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**COUNCIL DIRECTIVE**

**of 18 October 1982**

**laying down the basic rules necessary for testing migration of the constituents of plastic materials  
and articles intended to come into contact with foodstuffs**

(82/711/EEC)

(OJ L 297, 23.10.1982, p. 26)

Amended by:

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**COUNCIL DIRECTIVE****of 18 October 1982****laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs**

(82/711/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs <sup>(1)</sup>, and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas Article 2 of Directive 76/893/EEC laid down *inter alia* that materials and articles must not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs;

Whereas in order to achieve this objective in the case of plastic materials the suitable instrument is a specific directive within the meaning of Article 3 of Directive 76/893/EEC, the general rules of which shall also be applicable to the case in question;

Whereas, given the complexity of the problem, the Directive should initially be limited to fixing the basic rules for verification of constituent migration; whereas further directives, to be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC, will establish the methods of analysis necessary for the verification of such migration;

Whereas this Directive does not affect all aspects of plastic materials and articles; whereas it is therefore necessary to authorize the Member States, on the one hand, not to impose the labelling particulars laid down in Article 7 of Directive 76/893/EEC in accordance with paragraphs 4 and 5 of that Article and, on the other hand, to prohibit the marketing of materials and articles which, although conforming with the standards laid down by that Directive, do not comply with national provisions regarding other possible standards referred to in Article 3 or in the absence of these, with Article 2 of the Directive in question;

Whereas, in view of the analytical difficulties connected with the determination of the migration levels in food products, conventional tests should be chosen (liquids capable of simulating the attack on foodstuffs and standard test conditions) in order to reproduce, as far as possible, the migration phenomena which may occur in contact between the article and the foodstuff;

Whereas if such tests subsequently prove not to reflect reality Member States should be authorized to amend them provisionally, pending a Community decision;

Whereas, in the current state of analytical techniques, it is not possible to determine all the conditions under which conventional migration tests should be performed on materials and articles consisting of two or more layers, one or more of which does not consist entirely of plastics;

<sup>(1)</sup> OJ No L 340, 9. 12. 1976, p. 19.

<sup>(2)</sup> OJ No C 140, 5. 6. 1979, p. 173.

<sup>(3)</sup> OJ No C 227, 10. 9. 1979, p. 31.

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whereas a decision on the application of this Directive to such materials and articles should therefore be taken at a later date;

Whereas the adaptation of this Directive to technical progress is an implementing measure; whereas, in order to simplify and accelerate the procedure, this should be the responsibility of the Commission;

Whereas in all cases in which the Council confers on the Commission authority to implement the provisions relating to plastic materials and articles intended to come into contact with foodstuffs, a procedure should be laid down establishing close cooperation between Member States and the Commission within the Standing Committee for Foodstuffs set up under Decision 69/414/EEC <sup>(1)</sup>,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.
2. This Directive shall apply to plastic materials and articles, that is to say to materials and articles and parts thereof:
  - (a) consisting exclusively of plastics, or
  - (b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,

which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose.

3. For the purposes of this Directive, 'plastics' shall mean the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as 'plastics':

- (i) varnished or unvarnished regenerated cellulose film;
- (ii) elastomers and natural and synthetic rubber;
- (iii) paper and paperboard, whether modified or not by the addition of plastics;
- (iv) surface coatings obtained from:
  - paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,
  - mixtures of the waxes listed in the first indent with each other and/or with plastics.

4. This Directive shall not apply to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

A decision on the application of this Directive to the materials and articles referred to in the first subparagraph and on any adaptations to the Directive that may become necessary shall be taken at a later date.

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*Article 2*

The overall and specific migration levels of constituents of the materials and articles referred to in Article 1 into or onto foodstuffs or food

<sup>(1)</sup> OJ No L 291, 19. 11. 1969, p. 9.

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simulants must not exceed the limits laid down in Commission Directive 90/128/EEC <sup>(1)</sup> or in any other relevant specific directive.

*Article 3*

1. Verification of compliance of migration into foodstuffs with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests, the basic rules for which are laid down in the Annex to this Directive.

2. (a) However, where a Member State, as a result of new information or of a reassessment of existing information made since this Directive was adopted, has detailed grounds for establishing that for a given plastic material or article the basic rules laid down in the Annex for migration tests are technically unsuitable or because the actual conditions of use are basically different from the test conditions specified in the table in the Annex, that Member State may, within its territory and only for the particular case, temporarily suspend application of the basic rules referred to in the Annex and permit the use of more appropriate basic rules. It shall immediately inform the other Member States and the Commission thereof and give the reasons for its decision.
- (b) The Commission shall examine, as soon as possible, the reasons given by the Member States concerned and shall consult the Member States within the Standing Committee for Foodstuffs and shall then deliver its opinion forthwith and amend this Directive, if necessary. In that case, the Member State which has adopted the more appropriate basic rules may retain them until the said amendments enter into force.

**▼B***Article 4*

Adaptations to be made to Chapter II of the Annex to this Directive in the light of progress in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

*Article 5*

This Directive shall not affect national provisions relating to the other rules provided for in Article 3 of Directive 76/893/EEC nor the options open to Member States under Article 7 (4) and (5) of that Directive.

*Article 6*

Member States shall comply with this Directive not later than such time as a specific directive laying down the limits referred to in Article 2 (1) is implemented.

*Article 7*

This Directive is addressed to the Member States.

<sup>(1)</sup> OJ No L 75, 21. 3. 1990, p. 19, amended by OJ No L 349, 13. 12. 1990, p. 26.

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## ANNEX

**BASIC RULES FOR TESTING MIGRATION IN FOOD SIMULANTS**

The determination of migration in food simulants shall be carried out using the food simulants laid down in Chapter I of Annex and under the test conditions specified in Chapter II of Annex. However the determination of migration shall be restricted to the food simulant(s) and to the condition(s) of test which, in the specific case under examination, may be considered to be the most severe on the basis of experience.

## CHAPTER I

**Food simulants**1. *General case: plastic materials and articles intended to come into contact with foodstuffs of all types*

The tests shall be carried out using the food simulants mentioned below, taking a fresh sample of the plastic material or article for each simulant:

- distilled water or water of equivalent quality (= simulant A),
- 3 % acetic acid (w/v) in aqueous solution (= simulant B),
- 15 % ethanol (v/v) in aqueous solution (= simulant C),
- rectified olive oil <sup>(1)</sup> (= simulant D); if for technical reasons connected with the method of analysis it is necessary to use different food simulants, olive oil shall be replaced by a mixture of synthetic triglycerides <sup>(2)</sup> or by sunflower oil. If all the food simulants provided in this indent are inappropriate, other food simulants and conditions of time and temperature may be used.

However, the simulant A shall be used only in the cases mentioned specifically in the Table of this Annex.

2. *Special case: plastic materials and articles intended to come into contact with a single foodstuff or a specific group of foodstuffs*

The tests shall be carried out:

- using only the food simulant(s) specified as appropriate for the foodstuff or group of foodstuffs in the Directive 85/572/EEC <sup>(3)</sup>,
- where the foodstuff or group of foodstuffs is not included in the list referred to in the first indent, selecting the food simulant(s) prescribed in Section 1 which correspond most closely to the extractive capacity of the foodstuff or group of foodstuffs.

## CHAPTER II

**Test conditions (times and temperatures)**

1. The migration tests are to be carried out, selecting from the times and temperatures specified in the table those which correspond most closely to, but are not less than, the normal or foreseeable conditions of contact for the plastic materials or articles being studied.
2. Where a material or article passes a test at a given time and temperature, it need not be tested for a shorter time at the same temperature, nor for the same time at a lower temperature.
3. However if a plastic material or article is intended for a food contact application covered by two or more combinations of time and temperature taken from the Table, migration will be determined by subjecting that material or article successively to all the applicable test conditions, using the same aliquot of food simulant.
4. If a plastic material or article is intended to come into contact with foodstuffs at any condition of time, the conditions for testing will be the following:

<sup>(1)</sup> Characteristics of rectified olive oil:

- iodine index (Wijs) = 80 to 88,
- refraction index at 25 °C = 1,4665 to 1,4679,
- acidity (expressed in % of oleic acid) = 0,5 % maximum,
- peroxide index (expressed in milli-equivalents of oxygen per kg of oil) = 10 maximum.

<sup>(2)</sup> Characteristics of the standard synthetic triglycerides mixture as described in K. Figge's article, 'Food Cosmet. Toxicol' 10 (1972) 81.5.

<sup>(3)</sup> OJ No L 372, 31. 12. 1985, p. 14.

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- (a) where the plastic material or article may in actual use be employed at any temperature up to and including 70 °C and that is indicated by an appropriate labelling or instructions, only the 10 day test(s) at 40 °C shall be carried out;
- (b) where a plastic material or article may in actual use be employed at a temperature above 70 °C:
- (i) where no labelling or instructions are given to indicate temperature expected in real use, simulants B and C shall be used at reflux temperature, if possible, or at two-hour test(s) at 100 °C and simulant D shall be used for two hours at 175 °C;
  - (ii) where labelling or instructions are given to indicate conditions expected in real use, time and temperatures from the Table shall be selected.
5. By derogation from the conditions provided in the table and in paragraph 2, if the plastic material or article may in actual use be employed for periods of less than 15 minutes at temperatures between 70 °C and 100 °C and that is indicated by an appropriate labelling or instructions, only the two-hour test at 70 °C and the 10-day test at 40 °C shall be carried out. These tests shall be carried out separately taking different samples. For each of these two types of test, use a new sample of the same material or article to be examined.
6. If it is found that carrying out the tests under the conditions specified in the table causes physical or other changes in the plastic material or article which do not occur under normal or foreseeable conditions of use of that material or article, the migration tests shall be carried out under conditions more appropriate to the specific case.
7. For materials and articles intended for use in microwave ovens, migration testing shall use a conventional oven and appropriate time and temperature conditions selected from the Table.

Table

Conditions of contact in actual use	Test condition
<i>Contact time</i>	<i>Test time</i>
$t \leq 0,5$ hour	0,5 hour
$0,5 \text{ hour} < t \leq 1$ hour	1 hour
$1 \text{ hour} < t \leq 2$ hours	2 hours
$2 \text{ hours} < t \leq 24$ hours	24 hours
$t > 24$ hours	10 days
<i>Contact temperature</i>	<i>Test temperature</i>
$T \leq 5$ °C	5 °C
$5 \text{ °C} < T \leq 20$ °C	20 °C
$20 \text{ °C} < T \leq 40$ °C	40 °C
$40 \text{ °C} < T \leq 70$ °C	70 °C
$70 \text{ °C} < T \leq 100$ °C	100 °C or reflux temperature
$100 \text{ °C} < T \leq 121$ °C	121 °C <sup>(1)</sup>
$121 \text{ °C} < T \leq 130$ °C	130 °C <sup>(1)</sup>
$130 \text{ °C} < T \leq 150$ °C	150 °C <sup>(2)</sup>
$T > 150$ °C	175 °C <sup>(2)</sup>

<sup>(1)</sup> Use simulant C at reflux temperature.

<sup>(2)</sup> Use simulant D at 150 °C or 175 °C, in addition to simulants A, B and C used as appropriate at 100 °C or at reflux temperature.