

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 V

**COMPLIANCE**

*Article 17*

**Expression of migration test results**

1 To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2 By derogation from paragraph 1 for:

- a containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,
- b materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,
- c sheets and films that are not yet in contact with food,
- d sheets and films containing less than 500 millilitres or grams or more than 10 litres,

the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm<sup>2</sup> per kg of food.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.

3 By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:

- a mg/kg using the actual content of the container for which the closure is intended or in mg/dm<sup>2</sup> applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2;
- b mg/article if the intended use of the article is unknown.

4 For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:

- a mg/dm<sup>2</sup> applying the total contact surface of sealing article and sealed container if the intended use of the article is known;
- b mg/article if the intended use of the article is unknown.

*Article 18*

**Rules for assessing compliance with migration limits**

1 For materials and articles already in contact with food verification of compliance with specific migration limits shall be carried out in accordance with the rules set out in Chapter 1 of Annex V.

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*Status: Point in time view as at 14/01/2011.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, CHAPTER V. (See end of Document for details)*

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2 For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V.

3 For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2.

4 For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants A, B, C, D1 and D2 as set out in Annex III in accordance with the rules set out in Chapter 3, Section 3.1 of Annex V.

5 For materials and articles not yet in contact with food screening of compliance with the overall migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 3, Section 3.4 of Annex V. If a material or article fails to comply with the migration limit in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 4.

6 The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

7 Before comparing specific and overall migration test results with the migration limits the correction factors in Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.

#### *Article 19*

#### **Assessment of substances not included in the Union list**

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

**Status:**

Point in time view as at 14/01/2011.

**Changes to legislation:**

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