

1. Purpose

This document defines the measures for compliance with the regulatory requirements for materials and contact articles made from plastic which can be reasonably expected to come into contact with food.

2. Purview and application area

This operating standard applies to the entire Vitra Group and will be applicable to all products which can be reasonably expected to come into contact with food during normal or foreseeable use.

It also applies to corresponding raw materials and semi-finished goods, provided that these are delivered to Vitra.

3. Responsibility

Responsible for compliance Research & Development, Quality Planning, Quality Assurance, **Realization Procurement**, Strategic Direct Procurement & Value Management

4. Definition of terms (According to regulation (EU) 10/2011)

4.1 Food contact materials made from plastic:

- Materials and articles, as well as parts thereof, which are comprised exclusively of plastic
- Multiple-layer materials and items made from plastic that are held together by adhesives or held together in another way, each of which can be imprinted or coated with a coating, are also included
 - Plastic layers or plastic coating, which form two or more layers of different types of materials as seals in caps or fasteners
 - Plastic layers in multiple-layer composite materials and articles which are intended to come into contact with food, or are already in contact with food, or which can reasonably be assumed to come into contact with food
- Ion-exchange resins, rubber and silicone are not considered to be plastics

4.2 Abbreviations:

- RAPIDS - Regulatory Affairs Product Information Data Sheet
NIAS - non-intentionally added substances

5. Legal basis

- Regulation (EC) No. 1935/2004 on materials and articles that are intended to come into contact with food
- Regulation (EU) No. 10/2011 on materials and articles made from plastic that are intended to come into contact with food
- Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles that are intended to come into contact with food
- Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles that are intended to come into contact with food
- Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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6. Requirements for food contact materials made from plastic

6.1 Authorised substances

Only those auxiliary substances, additives and parent substances that are included in the current European Union list of Regulation (EU) No.10/2011 should be deliberately used in manufacturing.

Food contact material

- Must not be manufactured with "BADGE", "BFDGE" or "NOGE" (see Art. 1 of Regulation (EC) No. 1895/2005)

- Must not contain any substance that fulfils the criteria of Article 57 and is determined in accordance with Article 59 Paragraph 1 in a concentration of more than 0.1 percent by mass (weight/weight);

The food contact material is therefore not subject to the duty to inform in accordance with Article 33 of Regulation (EC) No. 1907/2006 (including all revisions and changes)

The manufacturer shall forward the corresponding RAPIDS for each auxiliary substance, additive and parent substance used to Vitra

6.2 Supplier

Only suppliers that fulfil the requirements of the regulation (EC) 2023/2006 for "good manufacturing practice" are the only suppliers that are approved for the production of food contact materials made from plastic.

These include an effective and documented quality assurance system, including a quality control system and the corresponding documentation of all information that applies to the manufacture of the article.

6.3 Declaration of conformity

Pursuant to Regulation (EU) No. 10/2011, the supplier shall issue a binding declaration of conformity, in accordance with Appendix IV of this regulation, and convey this to Vitra.

Amongst other things, this declaration of conformity must contain:

- Information on which materials with restrictions (SML, dual-use materials) are used (see Appendix IV of Regulation (EU) No. 10/2011; Article (6) and (7))
- Information on the types of foodstuffs (dry, aqueous, alcoholic, fatty) which are allowed to come into contact with the food, the maximum permitted duration and temperature of the food contact with the material/article
- Confirmation that the legal limits of the overall migration and the specific migration of material/article, as supplied (inclusive of coatings, colours, adhesives etc.), comply with the provisions of Regulation (EU) No. 10/2011

7. Verification of compliance with the requirements

7.1 Testing of the overall migration (OML)

The supplier shall allow the corresponding tests of the overall migration (OML), with all variants of the manufactured products, to be carried out by a testing institute authorised to carry out such validations at the following points in time:

- Before sampling for the initial sample inspection report (ISIR or ISTR)
- Once annually
- Upon modifications to material, production parameters or other end product-influencing criteria

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7.2 Testing of the specific migrations (SML)

The supplier shall allow the corresponding tests of the specific migration for the substances or their by-products named in the declaration of conformity, for which the Appendices I and II of Regulation (EU) 10/2011 contain restrictions and/or specifications for all variants of the manufactured products, to be carried out by a testing institute authorised to carry out such validations at the following points in time:

- Before sampling for the initial sample inspection report (ISIR or ISTR)
- Once annually
- Upon modifications to material, production parameters or other end product-influencing criteria

8. Distribution list

Research & Development, Quality Planning, Quality Assurance, Innovation Procurement, Realization Procurement, Strategic Direct Procurement & Value Management, Supplier Management

9. Change service

Changes are introduced by the Global Technics department and documented as follows:

1. In the footer under "Changed" with the date
 2. Current changes are marked in yellow
- (Refer to work instruction Q-G-0001-AA)

10. Proof of source

EU regulations may be found on the website of the European Union in the respective national language (<http://eur-lex.europa.eu>). Documents only in the German language here:

- Regulation (EC) No. 1935/2004
URL: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:EN:PDF>
(Retrieved: 2017-11-03)
- Regulation (EU) No. 10/2011
URL: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>
(Retrieved: 2017-11-03)
- Regulation (EC) No. 2023/2006
URL: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>
(Retrieved: 2017-11-03)
- Regulation (EC) No. 1895/2005
URL: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R1895&from=EN> (Retrieved: 2017-11-03)
- Regulation (EC) No. 1907/2006
URL: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140410&from=EN> (Retrieved: 2017-11-03)

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