

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



Joint EDQM-AESAN symposium “Recent developments in food contact materials and articles”

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Achievements: Resolution CM/Res(2020)9 and Guiding principles for food contact materials (FCM)

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Resolution CM/Res(2020)9 and Guiding Principles

Background

- CD-P-MCA and former CoE Committees have been working on food contact materials and articles for decades.
- Scope: Material groups not yet harmonised at EU level.
- A number of « old » Resolutions and Political Statements for specific material groups are outdated and need to be amended.
- Decision to develop overarching requirements applicable to all non-harmonised material groups considered by CD-P-MCA (→ avoid repetition in each Technical Guide)

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;

Resolution CM/Res(2020)9

- Adopted by the Committee of Ministers on 7 October 2020
 - acknowledged by 39 countries (incl 27 EU MS)
 - contribution to harmonisation and much wider use of EU principles
- Explanation of background and references to relevant legislation
 - need to set quality and safety standards to minimise health risks
- Recommendation to Governments to adopt suitable legislative or other measures in accordance with CoE Guiding Principles/Technical Guides (in the absence of specific EU measures)

Guiding Principles for food contact materials/articles

Appendix to Resolution CM/Res(2020)9

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

APPENDIX: GUIDING PRINCIPLES FOR FOOD CONTACT MATERIALS AND ARTICLES

Table of Contents

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

Guiding Principles for food contact materials/articles

- Appendix to Resolution CM/Res(2020)9
- « Frame » document; general requirements applicable to all fcm in the scope of CD-P-MCA
- References to EU legislation
 - Why? EU legislation applies anyway?
 - *strong commitment to EU legislation;*
 - *contributes to wider harmonisation;*
 - *material groups for which not specific EU measure exist*

Guiding Principles for food contact materials/articles

- Table of Contents:

1. Purpose and Scope

- safety and quality of food contact materials and articles under Regulation (EC) No 1935/2004 not covered by specific EU legal provisions or other measures
- applies to all food contact materials and articles under the scope of the resolution
- complements European legislation taking into account Council of Europe member States' legislations or recommendations
- general guidance
- Technical Guides specify the requirements for particular types of materials.

2. Definitions
3. General Requirements
 - 3.1 Substances used in the manufacture of fcm
 - 3.2 CD-P-MCA
 - 3.3 SML, SRL, OML, ORL, QM, QA
4. Risk Assessment
5. Labelling
6. Traceability
7. Good Manufacturing Practice
8. Compliance Documents
 - 8.1 supporting documentation
 - 8.2. Declaration of Compliance
9. Compliance Testing
10. Technical Guides

Guiding Principles for food contact materials/articles

- Table of Contents:

1. Purpose and Scope

2. Definitions

- Reference to definitions in Regulations (EC) No 1935/2004 and (EU) No 10/2011
- food contact, ORL/OML, QM, QMA, Q(SAR), SRL/SML
- Officially evaluated substances:
substances for which risk assessment has been carried out according to the principles stated under section 4, by a competent authority of a Council of Europe member State or a relevant European authority.

3. General Requirements

- 3.1 Substances used in the manufacture of fcm

- 3.2 CD-P-MCA

- 3.3 SML, SRL, OML, ORL, QM, QA

4. Risk Assessment

5. Labelling

6. Traceability

7. Good Manufacturing Practice

8. Compliance Documents

- 8.1 supporting documentation

- 8.2. Declaration of Compliance

9. Compliance Testing

10. Technical Guides

Guiding Principles for food contact materials/articles

- Table of Contents:

3. General requirements

3.1 Substances used in the manufacture of fcm

- only after risk assessment according to the principles; includes consideration of impurities, reaction and/or degradation products
- substances used have to comply to following criteria:
 - a. approved by competent authorities of CoE member States; or
 - b. in compliance with material-specific EU or national legislation or official recommendations (specified in the applicable Technical Guide); or
 - c. absence of release into food (incl impurities and known or foreseeable reaction or degradation products); limit of detection 0.01 mg/kg (provided they are not CMR, CMR suspected, nano).

If a, b, c not applicable: self-assessment by the operators, in accordance with internationally recognised scientific principles on risk assessment + EFSA guidance, provided not infringing EU or national legislations/official recommendations

Guiding Principles for food contact materials/articles

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 - 3.3 SML, SRL, OML, ORL, QM, QA

4. Risk Assessment

→ internationally recognised scientific principles; EFSA

5. Labelling

→ Article 15 Regulation (EC) No 1935/2004; shall not mislead consumers; not rule out foreseeable use

6. Traceability

→ Article 15 and 17 Regulation (EC) No 1935/2004; national legislation

7. Good Manufacturing Practice

→ Regulation (EC) No 2023/2006; national legislation

8. Compliance Documents
 - 8.1 supporting documentation
 - 8.2. Declaration of Compliance
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Guiding Principles for food contact materials/articles

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5. Labelling
6. Traceability
7. Good Manufacturing Practice

8. Compliance Documents

8.1 supporting documentation

- general explanation
- detailed information in Technical Guide „Documentation supporting compliance and safety“

8.2. Declaration of Compliance (DoC)

- content of DoC – recommended for all FCM/all material types
- based on Annex IV to Regulation (EU) No 10/2011 (adaptations where necessary);
- particular material related aspects in material specific Technical Guide, if needed.

9. Compliance Testing
10. Technical Guides

Guiding Principles for food contact materials/articles

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8. Compliance Documents
 - 8.1 supporting documentation
 - 8.2. Declaration of Compliance (DoC)
9. Compliance Testing

10. Technical Guides

- description of general content/structure

- Metals and alloys
 - Paper and board
 - Documentation supporting compliance and safety

 - Cork
 - Enamels
 - Coatings
 - Printing inks
 - Ion exchange resins
- (...)

➔ Work on specific Technical Guides is generally based on available legislation/recommendations/experiences in one or more member countries

Thank you for your attention



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