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

GUIDING PRINCIPLES FOR FOOD CONTACT MATERIALS AND ARTICLES

Draft

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Please use this **comment form** to enter your comments.	
Comments should be sent to: FCM.guiding_principles@edqm.eu.	

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1. Purpose and Scope

Resolution CM/Res(201X) Y, its Guiding Principles and the supplementary Technical Guides contribute to the protection of human health by ensuring the safety and quality of food contact materials and articles as defined in Regulation (EC) No 1935/2004, that are not covered by material specific legal provisions or other measures at the European Union (EU) level. The Resolution therefore complements the existing European legislation. This appendix provides general guidance, e.g. on the use of substances in the manufacture of food contact materials and articles, labelling and the need for a declaration of compliance and supporting compliance documentation. It applies to all food contact materials and articles under the scope of the Resolution and to the container-closure-system of medicinal products in cases considered appropriate by the competent authority responsible for granting their marketing authorisation. The supplementing Technical Guides detail the specific implementing provisions and further restrictions for the materials and articles under their scope.

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 respective Technical Guides.

In addition, the following definitions apply:

Food contact: direct (physical contact) or indirect contact of a food contact material or article with a food. Food contact materials and articles can transfer substances to food as a result of physical contact (including set-off), passing through different packaging components or layers in a multi-layer material or passing through the gas phase.

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 relevant European authority.

Overall release limit (ORL) or *overall migration limit* (OML)[1]: 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 ((Q)SAR): a simplified mathematical representation of complex chemical-biological interactions that seeks to predict the physicochemical and biological

[1] 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 this this Guiding Principles the general term 'release' is used for substance transfer from food contact materials and articles to food, including polymeric materials.

properties of molecules**.** It quantitatively relates the properties of a chemical (encoded in its chemical structure) to a physical property or to a biological effect (e.g. a toxicological endpoint).[2]

Set-off: transfer of substances to food from the non-food contact side of a food contact material or article through contact of the non-food contact surface with the food contact surface, e.g. during storage (stacking or reeling).

Specific release limit (SRL)[3] or *specific migration limit* (SML): the maximum permitted amount of a given substance released from a material or article to food or food simulants.

3. General Requirements

Food contact materials and articles shall be manufactured in accordance with Article 3 (1) of Regulation (EC) No 1935/2004 in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

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, throughout the supply chain, shall ensure that they use food contact materials and articles in a way that transfer of substances to foods from these materials and articles during food production, food preparation, handling, storage, and food consumption is of no concern.

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 any impurity, reaction and/or degradation products that may be present in the final material or article.

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 agreed between 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 respective Technical Guide; or
C. Absence of their release to food and absence of release to food of their impurities, known reaction or degradation products can be demonstrated with reasonable statistical certainty by a method of analysis in accordance with Article 34 of Regulation (EU) 2017/625 with a limit of detection not higher than 0.01 mg/kg. This limit shall apply to a group of compounds, if they

[2] See Joint Research Center (JRC): https://eurl-ecvam.jrc.ec.europa.eu/glossary/glossary/q-sars-quantitative-structure-activity-relationships; https://qsardb.jrc.ec.europa.eu/qmrf/

[3] 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.

are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group.

The substances used based on criterion 3.1 C and their impurities and known reaction or degradation products shall not belong to either one of the following categories (i.e. for substances belonging to the following categories the detection limit of 0.01 mg/kg does not apply):

- substances in nano-form[4],
- substances classified as "carcinogenic", "mutagenic" 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,
- substances which are assessed to be genotoxic, or predicted to be genotoxic using accepted (Q)SAR models in case that valid data (i. e. 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.

In case that none of the criteria A, B, C is 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.

3.2 Restrictions: specific release (or migration) and overall release (or migration), QM and QMA

3.2.1 Food contact materials and articles should not transfer their constituents to foodstuffs or food simulants in quantities exceeding the limits set out in relevant Technical Guides or, if not specified in a Technical Guide, in national legislation or recommendations (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").

3.2.2 A generic specific release or migration limit of 60 mg/kg applies to those listed substances for which no specific release or migration limit or other restrictions are provided in the relevant Technical Guide, if not indicated differently.

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

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.

[4] 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).

4. Risk Assessment

Safety evaluations of substances used in food contact materials and articles shall be in accordance with internationally recognised scientific principles on risk assessment, and follow, where applicable, the EFSA guidance(s) such as the EFSA Note for Guidance on plastic food contact materials[5]. The safety evaluations shall also take into account non-intentionally added substances (NIAS) as defined in Article 3 (9) of Regulation (EU) No 10/2011.

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 to ensure safe and appropriate use. The label shall be sufficiently clear to avoid any misuse or misinterpretation. It shall not mislead consumers and does not rule out reasonably foreseeable uses that consumers would normally expect for such a material or article, especially when dealing with 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.

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. If appropriate, guidelines on good manufacturing practices developed by trade and producer associations can also be taken into account without prejudice to any applicable member state legislation.

8. Supporting Documents and Declaration of Compliance

8.1 Documentation of compliance (supporting documents)

Appropriate documentation demonstrating that food contact materials and articles under the scope of the Resolution comply with the requirements applicable to them must be compiled as “documentation of compliance” by the business operator responsible.

At every step of manufacturing food contact materials and articles, compliance shall be demonstrated a) for each substance introduced, including its impurities and the reaction and degradation products which may be formed, and b) for the materials and articles resulting from this manufacturing step.

The compliance documentation is a record of especially:

- the substance(s) used and relevant risk assessment, the process(es) applied, and the reaction(s) and treatment(s) performed;

[5] 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.

- the safety of any released substances, relevant 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 maximum level of release;
- if applicable, the conditions and results of migration/release testing, i.e. the description and validation of the applied analytical methods, raw data, calculations, including modelling, descriptions and data of toxicological tests as well as reasoning used for the conclusion.

The compliance documentation is made available without delay to the competent authorities on their request.

The compliance 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 assumes responsibility for the suitability for food contact, including the safety of all released substances or, whenever applicable, explicitly informs the subsequent business operator in the supply chain of the compliance work that needs to be completed. The declaration also specifies the limitations to the applications, 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 manufacture and processing of food contact materials and articles. It is available at all marketing stages, other than the retail stage, and comprises, at least (if applicable) of:

- identity and address of the business operator issuing the declaration of compliance;
- the date the declaration was issued;
- identity and address of the manufacturer or importer of the food contact material/article;
- identity of the food contact material/article (final or intermediate) or substance intended for the manufacture of those (chemical name or description and trade name);
- whenever applicable, a statement that the substances used are specified:
  a) in the corresponding Council of Europe list of officially evaluated substances, or
  b) in European or national legislation or official recommendations as referenced in the respective Technical Guide, providing the exact reference;
- whenever applicable, a statement that
  - risk assessment has been performed by or on behalf of the business operator for substances that are detailed in the compliance documentation;
  - the use of these substances does not infringe relevant EU or national legislation or official recommendations;

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

- 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 complementing Technical Guide;

- adequate information relative to the substances used or degradation or reaction products thereof, for which restrictions and/or specifications are laid down in the applicable legal and other relevant provisions;

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

- 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 conditions, duration of contact, repeated or single contact, the highest food contact surface area to volume ratio for which compliance has been verified);

- information on substances used, impurities and/or reaction and degradation products, which also could be generated at later production stages, for which further compliance work needs to be conducted at the next stages of the supply chain to ensure compliance of the final product; and

- any additional requirements for particular types of food contact materials/articles specified in the respective Technical Guides, if applicable.

The written declaration is renewed in the event that substantial changes are made to the composition or to the production process that may affect substance release from materials/articles, or as a 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 in accordance with Regulation (EU) 2017/625. This may include experimental testing or theoretical calculations.

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 possible to test release into foodstuffs, food simulants are used to imitate the respective foodstuffs. 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 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[6] cover specific and detailed material requirements and principles and present a harmonised state-of-the-art approach as regards safety and quality of food contact materials and articles. However, they shall not prevent governments from maintaining, adopting or implementing stricter rules and provisions.

Technical Guides may cover the following areas:

- general provisions (especially purpose/scope, additional definitions);
- specific requirements related to the particular material, including particular labelling, if applicable;
- if applicable, officially evaluated substances used for the manufacture of the particular type of food contact material and 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 the 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.

[6] Technical Guides are available from the EDQM Secretariat.