Food Contact Materials
EU No. 10/2011 legislation

Welcome to the Intertek Webinar
March 1, 2012

By Sonja Grosemans and Nadine Thomis
Agenda

• Introduction to Intertek
• Framework Regulation EC 1935/2004 – EU regulations
• Plastic regulation (EU) 10/2011
  • Scope
  • Union list
  • Migration testing
  • Multilayer materials
  • Transitional provisions
• Declaration of Compliance
• Questions & Answers
An Extensive Global Network

- FTSE 100 company in the Support Services sector
- Market capitalisation at £3.3 billion
- Revenue generation of over £1bn in 2010
- Since 1885

More than 100 countries

More than 1,000 laboratories and offices

30,000 people
## Our Industries

### Our organisation
- Consumer Goods
- Commercial & Electrical
- Commodities
- Chemicals & Pharmaceuticals
- Industry & Assurance

### Industries we operate in
- Aerospace & Automotive
- Building Products
- Chemical
- Consumer Goods & Retailers
- Electrical & Electronic
- Energy
- Food & Agriculture
- Government & Institutions
- IT & Telecom
- Industrial
- Medical & Pharmaceutical
- Minerals
- Petroleum
- Toys, Games & Hardlines
- Textile, Apparel & Footwear

### What we do
- Testing
- Inspection
- Certification
- Auditing
- Outsourcing
- Advisory
- Training
- Quality Assurance
Services for the food and related industries

- Risk assessment & management
- Food regulatory support
- Food contact regulatory support
- Testing and inspection of food and food ingredients
- Physical and chemical testing of packaging materials
- Auditing (ISO 22000, BRC, IFS, FSSC)
- Training programs
- Sustainability services, LCA studies
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  • Union list
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  • Multilayer materials
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• Questions & Answers
• Materials and articles must not
  • Endanger human health
  • Bring about an unacceptable change in the composition the food
  • Bring about a deterioration in the organoleptic characteristics thereof
• Materials and articles shall be manufactured in compliance with good manufacturing practice (GMP)
• Goal: securing the protection of human health
Framework Regulation EC 1935/2004

- Applicable for all food contact materials including packaging materials, kitchen utensils and machines and other articles used for manufacturing of food.
- Applicable for all kind of materials: plastics, paper & board, glass, metals, ceramics etc.
- Other items:
  - Traceability
  - Labeling
  - Declaration of compliance (DoC)
  - Authorization of new substances
European Regulations for food contact materials

• Specific measure for materials:
  • Active and intelligent materials (EC/450/2009)
  • Regenerated Cellulose film (2007/42/EC)
  • Ceramics (84/500/EEC)
  • Recycled plastics 282/2008
  • As from 1st May 2011: New Legislation on Plastic materials (EU) 10/2011

• Specific measure on substances:
  • Nitrosamines in elastomers and rubbers
  • Vinyl chloride monomer (as from 1st May 2011 part of (EU) 10/2011
  • BADGE/BFDGE & NODGE (Epoxy derivates)

• In absence of a harmonized regulation the Council of Europe adopts resolutions (which are not binding unless transposed into national laws) for Paper & Board, Colorants, Printing inks, etc.
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Why new Regulation?

→ The European commission has updated and consolidated the regulations related to plastics in contact with foodstuffs.

Into force as of May 1\textsuperscript{st} 2011

→ Commission Regulation (EU) No 10/2011 is directly applicable in Member States
Regulation repeals rules on (as of 1 May 2011):

- Directive 2002/72/EC and six amendments
  - General rules
  - Authorised substances
  - Restrictions and specifications
  - Declaration of Compliance

- Vinyl chloride monomer directive

Regulation replaces (as of 1 Jan 2013):

- Directives on migration testing
  - Directive 82/711/EEC : Migration testing
  - Directive 85/572/EEC : Food Simulants

Transitional period
Plastic regulation (EU) 10/2011 - Scope

- Plastics mono-layers
- Plastic multilayer bound by adhesives
- Plastic layers or coatings forming gaskets in caps & closures
- Plastic layers in multi-material multi-layer materials
- All plastics can be coated and/or printed

- Remain covered by national legislation until specific community measure is adopted:
  - Adhesives, printing inks and coatings
- Excluded from the scope:
  - Ion exchange resins, rubber and silicones
Significant changes compared to Directive 2002/72:

• Plastic layers in multi-materials multilayer articles are included
• One single positive list of monomers and additives: Union list
• Expansion of the list of metal salts of authorized acids, phenols and alcohols that are permitted for use in plastics
• Changes in the simulants to be used for migration testing
• MPPO as simulant for testing dry food applications
• Separate sets of testing conditions for overall migration and specific migration testing
• Revised exposure time and temperature parameters for specific migration testing
• Screening tests as more severe tests than verification
Compositional requirements:

- Substance of good technical quality
- Union list of authorized substances
- Some substances may be used subject to national law
- Status of provisional list
- Restrictions on overall and specific migration
Union list:

- Only one list in Annex
- Only substances included in the Union list of authorised set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.
- The list contains:
  - Monomers or other starting substances
  - Additives excluding colorants
  - Polymer production aids excluding solvents
  - Macromolecules obtained from microbial fermentation
Substances authorized but not included in the Union list:

A few examples:

- **Colorants** and **Solvents** have to comply with Article 3 of 1935/2004 and national law

- **Non intentional added substances (NIAS)** (impurities, reaction intermediates, decomposition products) and **Catalysts**
  
  Risk assessment by the manufacturer based on internationally accepted risk assessment models, includes hazard assessment and exposure assessment
Management of the provisional list:

- Provisional list published on the SANCO website for information
- Substances on provisional list can continue to be used in accordance with national law
- Removal from provisional list if:
  - Included in the Union list
  - Decision is taken on non-inclusion in Union list
Migration testing provides information on the amount of substances that can migrate from the material into the food stuff.

- Overall Migration Limit (OML)
- Specific Migration Limit (SML)

- Maximum permitted quantity (QM) → Applies to the residual content of the component into the food contact material.
Overall migration limits (OML) = total of substances that can migrate (gravimetric analyses)

- Inertness limit 10 mg/dm²
- Only in food simulants A – D
- Does not cover volatile substances
- Expressed per food contact surface area, mg/dm²
- For infant food expressed per kg food
Specific migration limits (SML) = quantity of **one specific** substance that migrates (analytical analyses)

- Safety limit
- SML set out in Annex I
- If no SML specified in Annex I then 60 mg/kg
- Expressed in mg/kg
- Dual use additives/flavouring
  - No technical effect in food
  - Lowest restriction applies for authorised food additives
Plastic regulation (EU) 10/2011 – laboratory scale migration testing

Total immersion

Cell

Filling
### Plastic regulation (EU) 10/2011 – Used simulants

<table>
<thead>
<tr>
<th>Food type</th>
<th>Current situation</th>
<th>(EU) No 10/2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous food</td>
<td>distilled water (Simulant A)</td>
<td>10% ethanol (Simulant A)</td>
</tr>
<tr>
<td>acidic food</td>
<td>3% acetic acid (Simulant B)</td>
<td>3% acetic acid (Simulant B)</td>
</tr>
<tr>
<td>Alcoholic food</td>
<td>10% ethanol (Simulant C)</td>
<td>20% ethanol (Simulant C)</td>
</tr>
<tr>
<td>Semi-fatty food</td>
<td>50% ethanol (Simulant D (b))</td>
<td>50% ethanol (Simulant D1)</td>
</tr>
<tr>
<td>Fatty food</td>
<td>olive oil (Simulant D)</td>
<td>Vegetable oil (Simulant D2)</td>
</tr>
<tr>
<td>Dry food</td>
<td>No simulant assigned</td>
<td>MPPO (Simulant E)</td>
</tr>
</tbody>
</table>
New rules for migration testing (EU) No 10/2011:

Overall migration:
- 7 standard test conditions
- 2 alternative test conditions (high temperature)

Specific migration:
- Combination of contact times and temperatures

Repeated use
- Third test result compliant
- First test when proof of no increase and compliant
- First test compliant when non-detectable
Overall migration testing – new standard testing rules ((EU) No 10/2011):

<table>
<thead>
<tr>
<th>Test number</th>
<th>Contact time and contact temperature</th>
<th>Intended food contact conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>OM1</td>
<td>10d at 20°C</td>
<td>Frozen, refrigerated</td>
</tr>
<tr>
<td>OM2</td>
<td>10 d at 40°C</td>
<td>Long term storage including short term heating</td>
</tr>
<tr>
<td>OM3</td>
<td>2h at 70°C</td>
<td>Short term heating</td>
</tr>
<tr>
<td>OM4</td>
<td>1h at 100°C</td>
<td>High temperature application</td>
</tr>
<tr>
<td>OM5</td>
<td>2h at 100 °C or at reflux or 1h at 121°C</td>
<td>High temperature application up to 121 °C</td>
</tr>
<tr>
<td>OM6</td>
<td>4h at 100°C or at reflux</td>
<td>Any food contact conditions with food simulants A,B,C at temp &gt; 40°C</td>
</tr>
<tr>
<td>OM7</td>
<td>2h at 175°C</td>
<td>High temperature applications with fatty foods</td>
</tr>
</tbody>
</table>
Specific migration testing:
contact times previous situation versus (EU) 10/2011:

<table>
<thead>
<tr>
<th>Contact time in worst foreseeable use</th>
<th>Test time</th>
</tr>
</thead>
<tbody>
<tr>
<td>t ≤ 5 min</td>
<td>5 min</td>
</tr>
<tr>
<td>5 min &lt; t ≤ 0,5 hour</td>
<td>0,5 hour</td>
</tr>
<tr>
<td>0,5 h &lt; t ≤ 1 hour</td>
<td>1 hour</td>
</tr>
<tr>
<td>1 hour &lt; t ≤ 2 hours</td>
<td>2 hours</td>
</tr>
<tr>
<td>2 hours &lt; t ≤ 6 hours</td>
<td>6 hours</td>
</tr>
<tr>
<td>6 hours &lt; t ≤ 24 hours</td>
<td>24 hours</td>
</tr>
<tr>
<td>1 day &lt; t ≤ 3 days</td>
<td>3 days</td>
</tr>
<tr>
<td>3 days &lt; t ≤ 30 days</td>
<td>10 days</td>
</tr>
<tr>
<td>above 30 days</td>
<td>Specific conditions</td>
</tr>
</tbody>
</table>
Specific migration testing - special conditions (EU) 10/2011 for contact times above 30 days:

- Storage at frozen conditions:
  - Time/temperature condition: 10 days 20°C
- Storage at refrigerated conditions:
  - Time/temperature condition: 10 days 40°C
- Storage of 1 - ≤ 6 months at room temperature:
  - Time/temperature condition: 10 days 50°C
- Storage > 6 months at room temperature:
  - Time/temperature condition of testing: 10 days at 60°C
### Plastic regulation (EU) 10/2011 – Multilayer materials

<table>
<thead>
<tr>
<th>Plastic Multilayer</th>
<th>Multi-material multi-layer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Union list has to be respected for each layer</td>
<td>Union list has to be respected for each plastic layer</td>
</tr>
<tr>
<td>SML has to be respected</td>
<td>SML according to national law, Only vinylchloride monomer restriction</td>
</tr>
<tr>
<td>OML has to be respected</td>
<td>OML is not applicable</td>
</tr>
<tr>
<td>Declaration of compliance has to be issued</td>
<td>Declaration of compliance has to be issued only for the plastic layer</td>
</tr>
<tr>
<td>Functional barrier applies:</td>
<td>Functional barrier applies to plastic layer</td>
</tr>
<tr>
<td>- Maximum level of migration: 0,01 mg/kg of non authorized substances</td>
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</tr>
<tr>
<td>- not allowed: carcinogenic, mutagenic or toxic to reproduction</td>
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</tr>
</tbody>
</table>
Regulation (EU) No 10/2011 has entered into force May 1\textsuperscript{st} 2011

Transitional Provisions Regulation (EU) No 10/2011:

- Until December 31\textsuperscript{st} 2012 supporting documents based on rules 82/711/EEC

- As from 1 January 2013:
  - Supporting documents based on rules 82/711/EEC \textbf{or} based on (EU) 10/2011
  - Food simulants to be used according to (EU) 10/2011

- As from 1 January 2016:
  - All Supporting documents based on (EU) 10/2011

Materials and articles that have been lawfully placed on the market before 1 May 2011 may be placed on the market until 31 December 2012.
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Why have a DoC?

- Legal requirement
- Enables the user of the product to make an appropriate use of the product and to endorse liability for that use.
- Easy identification of the materials

Member states may retain or adopt national provisions for DoC’s in the absence of specific legislation at EU level

Some Member States consider that DoC requirement already exists for all Food Contact Materials

Strongly recommended as part of good business practice in other Member States.
Why Manage for Food Safety and Liability Avoidance..
Without the regulatory, supply chain knowledge and cooperation within the supply chain a declaration of compliance can not be issued.
(EU) 10/2011 – Declaration of Compliance (DoC)

Sharing information

- Raw Materials
- Base Materials
- Converters
- Caps, Closures & Seals
- Printing, Coating, Laminating
- Packers & Fillers
- Retailers

Documents

- State that composition complies
- Specify which specific migration determinations have to be made
- Test residual content

Make sure that food packaging can be used for the purpose (contact time, contact temperature, food type)
Applies to the final article but also intermediate stage up to starting substances.

Available at the marketing stage other than the retail stage.

 Shall permit an easy identification of the materials, articles or products from intermediate stages of manufacturing.

A new DoC should be issued if there are changes in the composition or production of the product that bring about changes in the migration.

Supporting documentation (evidence) are all in-house documents on which DoC is based.

Supporting documentation needs to be available at all stages and to enforcement authorities.

Equivalent information for non-plastic parts (adhesives, printing inks, coatings).

- Identity and address of the business operator
- Identity of the materials/articles
- Date of declaration
- Confirmation of compliance with requirements 1935/2004
- Adequate information on substances with a restriction or specification set out in (EU) 10/2011
- Adequate information on substances subject to a restriction in food (dual use additives)
- Use of a functional barrier and related requirements
- Specifications on the use of the material or article
  - Type of food
  - Time and temperature of treatment and storage
  - Ratio of food contact surface area to volume
Gathering all the available information about product composition → Assessment of the documents according to the EU and national legislation → Set up Test program (Overall & specific migration test) → Assistance with set-up Declaration of Compliance (DoC)
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Contact details

For more information:
 http://www.intertek.com/packaging/eu-food-contact-regulation/

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