

L.N. 138 of 2003

**FOOD SAFETY ACT
(CAP. 448)**

Materials in Contact with Foodstuffs (Draft) Regulations, 2003

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health has made the following regulations:

- 1.1 The title of these regulations is the Materials in Contact with Foodstuffs Regulations 2003. Citation and commencement.
- 1.2 These regulations shall come into force on the 1st September, 2003.
- 2.1 These Regulations shall apply to materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are intended for that purpose, hereinafter referred to as 'materials and articles'. Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which form part of foodstuffs and may be consumed together with those foodstuffs, shall not be subject to these regulations. Applicability of these regulations.
- 2.2 These regulations shall apply to materials and articles which are in contact with water which is intended for human consumption. It shall not, however, apply to fixed public or private water supply equipment.
- 3.3 These regulations shall not apply to antiques.
- 2.4 These regulations shall not apply to materials and articles exclusively intended for export.
- 3.1 Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could: General Safety Requirement.
- endanger human health,
 - bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

Provisions for
specific contact
materials.

4.1 The groups of materials and articles listed in the First Schedule and, where appropriate, combinations of these materials and articles shall be subject to the specific provisions laid down in the Third to Tenth Schedules.

2.2 Materials and articles for which no applicable specific provisions have as yet been laid down shall comply with internationally recognized standards, in particular those issued by the Council of Europe under the framework of the Partial Agreement in the Social and Public Health Field.

4.3 The specific provisions may include:

(a) a list of the substances the use of which is authorized to the exclusion of all others (positive list);

(b) purity standards for such substances;

(c) special conditions of use for these substances and/or the materials and articles in which they are used;

(d) specific limits on the migration of certain constituents or groups of constituents into or onto foodstuffs;

(e) an overall limit on the migration of constituents into or onto foodstuffs;

(f) if necessary, provisions aimed at protecting human health against any hazards which might arise through oral contact with materials and articles;

(g) other rules to ensure compliance with regulation 3.1;

(h) the basic rules necessary for checking compliance with the provisions of points (d), (e), (f) and (g);

(i) detailed rules concerning sample taking and the methods of analysis required to check compliance with the provisions of points (a) to (g).

Provisional
authorisation of
contact materials.

5.1 Notwithstanding regulation 4, the Food Safety Commission may, where a list of substances has been drawn up in accordance with regulation 4.3 (a), authorize the use in Malta of a substance not included in the list, subject to compliance with the following conditions:

(a) the authorization must be limited to a maximum period of two years;

(b) the Food Safety Commission shall ensure that official checks are carried out on materials and articles manufactured from a substance of which it has authorized the use;

(c) materials and articles thus manufactured must bear a distinctive indication which will be defined in the authorization.

6.1 Where, as a result of new information or of a reassessment of existing information made since any of the specific measures were adopted, there are detailed grounds for establishing that the use of a material or article endangers human health although it complies with the relevant specific provisions, the Food Safety Commission may temporarily suspend or restrict application of the provisions in question.

Temporary
suspension of
marketing.

7.1 Without prejudice to any exceptions provided for in any specific measures, materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by:

Labelling of Food
Contact Materials.

(a) — the words 'for food use',
— or a specific indication as to their use, such as coffee-machine, wine bottle, soup spoon,
— or the symbol prescribed in the Second Schedule;

(b) where appropriate, any special conditions to be observed when they are being used;

(c) — either the name or trade name and the address or registered office,

— or the registered trade mark,
of the manufacturer or processor, or of a seller established within Malta or the European Community.

7.2 The particulars listed in regulation 7.1 must be conspicuous, clearly legible and indelible:

(a) at the retail stage:

— on the materials and articles or on the packaging,
— or on labels affixed to the materials and articles or to their packaging,

— or on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; in the case mentioned in regulation 7.1 (c), however, the latter option shall only be open if these particulars or a label bearing them cannot, for technical reasons, be affixed to the said materials and articles at either the manufacturing or the marketing stage;

(b) at the marketing stages other than the retail stage:

- on the accompanying documents,
- on the labels or packaging,
- or on the materials and articles themselves.

7.3 However, the particulars provided for in regulation 7.1 (a) shall not be compulsory for materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

7.4 The particulars provided for in regulation 7.1 (a) and (b) shall be confined to materials and articles which comply:

(a) with the criteria laid down in regulation 4;

(b) with the specific measures laid down in these Regulations or, in the absence of such specific measures, with any other applicable provisions.

7.5 The specific measures shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them.

7.6 The particulars required under regulation 7.1 (a) and (b) shall be given at least one of the following languages:

- Maltese, English, Italian,

unless the purchaser is informed by other means. This provision shall not preclude such particulars appearing in several languages.

Repeal of L.N. 4 of 1996.

8.1 The Materials & Articles in Contact with Foodstuffs Regulations, 1996 are hereby repealed.

8.2 References in other regulations to the Materials & Articles in Contact with Foodstuffs Regulations shall henceforth be construed as references to these regulations.

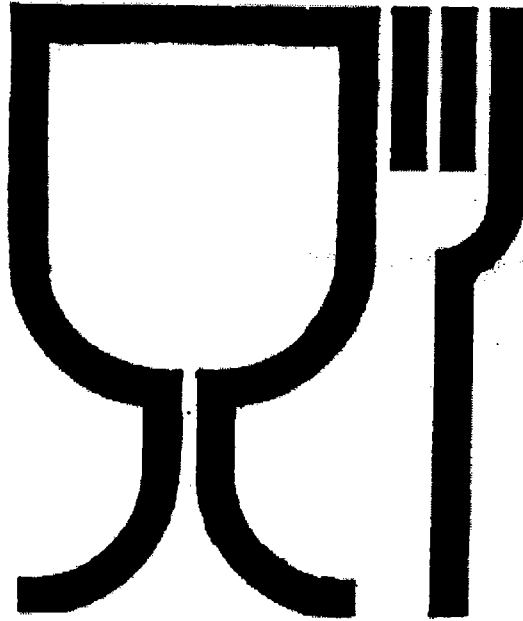
FIRST SCHEDULE

List of groups of materials and articles covered by specific measures

Plastics, including varnish and coatings
Regenerated cellulose
Elastomers and rubber
Paper and board
Ceramics
Glass
Metals and alloys
Wood, including cork
Textile products
Paraffin waxes and micro-crystalline waxes

SECOND SCHEDULE

**Symbol That May Accompany Materials And Articles Intended To-Come Into
Contact With Foodstuffs**



THIRD SCHEDULE

Ceramics

1. This Schedule contains specific provisions within the meaning of regulation 4.
2. This Schedule concerns the possible migration of lead and cadmium from ceramic articles which, in their finished state, are intended to come into contact with foodstuffs, or which are in contact with foodstuffs, and are intended for that purpose.
3. 'Ceramic articles' means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.
4. The quantities of lead and cadmium transferred from ceramic articles shall not exceed the limits laid down below.
5. The quantities of lead and cadmium transferred from ceramic articles shall be determined by means of a test, the conditions of which are specified in Part A, using the method of analysis described in Part B.
6. Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limit which may not be exceeded (mg/dm^2 or mg/litre) shall be that which applies to the vessel alone. The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions. The sum of the two lead and/or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the vessel alone.
7. A ceramic article shall be recognized as satisfying the requirements of these Regulations if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Parts A and B do not exceed the following limits:

Category	Extraction limits	
	Lead	Cadmium
Articles which can either be filled or not be filled with internal depth maximum 25 mm, measured from the lowest point to the horizontal plane passing through the upper rim.	0.8 mg/dm^3	0.07 mg/dm^3
All other articles which can be filled.	4.0 mg/l	0.3 mg/l

<i>Category</i>	<i>Extraction limits</i>	
	<i>Lead</i>	<i>Cadmium</i>
Cooking ware; packaging and storage vessels with a capacity of more than 3 litres.	1.5 mg/l	0.1 mg/l

8. However, where a ceramic article does not exceed the above quantities by more than 50 %, that article shall nevertheless be recognized as satisfying the requirements of these regulations if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Parts A and B and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50%.

PART A

Basic Rules For Determining The Migration Of Lead And Cadmium

1. *Test liquid ('simulant')*
4 % (v/v) acetic acid, in a freshly prepared aqueous solution.
2. *Test conditions*
 - 2.1. Carry out the test at a temperature of 22 ± 2 °C for a duration of $24 \pm 0,5$ hours.
 - 2.2. When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory. When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.
3. *Filling*
 - 3.1. Samples which can be filled
Fill the article with a 4 % (v/v) acetic acid solution to a level no more than 1 mm from the overflow point; the distance is measured from the upper rim of the sample. Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.
 - 3.2. Samples which cannot be filled
The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface

intended to come into contact with foodstuffs is completely covered by the test liquid.

4. *Determination of the surface area*

The surface area of the articles in category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in section 3 above.

PART B

Methods Of Analysis For Determining The Migration Of Lead And Cadmium

1. *Object and field of application*

The method allows the specific migration of lead and/or cadmium to be determined.

2. *Principle*

The determination of the specific migration of lead and/or cadmium is carried out by atomic absorption spectrophotometry.

3. *Reagents*

- All reagents must be of analytical quality, unless otherwise specified.
- Where reference is made to water, this always means distilled water or water of equivalent quality.

3.1. 4 % (v/v) acetic acid, in aqueous solution

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

3.2. Stock solutions

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution (3.1).

4. *Instruments*

4.1. Atomic absorption spectrophotometer

The instrument's detection limit for lead and cadmium must be equal to or lower than:

- 0,1 mg/litre for lead,
- 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in 4 % acetic acid (3.1) which gives a signal equal to twice the background noise of the instrument.

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5. *Method*

5.1. Preparation of the sample

The sample must be clean and free from grease or other matter likely to affect the test. Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tapwater and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested should not be handled after it has been cleaned.

5.2. Determination of lead and/or cadmium

- The sample thus prepared is tested under the conditions laid down in the Second Schedule.
- Before taking the test solution for determining lead and/or cadmium, homogenize the content of the sample by an appropriate method which avoids any loss of solution or abrasion of the surface being tested.
- Carry out a blank test on the reagent used for each series of determinations.

Carry out determinations for lead and/or cadmium under appropriate conditions by atomic absorption spectrophotometry.

FOURTH SCHEDULE

Regenerated Cellulose Film

1. This Schedule contains specific provisions within the meaning of regulation 4.
2. This Schedule shall apply to regenerated cellulose film within the meaning of the description given in Part A which either:
 - (a) constitutes a finished product in itself; or
 - (b) forms part of a finished product containing other materials,and which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact.
3. This Schedule does not apply to:
 - (a) regenerated cellulose film which, on the side intended to come into contact with foodstuffs or which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg/dm^2 ;
 - (b) synthetic casings of regenerated cellulose.
4. Only those substances or groups of substances listed in Part B may be used for the manufacture of regenerated cellulose film and only under the conditions laid down therein.
5. By way of derogation from paragraph 4, substances other than those listed in Part B may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method.
6. Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs.
7. At the marketing stages other than the retail stages, materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs shall be accompanied by a written declaration in accordance with regulation 7.5.
8. Paragraph 7 does not apply to materials and articles made of regenerated cellulose film which by their nature are clearly intended to come into contact with foodstuffs.
9. Where special conditions of use are indicated, the material or article made of regenerated cellulose film shall be labelled accordingly.

PART A

Description Of Regenerated Cellulose Film

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

PART B

List Of Substances Authorized In The Manufacture Of Regenerated Cellulose Film

As stipulated by Annex II of Commission Directive 93/10/EEC (OJ L 93, 17.4.1993, p. 27), as amended by Commission Directive 93/111/EEC (OJ L 310, 14.12.1993, p. 41).

Copies of the abovementioned Annexes shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

FIFTH SCHEDULE

Plastics

1. This Schedule contains specific provisions within the meaning of regulation 4.
2. This Schedule shall apply to plastic 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 Schedule, 'plastics' shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Other substances or matter may be added to such macromolecular compounds. However, the following shall not be regarded as 'plastics':
 - (a) varnished or unvarnished regenerated cellulose film, covered by the Fourth Schedule;
 - (b) elastomers and natural and synthetic rubber;
 - (c) paper and paperboard, whether modified or not by the addition of plastics;
 - (d) 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,
 - (e) ion-exchange resins;
 - (f) silicones.
4. This Schedule 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.
5. Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) (overall migration limit). However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in the following cases:

B 1604

- (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);
 - (b) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
 - (c) caps, gaskets, stoppers or similar devices for sealing.
6. Only those monomers and other starting substances listed in the Second Annex to this Schedule, Sections A and B, may be used for the manufacture of plastic materials and articles, subject to the restrictions specified.
7. By way of derogation from paragraph 6 the monomers and other starting substances listed in the Second Annex to this Schedule, Section B, may continue to be used until 31 December 2004 at latest.
8. The lists appearing in the Second Annex to this Schedule, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:
 - surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
 - epoxy resins,
 - adhesives and adhesion promoters,
 - printing inks.
9. An incomplete list of additives, which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in the Third Annex to this Schedule, Sections A and B. For the substances in the Third Annex to this Schedule, Section B, the specific migration limits shall apply as from 1 January 2004 when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in the Sixth and Seventh Schedules to these regulations.
10. Only the products obtained by means of bacterial fermentation listed in the Fourth Annex to this Schedule may be used in contact with foodstuffs.
11. General specifications related to plastic materials and articles are laid down in the Fifth Annex to this Schedule, Part A. Other specifications related to some substances appearing in the Second, Third and Fourth Annexes are laid down in the Fifth Annex to this Schedule, Part B.
12. The meaning of the numbers between brackets appearing in the column 'Restrictions and/or specifications' is explained in the Sixth Annex to this Schedule.

13. The specific migration limits in the list set out in the Second Annex to this Schedule are expressed in mg/kg. However, such limits are expressed in mg/dm² in the following cases:
 - (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;
 - (b) sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuffs in contact therewith.

In these cases, the limits set out in the Second Annex to this Schedule, expressed in mg/kg shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².
14. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in the Sixth and Seventh Schedules to these regulations and the further provisions set out in the First Annex to this Schedule.
15. The verification of compliance with the specific migration limits provided for in paragraph 14 shall not be compulsory, if it can be established that compliance with the overall migration limit laid down in paragraph 5 implies that the specific migration limits are not exceeded.
16. The verification of compliance with the specific migration limits provided for in paragraph 14 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.
17. The verification of compliance with the specific migration limits provided for in paragraph 14 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.
18. At the marketing stages other than the retail stages, the plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with regulation 7.5.
19. Paragraph 18 does not apply to plastic materials and articles, which by their nature are clearly intended to come into contact with foodstuffs.

PART I

***FURTHER PROVISIONS APPLICABLE WHEN CHECKING COMPLIANCE
WITH THE MIGRATION LIMITS****General provisions*

1. When comparing the results of the migration tests specified in the Sixth Schedule, the specific gravity of all the simulants should conventionally be assumed to 1. Milligrams of substance(s) released per litre of simulant (mg/l) will thus correspond numerically to milligrams of substance(s) released per kilogram of simulant and, taking into account the provisions laid down in the Seventh Schedule, to milligrams of substance(s) released per kilogram of foodstuff.
2. Where the migration tests are carried out on samples taken from the material or article or on samples manufactured for the purpose, and the quantities of foodstuff or simulant placed in contact with the sample differ from those employed in the actual conditions under which the material or article is used, the results obtained should be corrected by applying the following formula:

$$M = \frac{m \times a_2}{a_1 \times q} \times 1000$$

Where:

M is the migration in mg/kg;

m is the mass in mg of substance released by the sample as determined by the migration test;

a_1 is the surface area in dm^2 of the sample in contact with the foodstuff or simulant during the migration test;

a_2 is the surface area in dm^2 of the material or article in real conditions of use;

q is the quantity in grams of foodstuff in contact with the material or article in real conditions of use.

3. The determination of migration is carried out on the material or article or, if that is impracticable, using either specimens taken from the material or article or, where appropriate, specimens representative of this material or article. The sample shall be placed in contact with the foodstuff or simulant in a manner representing the contact conditions in actual use. For this purpose, the test shall be performed in such a way that only those parts of the sample intended to come into contact with foodstuffs in actual use will be in contact with the foodstuff or simulant. This condition is particularly important in the case of materials and articles comprising several layers, for closures, etc. The migration testing of caps, gaskets, stoppers or similar devices for sealing must 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.

It shall in all cases be permissible to demonstrate compliance with migration limits by the use of a more severe test.

4. In accordance with the provisions set out in paragraphs 14 to 17 of this Schedule, the sample of the material or article is placed in contact with the foodstuff or appropriate simulant for a period and at a temperature which are chosen by reference to the contact conditions in actual use, in accordance with the rules laid down in the Sixth and Seventh Schedules to these regulations. At the end of the prescribed time, the analytical determination of the total quantity of substances (overall migration) and/or the specific quantity of one or more substances (specific migration) released by the sample is carried out on the foodstuff or simulant.
5. Where a material or article is intended to come into repeated contact with foodstuffs, the migration test(s) shall be carried out three times on a single sample in accordance with the conditions laid down in the Sixth Schedule using another sample of the food or simulant(s) on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limit(s) is (are) not exceeded on the first test, no further test is necessary.

Special provisions relating to overall migration

6. If the aqueous simulants specified in the Sixth and Seventh Schedules are used, the analytical determination of the total quantity of substances released by the sample may be carried out by evaporation of the simulant and weighing of the residue.
If rectified olive oil or any of its substitutes is used, the procedure given below may be followed.
The sample of the material or article is weighed before and after contact with the simulant. The simulant absorbed by the sample is extracted and determined quantitatively. The quantity of simulant found is subtracted from the weight of the sample measured after contact with the simulant. The difference between the initial and corrected final weights represents the overall migration of the sample examined.
Where a material or article is intended to come into repeated contact with foodstuffs and it is technically impossible to carry out the test described in paragraph 5, modifications to that test are acceptable, provided that they enable the level of migration occurring during the third test to be determined. One of these possible modifications is described below.
The test is carried out on three identical samples of the material or article. One of these shall be subjected to the appropriate test and the overall migration

determined (M_1). The second and third samples shall be subjected to the same conditions of temperature but the period of contact shall be two and three times that specified and overall migration determined in each case (M_2 and M_3 , respectively).

The material or article shall be deemed to be in compliance provided that either M_1 or $M_3 - M_2$ do not exceed the overall migration limit.

7. A material or article that exceeds the overall migration limit by an amount not greater than the analytical tolerance mentioned below should therefore be deemed to be in compliance with this Schedule.

The following analytical tolerances have been observed:

- 20 mg/kg or 3 mg/dm² in migration tests using rectified olive oil or substitutes,
- 12 mg/kg or 2 mg/dm² in migration tests using the other simulants referred to in the Sixth and Seventh Schedules.

8. Without prejudice to the provisions of paragraph 7 of the Sixth Schedule, migration tests using rectified olive oil or substitutes shall not be carried out to check compliance with the overall migration limit in cases where there is conclusive proof that the specified analytical method is inadequate from a technical standpoint.

In any such case, for substances exempt from specific migration limits or other restrictions in the list provided in Part II of this Schedule, a generic specific migration limit of 60 mg/kg or 10 mg/dm², according to the case, is applied. However, the sum of all specific migrations determined shall not exceed the overall migration limit.

PART II

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES*GENERAL INTRODUCTION*

1. This Part contains the list of monomers or other starting substances. The list includes:
 - substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
 - natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers or the other starting substances required to synthesise them are not included in the list,
 - substances used to modify existing natural or synthetic substances.

2. The list does not include the 'salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing '... acid(s), salts' appear in the lists if the corresponding free acid(s) is (are) not mentioned. In each case the meaning of the term 'salts' is 'salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.

3. The list also does not include the following substances although they may be present:
 - (a) substances which could be present in the finished product as:
 - impurities in the substances used,
 - reaction intermediates,
 - decomposition products;
 - (b) oligomers and natural or synthetic macromolecular substances as well as their mixtures, if the monomers or starting substances required to synthesise them are included in the list;
 - (c) mixtures of the authorised substances.The materials and articles, which contain the substances indicated under points (a), (b) and (c) shall comply with the requirements stated in regulation 3.1.

4. Substances shall be of good technical quality as regards the purity criteria.

5. The list contains the following information:
 - column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
 - column 3 (Name): the chemical name,

- column 4 (Restrictions and/or specifications): These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer.
- 6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.
- 7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS Registry, the CAS number in the CAS Registry shall apply.
- 8. A number of abbreviations or expressions are used in column 4 of the table, the meanings of which are as follows:

DL = Detection limit of the method of analysis;

FP = Finished material or article;

NCO = Isocyanate moiety;

ND = not detectable. For the purpose of these regulations, 'not detectable' means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method;

QM = Maximum permitted quantity of the 'residual' substance in the material or article;

QM(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as total of moiety or substance(s) indicated. For the purpose of this Schedule the quantity of the substance in the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA = Maximum permitted quantity of the 'residual' substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Schedule the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with

appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

QMA(T) = Maximum permitted quantity of the 'residual' substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Schedule the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

SML = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Schedule the specific migration of the substance should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method;

SML(T) = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated. For the purpose of this Schedule the specific migration of the substances should be determined by a validated method of analysis. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.

Section A

List of authorised monomers and other starting substances

As stipulated by Section A of Annex II of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)
3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

Section B

List of monomers and other starting substances which may continue to be used pending a decision on inclusion in Section A

As stipulated by Section B of Annex II of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)
3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART III

***INCOMPLETE LIST OF ADDITIVES WHICH MAY BE USED IN THE
MANUFACTURE OF PLASTIC MATERIALS AND ARTICLES******GENERAL INTRODUCTION***

1. This Part contains the list of:
 - (a) substances which are incorporated into plastics to achieve a technical effect in the finished product. They are intended to be present in the finished articles;
 - (b) substances used to provide a suitable medium in which polymerization occurs (e.g. emulsifiers, surfactants, buffering agents etc.).The list does not include the substances, which directly influence the formation of polymers (e.g. the catalytic system).
2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing '...acid(s), salts' appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term 'salts' is 'salts of aluminium ammonium, calcium, iron, magnesium, potassium, sodium and zinc'.
3. The list does not include the following substances although they may be present:
 - (a) substances which could be present in the finished product such as:
 - impurities in the substances used,
 - reaction intermediates,
 - decomposition products;
 - (b) mixtures of the authorised substances.The materials and articles which contain the substances indicated in (a) and (b) shall comply with the requirements stated in regulation 3.1.
4. Substances shall be of good technical quality as regards the purity criteria.
5. The list contains the following information:
 - column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
 - column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
 - column 3 (Name): the chemical name,
 - column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),

- maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically laid down,
 - any type of specification related to the substance or polymer.
6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.
7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in EINECS and the CAS registry, the CAS number in the CAS registry shall apply.

Section A

Incomplete list of additives fully harmonised at Community level

As stipulated by Annex III of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)
3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

Section B

Incomplete list of additives referred to in paragraph 9 of this Schedule, second paragraph

As stipulated by Annex III of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)

3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

As stipulated by Annex IV of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)
3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART V

SPECIFICATIONS

Part A: General specifications

The material and article manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL = 0,02 mg/kg of food or food simulant, analytical tolerance included). However, the migration value of the primary aromatic amines listed in this Schedule are excluded from this restriction.

Part B: Other specifications

As stipulated by Part B of Annex V of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)
3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

PART VI

NOTES RELATED TO THE COLUMN 'RESTRICTIONS AND/OR SPECIFICATIONS'

As stipulated by Annex VI of Commission Directive 90/128/EEC (OJ L 75, 21.3.1990, p. 19), as amended by the Directives mentioned hereunder:

1. Commission Directive 92/39/EEC (OJ L 168, 23.6.1992, p.21)
2. Commission Directive 93/9/EEC (OJ L 90, 14.4.1993, p.26)
3. Commission Directive 95/3/EC (OJ L 41, 23.2.1995, p.44)
4. Commission Directive 96/11/EC (OJ L 61, 12.3.1996, p.26)
5. Commission Directive 1999/91/EC (OJ L 310, 4.12.1999, p.41)
6. Commission Directive 2001/62/EC (OJ L 221, 17.8.2001, p.18)
7. Commission Directive 2002/17/EC (OJ L 58, 28.2.2002, p.19)

Copies of the abovementioned Annex shall be accessible to the general public at the Foodstuffs, Chemicals & Cosmetics Directorate of the Malta Standards Authority.

SIXTH SCHEDULE

The Basic Rules Necessary For Testing Migration Of The Constituents Of Plastic Materials And Articles Intended To Come Into Contact With Foodstuffs

1. This Schedule constitutes a specific provision within the meaning of regulation 4.
2. This Schedule 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 Schedule, '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 Schedule 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.
5. The overall and specific migration levels of constituents of the materials and articles referred to in paragraph 2 into or onto foodstuffs or food simulants must not exceed the limits laid down in the Fifth Schedule or in any other relevant specific provisions.
6. 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 Part A of this Schedule.

7. However, where, as a result of new information or of a reassessment of existing information made since these Regulations were published, there are detailed grounds for establishing that for a given plastic material or article the basic rules laid down in Part A of this Schedule 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 Part A of this Schedule, the Food Safety Commission may, only for the particular case, temporarily suspend application of the basic rules referred to in Part A of this Schedule and permit the use of more appropriate basic rules.

PART A

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 Part and under 'conventional migration test conditions' specified in Chapter II of this Part.
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 the Seventh Schedule	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 the Seventh Schedule	Acetic acid 3 % (w/v)	Simulant B
Alcoholic foods	Foodstuffs for which test with the simulant C only is prescribed in the Seventh Schedule	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 the Seventh Schedule	Rectified olive oil or other fatty food simulants	Simulant D
Dry foods		None	None

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 Fifth Schedule.

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 regulation 7, 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 regulation 7, by a specific indication stating with which foodstuff(s) or group(s) of foodstuffs mentioned in the Seventh Schedule they may or may not be used. This indication shall be expressed:
 - (i) at the marketing stages other than retailstage, by using the 'reference number' or 'description of foodstuffs' provided in the Table of the Seventh Schedule;
 - (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 the Seventh Schedule.

Where the foodstuff(s) or group(s) of foodstuffs is (are) not included in the list specified in the Seventh Schedule, 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
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 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 abovementioned 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 hour
$1 \text{ h} < t \leq 2 \text{ hours}$	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 (*)
$130 \text{ °C} < T \leq 150 \text{ °C}$	150 °C (*)
$T > 150 \text{ °C}$	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 the Seventh Schedule. 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

Test condition with simulant D	Test conditions with isooctane	Test conditions with ethanol 95%	Test conditions with MPPO (*)
2 h at 175 °C	4,0 h at 60 °C (**)	6,0 h at 60 °C (**)	2 h at 175 °C
(*) MPPO = 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 the Seventh Schedule.

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.

SEVENTH SCHEDULE

List Of Simulants To Be Used For Testing Migration Of Constituents Of Plastic Materials And Articles Intended To Come Into Contact With Foodstuffs

1. This Schedule constitutes a specific provision within the meaning of regulation 4.
2. The simulants to be used for testing migration of the constituents of plastic materials and articles intended to come into contact with a single foodstuff or specific group of foodstuffs and the concentration of these simulants shall be those indicated in the Annex to Council Directive 85/572/EEC (OJ No L 372, 31.12.1985, p.14).

Copies of the above mentioned Annex shall be made available to the general public by the Foodstuffs, Chemicals and Cosmetics Directorate of the Malta Standards Authority.

3. Notwithstanding paragraph 2, the list of substances or materials whose use is authorized to the exclusion of all others may lay down procedures testing migration of particular constituents of plastic materials and articles which differ from those laid down in the Annex to Council Directive 85/572/EEC where this is appropriate.

EIGHTH SCHEDULE

Vinyl Chloride Monomer in Food Contact Materials and Articles

1. This Schedule constitutes a specific provision within the meaning of regulation 4.
2. This Schedule concerns the presence of vinyl chloride monomer in, and possible migration from, materials and articles prepared with vinyl chloride polymers or copolymers, hereinafter called 'materials and articles', which in their finished state are intended to come into contact with foodstuffs, or which are in contact with foodstuffs and are intended for that purpose.
3. Materials and articles must not contain vinyl chloride monomer in a quantity exceeding that laid down in Part A of this Schedule.
4. The analysis necessary for official control of the vinyl chloride monomer level in materials and articles intended to come into contact with foodstuffs shall be performed according to the method described in the Annex to Commission Directive 80/766/EEC (OJ L 213 , 16/08/1980 p. 0042 – 0046).
5. Materials and articles must not pass on to foodstuffs which are in or have been brought into contact with such materials and articles any vinyl chloride detectable by the method which complies with the criteria laid down in Part B of this Schedule.
6. The analysis necessary for official control of vinyl chloride released by materials and articles into foodstuffs shall be performed according to the method described in the Annex to Commission Directive 81/432/EEC (OJ L 167, 24/06/1981 p. 0006 – 0011)

PART A

Maximum vinyl chloride monomer level in materials and articles

One milligram per kilogram in the final product.

PART B

Criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles

1. The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the 'headspace' method.
2. For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit shall be 0.01 mg/kg.
3. Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, the Food Safety Commission may permit determination by simulants for these particular foodstuffs.

NINTH SCHEDULE

Release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers

1. This Schedule constitutes specific provisions within the meaning of regulation 4.
2. This Schedule concerns the release of N-nitrosamines and of substances capable of being converted into N-nitrosamines, hereinafter called 'N-nitrosatable substances', from teats and soothers, made of elastomer or rubber.
3. The teats and soothers referred to in paragraph 2 must not pass on to release-test liquid (saliva test solution) under the conditions specified in Part A of this Schedule any N-nitrosamine and N-nitrosatable substance detectable by a validated method which complies with the criteria laid down in Part B of this Schedule and which can detect the following quantities:
 - 0.01 mg in total of N-nitrosamines released/kg (of the parts of teat or soother made of elastomer or rubber),
 - 0.1 mg in total of N-nitrosatable substances/kg (of the parts of teat or soother made of elastomer or rubber).

PART A

Basic rules for determining the release of N-nitrosamines and N-nitrosatable substances

1. *Release-test liquid (saliva test solution)*

To obtain the release-test liquid, dissolve 4.2 g of sodium bicarbonate (NaHCO_3), 0.5 g of sodium chloride (NaCl), 0.2 g of potassium carbonate (K_2CO_3) and 30.0 mg of sodium nitrite (NaNO_2) in one litre of distilled water or water of equivalent quality. The solution must have a pH value of 9.

2. *Test conditions*

Samples of material obtained from an appropriate number of teats or soothers are immersed in the test-release liquid for 24 hours at a temperature of 40 ± 2 °C.

PART B

Criteria applicable to the method for determining the release of N-nitrosamines and N-nitrosatable substances

B 1630

1. The release of N-nitrosamines is determined in one aliquot of each solution obtained according to Part A of this Schedule. The N-nitrosamines are extracted from the aliquot with nitrosamine-free dichloromethane (DCM) and determined by gas chromatography.
2. The release of N-nitrosatable substances is determined in another aliquot of each solution obtained according to Part A of this Schedule. The nitrosatable substances are converted into nitrosamines by acidification of the aliquot with hydrochloric acid. Subsequently the nitrosamines are extracted from the solution with DCM and determined by gas chromatography.

TENTH SCHEDULE

Epoxy derivatives in materials and articles intended to come into contact with foodstuffs

1. This Schedule constitutes specific provisions within the meaning of regulation 4.
2. This Schedule shall apply to materials and articles 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 and which are manufactured with or contain one or more of the following substances:
 - (a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (hereinafter 'BADGE'), and some of its derivatives;
 - (b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (hereinafter 'BFDGE'), and some of their derivatives;
 - (c) other novolac glycidyl ethers (hereinafter 'NOGE'), and some of their derivatives.For the purposes of this Schedule, 'materials and articles' are:
 - (a) materials and articles made of any type of plastics;
 - (b) materials and articles covered by surface coatings;
 - (c) adhesives.
3. This Schedule shall not apply to containers or storage tanks having a capacity greater than 10 000 litres or to pipelines belonging to or connected with them, covered by special coatings called 'heavy-duty coatings'.
4. The materials and articles referred to in paragraph 2 shall not release the substances listed in Part I of this Schedule in a quantity exceeding the limit laid down in that Part. The use and/or presence of BADGE in the manufacture of those materials and articles may only be continued until 31 December 2004.
5. The materials and articles referred to in paragraph 2 shall not release the substances listed in Part II of this Schedule in a quantity which, when added, to the sum of BADGE and its derivatives listed in Part I, exceeds the limit laid down in Part II. The use and/or presence of BFDGE in the manufacture of those materials and articles may only be continued until 31 December 2004.
6. The quantity of NOGE components with more than two aromatic rings and at least one epoxy group as well as their derivatives containing chlorohydrin functions and having a molecular mass less than 1 000 daltons shall not be detectable in the materials and articles referred to in paragraph 2 at the detection limit of 0,2 mg/6 dm², including analytical tolerance. For the purpose of this Schedule, the detection limit specified in this paragraph should be verified by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated

method. The use and/or presence of NOGE in the manufacture of those materials and articles may only be continued until 31 December 2004.

7. The requirements of this Schedule shall not apply to materials and articles covered by surface coatings, and adhesives, referred to in points (b) and (c) of the second subparagraph of paragraph 1 which are brought into contact with foodstuffs before 1 September 2003. These materials and articles may continue to be placed on the market provided that the date of filling appears on the materials and articles, taking into account the requirements of the Labelling, Presentation and Advertising of Foodstuffs Regulations, 2002 (L.N. 5 of 2002).

PART I

Specific migration limit for BADGE and certain of its derivatives

1. The sum of the migration levels of the following substances:
 - (a) BADGE (= 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether;
 - (b) BADGE.H₂O;
 - (c) BADGE.HCl;
 - (d) BADGE.2HCl;
 - (e) BADGE.H₂O.HClshall not exceed the following limits:
 - 1 mg/kg in foodstuffs or in food simulants (analytical tolerance excluded),
or
 - 1 mg/6 dm² in accordance with the cases provided by paragraph 13 of the Fifth Schedule.
2. The migration testing shall be carried out in accordance to the rules established in the Sixth Schedule as well as in the Fifth Schedule. However in aqueous food simulants, this value should also include BADGE.2H₂O unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five substances listed in paragraph 1(a), (b), (c), (d) and (e) cannot exceed the limits provided in paragraph 1.
3. For the purpose of this Schedule, the specific migration of the substances listed in paragraph 1(a), (b), (c), (d) and (e) should be determined by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

PART II

Specific migration limit for BFDGE and certain of its derivatives

1. The sum of the migration levels of the following substances:
 - (a) BFDGE (= bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers);
 - (b) BFDGE.H₂O;
 - (c) BFDGE.HCl;
 - (d) BFDGE.2HCl;
 - (e) BFDGE.H₂O.HCladded to the sum of those listed in Part I, shall not exceed the following limits:
 - 1 mg/kg in foodstuffs or in food simulants (analytical tolerance excluded),
or
 - 1 mg/6 dm² in accordance with the cases provided by paragraph 13 of the Fifth Schedule.

2. The migration testing shall be carried out in accordance to the rules established in the Sixth Schedule as well as in the Fifth Schedule. However in aqueous food simulants, this value should also include BFDGE.2H₂O unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five substances listed in paragraph 1(a), (b), (c), (d) and (e), added to those listed in Part I, cannot exceed the limits provided in paragraph 1.

3. For the purpose of this Schedule, the specific migration of the substances listed in paragraph 1(a), (b), (c), (d) and (e) should be determined by a validated method of analysis. If such a method does not exist, an analytical method with appropriate performance characteristics may be used, pending the development of a validated method.

