Nanomaterials in food contact materials
- EU Regulatory issues

The content of this lecture does not necessarily represent the position of the European Commission
**Framework Regulation (EC) No 1935/2004**

**SPECIFIC MEASURES**

<table>
<thead>
<tr>
<th>EU harmonised</th>
<th>National</th>
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</thead>
<tbody>
<tr>
<td>- Regenerated cellulose film</td>
<td>- All others</td>
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<tr>
<td>- Plastics</td>
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<td>- Ceramics</td>
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<td>- Recycled Plastics</td>
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<td>- Active &amp; intelligent materials</td>
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<tr>
<td>- Individual substances</td>
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8.2.2012, Brussels
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

Requirements for plastic FCM

- List of authorised substances with specifications, use conditions, restrictions (SML, OML)
- Migration testing rules
- Rules for Multi-layer materials
- Functional barrier concept
- Declaration of compliance
- Supporting documentation

Plastics Regulation (EU) 10/2011

8.2.2012, Brussels
Requirements for active & intelligent materials

- List of authorised substances in active or intelligent components
- Conditions of use / restrictions
- Functional barrier concept
- Declaration of compliance
- Supporting documentation

A&I Regulation (EC) 450/2009
Plastic FCM and Nano

- Substances in nanoform can only be used when they have been subject to risk assessment and authorised in this form
- Substances with reference to nanosize included in the Union list of authorised substances
  - SiO$_2$ (size specification included)
  - Carbon black (size specification included)
  - TiN (size specification included)

Plastics Regulation (EU) 10/2011
Functional barrier and Nano

- Non authorised substances can be used behind a functional barrier that reduces their migration to non-detectable
- Functional barrier concept does not apply to
  - Mutagenic
  - Carcinogenic
  - Toxic to reproduction
  - In nanoform
- These substances can only be used after risk assessment and authorisation


8.2.2012, Brussels
Non-harmonised and Nano

- General safety requirements of Framework Regulation apply
- Member States may set out requirements in national legislation
Definitions on nano in EU

Food information Regulation

- ‘engineered nanomaterial’
- intentionally produced material
- one or more dimensions of the order of 100 nm or less or
- composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less,
- including structures, agglomerates or aggregates, size above the order of 100 nm but retain nanoscale characteristic properties

Properties that are characteristic of the nanoscale

(i) those related to the large specific surface area of the materials considered; and/or
(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material;
Definitions on nano in EU

Commission Recommendation

- ‘Nanomaterial’
- natural, incidental or manufactured material
- containing particles, in an unbound state or as an aggregate or as an agglomerate
- 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm
- threshold of 50 % may be replaced by a threshold between 1 and 50 %
- Derogation for fullerenes, graphene flakes and single wall carbon nanotubes
- Reference to specific surface area by volume of the material is greater than 60 m²/cm³
- Review by December 2014

Commission Recommendation on nanomaterial definition (EU) 696/2011