

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



FCM Resolution CM/Res(2020)9 **&** **CD-P-MCA work programme 2022-25**

Bahrke S, Carrilho T, Scientific Officers

10th meeting of the EFSA Network on Food Contact Materials
17 - 19 October 2023

Topics:

FCM requirements in Resolution CM/Res(2020)9

-

Technical Guidance

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CD-P-MCA Work programme 2022-25

The EDQM, a Directorate of the COUNCIL OF EUROPE

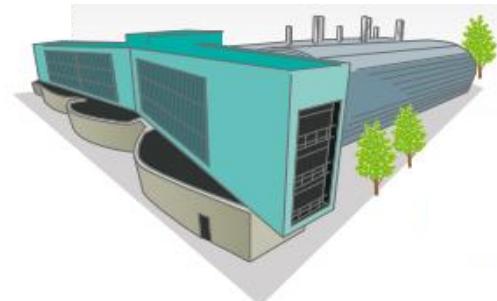
COUNCIL OF EUROPE

- ▶ Founded in 1949
- ▶ **Intergovernmental** organisation, Strasbourg
- ▶ **46** Member States
- ▶ More than 700 million citizens



The European Directorate for the Quality of Medicines and HealthCare (EDQM)

- ▶ Founded in 1964
- ▶ Work in the framework of a **Partial Agreement, 39 Members & the EU**
- ▶ Contribute to Public Health and **access to good quality medicines** and healthcare in Europe
- ▶ Oversee the **European Pharmacopoeia**



European Committee for FCM, CD-P-MCA

- **Designated representatives from 34** (out of 39) member States:
Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Republic of Moldova, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Republic of Türkiye, Ukraine and the United Kingdom
- Participation of the European Commission, Joint Research Centre, **EFSA**
- **Observers** from Georgia, Singapore, TFDA
- Latest **plenary meeting** in June 2023, working groups meet as needed
- The EDQM 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.

Resolution CM/Res(2020)9 for FCM

Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food

(Adopted by the Committee of Ministers on 7 October 2020
at the 1385th meeting of the Ministers' Deputies)

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia^[1] ("the Convention"), Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field; Recalling that protection of health is a social human right and an essential condition for social cohesion and economic stability; Acknowledging the need to set quality and safety standards to minimise the health risk posed to humans by certain material constituents when released from materials or articles intended for contact with foodstuffs; Considering that food contact materials and articles are also used in pharmaceutical applications when the said materials are deemed suitable and safe for that purpose; Having regard to the opportunity to enhance synergies between the food contact materials and articles and pharmaceutical sectors; Following an approach similar to that published by the European Medicines Agency (EMA) in the "Guideline on Plastic Immediate Packaging Materials", effective since 1 December 2005, which specifies that the provisions of Community legislation on plastic materials and articles for food contact should be taken into account, in cases indicated in the guideline; Having regard to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and specific EU measures for particular groups of food contact materials and articles adopted in accordance with that Regulation, Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin and Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products or relevant national legislation which, although not binding for all of the States Parties to the Convention, should nevertheless be taken into consideration;

Taking into account that the Technical Guides on food contact materials and articles and resolutions are widely recognised and used as a reference for the safety, quality and use of coatings, colorants, cork, glass, metals, paper and board, plastics, printing inks for food contact materials, resins for adsorption and ion exchange and elastomers such as rubber and silicones;

Taking into account that Resolution CM/Res(2013)9 and the applicable Technical Guide on metals and alloys used in food contact materials and articles are widely recognised and used as a reference for the safety and quality of such materials and articles;

Being convinced that each member State would benefit from harmonised state-of-the-art quality requirements and test procedures, described in the Technical Guides and published under the aegis of the EDQM;

Recommends to the governments of States Parties to the Convention that, in the absence of the specific measures referred to in Article 5 of Regulation (EC) No. 1935/2004, they adopt suitable legislative and other measures aimed at reducing the health risks arising from human exposure to constituents released from materials or articles for contact with food according to the appended "Guiding Principles for food contact materials and articles" and the Technical Guides published under the aegis of the EDQM to supplement this resolution. Likewise, in cases considered appropriate by the national competent authorities, the Committee of Ministers recommends that they apply these principles to materials and containers for pharmaceutical use in the absence of dedicated standards. This resolution shall not prevent governments from maintaining or adopting national measures that implement stricter or different rules and regulations.

Agrees that the CD-P-MCA, taking into account scientific or regulatory developments or needs, will update, as necessary, the appendix "Guiding Principles for food contact materials and articles" and the Technical Guides, published under the aegis of the EDQM to supplement this Resolution.

- Adopted 7 October 2020 by the Committee of Ministers of the Council of Europe (Partial Agreement of 39 member States), non-binding legal instrument

- The 'Guiding Principles' are in the Appendix

- Endorsed by the European Committee for Food Contact Materials and Articles (CD-P-MCA)



Member states to take measures to:

- Reduce health risks linked to contaminants in food (migration of metals, antioxidants, stabilisers, colorants, plasticisers from packaging, kitchenware or containers)
- Apply requirements where appropriate to pharmaceutical use materials and containers
- Adopt (or maintain) national rules that are stricter (or different)

[Appendix to Resolution CM/Res\(2020\)9/
GUIDING PRINCIPLES FOR FCM](#)

1. Purpose and Scope
2. Definitions
3. General Requirements
 - 3.1 Substances used in the manufacture of food contact materials and articles
 - 3.2 European Committee for Food Contact Materials and Articles (CD-P-MCA)
 - 3.3 SML, SRL, OML, ORL, QM and QMA
4. Risk Assessment
5. Labelling
6. Traceability
7. Good Manufacturing Practice
8. Compliance Documents
 - 8.1 Documents supporting compliance and safety (supporting documentation)
 - 8.2 Declaration of compliance
9. Compliance Testing
10. Technical Guides

Principle: in the manufacture of an FCM, use only

- a. Substances that are approved for material-specific applications (modalities for compiling/publishing/updating, e.g. substance lists to be defined)
- b. Substances that are stated in EU or national legislation/official recommendations (links in the technical guides)
- c. 'Non-evaluated' substances that are not migrating or released (LOD < 0.01 mg/kg if non-CMR, CMR suspect or nano form)

Principle: self-assessment of risks

- **If a, b, c not applicable:**
 - Business operators to ensure risk assessment
 - in accordance with internationally recognised scientific principles on risk assessment and EFSA's guidance (note for guidance, genotoxicity)
 - not infringing EU or national legislations/official recommendations

Principle: transparency in the distribution chain

- **Declaration of Compliance DoC:**

- Identity of business operator, importers, manufacturers
- Information on substances used and impurities (incl. formation at later stage)
- Conditions of use and restrictions

- **Supporting documentation:**

- Safety of substances, materials, treatment and processes
- Extent of release under the most severe conditions of use
- Experimental testing conditions
- Calculations (incl. modelling)

Technical Guides

- **Technical guides** cover **material-specific** aspects
 - Specific release limits, sample preparation, testing instructions, calculations
 - Metals and alloys, paper and board, compliance documentation
- Elaborated with contribution from **national experts, academia, and private sector**

Published technical guidances on materials, analytical testing, survey



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

English (PDF)

Detail

Add to cart



Metal release from enamelware

English (PDF)



Paper and board used in food contact materials and articles

English (PDF)

French (PDF)

Detail

Add to cart



Metals and alloys used in food contact materials and articles

English (EPUB, PDF)

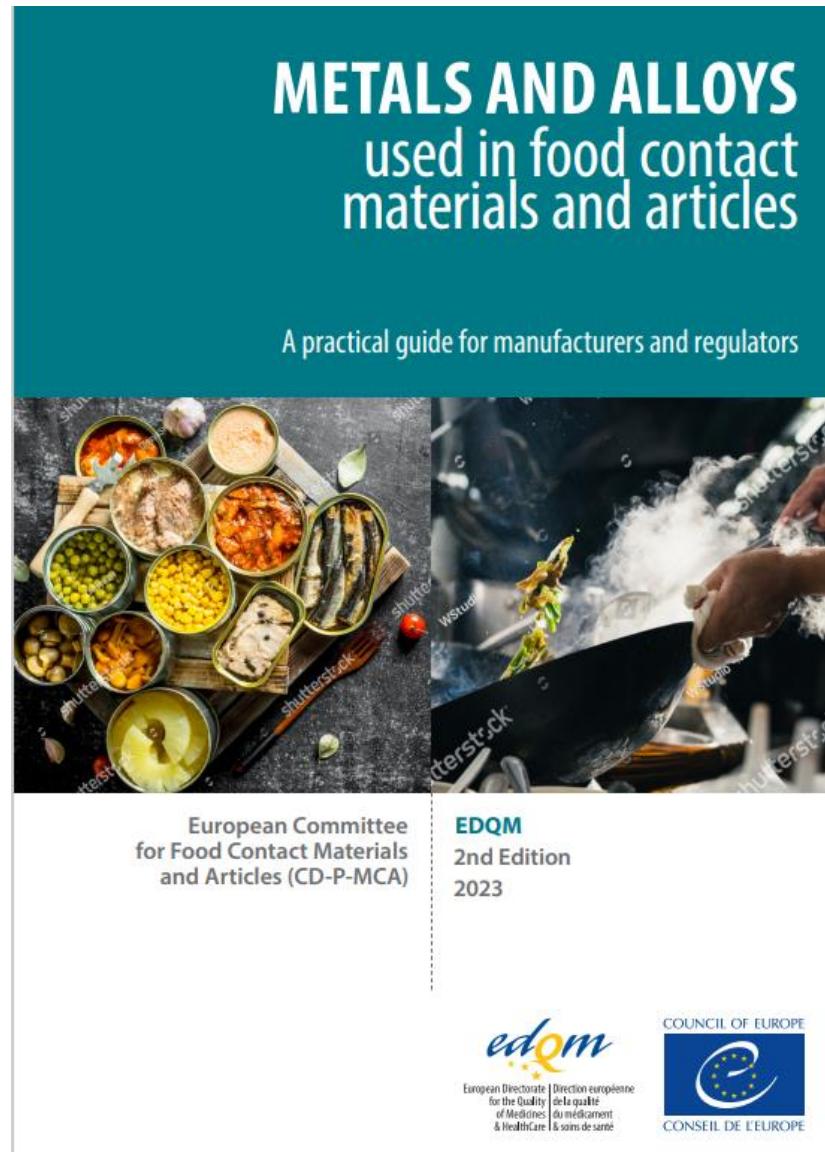
French (EPUB, PDF)

Detail

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- **FCM releases – download for FREE**

2nd edition of Metals & alloys guide **soon to be released**



Policy statements (some of them under revision)

 COUNCIL OF EUROPE

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Home > Resolutions & Policy statements

Resolutions & Policy statements

[Resolution CM/Res\(2020\)9 on the safety and quality of materials and articles for contact with food](#)

Material-specific guides:

Coatings	<u>Policy statement (v 2009)</u>
Cork stoppers	<u>Policy statement (v. 2007)</u>
Glass	<u>Policy statement (v. 2004)</u>
Inks	<u>Policy statement (v. 2007)</u>
Metals and alloys, Technical Guide 2013	<u>1st Edition download for FREE</u>
Paper and board, Technical Guide 2021	<u>1st Edition download for FREE</u>
Resins for ion exchange and adsorption	<u>Policy statement (v. 2009)</u>
Rubber	<u>Policy statement (v. 2004)</u>
Silicones	<u>Policy statement (v. 2004)</u>
Tissue paper	<u>Policy statement (v. 2004)</u>



<https://www.edqm.eu/en/food-contact-materials-and-articles>

Work programme 2022-25

Implementing Resolution CM/Res(2020)9:

- **Metals and alloys** - DRAFT 2nd edition of Technical Guide approved in 2022 & publication in preparation
- **Compliance Documentation** - preparation of new guidance document (2024)
- **Enamels** - preparation of new guidance document (2024)
- **Cork*** - review of technical documents (2024)

* There is currently a draft open for comments, prepared by PT agro-forest, cork industry, wine sector, NRL, research, academia and competent authorities

Work programme 2022-25

Implementing Resolution CM/Res(2020)9:

- **Resins for adsorption and ion exchange** - review of technical documents (2024)
- **Coatings** - review of technical documents and follow-up on EFSA-FIP taskforce (2025)
- **Officially evaluated substances** - compiling and updating lists of substances (ongoing)
- **Others (as feasible):** printing inks, rubber products and silicones - review of technical documents

Access to information on FCM on the EDQM webpages:

<https://www.edqm.eu/en/food-contact-materials-and-articles>

<https://helpdesk.edqm.eu/servicedesk/customer/user/login?destination=portals>



The screenshot shows the EDQM website's Food Contact Materials page. The top navigation bar includes links for Home, About us, European Pharmacopoeia, Reference Standards, Certification of Suitability, OMCL Network, Transfusion & Transplantation, and Patient & Consumer Health Protection. The main content area features a heading 'Food Contact Materials' with social media sharing icons (Twitter, Facebook, Google+, LinkedIn, Email). Below this is a text block about metals and alloys used in food contact materials, mentioning Resolution CM/Res(2013)9. A sidebar on the right provides 'Additional information' (General Information on the Technical Guide (Foreword), Use of Metals - Metals and alloys used in food contact materials and articles - 1st Edition (2013), Council of Europe Resolution CM/Res(2013)9) and 'Sales information' (Benefit from free shipping charges by ordering online!). A 'Visit the EDQM Store' button is also present.

To join the work, contact the secretariat at:

consumer.health@edqm.eu

Follow us on:   

Thank you for your attention!

