

The role of the Council of Europe/EDQM in setting standards for FCM in Europe

Luxembourg, 30 September 2015

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The Council of Europe

The Council of Europe is the continent's leading human rights organisation.

It includes 47 member states, 28 of which are members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law.

Public Health and consumer protection

EDQM's mission

- enabling the development,
- supporting the implementation, and
- monitoring the application

of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The [European Pharmacopoeia](#) is legally binding in member states.

Similarly, the EDQM develops guidance and standards in the areas of [blood transfusion](#), [organ transplantations](#) and [consumer health issues](#)

We are committed to working in partnership with regional, national and international agencies, authorities, institutions and industry associations for the wider benefit of all.

Council of Europe Resolutions on food contact materials

First resolution in 1989

- 14 member States

Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Spain, Sweden, Switzerland and the United Kingdom.

- colourants use in plastic materials

Today, 37 member states are eligible for participation and also the EC, JRC and EFSA.

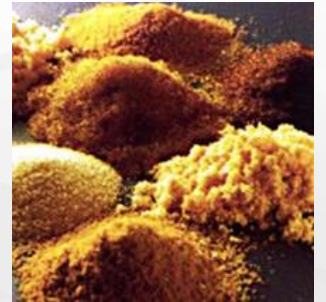
Further CoE Resolutions & guidance:

- Aids to polymerisation (1992)
- Silicones (1999)
- Paper and board (2002)
- Rubber products (2004)
- Lead leaching from glass (2004)



Further CoE Resolutions & guidance:

- Coatings (2004)
- Cork (2004)
- Resins for ion exchange and absorption (2004)
- Printing inks, varnishes: (2005)
- Metals and alloys (2013)



Material quality defined by:

- General requirements (such as absence of transfer, unacceptable change of foodstuffs, GMP)
- Monomers and additives included in lists based on evaluation by EFSA or member state
- Restrictions for substance use and release
- Test conditions
- Analytical methods

Example: Technical Guide on metals and alloys



Practical guide for manufacturers, regulators and control laboratories (private and public sector)



Specific release limits (SRLs) for metals and alloy components and impurities, e.g.:

SRL Ni 0.14 mg/kg, Pb 0.010 mg/kg

Guidelines on test conditions, measurements and analytical methods.



Cont'd Metals and alloys: complementary guidelines by CoE and JRC:

Open questions on e.g.
repeated use articles:

- reflecting « normal use » or « worst case »
under test conditions, e.g. temperature/time
for silverware or professional knives
 - testing in real food versus simulant
- => Collect data from experimental testing



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Discussion items concerning FCM at the level of CoE/EDQM expert committee

- official control laboratories: substances to be targeted (monomers, oligomers, additives), use of multi-analyte methods
- FCM substance database hosted by WIV-ISP
- question of material recycling, functional barriers
- requirements for material-specific *Declaration of Compliance*
- Framework Resolution for FCM not specifically EU regulated

Gouvernance at CoE/EDQM level & involvement of national authorities

Steering Committee CD-P-SC : Consumer Health
Protection Committee (open to 37 countries + EU, EFSA,
JRC, observers)
=> reports to Committee of Ministers

Committee of Experts P-SC-EMB : Committee of Experts
on packaging and working groups (open to 37 countries +
EU, EFSA, JRC, observers)

Working groups per type of material: metals and alloys,
paper and board, printing inks, others when needed

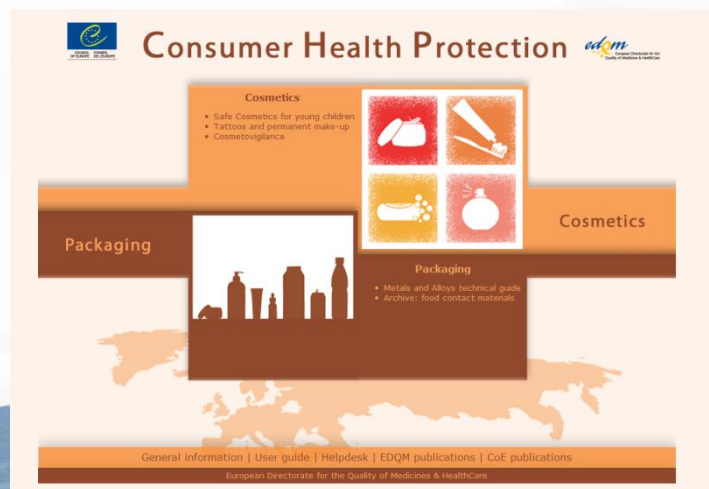
Access to information

Consumer Health Protection website:

<http://www.edqm.eu/en/consumer-health-protection-1415.html>



Cosmetics & Packaging guides
paper copies and
restricted website, EPUB
www.chp.edqm.eu





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Thank you for your attention!