

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



Council of Europe

Resolution on food contact materials and articles

Resolution Res/CM(2020)9

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9 November 2020

Working Group on Food Contact Materials of the Toxicological Safety Section of the Standing Committee on Plants, Animals, Food and Feed (**SC-PAFF**)

Resolution CM/Res(2020)9

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.

Adoption 7 October 2020



[New Council of Europe resolution to strengthen safety of food contact materials](#)

- The Committee of Ministers of the Council of Europe has adopted a new resolution on the safety and quality of materials and articles for contact with food.
- This instrument is expected to improve the protection of consumers from contaminants (metals, antioxidants, stabilisers, colorants, plasticisers, etc.) potentially released by material in contact with food, such as containers, work surfaces or packaging.
- These principles were elaborated by the European Committee for Food Contact Materials and Articles (CD-P-MCA) and supplement the relevant European Union and national regulations.
- Overall, the resolution aims at harmonising regulatory approaches to consumer health protection across Europe.
- The annex to this resolution includes guiding principles for the implementation of suitable policies in the member states and technical guidance for specific materials, such as paper and board, metals and alloys, coatings or silicones.

Resolution CM/Res(2020)9

Appendix to Resolution CM/Res(2020)9

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

APPENDIX: GUIDING PRINCIPLES FOR FOOD CONTACT MATERIALS AND ARTICLES

[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](#)

Appendix: Guiding Principles / Technical Guides

- **Scope:** all FCM under Regulation (EC) No 1935/2004 **which are not covered by specific measures** at the EU level
- 'Harmonised approach' to ensure safety and quality
- **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

Appendix: Guiding Principles

- Requirements applicable to all material types / avoid repetition in each technical guide
- References to existing EU-provisions (Reg. 1935/2004; GMP, Traceability, etc.)
- Key elements
 - Principles for intentionally-used substances
 - Compliance documentation and declaration of compliance for all FCM

Principles for intentionally-used substances

- a. Approved for material-specific applications (modalities for compiling/publishing/updating, e.g. substance lists to be agreed)
- b. Referenced in EU or national legislations/official recommendations (links in the technical guides)
- c. 'Non-evaluated': no migration ($LOD < 0.01 \text{ mg/kg}$) provided they are non-CMR, CMR suspect, nano

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

Compliance Documents

- Description of documentation supporting compliance and safety (**supporting documentation**)
 - > Detailed information expected in specific technical guide
- Content of **declaration of compliance** (DOC) – recommended for all FCM/all material types
- **DoC** based on Annex IV to Reg. (EU) No 10/2011 (adaptations where necessary)

Resolution CM/Res(2020)9...

...calls for harmonised measures in the following countries:

European Pharmacopoeia Members

Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom and the European Union.

Member and observer states of the Ph. Eur. (2020)



... and others benefit from the European experience, such as the **European Pharmacopoeia Observers**

Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, India, Israel, Japan, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Mexico, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, the United States of America, Uzbekistan, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

CD-P-MCA: European Committee for FCM

Intergovernmental Steering Committee

- reports to the Committee of Ministers of the Council of Europe
- **Members:** delegates from the 39 Ph. Eur. countries incl 27 EU member states
- Plenary sessions 1-2 times a year
- *Ad hoc* WG, teleconf., e-WG
- Rapporteurs assigned to projects
- To join the work, contact the secretariat at consumer.health@edqm.eu

CD-P-MCA: On-going activities

Technical Guides supplementing Resolution CM/Res(2020)9:

- DoC + Compliance Documentation (new document)
- Metals and alloys
- Paper and Board
- Coatings (follow-up EFSA-FIP taskforce), cork, resins for adsorption and ion exchange, printing inks
- Printing inks (peer-review of multi-analyte methods)
- Enamels – proposal to elaborate guidance

Access to FCM information

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

Home > Patient & Consumer > Food Contact Materials > Food Contact Materials and articles

Food Contact Materials and articles

In the field of consumer health, the EDQM helps ensure the safety of Food contact materials articles in Europe, providing the secretariat of the [European Committee for Food Contact Materials and Articles \(CD-P-MCA\)](#). The CD-P-MCA was created to address emerging risks to human health arising from the use of Food Contact Materials and Articles, and is responsible for developing standards and policies that enhance consumer health protection in this field.

The Committee is composed of representatives of countries, which are parties to the [Convention on the elaboration of a European Pharmacopoeia](#). The Committee and its terms of reference have been established by the [Council of Europe Committee of Ministers](#).

As the technical secretariat, the EDQM ensures close co-operation with equivalent bodies in other international institutions, in particular with the [European Commission \(EC\)](#).

Activities

The European [Committee for Food Contact Materials and Articles \(CD-P-MCA\)](#) develops standards and examines questions related to the safety and quality of food contact materials.

In October 2020, the Committee of Ministers of the Council of Europe adopted [Resolution CM/Res\(2020\)9 on the safety and quality of materials and articles for contact with food](#). This instrument is expected to improve the protection of consumers from contaminants (metals, antioxidants, stabilisers, colorants, plasticisers, etc.) potentially released by material in contact with food, such as containers, work surfaces or packaging. These guidelines were elaborated by the European Committee for Food Contact Materials and Articles (CD-P-MCA) and supplement the relevant European Union and national regulations.

Overall, the resolution aims at harmonising regulatory approaches to consumer health protection across Europe. The annex to this resolution includes guiding principles for the implementation of suitable policies in the member states and technical guidance for specific materials, such as paper and board, metals and alloys, coatings or silicones.

In June 2013, Council of Europe member states [adopted Resolution CM/Res\(2013\)9 on metals and alloys used in food contact materials and articles](#). A technical guide is available that presents this resolution and practical guidelines for its

MORE INFORMATION

Terms of Reference of the [European Committee for Food Contact Materials and Articles \(CD-P-MCA\)](#)

PUBLICATIONS

More information on the [Food Contact Materials and Articles publications](#).

Visit the EDQM's [Free Publications page](#) to download the latest information on analytical methods and guidance documents under the tab "Food contact materials and articles"

Thank you for your attention



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