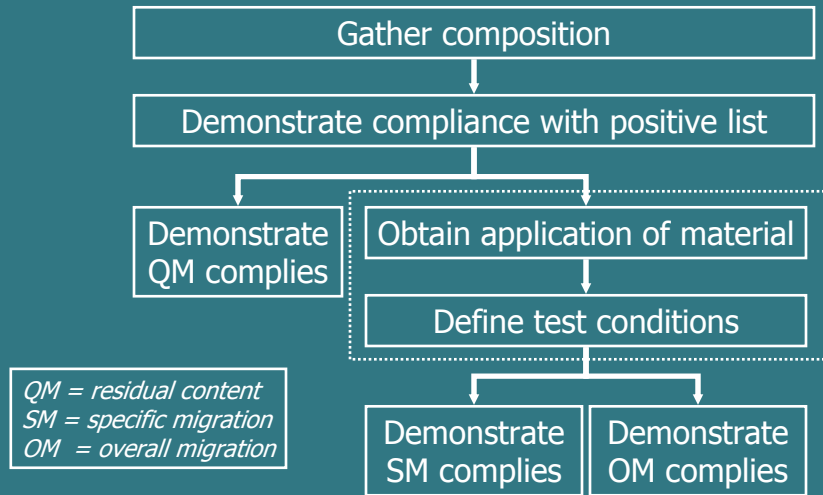
Combined materials

- Plastic not exclusively made from plastic (with or without adhesives) excluded from EU Plastics Directive, but may be regulated by some national legislation
- Limits of same component can be different for different materials.
- But must always comply with article 3 of Regulation (EC) 1935/2004

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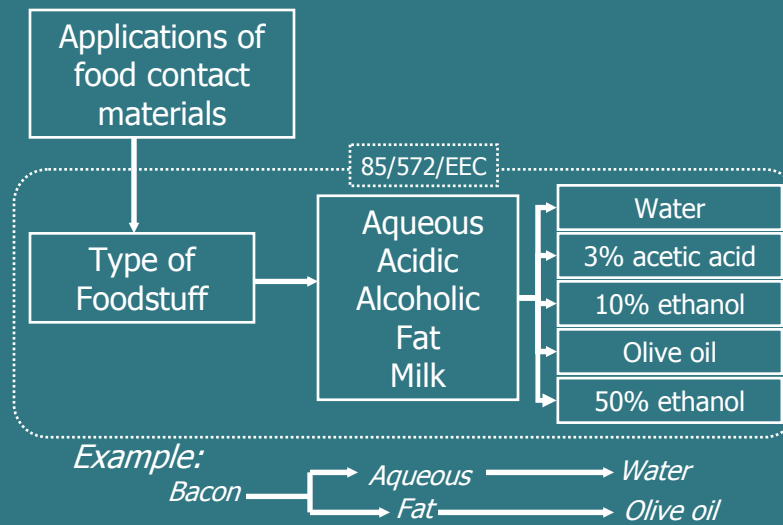
Demonstrating compliance



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Selection of test simulants



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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*

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Migration cell

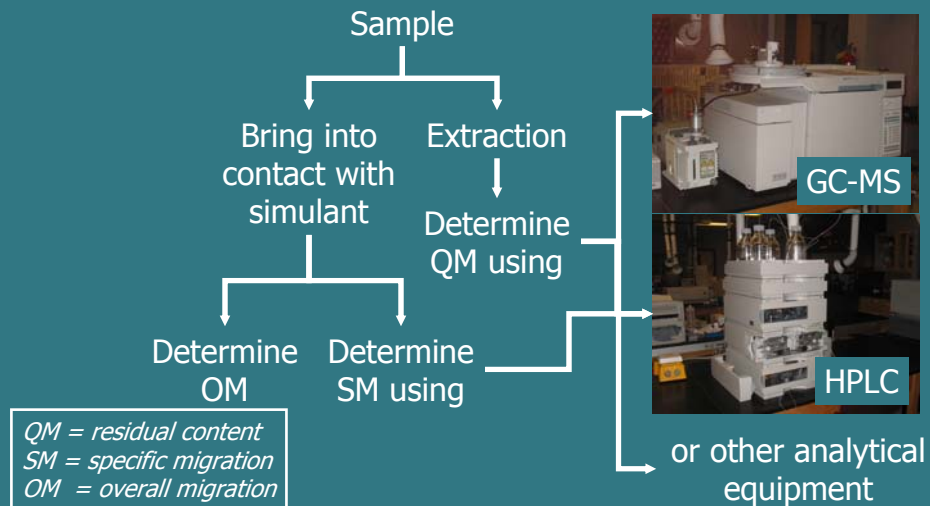
Important for multilayers: single side contact



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Determination of OM/SM/QM



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Mutual Recognition, present status

The Principle : Free Movement

- Product legally manufactured and/or marketed in another Member State benefit from a presumption of safety
- Non compliance with national positive list or other technical specifications is not sufficient to justify a restriction to market
- Member State of destination cannot restrict placement of the product on its national market unless it demonstrates a real risk to public health
- That determination must be based on a case by case risk assessment

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Mutual Recognition, future

The Exception : Justified Restriction

- The Commission adopted on 14 February 2007 a proposal for a Regulation which impose safeguards to Member state restrictive decision:
 - Member State must inform the operator in writing of its intention to restrict marketing
 - Member State must give the reasons by setting out sufficient technical or scientific evidence that the decision is "justified" and "appropriate" to protect human health
 - Economic operator must have 20 days to comment
 - Member State must respond to the comments on the basis of scientific and technical arguments
 - Member State must inform the operator in writing if it decides not to restrict access
 - Member State must specify the legal remedies available under national law
- Burden of proof is with that Member State

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Mutual Recognition, future

Status of Positive Lists

- Member States that have positive lists must allow, through a simplified procedure, the inclusion of components of products originating from other Member States which are not yet listed
- Procedures for inscription of ingredients on positive lists must be:
 - Easily accessible
 - Be concluded within a reasonable timeframe (90 days according to the Commission)
- Decisions on ingredients on positive lists must
 - Be of general application
 - Be susceptible to an effective judicial review

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Future EU food contact legislation

- Regulation on Active and intelligent packaging
- Regulation on recycling of polymers
- Additive list of 2002/72 becomes complete
- 5th amendment to the 2002/72/EC (plastics)
 - Addition of new and modification of existing monomers and additives
 - Antimicrobials?

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FDA legislation

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

For more information on FDA: Paper of David Ettinger at Wednesday 16 May at 11.00-11.30

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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!!!

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Conclusions

- EU directives and regulations applies to all EU member states
- Member states of the EU can have additional legislation
- Food contact legislation is evolving in EU
- Mutual recognition can be used
- FDA compliance \neq EU compliance
- Council of Europe resolutions have no legal status

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Thank you!

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Keller and Heckman LLP
Brussels Belgium
Tel: +32 2 6455083
Fax: +32 2 6455050
veraart@khlaw.com

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