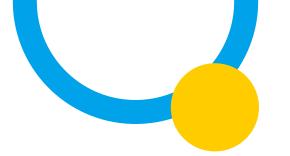


European Directorate for the Quality of Medicines & HealthCare

Council of Europe







Joint EDQM-AESAN Symposium on FCM, Madrid, 18-19 September 2024

The Council of Europe's European Committee on Food contact materials and articles (CD-P-MCA)

Laurent Mallet and Susanne Bahrke EDQM, Council of Europe











II - The EDQM

III - The CD-P-MCA











European
Directorate for
the Quality of
Medicines &
HealthCare





Council of Europe

- ★ Founded in 1949
- *** 46 member countries**
- ★ To promote democracy, human rights and the rule of law
- ★ Headquartered in Strasbourg

★ More than 700 million citizens

★ Core values:

- Human rights
- Democracy
- Rule of law







Committee of Ministers



Parliamentary Assembly



Congress of Local and Regional authorities



European Court of Human Rights



Commissioner of Human Rights



Conference of INGOs





EDQM

- ★ Founded in 1964
- ★ Partial Agreement(39 Members & the EU+ 33 observers)
- ★ Wide scope of activities



Our vision

Together for better health, for all

Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders





Key figures

Administrative entities





More than **400 staff members 30 nationalities** and dozens of different professions









Metz

Areas

- **★**Medicinal products
- ★ Substances of Human Origin ★Pharmaceutical care
- ★Consumer health

Working with a global network of almost 2 000 experts from a wide variety of scientific disciplines

- **★5** steering committees directly answerable to the Committee of Ministers
- **★3** subordinate committees
- **★1** treaty-based body (EPC)
- **★2** steering committees (BSP, CEP)
- **★2** networks
- ★More than **100** expert groups





Four policy areas & a wide portfolio of activities



Medicinal products

Official standards for manufacture and quality control of pharmaceuticals **European Pharmacopoeia**,

European Pharmacopoeia, reference standards, biological standardization

Certificates of Suitability confirming compliance with European Pharmacopoeia and inspections

Certification of suitability

Control of medicines
Network of Official Medicines
Control Laboratories (OMCL)



Substances of human origin

Quality & safety standards

Data collection

Improving quality system / capacity building of Blood and Tissues & Cells Establishments



Pharmaceutical care

Policies & model approaches for the safe use of medicines

Cooperation to combat falsification of medical products



Consumer health

Safety standards for cosmetics, tattoos and food contact materials

Control of cosmetics
Network of Official
Cosmetics Control
Laboratories (OCCL)





Intergovernmental Committees





European Committee on Blood Transfusion (CD-P-TS) European Committee on Organ Transplantation (CD-P-TO) European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) **European Committee** for Food Contact Materials and Articles (CD-P-MCA) European Committee for Cosmetics and Consumer Health (CD-P-COS)

European Pharmacopoeia Commission Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO) Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED)







CD-P-MCA

Main objective



Ensures safety and quality of food contact materials and articles and harmonises measures supplementing EU & national laws

Standard setting



- Resolutions/Recommendations
- Technical guides e. g. Metal and alloys. Paper and board

Steering committee

Reports to the CoE Council of Ministers, prepares recommendations such as Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food and guidelines for specific materials.

Designated representatives from 36 (out of 39) member States



Participation of the **European Commission**, Joint Research Centre, EFSA.

Observers from Georgia, Singapore, and Taiwan Food and Drug Agency (TFDA).







The EDOM coordinates the CD-P-MCA work programme and is an observer to the EC WG FCM of the Toxicological Safety Section of the SC-PAFF, EFSA FCM Network and the JRC Taskforce on kitchenware testing.

EDQM and its partners







- ★ European Commission
- ★ European Medicines Agency
- ★ European Food Safety Authority
- ★ European Chemicals Agency





Stakeholder engagement in the work





Working groups

Working groups include experts nominated by member states and observers (including professional associations).

Selection criteria:

- technical and scientific expertise in the required fields
- ★ Experimental testing capacity
- ★ Access to relevant information and data
- ★ Balanced representation of sectors, branches and geographical regions

Declaration of interest form (Dol) and confidentiality undertaking form.



Stakeholder consultation

Invitations sent to national competent authorities (via CD-P-MCA members, participants and observers; relevant scientific/professional associations; and others designated by any of the above.

Consultation period: 6 weeks

Each comment is assessed and decisions on acceptance are documented.



Putting standards into practice

Monitoring compliance with the applicable rules

- ★ Official control activities/market surveillance campaigns at the national level
- ★ Companies' own checks
- ★ Rapid alert system for food and feed RASFF

Capacity building activities

- Development of suitable analytical methods
- ★ Proficiency testing
- ★ European laboratories network for FCM







Work programme 2024-27

Implementing Resolution CM/Res(2020)9:





Metals and alloys

2nd edition of Technical

Guide 2024

Compliance Documentation

1st edition of new guidelines in preparation

Cork review of technical documents

2025

Enamels

new guidance document in preparation

Coatings

review of technical documents

2027

Ion exchange resins

review of technical documents





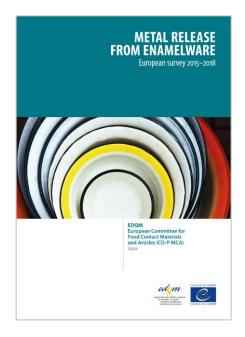


Published technical guidance on materials, analytics testing, survey



Food contact materials and articles – substances migrating from printing inks to food or food simulants

Download



Metal release from enamelware

Download



Metals and alloys used in food contact materials and articles

Download



Paper and board used in food contact materials and articles

Download





Policy statements

(some of them under revision)

Resolution CM/Res(2020)9

on the safety and quality of materials and articles for contact with food <u>More info</u>



Material-specific guides

Coatings

Policy statement (v 2009)

Cork stoppers

Policy statement (v. 2007)

Glass

Policy statement (v. 2004)

Inks

Policy statement (v. 2007)

Metals and alloys, Technical Guide 2013

1st Edition download for FREE

Paper and board, Technical Guide 2021

1st Edition download for FREE

Resins for ion exchange and adsorption

Policy statement (v. 2009)

Rubber

Policy statement (v. 2004)

Silicones

Policy statement (v. 2004)

Tissue paper

Policy statement (v. 2004)





Access to information on FCM on the EDQM webpages



<u>2023 Highlights</u> <u>EDQM annual report</u>

FCM webpage HelpDesk

To join the work, contact the secretariat at: consumer.health@edqm.eu

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