COMMITTEE OF MINISTERS
COMITÉ DES MINISTRES

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

**MINISTERS' DEPUTIES** Resolutions **CM/Res(2020)9** 7 October 2020

# 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;

[1] States concerned: 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 and United Kingdom.

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.

**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**

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## 1. Purpose and Scope

Resolution CM/Res(2020)9, its Guiding Principles and the supplementary Technical Guides contribute to the protection of human health by ensuring, as defined in relevant European legislation, i.e. Regulation (EC) No. 1935/2004, the safety and quality of food contact materials and articles that are not covered by specific European legal provisions or other measures, e.g. at the European Union (EU) level. The resolution therefore complements European legislation taking into account Council of Europe member States' legislations or recommendations. This appendix provides general guidance, e.g. on the use of substances in the manufacture of food contact materials and articles, labelling of these materials and articles and the need for a declaration of compliance and supporting documentation. It applies to all food contact materials and articles under the scope of the resolution. The Technical Guides specify the requirements (or derogations from the principles stated hereafter) for particular types of materials, such as paper and board or metals, and testing.

## 2. Definitions

The definitions of Regulation (EC) No. 1935/2004 and, where appropriate, of Regulation (EU) No. 10/2011, apply in the context of the resolution, the Guiding Principles and the applicable Technical Guides.

In addition, the following definitions apply:

*Food contact*: direct (physical) contact or indirect (through the gas phase or through different packaging components or layers in a multi-layer material) contact of a food contact material or article with a food.

*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.

*Overall release limit (ORL) or overall migration limit (OML)*:[2] the maximum permitted amount of non-volatile substances released from a material or article into food simulants.

*QM*: the maximum permitted quantity of a substance in the final material or article expressed as mass per mass concentration.

*QMA*: the maximum permitted quantity of a substance in the final material or article expressed as mass per surface area in contact with food.

(*Quantitative) structure-activity relationship models ((Q)SAR models*): theoretical models that can be used to quantitatively or qualitatively predict the physicochemical, biological (e.g. an (eco) toxicological endpoint) and environmental fate properties of compounds from the knowledge of their chemical structure.[3]

*Specific release limit (SRL)*[4] or specific migration limit (SML): the maximum permitted amount of a given substance released from a material or article into food or food simulants.

## 3. General Requirements

Food contact materials and articles shall comply with Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006, or with relevant national legislation. Under normal or foreseeable conditions of use, they shall not transfer their constituents to food in quantities which could:

[2] The term 'OML' is especially used in connection with polymeric materials (e.g. plastics), whereas the term "release" is understood to designate any mechanism of substance transfer from a food contact material and article to food. In the context of these Guiding Principles the general term 'release' is used for substance transfer from food contact materials and articles to food, including polymeric materials.

[3] Practical Guide – How to use and report (Q)SARs, ISBN: 978-92-9247-809-4, European Chemicals Agency, 2016. Available online at https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf.

[4] The term 'SRL' was introduced in the context of metals and alloys used in food contact materials. Whereas the more general term 'release' may be applied to various materials, the term 'migration' is especially used in connection with polymeric materials (e.g. plastics), where release is commonly dominated by physical processes such as diffusion.

a. endanger human health; or

b. bring about an unacceptable change in the composition of the food; or

c. bring about a deterioration in the organoleptic characteristics thereof.

In addition, food business operators shall ensure that they use food contact materials and articles during food production or preparation, storage and distribution in a way that does not compromise compliance with applicable Council of Europe Technical Guides, EU and member States' legislation or recommendations for food contact materials and articles.

**3.1 Substances used in the manufacture of food contact materials and articles**

In the manufacture of food contact materials and articles, substances may only be used after risk assessment has been performed according to the principles stated hereafter under section 4; assessment includes consideration of impurities, reaction and/or degradation products.

Substances can be used in the manufacture of food contact materials and articles, in compliance with any restrictions applicable to them, if they meet any of the following criteria:

a. they are approved by competent authorities of the Council of Europe member States concerned, in accordance with the procedures for the elaboration of lists of officially evaluated substances; or

b. their use is in compliance with material-specific provisions in EU or national legislation or official recommendations, as specified in the applicable Technical Guide; or

c. absence of their release into food and absence of release into food of their impurities, and known or foreseeable reaction or degradation products can be demonstrated by a method of analysis in accordance with Article 34 of Regulation (EU) No. 2017/625 or relevant national legislation with a limit of detection not higher than 0.01 mg/kg. This limit shall apply to groups of compounds if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group.

In the case of substances, their impurities and known or foreseeable reaction or degradation products that belong to any of the following categories and meet criterion 3.1 c, demonstrating absence of release is not sufficient and therefore a specific risk assessment must be performed:

- substances in nano-form;[5]

- substances classified as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No. 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures;

- substances which are assessed to be genotoxic or predicted to be genotoxic using (Q)SAR models if valid data (e.g. complying with the European Food Safety Authority's (EFSA) criteria) confirming absence of genotoxicity are not available.

Criterion 3.1 c applies without prejudice to applicable European and national provisions or the provisions set out in the applicable Technical Guide.

d. When none of the criteria a, b and c are met and without prejudice to applicable European and national provisions, or the provisions set out in the applicable Technical Guide, substances may be used in the manufacture of food contact materials and articles, if they are risk-assessed in accordance with section 4 by or on behalf of the responsible business operator and in compliance with Article 3 of Regulation (EC) No. 1935/2004 or relevant national legislation.

[5] Nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterials (OJ L 275, 20.10.2011, p. 38).

### 3.2 European Committee for Food Contact Materials and Articles (CD-P-MCA[6])

The CD-P-MCA, in accordance with its terms of reference and resources permitting, prepares technical guidance that supplements the Guiding Principles of the resolution. Further to section 3.1 a, the Committee agrees on the procedures for creating, publishing and updating lists of officially evaluated substances.

When new substances are subject to assessment and/or authorisation for use in the manufacture of food contact materials and articles, member States are advised to share relevant information with the CD-P-MCA with a view to updating any lists of evaluated substances as indicated in 3.1 a.

### 3.3 SML, SRL, OML, ORL, QM and QMA

3.3.1 Food contact materials and articles should not transfer their constituents to foodstuffs or food simulants in quantities exceeding the limits set out in the applicable Technical Guides (i.e. specific or overall release or migration limits or restrictions for the material composition to limit the amount of certain components referred to as “QM” and “QMA”).

3.3.2 Unless otherwise specified, a generic SML or SRL of 60 mg/kg applies to those substances listed in the applicable Technical Guide for which no specific release or migration limit or other restrictions are provided.

## 4. Risk Assessment

The safety of substances used in food contact materials and articles shall be evaluated in accordance with internationally recognised scientific principles on risk assessment, and with, where appropriate, EFSA guidance.[7] The safety evaluations shall also take into account impurities and known or foreseeable reaction and degradation products.

The risk assessment should be reviewed whenever relevant composition or process changes are implemented or new scientific or other data become available.

## 5. Labelling

Food contact materials and articles not yet in contact with food when placed on the market shall be labelled in accordance with Article 15 of Regulation (EC) No. 1935/2004 or relevant national legislation to ensure safe and appropriate use. The label shall be sufficiently clear to avoid any misuse or misinterpretation. It shall not mislead consumers and not rule out reasonably foreseeable uses of repeated use articles.

## 6. Traceability

Traceability of food contact materials and articles shall be ensured at all stages in accordance with Articles 15 and 17 of Regulation (EC) No. 1935/2004 or relevant national legislation.

## 7. Good Manufacturing Practice

Food contact materials and articles shall be manufactured in accordance with Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, or with relevant national legislation. If appropriate, guidelines on good manufacturing practice developed by trade and producer associations can also be taken into account without prejudice to any applicable member State legislation.

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[6] CD-P-MCA stands for Standing Committee – Partial Agreement – European Committee for Food Contact Materials and Articles (*Comité directeur - Accord partiel - Comité européen sur les matériaux et objets pour contact alimentaire*).

[7] Note for guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials:
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.21r;
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2379;
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.5113.

## 8. Compliance Documents

### 8.1 Documents supporting compliance and safety (supporting documentation)

Appropriate documentation, demonstrating that food contact materials and articles under the scope of the resolution comply with the requirements applicable to them, must be available from each business operator along the supply chain. It should be compiled as “supporting documentation” and provided to the competent authorities on request, without undue delay.

The supporting documentation is a record, especially of:

- the substance(s) used and corresponding risk assessment (including reference to relevant legislation or recommendation), the process(es) applied, and the reaction(s) and treatment(s) performed;

- the safety of released substances, including impurities and reaction and degradation products, and evidence for compliance with the applicable requirements supported with data or other adequate reasoning, taking into account the level of release or migration under the most severe conditions of use;

- if applicable, the conditions and results of migration/release testing, i.e. the description of the applied methods and other relevant information, calculations (including modelling), toxicological test descriptions and data as well as the reasoning used for the conclusion.

The supporting documentation may be confidential; however, protection of information in the documentation must not compromise the safety of food contact materials and articles and must not prevent a business operator from disclosing safety information related to released substances and conditions of use in the declaration of compliance.

### 8.2 Declaration of compliance

Food contact materials and articles under the scope of the resolution are to be accompanied by a declaration of compliance.

The declaration of compliance means that the manufacturer of the food contact material or article assumes responsibility for the suitability for food contact, including the safety of all released substances or, whenever applicable, explicitly informs the next business operator in the supply chain of the compliance work that needs to be completed. The declaration also specifies the limitations to the applications of the food contact material or article, any further processing and treatments as well as conditions of food contact and is based on the documentation referred to under 8.1.

The declaration of compliance provides all relevant information to enable subsequent business operators along the supply chain to carry out any additional compliance work in order to deliver safe and compliant food contact materials and articles.

A declaration of compliance is issued at all stages of the supply chain. It is available at all marketing stages, other than the retail stage, and includes, at least (if applicable):

a. the identity and address of the business operator issuing the declaration of compliance;

b. the date the declaration was issued;

c. the identity and address of the manufacturer or importer of the food contact material/article;

d. the identity of the food contact material/article (final or intermediate) or substance intended for the manufacture of the said material/articles (chemical name or description and trade name);

e. confirmation that the food contact material or article (final or intermediate) or substance intended for the manufacture of any material or article complies with the applicable legal or other relevant provisions and requirements laid down in the Guiding Principles and in the applicable Technical Guide;

f. specifications and conditions ensuring safe use of the food contact material/article (e.g. types of foods for which it can be used, maximum temperature, duration of contact, repeated or single contact, the highest food contact surface area to volume ratio for which compliance has been verified);

g. whenever applicable, a statement that the substances used are specified:

   i. in the corresponding Council of Europe list of officially evaluated substances; or

   ii. in European or national legislation or official recommendations as referenced in the applicable Technical Guide, providing the exact reference;

h. whenever applicable, a statement that:

   i. risk assessment has been performed by or on behalf of the business operator for substances that are detailed in the supporting documentation;

   ii. the use of these substances does not infringe relevant EU or national legislation or official recommendations;

   iii. the use of these substances is not in conflict with the provisions set out in the applicable Technical Guide;

i. adequate information on the substances used, impurities and reaction and degradation products for which restrictions and/or specifications apply;

j. adequate information on the substances which are subject to a restriction regarding their use in food (dual use additives);

k. information on substances used, impurities and reaction and degradation products, including those known or foreseen to be generated at later production stages, for which the business operator has identified that further compliance work needs to be conducted at the next stages in the supply chain.

If necessary, additional requirements or derogations for particular types of food contact materials/articles may be specified in the applicable Technical Guides.

The declaration is renewed whenever substantial changes are made to the composition or to the production process that may affect the compliance of materials/articles, or in response to relevant scientific or regulatory developments.

**9. Compliance Testing**

Compliance of the food contact materials and articles with the relevant provisions and restrictions shall be verified by appropriate scientific methods (including modelling or worst case calculations) in accordance with Regulation (EU) No. 2017/625 or relevant national legislation.

Tests on release from the material or article into foodstuffs are carried out under the reasonable worst-case conditions during manufacture, storage, distribution and normal or foreseeable use, with respect to time, temperature and composition of the foodstuff.

When it is not feasible or not practical to test release into foodstuffs, food simulants are used to imitate the respective foodstuffs. The food simulants and conditions of contact are selected in such a way that release is at least as high as into food. Specifications for the choice of simulants and test conditions may be laid down in the relevant Guidelines of the Joint Research Centre (JRC) of the European Commission and the applicable Technical Guides.

For verification of compliance with the SML or SRL, solely release from food contact materials and articles (not contamination from any other sources) is taken into account.

**10. Technical Guides**

The Technical Guides supplementing the resolution[8] cover specific and detailed material requirements and principles as regards the safety and quality of food contact materials and articles.

Technical Guides may cover the following areas:

- general provisions (especially purpose/scope, additional definitions);
- specific requirements (or derogations from general principles) related to the particular material, including particular labelling requirements, if applicable;
- if applicable, officially evaluated substances used for the manufacture of the particular type of food contact material or article including relevant restrictions and specifications applicable to them;
- if applicable, material-specific provisions in European or national legislation or official recommendations;
- testing conditions and methods of analysis;
- additional information relating to supporting documentation and declaration of compliance, if applicable.

Technical Guides are published under the aegis of the EDQM and will be regularly updated, as necessary, by the CD-P-MCA.

[8] Technical Guides are available on the EDQM Website.