

Using biodegradable materials in food packaging: food contact considerations

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Outline

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

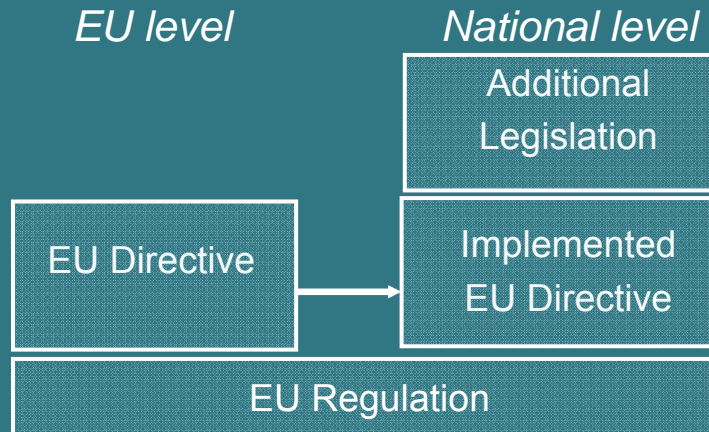
Who is Keller and Heckman?

- 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.

Why food contact legislation?

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

EU & national legislation



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

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

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

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

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

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

Materials used for/in combination with biodegradable food contact materials

Parts used for a biodegradable materials can fall in the following categories:

- Plastics
- Coatings
- Adhesives
- Regenerated cellulose
- Paper

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

Additives in plastic

		<i>Now</i>	<i>Future</i>
<i>Components on EU list</i>		May be used	May be used
<i>New components (after 1/1/2007)</i>	Dossier filed	May be used*	May be used after adoption in EU directive
	No dossier filed	May be used*	May not be used
<i>Components not (yet) on EU list, but marketed legally before 1/1/2007</i>	Dossier filed before 1/1/2007	May be used*	May be used
	Dossier filed after 1/1/2007	May be used*	May be used after adoption in EU directive
	No dossier filed	May be used*	May not be used

**if complies with requirements of Framework Regulation*

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

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

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)

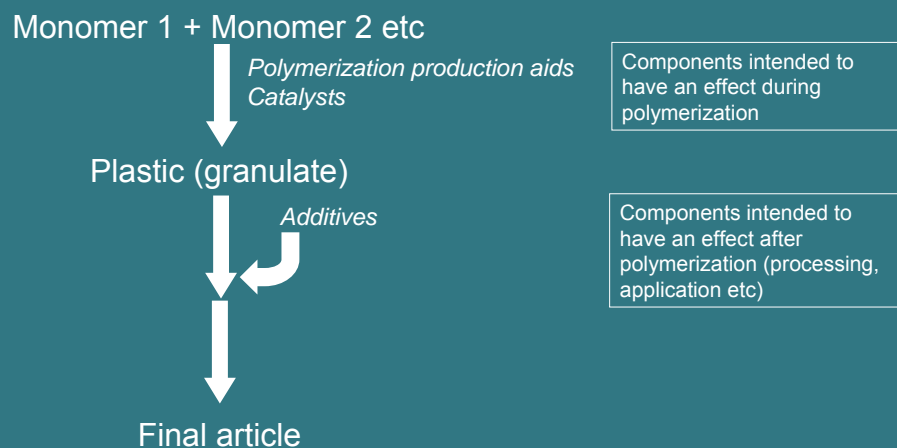
Legislative status of Paper

- 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

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

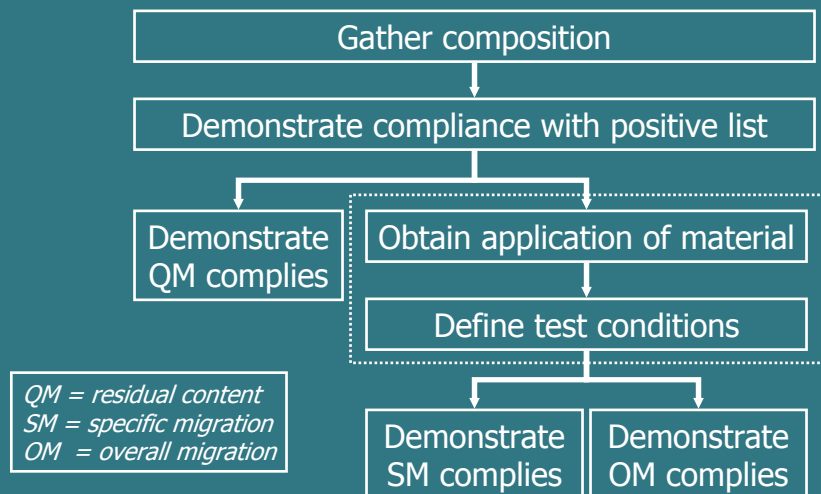
Generic process (legislation)



Actions in case of new feature

<i>Proposed change of polymer</i>	<i>Action</i>
New bio-polymerization process	Process must be on positive list
New monomer	Must be (placed) on the list of monomers
New additive	Must be safe (and must be on the list of additives in future)
New polymerization production aids	Must be safe

Demonstrating compliance

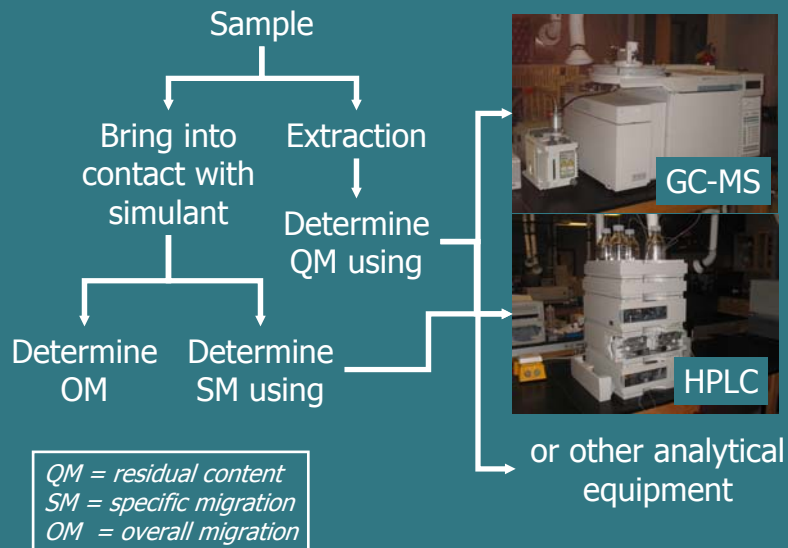


Migration cell

Important for multilayers: single side contact



Determination of OM/SM/QM



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
- Now case law, not always clear

Mutual Recognition, new regulation in preparation

- 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

Mutual Recognition, new legislation on 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

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?

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....

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!!

Contradiction in demands

During storage

Inert no components migrating to the food



After use

Break down as fast as possible



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
- Additives used in plastics will be considered as complete soon and will be fully harmonized
- Mutual recognition can be used in some cases, but be careful
- FDA compliance \neq EU compliance
- Council of Europe resolutions have no legal status
- Biodegradable plastics are treated identical as non-biodegradable plastics; same rules do apply
- Good biodegradable aspects can be in contradiction with low migration during contact with food.



Thank you!

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