Workshop on Food Contact Material legislation in the EU

Bangkok, Thailand, 1st November 2007

National legislations and Council of Europe’s Resolutions on Food Contact Materials

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Summary

- General introduction
- An outline of national laws
- Council of Europe
- Inventory of the Resolutions and Guidelines
- The main content of the Resolutions and Technical documents
- Future perspectives
GENERAL INTRODUCTION

- It is impossible and not useful here to attempt summarizing the existing rules in the 27 Member States of EU or explain in detail the numerous CoE Resolutions.
- For plastics, RCF and ceramic the rules are often those which derive from the transposition of EU rules.
- Additional rules may exist at national or international level (CoE) related to subjects or materials not completely or not yet harmonized.
Therefore the aim of this lecture is:

- indicate the more important and complete legislations existing at national and CoE level

and

- summarize the more common rules
NATIONAL LEGISLATIONS IN EUROPEAN UNION (EU)
European Union in 2007

27 Member States
Inventory of the EU and national laws

(Version updated 8 August 2007)

- **PART I:** EUROPEAN DIRECTIVES AND REGULATIONS
- **PART II:** OTHER EU DIR/REGUL RELATED TO FCM MAT.
  - CONTROL
  - TIN IN CANNED FOODSTUFFS
  - TIN IN CANNED FOODSTUFFS: CONTROL
  - GENERAL FOOD LAW
  - HYGIENE OF FOODSTUFFS
  - MARKETING AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS
- **PART III:** REFERENCES OF NATIONAL LEGISLATION
- **PART IV:** SALES AGENTS
Main Member States laws on materials and articles in contact with foodstuffs

<table>
<thead>
<tr>
<th>FRANCE</th>
<th>BELGIUM</th>
<th>GERMANY</th>
<th>ITALY</th>
<th>SPAIN</th>
<th>NETHERLANDS</th>
</tr>
</thead>
</table>

- Plastics
- Cleaning agents
- Coatings
- Elastomers & rubbers
- Ionisation
- Metals
- Paper & Paperboard
- RCF
- Wood

- Plastics
- Tin
- RCF
- Paper & Paperboard
- Ceramics
- Glass

- Lebensm. und Futterm. BGBI
- 53 BFR Recommend. (By Polymer Type)

- Plastics
- Rubbers
- RCF
- Paper & Paperboard
- Glass
- Stainless steel

- Macromolec. Compounds
Main national Rules on Plastics

- **National Laws**
  - France, Belgium, Italy, Holland, Spain

- **Recommendations**
  - Germany (BgVV)

- **Other Member States**
  - No specific rules. They apply EU general rules and mutual recognition principle
Main national Rules on Plastics

Plastic rules are mainly composed by:

- a positive list
- an overall migration limit
- restrictions (SML or % of use)
- a conventional migration testing (t,T, food simulants)
Some examples of differences for plastics

<table>
<thead>
<tr>
<th></th>
<th>BE/FR/IT/NL</th>
<th>DE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OML</strong></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>SML</strong></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>% of use</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>Colorants</strong></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>Catalysts</strong></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Main national Rules on Paper

- **National laws**
  - France, Belgium, Italy, The Netherlands

- **Recommendations**
  - Germany (BgVV)

- **Other Member States**
  - No specific rules. They apply EU general rules and mutual recognition principle
Some examples of differences for paper

<table>
<thead>
<tr>
<th>Category</th>
<th>Regions</th>
<th>Status</th>
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<tr>
<td>OML</td>
<td>BE/FR/NL</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>DE, IT</td>
<td>No</td>
</tr>
<tr>
<td>SML</td>
<td>BE/NL</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>DE/FR/IT</td>
<td>No</td>
</tr>
<tr>
<td>Colorants</td>
<td>FR</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Other MS</td>
<td>No</td>
</tr>
</tbody>
</table>
How national rules can be find through Internet?

- The EU website
- Google
- Decernis Data Bank
COUNCIL OF EUROPE RESOLUTIONS
Council of Europe (CoE) is different from EU
It groups together 47 countries
It has its headquarters in Strasbourg
Norway and Switzerland take part
Partial Agreement in the Social and Public Health Field
CoE adopts Resolutions on FCM, which are not binding unless they are transposed into national laws.

The Resolutions and the related Technical Documents may constitute an appropriate reference document in absence of an EU/EC/national laws.

The importance of the activity of the CoE was underestimated as the great majority of the countries did not transpose the CoE Resolutions.
Current Inventory

- Resolution AP(89)1 on colorants in plastics
- Resolution AP(92)2 on aids to polymerization for plastics.
- Resolution AP(2002)1 on paper and board
- Guidelines concerning metals and alloys
- Resolution AP(2004)1 on coatings
- Resolution AP(2004)2 on cork
- Resolution AP(2004)3 on ion exchange resins
Cont.

- Resolution AP(2004)4 on rubber
- Resolution AP(2004)5 on silicones
- Resolution AP(2005)2 on packaging inks
- Guidelines concerning glass
- Guidelines concerning paper kitchen towels and napkins
CoE Package on Paper and Board
CoE Package on Paper and Board

- Res. AP (89)1: General requirements
- Tech Doc No 1: List of substances (incomplete)
- Tech Doc No 2: Guidelines on test conditions and methods of analysis
- Tech Doc No 3: Guidelines for recycled fibres
- Tech Doc No 4: The CEPI Guide for GMP
- Tech Doc No 5: Practical Guide
- Tech Doc No 6: Safety Evaluation of substances
Resolution on Paper and Board

- Inventory lists
- SML and other restrictions are applicable
- No OML
- GMP
- Suitable microbiological quality
- No release of substances having an antimicrobial effect
Rules on Recycled fibers

Recycled fibres can be used:

- if it originates from specified qualities
- if they are subject to appropriate processing and cleaning
- if the finished materials comply with the restrictions in the Regulation
The Committee has subdivided the substances in two lists:

- **List 1** - Substances approved by the Committee of experts
- **List 2** - Substances not yet approved by the Committee of experts
CoE Package on Coatings
Resolution and Technical Documents

Res.AP (2004)1: General requirements
- Tech Doc No 1: List of substances
- Tech Doc No 2: Guidelines on test conditions and methods of analysis
- Tech Doc No 3: The CEPE Guide for GMP
Resolution on Coatings

- It is quite similar to EU Plastics Directives
- Overall and specific migration limits are identical
- Migration testing is identical
- The real difference is in the lists of substances authorized, which likely it is incomplete
- Substances divided into the usual 2 lists as for paper and board
CoE Package on Packaging inks
Packaging Inks Package

Res AP(2005)2: General requirements

- Tech Doc No 1: Requirement for the selection of Inventory lists
  Inventory lists of: Additives//Binders//Dyes//Pigments

- Tech Doc No 2:
  1. CEPI GMP on Packaging Inks
  2. FPE GMP on flexible and fibers-based packaging

- Tech Doc No 3: Guidelines on test conditions and methods of analysis
Resolution on Packaging Inks

- It covers packaging inks applied to the non food contact surface of any material or article.

- It contains an inventory list of additives/binders/dyes/pigments subdivided into:
  - List 1 (substances evaluated) and
  - List 2 (substances not evaluated)

- Application of GMP (set off should be avoided)
  - OML and SML (for evaluated substances) and other restrictions apply
  - Other not listed substances should be ND (DL = 10 ppb)
CoE Package on Paper Kitchen Towels and Napkins
Guidelines

- Field of application
- Definition of tissue paper kitchen towels and napkins
- Specifications (no OML; only SML and other specific restrictions)
- Raw materials
- Test conditions and methods of analysis
- Recycled fibres
- Good manufacturing practices
Guidelines

Cont.

- Appendix 1: non-fibrous constituents
- Appendix 2: substances typically used
- Appendix 3: specific migration testing method
- Appendix 4: some specific methods
CoE Package on Rubber
Resolution and Technical Documents on Rubber

Res AP(2004)4: General requirements

- Tech Doc No 1: List of substances
- Tech Doc No 2: Practical Guide
- Appendix: List of substances authorized in MS
Definitions

- They should be manufactured according to GMP
- Overall and Specific migration limits as in plastics
- Migration testing similar to plastics
- 3 categories of substances according to their risk of exposure estimated by an equation which takes into account the S/V, the time and T of contact and number of times that the article is used
Resolution on Rubber

- The category having a risk for migration negligible is exempted from migration testing
- Inventory list subdivided in 2 lists (evaluated or not) as in paper and board
- Criteria purity for the finished article:
  - Nitrosamines DL = 10 ppb
  - N-nitrosatable substances DL = 100 ppb
  - Aromatic amines not listed DL = 10 ppb
CoE Package on Ions Exchange Resins (IER)
CoE Package on IER

- It contains on the Resolution and the Technical Document N.1 on the Inventory Lists
- The lists contain monomers, chemical modifiers and polymerisation aids
- The lists are subdivided in two lists:
  - List 1: substances evaluated
  - List 2: substances not evaluated and, then, not approved
CoE Package on Corks
CoE Package on Corks

- It contains the Resolution and the Technical Document N.1 on the Inventory Lists

- The Resolution contains:
  - Field of application
  - Definition
  - Specifications (but not an OML)
CoE Package on Corks

The technical documents will contain:

- Inventory Lists of monomers, additives and processing aids with SML and other Restrictions (to be completed)
- GMP (to be prepared)
- Migration Testing (to be prepared)
CoE Resolution on Silicones
CoE Package on Silicones

- It contains the Resolution and the Technical Document N.1 on the Inventory Lists.

- The Resolution contains:
  - Definition
  - Description of the silicone product group
  - Specifications such as
    - OML, SML and other specific restrictions
    - Reference to plastic migration testing conditions
The Technical Document n. 1 contains the inventory list of substances (starting substances, polymerization aids and additives) subdivided in 2 lists:

- List 1 contains substances approved
- List 2 contains substances not approved
CoE Package on Colorants
Resolution on Colorants

- It contains only the Resolution
- The Resolution contains the following requirements:
  - No visible migration and description of the method
  - Purity criteria related to metals
  - Specifications on some substances such as aromatic amines, carbon black, PCBs, etc.
CoE Package on Polymerizations aids
Resolution on Aids to Polymerization

- Scope (it covers only plastics)
- Definition
- Safety clause
- Inventory lists of substances banned
Resolution on Aids to Polymerization

- Specific Inventory list of classes of substance to be used as aids to polymerization under certain restrictions which take into account SCF evaluations and national restrictions existing at that time. Also plastic substances may be used
- OML and SML in accordance to EU plastics rule
- Migration testing according to EU plastic rules (82/711/EEC etc.)
CoE Guidelines on Cristal Glass
CoE Guidelines on Lead from Glass

- The Guidelines contains the following requirements:
  - Introduction
  - Field of application (crystalline glass and crystal glass tablewares)
  - Lead Leaching from glass hollow- and flat-wares
  - Safety aspects
  - Test methods
  - Conclusions

- Appendix 1: Parameters influencing lead leaching
- Appendix 2: Limit values in certain foodstuffs
CoE Guidelines on Metals and Alloys
The following metallic materials are covered by the Guidelines:

- Aluminium, Chromium, Copper, Iron, Lead, Manganese, Nickel, Silver, Tin, Titanium, Zinc Stainless and other alloys

The Guidelines also cover the below listed metals which may be present as impurities in some metallic materials and then migrate:

- Cadmium, Cobalt and Mercury
Future Perspectives in CoE
Perspectives in CoE
Change the speaker, please!
Main EU Websites on FCM

EU
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

Joint Research Center
http://crl-fcm.jrc.it/

Council of Europe
http://www.coe.int/T/E/Social_Cohesion/soc-sp/Public_Health/Food_contact/
THANK YOU FOR YOUR ATTENTION!