L.N. 316 of 2006

FOOD SAFETY ACT
(CAP. 449)

Materials in Contact with Foodstuffs (Amendment) Regulations, 2006

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

Citation.

1. The title of these regulations is the Materials in Contact with Foodstuffs (Amendment) Regulations, 2006, and they shall be read and construed as one with the Materials in Contact with Foodstuffs Regulations, 2003, hereinafter referred to as "the principal regulations".

L.N. 138 of 2003.

Scope and commencement.

2. (1) These regulations implement the provisions of Commission Directive 2005/79/EC of the 18th November, 2005, and they shall enter into force on the 19th November, 2006:

Provided that PVC gaskets containing epoxidised soybean oil, with reference number 88640 in section A of Annex III to Directive 2002/72/EC, which are used to seal glass jars containing infant formulae and follow-on formulae as defined by the Infant Formulae and Follow-on Formulae Regulations, 2002 (L.N. 208 of 2002) or containing processed cereal-based foods and baby foods for infants and young children as defined by the Processed Cereal-based Foods and Other Foods for Infants and Young Children Regulations, 2002 (L.N. 207 of 2002), filled before 19 November 2006 and which comply with the restrictions and/or specifications provided for in Section A of Annex III to Directive 2002/72/EC as amended by Directive 2004/19/EC, may continue to be placed on the market provided that the date of filling appears on the materials and articles.

Provided further that the date of filling may be replaced by another indication, in the case that that indication permits the identification of the date of filling. Upon request by the Food Safety Commission, the date of filling shall be made available to the said Commission.

(2) The foregoing two provisos shall apply without prejudice to the Labelling, Presentation and Advertising of Foodstuffs Regulations.

Substitutes the Fifth Schedule to the principal regulations.

3. For the Fifth Schedule to the principal regulations, there shall be substituted the following:-

"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' means 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. 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 or by the addition of plastics;
   d) Surface coatings obtained from:
      - Paraffin waxes, including synthetic paraffin waxes, and/or microcrystalline waxes,
      - Mixtures of the waxes listed in the first indent with each other and/or with plastics,
   e) Ion-exchange resins;
   f) Silicons.

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 consistent 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:
   a) Articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 50 millimetres (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, section A may be used for the manufacture of plastic materials and articles subject to the restrictions set out therein.

7. 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:
   a) surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
   b) epoxy resins,
   c) adhesives and adhesion promoters,
   d) printing inks.

8. A list of additives which may be used for the manufacture of plastic materials and articles, together with the restriction and/or specifications on their use, is set out in the Third Annex to this Schedule.

9. For the additives listed in the Third Annex to this Schedule, Section B, the verification of compliance with the specific migration limits in simulant D or in the test media of substitute tests as laid down in paragraph 6 of the Sixth Schedule and paragraph 2 of the Seventh Schedule shall apply from the 1st July, 2006.

10. The lists in the Third Annex to this Schedule, Sections A and B do not yet include the following additives:
    a) Additives used only in the manufacture of:
       - Surface coatings obtained resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,
       - Epoxy resins,
       - Adhesives and adhesion promoters,
       - Printing inks;
    b) Colorants;
    c) Solvents.

11. Any person interested in the inclusion in the list referred to in paragraph 8 of an additive, which is already placed on the market in one or more of the Member States, shall submit data evaluation of its safety by the European Food Safety Authority by the 31st December, 2006 at the latest. For the submission of the required data, the applicant shall consult the "Guidelines of the European Food Safety Authority for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation".

12. If during the examination of the data referred to in paragraph 11, the European Food Safety Authority calls for supplementary information, the additive may

continue to be subject to national law until the Authority has issued an opinion, provided that the information is submitted within the time limits specified by the Authority.

13. Only the products obtained by means of bacterial fermentation listed in the Fourth Annex to this Schedule may be used in contact with foodstuffs.

14. Additives referred to in paragraph 8, which are authorised as food additives by Council Directive 89/107/EEC or flavourings by Council Directive 88/388/EEC shall not migrate into:
    a) Foodstuffs in quantities having a technological function in the final foodstuffs;
    b) Foodstuffs for which their use is authorised as food additives or flavourings, in quantities exceeding the restrictions provided for in Directive 89/107/EEC or in Directive 88/388/EEC or in paragraph 8 of this Schedule, whichever is the lower;
    c) Foodstuffs for which their use is not authorised as food additives or flavourings, in quantities exceeding the restrictions set out in paragraph 8 of this Schedule.

15. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs and which contain additives referred to in paragraph 14, shall be accompanied by a written declaration containing the information referred to in paragraph 24 (b).

16. By way of derogation from paragraph 14, when the substances referred to in point (a) of paragraph 14 are used as active components of active food contact materials and articles, they may be subject to national provisions.

17. 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.

18. The meaning of the numbers between brackets appearing in the column ‘Restrictions and/or specifications’ is explained in the Sixth Annex to this Schedule.

19. The specific migration limits in the list set out in the Second and Third Annex to this Schedule are expressed in mg/kg. However, such limits are expressed in mg/dm^2 in the following cases:

    a) Articles which are containers or are comparable to containers or which can be filled, with a capacity less than 500 ml or more than 10 litres;
    b) Sheet, film or other material or articles which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact therewith.

In those cases, the limits set out in the Second and Third 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/dm^2.

20. 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.

21. The verification of compliance with the specific migration limits provided for in paragraph 20 shall not be compulsory, if the value of overall migration determination implies that the specific migration limits referred to in that paragraph are not exceeded.

22. The verification of compliance with the specific migration limits provided for in paragraph 20 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.

23. The verification of compliance with the specific migration limits provided for in paragraph 20 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.

24. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration, which shall:
    a) Be in accordance with regulation 7.5;
    b) Provide, for substances which are subject to a restriction in food, adequate information obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Commission Directives 95/31/EC, 95/45/EC and 2002/82/EC to enable the user of these materials and articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

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 stimulant (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 dm² of the sample in contact with the foodstuff or simulant during the migration test;
a_2 is the surface area in dm² 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 20 to 23 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 (M1). 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 (M2 and M3, respectively).
   The material or article shall be deemed to be in compliance provided that either M1 or M3 - M2 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 following substances are not included even if they are intentionally used and are authorised:

   (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing "… acid(s), salts" appear in the lists, if the corresponding free acid(s) is (are) not mentioned;

   (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to:

      (i) substances whose name contains "… acid(s), salts" which appear in the lists, if the corresponding free acid(s) is (are) not mentioned,

      (ii) substances referred to in note 38 of Annex VI. to Directive 2002/72/EC.

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 dm^2 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. For the purpose of this Schedule the quantity of the substance in the material or article shall 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 specific limit may be used, pending the development of a validated method;
   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 dm^2 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 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)
3. Commission Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35-45)

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 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)
3. Commission Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35-45)

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, including "polymeric additives". They are intended to be present in the finished articles;
   b. substances used to provide a suitable medium in which polymerisation occurs.

   For the purposes of this Part, the substances referred to in (a) and (b) are hereinafter referred to as "additives".

   For the purpose of this Part, "Polymeric additives" means any polymer and/or prepolymer and/or oligomer which may be added to plastics in order to achieve a technical effect but which cannot be used in absence of other polymers as the main structural component of finished materials and articles. It includes also substances which may be added to the medium in which polymerisation occurs.

   The list does not include:
   a. the substances which directly influence the formation of polymers;
   b. colorants;
   c. solvents.

2. The following substances are not included even if they are intentionally used and are authorised:

   (a) salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols. However, names containing "… acid(s), salts" appear in the lists, if the corresponding free acid(s) is (are) not mentioned;

   (b) salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols. For these salts a Group SML = 25 mg/kg (expressed as Zn) apply. The same restriction for Zn applies to:

      (i) substances whose name contains "… acid(s), salts" which appear in the lists, if the corresponding free acid(s) is (are) not mentioned,
      (ii) substances referred to in note 38 of Annex VI. of Commission Directive 2002/72/EC as amended.

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 dm^2 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.

Section A

Incomplete list of additives fully harmonised at Community level

As stipulated by Annex III of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)
3. Commission Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35-45)

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

As stipulated by Annex III of Commission Directive 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)
3. Commission Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35-45)

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 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)

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 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)
3. Commission Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35-45)

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 2002/72/EC (OJ L 220, 15.08.2002, p. 18-58), as amended by the Directives mentioned hereunder:

1. Commission Directive 2004/1/EC (OJ L 7, 13.01.2004, p. 45)
2. Commission Directive 2004/19/EC (OJ L 71, 10.03.2004, p. 8-21)
3. Commission Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35-45)

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

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