the Commission Regulation (EU) No 10/2011. (See end of Document for details)

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1 Article 2 Article 3 Article 4	Subject matter Scope Definitions Placing on the market of plastic materials and articles
	CHAPTER II
	COMPOSITIONAL REQUIREMENTS
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	Authorised substances
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	CHAPTER III
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-

ANNEX I

Substances

- Union list of authorised monomers, other starting substances, macromolecules 1. obtained...
- 2. Group restriction of substances

- 3. Notes on verification of compliance
- 4. Detailed specification on substances

ANNEX II

Restrictions on materials and articles

- 1. Plastic materials and articles shall not release the following substances...
- 2. Primary aromatic amines which are not listed in Table 1...

ANNEX III

Food simulants

- 1. Food simulants
- 2. General assignment of food simulants to foods
- 3. Specific assignment of food simulants to foods for migration testing...

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- 4. Food simulant assignment for testing overall migration
- 5. General derogation to the assignment of food simulants

ANNEX IV

Declaration of compliance

The written declaration referred to in Article 15 shall contain... the identity and address of the business operator issuing the...

ANNEX V COMPLIANCE TESTING

CHAPTER 1

Testing for specific migration of materials and articles already in contact with food

- 1.1. Sample preparation
- 1.2. Conditions of testing
- 1.3. Analysis of migrated substances
- 1.4. Account of substances originating from other sources

CHAPTER 2

Testing for specific migration of materials and articles not yet in contact with food

- 2.1. Verification method
 - 2.1.1. Sample preparation
 - 2.1.2. Choice of food simulant
 - 2.1.3. Conditions of contact when using food simulants
 - 2.1.4. Specific conditions for contact times above 30 days at room...
 - 2.1.5. Specific conditions for combinations of contact times and temperature
 - 2.1.6. Repeated use articles
 - 2.1.7. Analysis of migrating substances
 - 2.1.8. Verification of compliance by residual content per food contact surface...
- 2.2. Screening approaches
 - 2.2.1. Replacing specific migration by overall migration
 - 2.2.2. Residual content
 - 2.2.3. Migration modelling
 - 2.2.4. Food simulant substitutes
 - 2.2.5. Single test for successive combinations of time and temperature

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CHAPTER 3

Testing for overall migration

- 3.1. Standardised testing conditions
- 3.2. Substitute overall migration tests for tests with food simulant D2...
- 3.3. Verification of compliance
 - 3.3.1. Single use articles and materials
 - 3.3.2. Repeated use articles and materials
- 3.4. Screening approaches
 - 3.4.1. Residual content
 - 3.4.2. Food simulant substitutes

CHAPTER 4

Correction factors applied when comparing migration test results with migration limits

- 4.1. Correction of specific migration in foods containing more than 20...
- 4.2. Correction of migration into food simulant D2
- 4.3. Combination of correction factors 4.1 and 4.2.

ANNEX VI

Correlation tables

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- (1) OJ L 338, 13.11.2004, p. 4.
- **(2)** OJ L 220, 15.8.2002, p. 18.
- **(3)** OJ L 44, 15.2.1978, p. 15.
- **(4)** OJ L 135, 30.5.2009, p. 3.
- OJ L 354, 31.12.2008, p. 16.
- **(6)** OJ L 354, 31.12.2008, p. 34.
- **(7)** OJ L 31, 1.2.2002, p. 1.
- SCF opinion of 4 December 2002 on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials. http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf
- Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the introduction of a Fat (consumption) Reduction Factor for infants and children, The EFSA Journal (2004) 103, 1-8.
- (10) OJ L 297, 23.10.1982, p. 26.
- (11) OJ L 213, 16.8.1980, p. 42.
- (12) OJ L 167, 24.6.1981, p. 6.
- (13) OJ L 165, 30.4.2004, p. 1.

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