

1.1.1 REFERENCE DOCUMENTS

FCM Legislation

- Regulation (EC) No 1935/2004 of October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538470669358&uri=CELEX:32004R1935>
- Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538470331108&uri=CELEX:32006R2023>

EU legislation on specific materials

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (amendments Regulation (EU) 2017/752 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, Regulation (EU) 2016/1416, Regulation EU 2015/174, Regulation EU 202/2014, Regulation EU 1183/2012, Corrigendum to Regulation EU 1183/2012, Regulation EU 1282/2011, Regulation EU 321/2011 - restricting Bisphenol A use in plastic infant feeding bottles).
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538470703434&uri=CELEX:32011R0010>
- Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538470990355&uri=CELEX:32009R0450>
- Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538471475056&uri=CELEX:32008R0282>
- Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538471696369&uri=CELEX:31984L0500>
- Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538471820480&uri=CELEX:32007L0042>
- Regulation (EU) No 284/2011 of 22 March 2011, laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China.
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538472001483&uri=CELEX:32011R0284>

Legislation on Specific Substances

- Commission Regulation 1895/2005/EC of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538472118856&uri=CELEX:32005R1895>

- Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1538472243077&uri=CELEX:31993L0011>

Non-harmonised materials

- Non-harmonised food contact materials in the EU: Regulatory and market situation: BASELINE STUDY: Final report

<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study>

EU Guidelines

- Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_reg_en.pdf

- Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_reg_en.pdf

- EU Guidance to the Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_legis_active-intelligent_guidance.pdf

- EU guidelines on conditions and procedures for the import of polyamide and melamine kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China.

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_legis_china_guidelines_import-polyamide-melamine.pdf

EFSA's guidelines for substances authorisation applications

- <http://www.efsa.europa.eu/en/applications/foodcontactmaterials/regulationsandguidance>

- 1. Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials, EFSA, May, 2017, www.efsa.europa.eu/publications

<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2017.EN-1224>

- 2. Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials, EFSA, May, 2017, www.efsa.europa.eu/publications

<https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2008.21r>

- EFSA's opinions on substances to be used in food contact materials
<http://www.efsa.europa.eu/en/topics/topic/food-contact-materials>

National Guides

- Food contact materials and articles: Printing Inks (Check lists for compliance in industry and trade and control by food inspection), Nordic Council of Ministers, 2012, www.norden.org/en/publications
<http://orbit.dtu.dk/files/8063088/Prining%20inks%20Nordisk%20rapport.pdf>
- Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food, 2011, www.iss.it
<http://www.cepi.org/system/files/public/documents/publications/foodcontact/2011/CARTONI E CARTONE PRODUZIONE Bozzatrad-20110228-00007-01-E.pdf>