Workshop on Food Contact Material legislation in the EU

Bangkok, Thailand, 1st November 2007

Compliance with legislation

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Scope

Legal requirements:
- Framework Regulation
- Plastics Directive

Certification chain

Content of a declaration

Migration experiments

Risk assessment
Framework Regulation 1935/2004

Article 16

Specific measures shall require:
- Declaration of compliance
- Supporting documentation

In the absence of specific measure, National Authorities may set requirements.

Article 9 requires:

- Declaration of Compliance according to Article 16 of Framework regulation
  - Not required at retail stage
- Issued by business operator
  - (Details in Annex)
- Supporting documentation available to authorities
Scope of Declaration

Compliance with Directive 2002/72/EC and regulation 1935/2004 of:
- Plastics materials and articles
- Substances intended for manufacture of plastics materials and articles
Substances intended for plastics

- Monomers, additives, polymer production aids
  - Purity requirements
  - Restrictions

- Polymers
  - Composition compliant with plastics directive
  - National legislation
  - Article 3 of Framework Regulation
Content of a Declaration (1/2)

- Identity of operator or importer
- Identity of materials
- Date of issue
- Information on substances with restrictions for FCM and foods (restrictions and purity criteria)
Content of a Declaration (2/2)

- Specifications of use
  - Food types
  - Time and temperature conditions
  - Ratio of surface to volume (conventional 6 dm²/kg food)

- Functional barrier for non authorized substances
  - Not CRM substance
  - Migration < 10 ug/kg food
  - Declaration should allow identification of applicable product
How to demonstrate compliance

**Determination of:**
- Composition
- Purity requirements and specifications
- Overall migration
- Specific migration of listed substances
- Residual content
- Compliance with Article 3 (risk assessment of non-harmonized substances)
- Compliance with National regulations
- Organoleptic properties
Chain of certification

- Certificate
  - Composition
  - Migration data
  - Instruction of use

- Raw material supplier
  - Certificate
    - Authorized substance
    - Restriction
    - SML; QM; QMA; purity

- Converter

- Packaging supplier
  - Printer

- Retail, Food packer
  - Certificate
    - Suitable for specified application

- Complying with conditions of use
  - or
  - Re-test
Role of stakeholders
Raw material suppliers

- Monomers and additives
  - Manufactured according to good manufacturing practice (GMP)
  - Supporting documents available to demonstrate GMP
  - Draft declaration for suitability in FCM (purity criteria) including:
    - Conditions of use of additives (e.g. maximum use temperature)
    - Restriction applicable to the substance
Polymer producer should:

- Have available declarations for monomers and additives used to manufacture the polymer
- Produce under GMP system
- Certify that the polymer is suitable for FCM
  - Identify substances with restrictions
  - Certify compliance with QM restrictions
- Archive supporting documentation
Converter/printer should:

- Have available declarations for polymers and additives used to manufacture the FCM
- Produce under GMP
- Establish conditions of use (food type, time and temperature conditions, surface to volume ratio)
- Determine relevant migrations
- Archive supporting documentation
- Draft a certificate of compliance
Food packer should:

- Have available declarations from packaging supplier
- Respect conditions of use specified
- **OR**
- Determine relevant migrations
- Maintain supporting documentation
Compliance check by enforcement authorities

- Analytical examinations
  - OR
- Inspection of declarations of compliance and supporting documents
  - AND
- In case of doubts: analytical examinations
Compliance of composition
Compositional examination

Collect data

Substances on positive list

YES

Analytical examination of composition

Thin layer chromatography
Infra red spectrometry
GC/MS and HPLC/MS
Pyrolyse GC/MS

NO

Stop investigation?
Material does not comply with Legislation?
Composition compliant

- Directive 2002/72/EC only for monomers and additives in plastic materials and articles
- Requirements for non-harmonised substances/materials:
  - Listed at national level
  - Substance behind a barrier
  - Substance compliant with Framework Regulation

- Therefore the material may be suitable for FCM
Some Non-harmonised substances

- **Catalyst** (Germany; Netherlands)
- **Initiators** (Germany; Netherlands)
- **Cross-linkers** (Germany; Netherlands)
- **Oligomers**
- **Reaction products**
- **Decomposition products**
- **Colorants** (France)
Migration experiments
Selection of test conditions

Packaging application

Type of foodstuff (85/572/EEC)

Food category
  - water
  - acidic
  - alcoholic
  - fatty
  - dairy products

Contact conditions (82/711/EEC)

Contact
  - sterilisation
  - 3 Mnd - room temp.
  - refrigerated
  - Microwave
  - Any condition

Simulant
  - water
  - 3% acetic acid
  - 10% ethanol
  - Olive oil or substitutes
  - 50% ethanol

Test conditions
  - 2 h – 121°C
  - 10 d - 40°C
  - 10 d – 20°C
  - 0.5 h – 130°C
  - 2 h -175°C
Some examples

- PE film for contact at room temperature with all food types
  - Simulants: 3% acetic acid; 10 % ethanol and olive oil
  - Test condition: 10 days at 40°C

- Fruit juice, pasteurized for 30 min at 90°C and stored for 1 year at room temperature
  - Simulant: 3% acetic acid
  - Test conditions: 30 min at 100°C followed by 10 d at 40°C

- Sausage in plastic bag stored for 3 month at ambient and heated for 1.5 min in a microwave
  - Testing: olive oil – 10 d at 40°C followed by 0.5 h at 130°C
    - water – 10 d at 40°C followed by 0.5 h at 100°C
Migration protocols according to CEN*

- Protocols drafted for migration
  - EN 1186  Overall migration
  - EN 13130  Specific migration

* European Committee for Standardization
Overall migration

- Overall migration is sum of all (volatile and non-volatile) substances (excluding water) migrating into food or food simulants.

- Determination of non-volatile substances described in EN 1186 part 1 – 15 (available from national standardization institutes).

- No validated methods available for the determination of all non-volatile substances!
EN 1186 - Overall migration of non-volatile substances in aqueous food simulants

- Contact of sample with simulant submersion, cell, filling, pouch,
- After exposure time, separate simulant from sample
- Evaporate simulant to dryness
- Weigh the residue
- Calculate OM (mg/kg or mg/6 dm²) using the conventional ratio of 6 dm²/kg food or actual ratio
- Compliant, if OM is <60 ± 12 mg/kg
Migration cell for single sided contact

TNO migration cell
Migration cell for testing can ends
Overall migration in olive oil

- Weigh the test sample at constant weight (W1)
- contact the sample with oil
- after exposure, remove oil
- weigh the sample at constant weight (W2)
- Extract the oil from the sample
- Determine the amount of oil by GC analysis (F)
- Calculate the migration
  \[ M_{\text{mg/sample}} = W1 - W2 + F \]

Compliant, if OM is $< 60 \pm 20 \text{ mg/kg}$
Critical points in the OM determination in oil

■ Weight of test sample
  ■ Sample may be moisture sensitive
  ■ Conditioning necessary
    ■ In a desiccator at constant humidity of 50%
    ■ Vacuum drying and reconditioning

■ Determination of absorbed oil
  ■ Incomplete extraction
  ■ Interference from plastic
  ■ Incomplete trans-esterification
  ■ Too large amount of oil absorbed
Specific migration – EN 13130

- Contact of sample with simulant
- After exposure time, separate simulant from sample
- Determine the substance by a suitable technique e.g. GC/FID; GC/MS; HPLC; IR; spectrometry
- Calculate SM (mg/kg or mg/6 dm²) using the conventional ratio of 6 dm²/kg food or actual ratio
- Compliant, if SM < SML (apply relevant correction factor first)
Analytical techniques

- Liquid chromatography (HPLC, SEC, LCxSEC; detection: IR, MS; light-scattering, viscosity (SEC))
- Gas chromatography (GC-MS; Pyrolysis GC-MS; GC-sniff; GCxGC)
- Mass spectrometry (MALDI-MS; APCI/ESI-MS)
- Infrared spectrometry
- Thin layer chromatography
- Nuclear magnetic resonance spectrometry (600 MHz, magic angle spinning)
- Microscopy techniques (SEM)
- Chemnometrics (PCA, PLS, PC-DA, etc.)
- Thermal analysis (TGA; DSC)
- Elemental analysis (ICP-MS; ICP-AES; AAS)
Mathematical modeling

- Use of mathematical model to calculate/predict the migration of substances.
- Model for some polymers available, based on overestimation
- If a limit is exceeded then migration experiments are required
- Free installation from:
Functional barrier

- Substances not authorized may be used behind a barrier (<10 ug/kg)

- Demonstration of functional barrier should take into account a lag-time as well as set-off

Situation at T₀

Food

Migration after 10 d at 40°C

Situation after storage for 3 month

Situation at T₀

Food

Migration after 10 d at 40°C
Should any material be tested

No, if:

- Modelling demonstrates compliance
- OM is < SML
- Worst case approach is applied
  - Thickest layer
  - Worst case time/temperature conditions
- Residual content is < SML
How to deal with non-authorized substances

Compliance with Article 3 of Framework Regulation (EC) No 1935/2004
What are non-authorized substances

- Substances not regulated but allowed to be present in FCM
  - Oligomers
  - Reaction products
  - Decomposition products
- Substances excluded e.g. catalysts, initiators, chain stop, transfer, scission or extending agents, cross linkers, redox agents, etc.
Risk assessment

- Non-harmonized substances compliant with national regulations?
- Migration data
- Exposure assessment
- Toxicological properties
  - SAR (Structural alert relationship)
  - Mutagenicity data
  - General toxicity data
- Risk assessment performed on data
- Include conclusions in declaration of compliance
Deterioration of organoleptic characteristics

- Requires organoleptic testing
- Related to type of food
- Therefore in first instance, responsibility of food packer
- Converter may be responsible as well
  - e.g. strong off-flavour due to styrene
Thank you for your attention