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

eı
)

Article 2 Scope

Article 3 Definitions

Article 4 Placing on the market of plastic materials and articles

CHAPTER II

COMPOSITIONAL REQUIREMENTS

SECTION 1

Authorised substances

- Article 5A Regulations and devolved powers
- Article 6 Derogations for substances not included in the ... list
- Article 7 Establishment and management of the provisional list

SECTION 2

General requirements, restrictions and specifications

- Article 8 General requirement on substances
- Article 9 Specific requirements on substances
- Article 10 General restrictions on plastic materials and articles
- Article 11 Specific migration limits
- Article 12 Overall migration limit

CHAPTER III

SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

- Article 13 Plastic multi-layer materials and articles
- Article 14 Multi-material multi-layer materials and articles

CHAPTER IV

DECLARATION OF COMPLIANCE AND DOCUMENTATION

- Article 15 Declaration of compliance
- Article 16 Supporting documents

CHAPTER V

COMPLIANCE

Article 17	Expression of migration test results
Article 18	Rules for assessing compliance with migration limits
Article 19	Assessment of substances not included in the Union list

CHAPTER VI

FINAL PROVISIONS

- Article 20 Amendments of EU acts
- Article 21 Repeal of EU acts
- Article 22 Transitional provisions
- Article 23 Entry into force and application
 - Signature

ANNEX I

Substances

- 1. ... List of authorised monomers, other starting substances, macromolecules obtained...
- 2. Group restriction of substances
- 3. Notes on verification of compliance
- 4. Detailed specification on substances

ANNEX II

Restrictions on plastic materials and articles

The following restrictions on plastic materials and articles apply: Plastic materials and articles shall not release the substances in...

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...
- 4. Food simulant assignment for testing overall migration

5. General derogation to the assignment of food simulants

ANNEX IV

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

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 materials and 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

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

- (**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.
- (5) 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.
- (8) 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
- (9) 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.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011.