Legislation of Food Contact Materials in the European Union, the Netherlands and USA.
TNO short introduction

- Independent Contract Research Organization
- Based in the Netherlands 5000 employees
- 5 Business centers, 15 Locations

TNO Quality of Life core activities

- Pharma
- Chemistry
- Food and Nutrition
- Prevention and Healthcare
- Work and Employment
Outline of the presentation

• Regulations on Food Contact Materials in the EU
• Requirements of Plastic Directive
• Regulations on Food Contact Materials in The Netherlands
• Regulations on Food Contact Materials in the U.S.
Regulations on Food Contact Materials (FCM*)

- European directives
  - Implemented in national regulations

- National regulations
  - Differences in each country,
    Netherlands: Verpakkingen- en Gebruiksartikelenbesluit (VGB)
  - Germany: Empfehlungen of BfR, Bedarfsgegenständeverordnung

- Council of Europe resolutions
  - No legal status, Preface to EU Directives.

- FDA (USA Food and Drug Administration)
  - Does not guarantee compliance with European systems

*FCM everything that will or can expected to be in contact with food like: Packaging (metal, plastics, coated metal), Filters, Machinery, Conveyor belts
The Framework Regulations (EC) 1935/2004 (1)

Applies to all food contact materials (direct and indirect) + active and intelligent packaging

- Establishes a “general safety requirement” (Art. 3)
  - manufacture in compliance with **GMP** so that constituents do not transfer to food in quantities that could **endanger human health** or bring about an **unacceptable change in composition** or **organoleptic characteristics** of food
  - Labeling, advertising, or presentation shall not mislead consumers
The Framework Regulations (EC) 1935/2004 (2)

- Establishes labeling, certification and record-keeping requirements
  - Labeling by a symbol “for food–contact”
  - Traceability (one step down and one step up)
  - Product name, name and address of seller

- Qualifies the procedures for Food Contact Materials

- Provides for the requirements for the adoption for specific “measures” for specific types of materials like:
  - A&I Packaging, Ceramics, Printing inks, Woods, **Rubbers**, Glass, Silicones
EU Regulations

Framework Regulation 1935/2004

Specific Directives
- Plastics 2002/72*
- Ceramics 84/500*
- Cellophane 93/10*
- Nitrosamines 93/11
- Regenerated cellulose 2007/42
- Vinylchloride 78/142*

Special Directives
- Basic rules for migration testing
- Test conditions 82/711/EEC*
- Simulant selection 85/572/EEC*

* means amendments are connected

Implemented in National Legislation

Specific regulations
- Epoxy comp. 1895/2005
- GMP 2023/2006
- Gaskets 372/2007

Karl Ehler B.Sc.
The Plastic Directive 2002/72/EC

- Applies to food contact materials and articles made entirely of plastics
- Applies to multi-layer articles made of plastics and bound together by adhesives
- Requires positive lists of authorized starting materials
  - Separate list of monomers, additives
  - New components added on lists by petition process
- Limits on migration into food
  - Overall migration limit (OML) 60mg/kg/foodstuff
  - Component-specific restrictions, (SML), depending on toxicity data.
- Requirements on residual content in the polymer (QM) and Purity
Content of 4th Amendment to 2002/72/EC

- Introduction of Fat (Consumption) Reduction Factors (FRF)
- Introduction of Functional Barrier (FB) (DL = 10 µg/kg food)
- Detailed description of Documentation of Compliance (DoC) and Supporting Documents (SD)
- Other rules (milk, infants, control)
Selection of the Test protocol
according 97/48/EC and 85/572 EEC

Plastic as food contact material

Type of food

Contact conditions

Food category

Water
Acid
Alcoholic
Fat
dairy products

Contact

sterilization
3 Month - room temp.
refrigerated
Microwave
Any conditions

Test conditions

water
3% acetic acid
10% ethanol
olive oil
50% ethanol

2 h – 121 °C
10 d - 40°C
10 d – 20°C
0.5 h – 130°C
2 h – 175°C
Dutch regulations

- Packaging and Food Utensils Regulation
  - I Plastics (EU Directives inclusive)
  - II Paper and Paperboard
  - III Rubber elastomers
  - IV Metals
  - V Glass and glass ceramics
  - VI Ceramics (EU Directives inclusive)
  - VII Regenerated cellulose (EU Directives inclusive)
  - VIII Textile
  - IX Wood and Cork
  - X Coatings

Karl Ehlert B.Sc.
Under which category falls my rubber product.

- **Category 1:**
  - Baby articles
  - Teeters
  - Articles intended for babies and toddlers
  - Articles intended to come into contact with baby food

- **Category 2:**
  Rubber articles to which the product of $R_1$, $R_2$, $R_3$ and $R_4$ is higher than 0.001.

- **Category 3:**
  Rubber articles to which the product of $R_1$, $R_2$, $R_3$ and $R_4$ is smaller than 0.001.
Definition of the factors $R_1$, $R_2$, $R_3$ and $R_4$

- $R_1$ Depend on the relative contact area (RO) between the rubber and food. Expressed in cm² rubber area per kg food. 
  $R_1$ can be calculated as follows:
  - $R_1 = \frac{R0}{100}$
  - If the relative contact area $> 100$ cm²/kg, then $R_1 = 1.00$

- $R_2$ Depends on the temperature
  - $R_2 = 0.05 \cdot e^{0.023T}$
  - If Temperature $> 130°C$, then $R_2 = 1.00$

- $R_3$ Depend on the time of contact
  - $R_3 = \frac{t}{10}$
  - If contact time longer than 10 hours, then $R_3 = 1.00$

- $R_4$ depend on the total times an articles comes into contact with food
  - $10 \log R_4 = 6 - 2^{10} \log N$
  - If total times an article comes into contact with food $\leq 1000$, then $R_4 = 1.00$
Example 1: Glass jar for preserving food with a rubber ring.

The rubber ring has an outside diameter of 10.2 cm, whereas the thickness is 4 x 4 mm. The capacity of the jar may vary from 0.25 to 25 l. The food is preserved for 1 hour at 100 °C and subsequently stored at room temperature for maximum 1 year. The rubber ring will be re-used once a year over a period of 5 years.
• Contact area: 15.5 cm²/jar:
• For a jar of 2 l $R_1 = 0.078$
• Contact temp. 100°C $R_2 = 0.5$
• Contact time: 1 h $R_3 = 0.1$
• Number of times of exposure: 5 times

• For a jar of 25 l $R_1' = 0.0062$
• Contact temp. 20°C $R_2' = 0.079$
• Contact time: 360 days $R_3' = 1$
• R4 = 1.00

• $R_{\text{Total}}$ depends on the capacity of the jar, temperature and time conditions. In this example all these parameters may vary. Therefore the $R$-total is calculated for the different situations

$R_{\text{Total}}$ for a 2 l jar at 100°C $= (0.078 \times 0.5 \times 0.1 \times 1) = 0.0039$
$R_{\text{Total}}$ for a 2 l jar at 20°C $= (0.078 \times 0.079 \times 1 \times 1) = 0.0061$
Rsum$ = 0.0039 + 0.0061 = 0.01$

$R_{\text{Total}}$ for a 25 l jar at 100°C $= (0.0062 \times 0.5 \times 0.1 \times 1) = 0.00031$
$R_{\text{Total}}$ for a 25 l jar at 20°C $= (0.0062 \times 0.079 \times 1 \times 1) = 0.00049$
Rsum$ = 0.00031 + 0.00049 = 0.0008$

Category II

Category III
Components to that may be used to produce rubber articles and their categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Spec. migr. limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3</td>
<td>1 2</td>
</tr>
</tbody>
</table>

- Monomers
  - Acrylnitril + +
  - Butadiene + + +
- Accelerators, maximum 3%
- Activators
- Protecting aides
  - 2.2’methylenebis + + + 0.15 1.5
    - (4-methyl-6-tert. butylphenol)
- Plastizers, Fillers, Emulsifiers

Overall migration limits of rubber articles

- Normal overall migration limit 60mg/kg/foodstuff
- Overall migration limit for rubber articles
  - Category 1 products 20 mg/kg/foodstuff
  - Category 2 products
    - Determined in 3% acetic acid: 100 mg/kg/foodstuff
    - Determined in other simulants: 60mg/kg/foodstuff

Karl Ehlert B.Sc.
Compliance tests at TNO

1. Gather all necessary elements
2. Components on positive list EU/National legislation
   - YES: Analytical investigation on the composition
     GC/MS and HPLC/MS
   - NO: End of investigation
     Material not in compliance with the legislation, Registration?
FDA requirements for food contact materials

- Food additive regulation
  - Direct additives: part 172
    - Food ingredients
    - Technical effect on the food
  - Secondary direct additives
  - Indirect additives
    - Food contact materials
    - No technical effect on the food

- Exemptions

- Food contact notification
21 CFR part 170 to 186

- 174 – General
- 175 – Adhesives and coatings
- 176 – Paper and Paperboard
- 177 - Polymers
- 178 – Adjuvants, Production aids and sanitizers
- 181 – Prior- Sanctioned substances
- 182, 184, 186 – GRAS substances
21 CFR part 177

- 177.1010 – Acrylic and modified acrylic plastics
- 177.1020 – Acrylonitrile/butadiene/styrene copolymer
- 177.1210 – Closure with sealing gaskets for food containers
- 177.1390 – Laminates
- 177.1500 – Nylon resins
- 177.1520 – Olefin Polymers
- 177.1580 – Polycarbonate
- 177.1590 – Polyester elastomers
- 177.2600 – Rubber articles intended for repeated use.
Example 2: Colored Polypropylene article

- Polypropylene \( \rightarrow 177.1520 \)
- Triisopropanolamine \( \rightarrow 177.1520 \)
- Irganox 1076 \( \rightarrow 178.2010 \)
- Titanium dioxide \( \rightarrow 178.3297 \)
- Calcium stearate \( \rightarrow 184.1229 \)
- 2,6-di-tert-butyl-4-ethylphenol \( \rightarrow 178.2010 \) *

* For use only in contact with non alcoholic foods
21 CFR part 177.2600 Rubber articles

- Elastomers
- Vulcanization agents
- Accelerators (not more than 1.5%)
- Retarders (not more than 10%)
- Activators (not more than 5%)
- Antioxidants (not more than 5%)
- Plasticizers (not more than 30%)
- Fillers
- Colorants
- Lubricants (not more than 2%)
- Emulsifiers
- Miscellaneous (not more than 5%)
Example 3: rubber article to come into contact with aqueous food

- Polyisoprene
- Benzoylperoxide 0.5%  Accelerators
- Dibenzylamine 0.1%  Accelerators 0.6%
- BHT 0.5%  Antioxidants
- Castor oil 10%  Plasticizers
- Barium sulfate 5%  Fillers

When extracted with water at reflux

1\textsuperscript{st} extractives < 20 mg/in\textsuperscript{2} during 7 hours extraction

2\textsuperscript{nd} extractives < 1 mg/in\textsuperscript{2} during 2 hours extraction
Regulations on Food Contact Materials in the US

1. Gather all necessary elements

2. Components on positive list CFR 21 section 170-190
   - YES
   - NO
     - Component part of exemption?
       - YES
         - Perform relevant tests
       - No
         - FCN
Conclusions

- EU regulations are focused on the starting components (monomers and additives)
- FDA regulations are focused on the type of material (end product).
- EU: restriction to residual content and specific migration limits
- FDA: restriction to added amounts
- EU: migration testing
- FDA: Extraction testing

- In Europe applies EU regulations and not FDA regulations
Thank you for your attention

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