COMMISSION DIRECTIVE 97/48/EC

of 29 July 1997

amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 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,

Whereas Council Directive 82/711/EEC 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 [2], as amended by Directive 93/8/EEC [3], does not specify the migration tests to be carried out in cases where the fatty food simulants are inappropriate;

Whereas the application of the test using the fatty food simulants is time consuming and difficult to conduct and therefore alternative tests in some specified conditions should be permitted;

Whereas it is not clear whether Directive 82/711/EEC authorizes the use of plastic materials and articles which are not intended to come into contact with foodstuffs of all types but which are intended to come into contact with more than one single foodstuff or more than one specific group of foodstuffs; whereas this use may be authorized without posing any problem to health provided an appropriate indication informs the consumer or the retailer of the type(s) of foodstuff(s) with which it may or may not come into contact;

Whereas the indication of an excessive number of foodstuffs types which could be in contact with some plastic materials and articles may not be easy to understand and therefore these materials and articles should be submitted to all the food simulants or test media provided by this Directive to protect the consumer;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 82/711/EEC is replaced by the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 July 1998. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities.*

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 July 1997.

For the Commission

Martin BANGEMANN

Member of the Commission

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[1] OJ No L 40, 11. 2. 1989, p. 38.
[2] OJ No L 297, 23. 10. 1982, p. 26.
[3] OJ No L 90, 14. 4. 1993, p. 22.

ANNEX

'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 ≤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 Directive 85/572/EEC	Rectified olive oil or other fatty food simulants	Simulant D
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.

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