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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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► <u>M1</u> Commission Directive 93/8/EEC of 15 March 1993	L 90	22	14.4.1993
► <u>M2</u> Commission Directive 97/48/EC of 29 July 1997	L 222	10	12.8.1997

**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⁽¹⁾, and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament⁽²⁾,Having regard to the opinion of the Economic and Social Committee⁽³⁾,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;

⁽¹⁾ OJ No L 340, 9. 12. 1976, p. 19.

⁽²⁾ OJ No C 140, 5. 6. 1979, p. 173.

⁽³⁾ 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 ⁽¹⁾,

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

⁽¹⁾ 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 ⁽¹⁾ 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.

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

▼ **M2***ANNEX***BASIC RULES FOR OVERALL AND SPECIFIC MIGRATION TESTING**

1. 'Migration tests' for the determination of specific and overall migration shall be carried out using the 'food simulants' laid down in Chapter I of this Annex and under 'conventional migration test conditions' specified in Chapter II of this Annex.
2. 'Substitute tests' which use the 'test media' under the 'conventional substitute test conditions' as set out in Chapter III shall be carried out if the migration test using the fatty food simulants (see Chapter I) is not feasible for technical reasons connected with the method of analysis.
3. 'Alternative tests' indicated in Chapter IV are permissible instead of migration tests with fatty food simulant when the conditions specified in Chapter IV are fulfilled.
4. In all three cases it is permissible:
 - (a) to reduce the number of tests to be carried out to that or those which, in the specific case under examination, is (are) generally recognized to be the most severe on the basis of scientific evidence;
 - (b) to omit the migration or the substitute or the alternative tests where there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article.

CHAPTER I

Food simulants1. **Introduction**

As it is not possible always to use foodstuffs for testing food contact materials, food simulants are introduced. They are classified by convention as having the character of one or more food types. The food types and the food simulants to be used are indicated in Table 1. In practice various mixtures of food types are possible, for instance fatty and aqueous foods. They are described in Table 2 accompanied by the indication of the food simulant(s) to be selected in carrying out the migration tests.

Table 1*Food types and food simulants*

Food type	Conventional classification	Food simulant	Abbreviation
Aqueous foods (i.e. aqueous foods having a pH >4,5)	Foodstuffs for which test with the simulant A only is prescribed in Directive 85/572/EEC ⁽¹⁾	Distilled water or water of equivalent quality	Simulant A
Acidic foods (i.e. aqueous foods having a pH ≤4,5)	Foodstuffs for which test with the simulant B only is prescribed in Directive 85/572/EEC	Acetic acid 3 % (w/v)	Simulant B
Alcoholic foods	Foodstuffs for which test with the simulant C only is prescribed in Directive 85/572/EEC	Ethanol 10 % (v/v) This concentration shall be adjusted to the actual alcoholic strength of the food if it exceeds 10 % (v/v)	Simulant C
Fatty foods	Foodstuffs for which test with the simulant D only is prescribed in	Rectified olive oil or other fatty food simulants	Simulant D

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Food type	Conventional classification	Food simulant	Abbreviation
	Directive 85/572/EEC		
Dry foods		None	None

(¹) OJ No L 372, 31. 12. 1985, p. 14.

2. Selection of food simulants

2.1. Materials and articles intended for contact with all food types

The tests shall be carried out using the food simulants mentioned below, which are considered the more severe, at the test conditions specified in Chapter II, taking a new test specimen of the plastic material or article for each simulant:

- 3 % acetic acid (w/v) in aqueous solution,
- 10 % ethanol (v/v) in aqueous solution,
- rectified olive oil ('reference simulant D').

However this reference simulant D may be replaced by a synthetic mixture of triglycerides or sunflower oil or corn oil with standardized specifications ('Other fatty food simulants', called 'simulants D'). If, when using any of these other fatty food simulants, the migration limits are exceeded, for the judgement of non compliance a confirmation of the result by using olive oil is obligatory, when technically feasible. If this information is not technically feasible and the material or article exceeds the migration limits it shall be deemed not in compliance with the Directive 90/128/EEC.

2.2. Materials and articles intended for contact with specific food types

This case refers only to the following situations:

- (a) when the material or article is already in contact with a known foodstuff;
- (b) when the material or article is accompanied, according to the rules of Article 6 of Directive 89/109/EEC, by a specific indication stating with which food types described in Table 1 it may or may not be used, for example 'only for aqueous foods';
- (c) when the material or article is accompanied, according to the rules of Article 6 of Directive 89/109/EEC, by a specific indication stating with which foodstuff(s) or group(s) of foodstuffs mentioned in Directive 85/572/EEC they may or may not be used. This indication shall be expressed:
 - (i) at the marketing stages other than retail stage, by using the 'reference number' or 'description of foodstuffs' provided in the Table of Directive 85/572/EEC;
 - (ii) at the retail stage using an indication which shall refer to only a few foods or groups of food, preferably with examples which are easy to understand.

In these situations the tests shall be carried out using for the case under (b) the food simulant(s) indicated as examples in Table 2 and for the case under (a) and (c) the food(s) simulant(s) mentioned in Directive 85/572/EEC. Where the foodstuff(s) or group(s) of foodstuffs is (are) not included in the list specified in Directive 85/572/EEC, select the item from Table 2 which corresponds most closely to the foodstuff(s) or group(s) of foodstuffs under examination.

If the material or article is intended to come into contact with more than one foodstuff or group(s) of foodstuffs having different reduction factors, for each foodstuff apply the appropriate reduction factors to the test result. If one or more results of such calculation exceed the restriction, then the material is not suitable for that particular foodstuff or group(s) of foodstuff.

The tests shall be carried out at the test conditions specified in Chapter II, taking a new test specimen for each simulant.

▼ M2**Table 2***Food simulants to be selected for testing food contact materials in special cases*

Contact foods	Simulant
Only aqueous foods	Simulant A
Only acidic foods	Simulant B
Only alcoholic foods	Simulant C
Only fatty foods	Simulant D
All aqueous and acidic foods	Simulant B
All alcoholic and aqueous foods	Simulant C
All alcoholic and acidic foods	Simulants C and B
All fatty and aqueous foods	Simulants D and A
All fatty and acidic foods	Simulants D and B
All fatty and alcoholic and aqueous foods	Simulants D and C
All fatty foods and alcoholic and acidic foods	Simulants D, C and B

CHAPTER II

Migration test conditions (times and temperatures)

1. The migration tests are to be carried out, selecting from the times and temperatures specified in Table 3 those which correspond to the worst foreseeable conditions of contact for the plastic material or article being studied and to any labelling information on maximum temperature for use. Therefore if the plastic material or article is intended for a food contact application covered by a combination of two or more times and temperatures taken from the table, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

2. **Contact conditions generally recognized as more severe**

In application of the general criteria that the determination of migration should be restricted to the test conditions which, in the specific case under examination, are recognized to be the most severe on the basis of scientific evidence, some specific examples for the test contact conditions are given below.

- 2.1. *Plastic materials and articles intended to come into contact with foodstuffs at any condition of time and temperature*

Where no labelling or instructions are given to indicate contact temperature and time expected in actual use, depending on food type(s), simulant(s) A and/or B and/or C shall be used for 4 hours at 100 °C or for 4 hours at reflux temperature and/or simulant D shall be used only for 2 hours at 175 °C. These conditions of time and temperature are conventionally considered to be the more severe.

- 2.2. *Plastic materials and articles intended to come into contact with foodstuffs at room temperature or below for an unspecified period*

Where the materials and articles are labelled for use at room temperature or below or where the materials and articles by their nature are clearly intended for use at room temperature and below, the test shall be carried out at 40 °C for 10 days. These conditions of time and temperature are conventionally considered to be the more severe.

3. **Volatile migrants**

When testing for the specific migration of volatile substances, the test(s) with simulant(s) shall be performed in a manner which recognizes the loss

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of volatile migrants which may occur in the worst foreseeable conditions of use.

4. Special cases

- 4.1. For materials and articles intended for use in microwave ovens, migration testing may use either a conventional or a microwave oven provided the appropriate time and temperature conditions are selected from Table 3.
- 4.2. If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.
- 4.3. By derogation from the test conditions provided in Table 3 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 (e.g. 'hot fill') and is so indicated by appropriate labelling or instructions, only the 2 hours test at 70 °C shall be carried out. However if the material or article is intended to be used also for storage at room temperature, the above-mentioned test is replaced by a test at 40 °C for 10 days conventionally considered more severe.
- 4.4. In those instances where the conventional conditions for migration testing are not adequately covered by the test contact conditions of Table 3 (for instance contact temperatures greater than 175 °C or contact time less than 5 minutes), other contact conditions may be used which are more appropriate to the case under examination, provided that the selected conditions may represent the worst foreseeable conditions of contact for the plastic materials or articles being studied.

Table 3

Conventional conditions for migration tests with food simulants

Conditions of contact in worst foreseeable use	Test conditions
Contact time	Test time
$t \leq 5 \text{ min}$	See the conditions in point 4.4.
$5 \text{ min} < t \leq 0,5 \text{ hours}$	0,5 hours
$0,5 \text{ h} < t \leq 1 \text{ hour}$	1 hours
$1 \text{ h} < t \leq 2 \text{ hours}$	2 hours
$2 \text{ h} < t \leq 4 \text{ hours}$	4 hours
$4 \text{ hours} < t \leq 24 \text{ hours}$	24 hours
$t > 24 \text{ hours}$	10 days
Contact temperature	Test temperature
$T \leq 5 \text{ °C}$	5 °C
$5 \text{ °C} < T \leq 20 \text{ °C}$	20 °C
$20 \text{ °C} < T \leq 40 \text{ °C}$	40 °C
$40 \text{ °C} < T \leq 70 \text{ °C}$	70 °C
$70 \text{ °C} < T \leq 100 \text{ °C}$	100 °C or reflux temperature
$100 \text{ °C} < T \leq 121 \text{ °C}$	121 °C (*)
$121 \text{ °C} < T \leq 130 \text{ °C}$	130 °C (*)

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Contact temperature	Test temperature
130 °C < T ≤ 150 °C	150 °C (*)
T > 150 °C	175 °C (*)

(*) This temperature shall be used only for simulant D. For simulants A, B or C the test may be replaced by a test at 100 °C or at reflux temperature for a duration of four times the time selected according to the general rules of paragraph 1.

CHAPTER III

Substitute fat test for overall and specific migration

1. If the use of the fatty food simulants is not feasible for technical reasons connected with the method of analysis, use instead all test media prescribed in Table 4 under the test conditions corresponding to the test conditions for simulant D.

This table gives some examples of the most important conventional migration test conditions and their corresponding conventional conditions of the substitute tests. For other test conditions not stated in Table 4, take into account these examples as well as the existing experience for the type of polymer under examination.

Use for each test a new test specimen. Apply for each test medium the same rules prescribed in Chapters I and II for simulant D. Use, where appropriate, the reduction factors established in Directive 85/572/EEC. To ascertain compliance with any migration limit, select the highest value obtained using all the test media.

However if it is found that carrying out these tests causes physical or other changes in the test specimen which do not occur under the worst foreseeable conditions of use of the material or article under examination, the result for this test media shall be discarded and the highest of the remaining values shall be chosen.

2. By derogation of point 1, it may be possible to omit one or two of the substitute tests provided in Table 4, if these tests are generally recognized as not appropriate for the sample under consideration on the basis of scientific evidence.

Table 4*Conventional conditions for substitute tests*

Test condition with simulant D	Test conditions with isooctane	Test conditions with ethanol 95 %	Test conditions with MPPO (*)
10 d at 5 °C	0,5 d at 5 °C	10 d at 5 °C	—
10 d at 20 °C	1 d at 20 °C	10 d at 20 °C	—
10 d at 40 °C	2 d at 20 °C	10 d at 40 °C	—
2 h at 70 °C	0,5 h at 40 °C	2,0 h at 60 °C	—
0,5 h at 100 °C	0,5 h at 60 °C (**)	2,5 h at 60 °C	0,5 h at 100 °C
1 h at 100 °C	1,0 h at 60 °C (**)	3,0 h at 60 °C (**)	1 h at 100 °C
2 h at 100 °C	1,5 h at 60 °C (**)	3,5 h at 60 °C (**)	2 h at 100 °C
0,5 h at 121 °C	1,5 h at 60 °C (**)	3,5 h at 60 °C (**)	0,5 h at 121 °C
1 h at 121 °C	2,0 h at 60 °C (**)	4,0 h at 60 °C (**)	1 h at 121 °C
2 h at 121 °C	2,5 h at 60 °C (**)	4,5 h at 60 °C (**)	2 h at 121 °C
0,5 h at 130 °C	2,0 h at 60 °C (**)	4,0 h at 60 °C (**)	0,5 h at 130 °C
1 h at 130 °C	2,5 h at 60 °C (**)	4,5 h at 60 °C (**)	1 h at 130 °C
2 h at 150 °C	3,0 h at 60 °C (**)	5,0 h at 60 °C (**)	2 h at 150 °C

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Test condition with simulant D	Test conditions with isooctane	Test conditions with ethanol 95 %	Test conditions with MPPPO (*)
2 h at 175 °C	4,0 h at 60 °C (**)	6,0 h at 60 °C (**)	2 h at 175 °C

(*) MPPPO = Modified polyphenylene oxide

(**) The volatile tests media are used up to a maximum temperature of 60 °C. A precondition of using the substitute tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (e.g. melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed, then proceed with the substitute tests using new specimens.

CHAPTER IV

Alternative fat tests for overall and specific migration

1. It is permissible to use the result of alternative tests as specified in this Chapter provided that both the following conditions are fulfilled:
 - (a) the results obtained in a 'comparison test' show that the values are equal to or greater than those obtained in the test with simulant D;
 - (b) the migration in alternative test does not exceed the migration limits, after application of appropriate reduction factors provided in Directive 85/572/EEC.

If either or both conditions are not fulfilled, then the migration tests must be performed.

2. By derogation of the condition previously mentioned in paragraph 1 (a), it is possible to omit the comparison test if there is other conclusive proof based on scientific experimental results that the values obtained in the alternative test are equal to or greater than those obtained in the migration test.

3. **Alternative tests**3.1. *Alternative tests with volatile media*

These tests use volatile media such as isooctane or ethanol 95 % or other volatile solvents or mixture of solvents. They shall be carried out at the contact conditions such that the condition under 1 (a) is fulfilled.

3.2. *'Extraction tests'*

Other tests, which use media having a very strong extraction power under very severe test conditions, may be used if it is generally recognized, on the basis of scientific evidence, that the results obtained using these tests ('extraction tests') are equal to or higher than those obtained in the test with simulant D.