Council of Europe activities

on Food Contact Materials
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European Directorate for the Quality of Medicines & HealthCare (EDQM)
HealthCare Activities: Technical Guides - Resolutions & Recommendations

- **Steering Committees and experts** develop guides to ensure quality and good practices & protect consumers, e.g.
  - Safe cosmetics for young children
  - **Metals & alloys used in food contact materials**
  - Guidance on essential oils in cosmetic products
  - Hydrogen peroxide in cosmetic products
  - Safer tattooing: overview of current knowledge and challenges of toxicological assessment

- **Council of Europe Recommendations and Resolutions:**
  Adopted by the [Committee of Ministers]: “... Recommends to the governments of member States Parties to the Convention that they adopt legislative and other measures ...”
Food contact materials and articles

- **Steering Committee (2018)** supported by the Secretariat Committee for food contact materials and articles (Partial Agreement) (CD-P-MCA) - ToR renewed every two years.
- **Members**: delegates from the 38 countries of the Pharmacopoeia Convention (27 countries have appointed representatives).
- Rapporteurs assigned to projects (members or participants).
- Plenary sessions: 1-2 times a year, in Strasbourg.
- *Ad hoc* working groups: flexible in time and place; ± 1-2 times a year meetings, teleconferences.
- *Ad hoc* electronic working groups, teleconferences.
FCM Resolution – Guiding Principles / Technical Guides

- **Scope**: all FCM under Regulation (EC) 1935/2004 which are not covered by specific measures at the EU level
- **Best practices** to ensure quality and safety:
  - Principles for the intentional use of substances
  - Compliance documentation and declaration of compliance for all FCM
- Technical guides to cover material-specific issues (restrictions for substances to be used in the manufacture, testing issues, etc)
- Technical guide for compliance documentation and declaration of compliance
Other on-going activities

- Compliance Documentation – Technical guide supplementing the Resolution.
- Paper and Board – Technical guide supplementing the Resolution.
- Printing inks – Peer-review of multianalyte method.
- Enamels – Survey led by Slovenia on current situation in CoE member States.
- Coatings – Follow-up EFSA-FIP taskforce.
- Cork, Ion exchange resins, Printing inks.
Paper and Board: Technical guide

• Substances intentionally used: links to member state(*) legislations/official recommendations.
• Table with SMLs for certain substances.
• Reference to standards and tests.
• Restrictions for the use of recycled fibres.
  • Functional barrier / absorbent.
  • Reference method for assessing barrier efficiency.
  • 10 ppb migration limit, no CMR, nano.
  • Specific requirements in the compliance documentation and declaration of compliance.

(*) France, Germany, Italy, Netherlands.
Printing Inks: Multi-analyte method peer-review

- Study’s scope: determination of interlaboratory reproducibility (precision)
- 14 laboratories
- Both GC and LC based analysis
- Analytes: 6 photoinitiators, 3 degradation products, 1 plasticiser
- Matrices: 95% EtOH, dry food (flour or ground baking product)
- Common extraction/purification step
Selection / Development of the method

- Questionnaire for existing methods.
- Optimisation of GC-MS/MS and LC-MS/MS detection parameters.
- Feasibility study (May 2019): analytes in 95 % ethanol (12 laboratories participated).
  - 10 μg/L achievable LOD
  - linearity > 0.99
  - mean recoveries 95 – 120 %
  - RSD < 20 %
- Extraction procedure from dry food
  - Carrez and QuEChERS based - comparison
Thank you for your attention