

Nanotechnology

Regulatory aspects related to Food contact materials



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The content of this lecture does not necessarily represent the position of the European Commission

Summary

- Rules applicable to all FCM
- Rules on plastic FCM
- Substances in nanoform risk assessed by EFSA
- Substances for which the nanoform was included when authorised
- Rules on active and intelligent materials
- Food additives in nanoform
- Conclusion



Rules applicable to all FCM

- Do not endanger human health
- Do not change composition of the food in unacceptable way
- Do not mislead the consumer
- Be manufactured according to good manufacturing practice
- Traceability
- Labelling

Framework Regulation (EC) 1935/2004



Rules applicable to all FCM

■ **Quality assurance system**

- **Suitability of the starting materials**
- **Processes design and operation**
- **Premises and equipment**
- **Qualification of staff**

■ **Documentation**

■ **Quality control**

Regulation on Good Manufacturing Practice (EC) 2032/2006



What is plastic food contact material?

■ **If it is made by a macromolecular substance obtained**

- **By a polymerisation process such as polyaddition, polycondensation, or by any other similar process of monomers and other starting substances; or**
- **By chemical modification of natural and synthetic macromolecules; or**
- **By microbial fermentation**

Not covered are natural macromolecules which are not chemically modified

[Directive 2002/72/EC](#)

Rules applicable to plastic FCM

- Only listed monomers can be used for the manufacture (with exceptions)
 - Behind a functional barrier, migration below 10 ppb not CMR
- Only listed additives can be used for the manufacture (with exceptions)
 - Colorants
 - Solvents
 - Additives on the provisional list
 - Behind a functional barrier, migration below 10 ppb not CMR
- Polymer production aids listed and according to national law
- Aids to polymerisation (e.g catalysts) according to national law

Directive 2002/72/EC



Rules applicable to plastic FCM

- Is the use of a substance in nanoform authorised if the substance is mentioned in the list of authorised substances?
- Authorisation is based on risk assessment by EFSA/SCF
- Usually data provided for the risk assessment did not include nanoform
- Applicant or business operator obligation to inform Commission on new scientific data or technical information that might affect safety assessment
- Use of substance in nanoform triggers this obligation
- Commission has not been informed of any use
- Clarification in the future: nanoform only authorised if included in specification

Directive 2002/72/EC and Regulation (EC) 1935/2004



Substances in nanofom risk assessed by EFSA

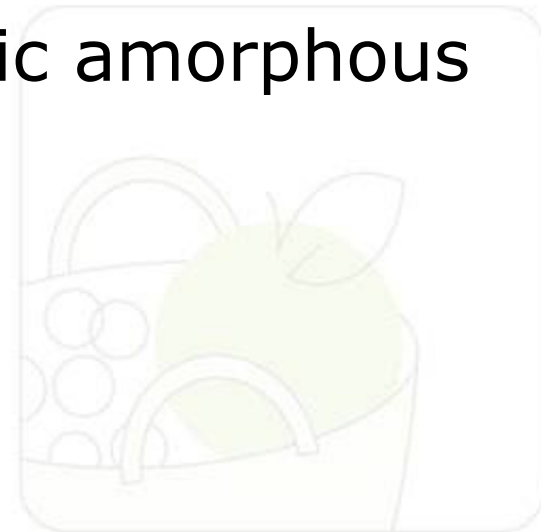
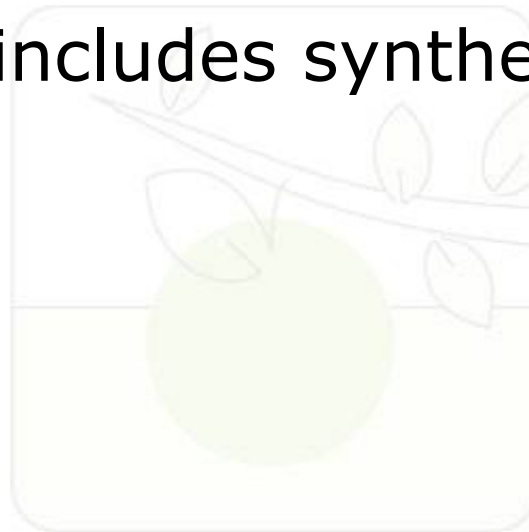
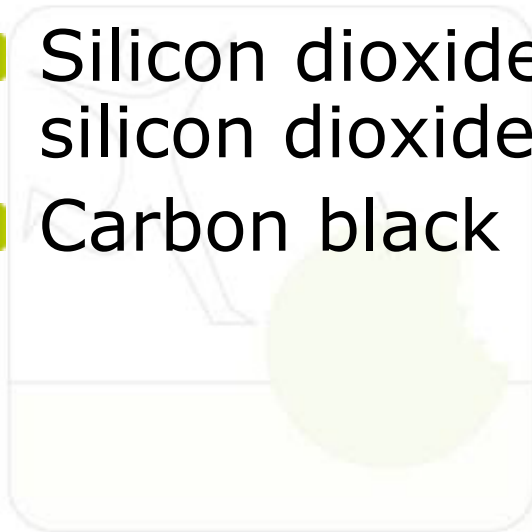
- Silicon dioxide coating (SiO_x) (max thickness 100 nm) formed from the monomers hexamethyldisiloxane and hexamethyldisilazane in situ on the inner surface of PET articles.
- Titanium nitride (TiN), nanoparticles, to be used as an additive in polyethylene terephthalate (PET) bottles up to 20 mg/kg

http://www.efsa.europa.eu/en/scdocs/doc/afc_op_ej452-454_14thlist_op_en,7.pdf

http://www.efsa.europa.eu/en/scdocs/doc/cef_op_ej888-890_21stlist_en,3.pdf

Substances for which the nanoform was included when authorised

- Silicon dioxide includes synthetic amorphous silicon dioxide
- Carbon black



What is an active or intelligent material?

■ Active material

- aims at extending the shelf-life or maintaining or improving the condition of packaged food by deliberately incorporating components that release or absorb substances of packaged food or the environment surrounding food

■ Intelligent material

- monitors the condition of packaged food or the environment surrounding the food

Regulation (EC) 1935/2004 and Regulation (EC) 450/2009

What is an active or intelligent material?

■ Active materials include

- releasers
- absorbers
- grafted substances with a function on the food

■ Intelligent material include

- Labels with indicators or sensors
- materials with incorporated indicators or sensors

Regulation (EC) 1935/2004 and Regulation (EC) 450/2009

Specifications on food additives

- Current specifications do not refer to particle size (TiO₂, Vegetable carbon, Al, Ag, Au, SiO₂, silicates, Beta-cyclodextrine, ...)
- Can be clarified in a new regulation on specifications, to be adopted at the moment food additives are entered in the annexes of Regulation (EC) No 1333/2008
- Possibility to update and revise current specifications where this is necessary
 - e.g. In light of international developments in JECFA
 - Changes required following EFSA re-evaluations
 - Other changes.....



Specifications on food additives

- change in particle size, for example through nanotechnology
- materials shall be considered as a different additive
- Before placing it on the market it is required
 - a new entry in the Community lists or
 - a change in the specifications

Rules on active and intelligent materials

- Substances forming the active or intelligent component which are not intended to be released need to apply for authorisation

- Exempted

- Substances used behind a functional barrier reducing the migration to non detectable (10ppb)

- Not exempted in any case

- Substances that are carcinogenic
- Substances that are mutagenic
- Substances toxic to reproduction
- Substance in nanoform

Regulation (EC) 450/2009

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902781209.htm



Conclusion

- Nano in plastic food contact materials covered by the current EU legislation on plastics
- Nano in active and intelligent materials covered by the current EU legislation on AIM and food legislation
- Nano in other materials subject to general framework regulation and national legislation