This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

►**B**

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:

		Official Journal		
		No	page	date
►**M1**	Commission Directive 93/8/EEC of 15 March 1993	L 90	22	14.4.1993
►**M2**	Commission Directive 97/48/EC of 29 July 1997	L 222	10	12.8.1997

▼B

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.

▼B

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 or 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.

▼M1

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.

▼M1

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 simulants

1. **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 $\leq 4,5$)	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