

SCHEDULE 2

Regulations 9 and 13

Provisions Applicable when Testing Compliance with the Migration Limits

General Provisions

1. When the results of the migration tests specified in this Schedule and, where appropriate Schedule 3, are analytically determined, the specific gravity of any simulants used shall be assumed to be 1, so that milligrams of any substance released per litre of simulant will correspond numerically to milligrams of that substance released per kilogram of that simulant.

2. Where any migration test specified in this Schedule and, where appropriate, Schedule 3 is carried out on any sample taken from any plastic material or article and the quantities of food or simulant placed in contact with the sample differ from those employed in the actual conditions under which the plastic material or article is used or is to be used, the results obtained should be corrected by applying the formula $M = ((m \cdot a_2 / a_1 \cdot q) \cdot 1000)$ where —

- (a) M is the migration in mg/kg;
- (b) m is the mass in the mg of substance released by the sample as determined by the migration test;
- (c) a_1 is the surface area in square decimetres of the sample in contact with the food or simulant during the migration test;
- (d) a_2 is the surface area in square decimetres of the plastic material or article in actual conditions of use; and
- (e) q is the quantity in grams of food in contact with the plastic material or article in actual conditions of use.

3.—(1) Subject to sub-paragraph (2), any testing of migration from any plastic material or article shall be carried out on that plastic material or article.

(2) In any case where determination in accordance with sub-paragraph (1) above is impracticable, such testing shall be carried out, using either specimens taken from that plastic material or article, or where appropriate, specimens representative of that plastic material or article.

(3) Any sample used for such testing shall be placed in contact with the simulant or food, as the case may be, in a manner representing the contact conditions in actual use, and for this purpose the testing shall be carried out in such a way that only those parts of the sample intended to come into contact with food in actual use will be in contact with the simulant or food.

(4) Any migration testing of caps, gaskets, stoppers or similar devices for sealing shall be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.

4.—(1) Any sample of plastic material or article shall be placed in contact with the appropriate simulant or the food for a period and at a temperature which are chosen by reference to the contact conditions in actual use in accordance with the provisions of this Schedule and, where appropriate, Schedule 3.

(2) At the end of the period referred to in sub-paragraph (1), analytical determination of the total quantity of substances (overall migration), each specific quantity of a substance (specific migration) or, as the case may be, both that total and that specific quantity released by the sample shall be carried out on the simulant or food, as the case may be.

(3) Verification that migration into food complies with a migration limit specified in regulation 9 or in Annex II, III or IV (for the purposes of this Schedule and Schedule 3 referred to together

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as “the Annexes”) shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use in accordance with the provisions of this Schedule.

(4) Verification that migration into food simulants complies with a migration limit specified in regulation 9 or the Annexes shall be carried out in accordance with the provisions of this Schedule and using conventional migration tests, the basic rules for which are set out in Schedule 3.

5. Where a plastic material or article is intended to come into repeated contact with food, any migration test shall (subject to paragraph 7 below) be carried out three times on a single sample in accordance with the conditions laid down in this Schedule and, where appropriate, Schedule 3 using separate samples of the simulant or, as the case may be food, on each occasion, and the level of the migration found in the third test shall be treated as the level relevant to that test.

Special provisions relating to the fat reduction factor

6.—(1) Subject to paragraph 7, the results of tests for specific migration in foods containing more than 20% fat shall be corrected by the fat reduction factor (“FRF”), being a factor between 1 and 5 (expressed as M_{FRF}) by which measured migration of lipophilic substances listed in Annex IVa into a fatty food or simulant D and its substitutes are divided before comparison with specific migration limits.

(2) The following equations shall be applied before comparison with the specific migration limit —

- (a) $M_{FRF} = M/FRF$, and
- (b) $FRF = (\text{g fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$.

7.—(1) Correction by the FRF may not be used —

- (a) where the plastic material or article is in contact or is intended to be brought into contact with foods intended for infants and young children;
- (b) for substances listed in the Annexes having a restriction in column (4) of SML = ND;
- (c) for substances not listed in the Annexes and used behind a plastic functional barrier with a migration limit of 0.01 mg/kg;
- (d) except in the circumstances specified in sub-paragraph (2), for plastic materials or articles —
 - (i) for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact with it, due to shape, use or other factors, and
 - (ii) where the migration is calculated using the conventional surface area/volume conversion factor of 6 dm²/kg.

(2) For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more than 20% fat —

- (a) the migration may be calculated as concentration (expressed as mg/kg) in the food or food simulant and corrected by the FRF; or
- (b) the migration may be re-calculated as mg/dm² without applying the FRF,

and provided the value resulting from the calculation under either sub-paragraph (a) or (b) is below the SML the plastic material or article shall be considered to be in compliance.

8. If use of the FRF under paragraph 6 or 7(2) produces a result that indicates the overall migration limit has been exceeded, the plastic material or article in question shall not be considered to be in compliance.

Special provisions relating to the correction of specific migration in simulant D

9. The specific migration of those lipophilic substances listed in Annex IVa into simulant D and its substitutes shall be corrected by —

- (a) the simulant D reduction factor (“DRF”), being the reduction factor referred to in paragraph 2(2) of Part 3 and paragraphs 2 and 3 of Part 4 of Schedule 3, provided that —
 - (i) in cases where the specific migration into simulant D is higher than 80% of the content of the substance in the finished plastic material or article, it can be demonstrated by scientific or experimental evidence, such as testing with the most critical foods, that the DRF is appropriate, and
 - (ii) the substance is not one mentioned in paragraph 7(1)(b) or (c);
- (b) the FRF, provided that the fat content of the food to be packed is known and the requirements of paragraphs 6, 7 and 8 are fulfilled; or
- (c) the total reduction factor (“TRF”), being the factor —
 - (i) by which a measured specific migration into simulant D or a substitute shall be divided before comparison with the specific migration limit, and
 - (ii) which is obtained by multiplying the DRF by the FRF with a maximum value of 5, when both factors are applicable.

Special provisions relating to overall migration

10.—(1) Subject to sub-paragraph (2), any method of analytical determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.

(2) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with regulation 9 it shall be a defence for the person charged to prove that—

- (a) if an aqueous simulant specified in Schedule 3 had been used, and the analytical determination of the total quantity of substances released by a sample of the plastic material or article tested had been carried out by evaporation of the simulant and weighing of the residue; or
- (b) if rectified olive oil or any of its substitutes had been used as a simulant and—
 - (i) a sample of the plastic material or article had been weighed before and after contact with the simulant;
 - (ii) the simulant absorbed by the sample had been extracted and determined quantitatively;
 - (iii) the quantity of simulant so found had been subtracted from the weight of the sample measured after contact with the simulant; and
 - (iv) the difference between the initial and corrected final weights had been determined to represent the overall migration of the sample examined,

there would have been no such excess so determined.

11.—(1) Where a plastic material or article is intended to come into repeated contact with food and it is technically impossible to carry out the test described in paragraph 5, the test shall be modified in accordance with sub-paragraph (2) or in such other way so as to enable the level of migration occurring during the third such test to be determined, and such a determination may be used as evidence of the overall migration in relation to a plastic material or article.

(2) Three identical samples of the plastic material or article are to be procured, following which—

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- (a) the first sample is to be subjected to the appropriate test according with paragraph 4 and the overall migration determined (M_1);
 - (b) the second and third samples are to be subjected to the same conditions of temperature but the period of contact is to be respectively two and three times that specified and the overall migration determined in each case (M_2 and M_3).
- (3) Where a modified test has been carried out in accordance with sub-paragraph (2), provided that either M_1 or $M_3 - M_2$ did not exceed the overall migration limit, the plastic material or article subjected to the test shall be deemed to be in compliance with that limit.

12.—(1) Any plastic material or article which exceeds its overall migration limit by an amount not exceeding the analytical tolerance specified in sub-paragraph (2) shall be deemed for the purposes of these Regulations not to exceed its overall migration limit.

- (2) The following analytical tolerances shall be applied for limits of overall migration—
- (a) 20 mg/kg or, as the case may be, 3 milligrams per square decimetre in migration tests using as a simulant rectified olive oil or substitutes;
 - (b) 12mg/kg or, as the case may be, 2 milligrams per square decimetre in migration tests using other simulants referred to in Schedule 3.

Special provisions relating to caps, lids, gaskets, stoppers and similar sealing articles

13.—(1) If the intended use is known, caps, lids, gaskets, stoppers and similar sealing articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use and on the assumption that such articles are in contact with a quantity of food filling the container.

(2) The results of any tests carried out under sub-paragraph (1) shall be expressed in mg/kg or mg/dm^2 as appropriate in accordance with the requirements of regulation 9(2) , taking into account the total contact surface of sealing article and container that is potentially in contact with the food.

(3) If the intended use of an article of the type mentioned in sub-paragraph (1) is not known, it shall be —

- (a) tested separately from the container for which it is intended, with the result being expressed in mg/article; and
- (b) the value added, if appropriate, to the quantity migrated from that container.