

Additives for plastic and EU Food-Contact legislation

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Outline

- Definition of additives
- Overview of legislative status additives in food contact materials
- Demonstrating compliance
- Who has to do what? & statements needed
- 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.

Definition of additives according the food contact legislation

What are additives?

The American Heritage Science Dictionary :

A substance added in small amounts to something else to improve, strengthen, or otherwise alter it. Additives are used for a variety of reasons. They are added to food, for example, to enhance taste or color or to prevent spoilage. They are added to gasoline to reduce the emission of greenhouse gases, and to plastics to enhance molding capability.

What are additives? (2)

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:

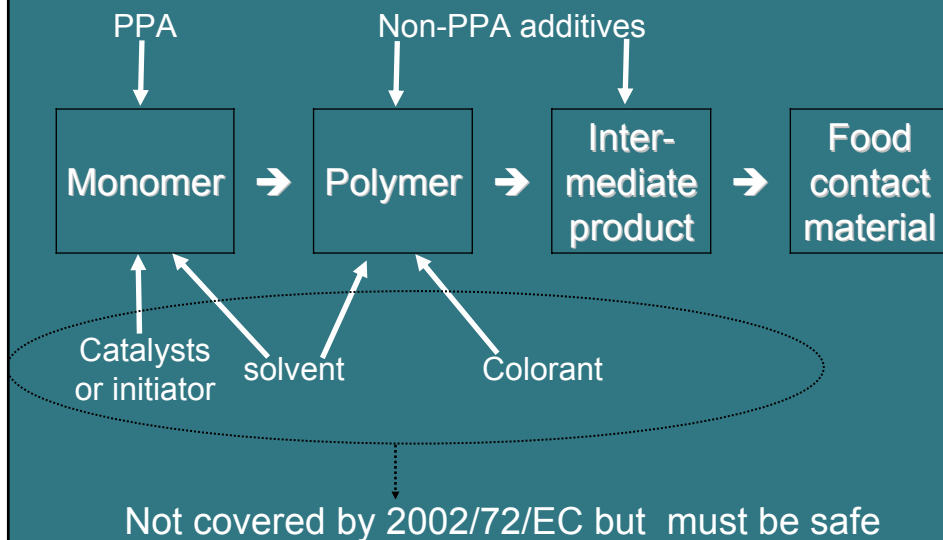
- (a) Aids to polymerization: the substances which directly influence the formation of polymers (catalysts, initiators etc);
- (b) colorants;
- (c) solvents.’;

What are additives? (3)

Polymeric additives

Any polymer and/or prepolymer and/or oligomer which may be added to plastics in order to achieve a technical effect but which cannot be used in absence of other polymers as the main structural component of finished materials and articles. It includes also substances which may be added to the medium in which polymerization occurs.

What are additives? (4)

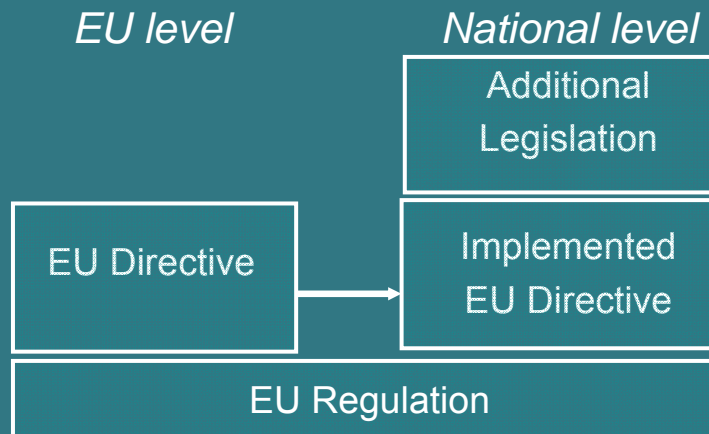


Overview of the EU food contact legislation

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 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

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

2002/72/EC plastic directive

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

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)

Special additives

Active additives

Regulation 1935/2004:

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

A specific regulation will be published (2008?)

Antimicrobials

Some have a favorable opinion of the EFSA, but are not on the EU positive list of approved additives (political discussion)

Plasticizers in lids

Temporarily (higher) specific migration limits are allowed until 30 June 2008

Demonstrating compliance with the legislation

Restrictions










Finished product:

- Overall migration

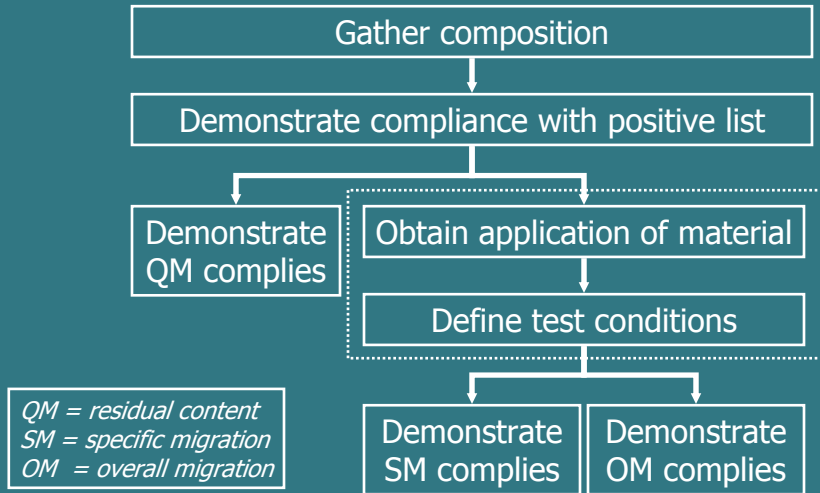
Specific components:

- Specific migration (in mg/kg food or mg/dm²)
- Residual content (in mg/kg FP or mg/dm²)
- Other, like restriction on specific impurities, viscosity of substance, Mw restriction etc

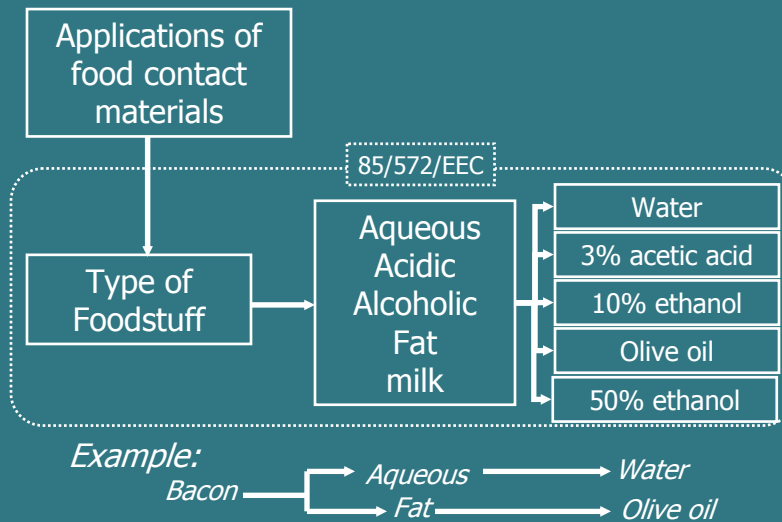
Demonstrating compliance

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

Demonstrating compliance



Selection of test simulants



Selection of test time & temperature

82/711/EEC and amendments

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

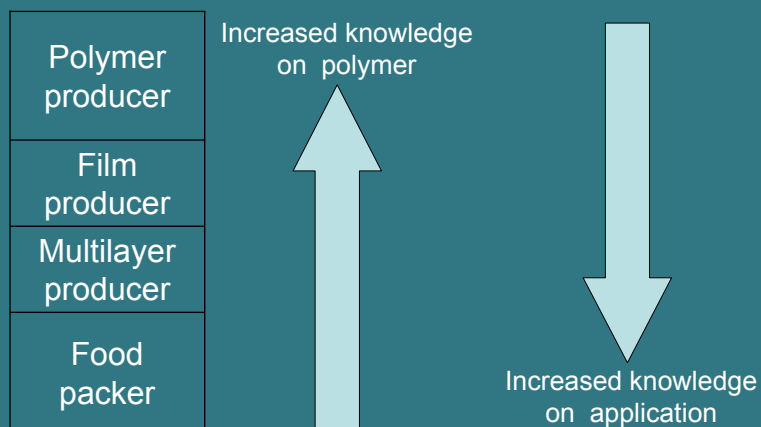
*Example: Storage for 3 months at room temperature:
Test conditions: 10 days at 40°C*

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">•State composition does comply•Specify which specific migrations has to determined in FP•test residual content
Film producer	<ul style="list-style-type: none">•State composition does comply•Specify which specific migrations has to determined in FP
Multilayer producer	<ul style="list-style-type: none">•State composition does comply•Test specific migration•Test overall migrations
Food packer	<ul style="list-style-type: none">•Make sure that food packaging is 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 less 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

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)

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)
 - 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....

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!!!

Summary of evaluation

- Is the material 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

- The legislative status of substances in plastic depends on the function and application as defined in the EU food contact legislation
- EU directives and regulations applies to all EU member states
- 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 \neq EU compliance
- Council of Europe resolutions have no legal status



Thank you!

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