L.N. 176 of 2008

FOOD SAFETY ACT
(CAP. 449)

Materials in Contact with Foodstuffs (Amendment) Regulations, 2008

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister for Social Policy has made the following regulations:–

Citation and commencement.

1. (1) The title of these regulations is the Materials in Contact with Foodstuffs (Amendment) Regulations, 2008, 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.

(2) These regulations shall enter into force on the 1st May, 2008.

Scope.

2. (1) Regulation 3 implements the provisions of Commission Directive 2007/19/EC of 2 April 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

(2) The trade in and use of plastic materials and articles intended to come into contact with food and complying with Directive 2002/72/EC, as amended by Directive 2007/19/EC, shall be permitted as from 1 May 2008.

(3) The manufacture and importation into the Community of lids containing a gasket which do not comply with restrictions and specifications for Ref. No 30340; 30401; 36640; 56800; 76815; 76866; 88640 and 93760 laid down in Directive 2002/72/ EC as amended by Directive 2007/19/EC, shall be prohibited as from 1 July 2008.

(4) The manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with restrictions and specifications for phthalates Ref. No 74560; 74640; 74880; 75100; 75105 laid down in Directive 2002/72/EC as amended by Directive 2007/19/EC shall be prohibited as from 1 July 2008.

(5) Without prejudice to regulations 2(3) and 2(4), the manufacture and importation into the Community of plastic materials

(5) Without prejudice to regulations 2(3) and 2(4), the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with Directive 2002/72/EC as amended by Directive 2007/19/EC, shall be prohibited as from 1 May 2009.

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

Amends the Fifth Schedule to the principal regulations.

"FIFTH SCHEDULE

Plastics

1. This Schedule contains specific provisions within the meaning of regulation 4.

2. This Schedule shall apply to the following 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 (hereafter referred to as 'plastic materials and articles'):

    (a) materials and articles and parts thereof consisting exclusively of plastics;
    (b) plastic multi-layer materials and articles;
    (c) plastic layers or plastic coatings, forming gaskets in lids that together are composed of two or more layers of different types of materials.

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:
        (i) Paraffin waxes, including synthetic paraffin waxes, and/or microcrystalline waxes,
        (ii) Mixtures of the waxes listed in the first indent with each other and/or with plastics;
    (e) Ion-exchange resins;
    (f) Silicones.

4. Without prejudice to paragraph 2(c), 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. For the purposes of this Schedule the following definitions shall apply:

(a) "plastic multi-layer material or article" means a plastic material or article composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by other means;

(b) "plastic functional barrier" means a barrier consisting of one or more layers of plastics which ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([1]) and with this Schedule;

(c) "non-fatty foods" means foods for which in migration testing simulants other than simulant D are laid down in the Seventh Schedule.

6. Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 60 milligrams of the constituents released per kilogram of foodstuff or food stimulant (mg/kg) (overall migration limit).

However, this limit shall be 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) in the case of the following:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 millilitres (ml) or more than 10 litres (l);

(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.

7. For plastic materials and articles intended to be brought into contact with or already in contact with food intended for infants and young children, as defined in the Infant Formulae and Follow-On Formulae Regulations, 2007 and the Processed Cereal-Based Foods and Other Foods for Infants and Young Children Regulations, 2007, the overall migration limit shall always be 60 mg/kg.

L.N. 304 of 2007
L.N. 227 of 2007

[1] OJ L 338, 13.11.2004, p. 4.

8. Only those monomers and other starting substances listed in the Part II of this Schedule, Section A may be used for the manufacture of plastic materials and articles subject to the restrictions set out therein.

9. The lists appearing in the Part II of 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.

10. 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 Part III of this Schedule.

11. For the additives listed in Part III of 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 May, 2008.

12. The lists in the Part III of this Schedule, Sections A and B do not yet include the following additives:

    (a) Additives used only in the manufacture of:
        (i) Surface coatings obtained resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints,
        (ii) Epoxy resins,
        (iii) Adhesives and adhesion promoters,
        (iv) Printing inks;
    (b) Colorants;
    (c) Solvents.

13. Any person interested in the inclusion in the list referred to in paragraph 10 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”.

14. If during the examination of the data referred to in paragraph 13, 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.

15. For the use of additives for the manufacture of plastic layers or plastic coatings in lids referred to in paragraph 2(c), listed in Part III of this Schedule, the restrictions and/or specifications on their use set out in that Part of this Schedule shall apply, without prejudice to paragraph 11;

16. For the use of additives exclusively acting as polymerization production aids which are not intended to remain in the finished article (hereinafter PPAs), for the manufacture of plastic materials and articles, listed in Part III of this Schedule, the restrictions and/or specifications on their use set out in that Part of this Schedule shall apply, without prejudice to paragraph 11;

17. The use of azodicarbonamide, Ref. No 36640 (CAS No 000123-77-3) in the manufacture of plastic materials and articles is prohibited.

18. Only the products obtained by means of bacterial fermentation listed in the Part IV of this Schedule may be used in contact with foodstuffs.

19. Additives referred to in paragraph 10, 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 10 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 10 of this Schedule.

20. 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 19 shall be accompanied by a written declaration containing the information referred to in paragraph 37.

21. By way of derogation from paragraph 19, when the substances referred to in point (a) of paragraph 19 are used as active components of active food contact materials and articles, they may be subject to national provisions.

22. General specifications related to plastic materials and articles are laid down in the Part V of this Schedule, Part A. Other specifications related to some substances appearing in Parts II, III and IV of this Schedule are laid down in Part V of this Schedule, Part B.

23. The meaning of the numbers between brackets appearing in the column 'Restrictions and/or specifications' is explained in Part VI of this Schedule.

24. The specific migration limits in the list set out in Parts II and III of 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 Parts II and III of 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.

25. For plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children as defined in the Infant Formulae and Follow-On Formulae Regulations, 2007 and the Processed Cereal-Based Foods and Other Foods for Infants and Young Children Regulations, 2007, the SMLs shall always be applied as mg/kg.

26. In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Schedule.

27. By way of derogation from paragraph 26, a layer which is not in direct contact with food and is separated from the food by a plastic functional barrier, may, provided that the finished material or article complies with the specific and overall migration limits specified in this Schedule:

(a) not comply with the restrictions and specifications set in this Schedule,
(b) be manufactured with substances other than those included in this Schedule or in the national lists concerning the plastic materials and articles intended to come into contact with food.

28. The migration of the substances referred to in paragraph 27(b) into food or simulant shall not exceed 0,01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council ([2]). This limit shall always be expressed as concentration in foods or simulants. It shall apply to

[2] OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.

a group of compounds, if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.

29. The substances referred to in paragraph 27(b) shall not belong to either of the following categories:

(a) substances classified as proved or suspect "carcinogenic", "mutagenic" or "toxic to reproduction" substances in Annex I to Council Directive 67/548/EEC ([3]);
(b) substances classified under the self-responsibility criteria as 'carcinogenic', 'mutagenic' or 'toxic to reproduction' according to the rules of Annex VI to Directive 67/548/EEC.

30. 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 Part I of this Schedule.

31. The verification of compliance with the specific migration limits provided for in paragraph 30 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.

32. The verification of compliance with the specific migration limits provided for in paragraph 30 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.

33. The verification of compliance with the specific migration limits provided for in paragraph 30 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.

34. Notwithstanding paragraph 30, for phthalates (Ref. No 74640, 74880, 74560, 75100, 75105) referred to in the Part III of this Schedule, Part B, the verification of the SML shall only be performed in food simulants. However, verification of the SML may be performed in food where the food has not already been in contact with the material or article and is pre-tested for the phthalate and the level is not statistically significant or greater than or equal to the limit of quantification.

[3] OJ 196, 16.8.1967, p. 1.

35. At the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles, shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

36. The declaration referred to in paragraph 35 shall be issued by the business operator and shall contain the information laid down in Part VIa of this Schedule.

37. Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Schedule shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

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:

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

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. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF):

‘Fat Reduction Factor’ (FRF) is a factor between 1 and 5 by which measured migration of lipophilic substances into a fatty food or stimulant D and its substitutes shall be divided before comparison with the specific migration limits.

General rules

Substances considered ‘lipophilic’ for the application of the FRF are listed in Part IVa of this Schedule. The specific migration of lipophilic substances in mg/kg (M) shall be corrected by the FRF variable between 1 and 5 (MFRF). The following equations shall be applied before comparison with the legal limit:

$M_{FRF} = M/FRF$

And

FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100

This correction by the FRF is not applicable in the following cases:

(a) when the material or article is or is intended to be brought in contact with food containing less than 20 % fat;
(b) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 91/321/EEC and 96/5/EC;
(c) for substances in the Community lists in Annexes II and III having a restriction in column (4) SML= ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg;
(d) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

This correction by the FRF is applicable under certain conditions in the following case:

For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more than 20 % fat, either the migration is calculated as concentration in the food or food simulant (mg/kg) and corrected by the FRF, or it is re-calculated as mg/dm2 without applying the FRF. If one of the two values is below the SML, the material or article shall be considered in compliance.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

4. Correction of specific migration in food simulant D:

The specific migration of lipophilic substances into simulant D and its substitutes shall be corrected by the following factors:

(a) the reduction factor referred to in point 3 of the Annex to Directive 85/572/EEC, hereinafter termed simulant D Reduction Factor (DRF).

The DRF may not be applicable when the specific migration into simulant D is higher than 80 % of the content of the substance in the finished material or article (for example thin films). Scientific or experimental evidence (for example testing with the most critical

foods) is required to determine whether the DRF is applicable. It is also not applicable for substances in the Community lists having a restriction in column (4) SML = ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg.

(b) the FRF is applicable to migration into simulants, provided the fat content of the food to be packed is known and the requirements mentioned in paragraph 4 (a) are fulfilled.

(c) the Total Reduction Factor (TRF) is the factor, with a maximum value of 5, by which a measured specific migration into simulant D or a substitute shall be divided before comparison with the legal limit. It is obtained by multiplying the DRF by the FRF, when both factors are applicable.

5. 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.

6. In accordance with the provisions set out in paragraphs 30 to 33 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.

7. 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.

8. Caps, lids, gaskets, stoppers and similar sealing articles:

(a) If the intended use is known, such articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use. It is assumed that these articles are in contact with a quantity of food filling the container. The results shall be expressed in mg/kg or mg/dm^2 in accordance to the rules of paragraphs 7 and 24 of this Schedule taking into account the whole contact surface of sealing article and container.

(b) If the intended use of these articles is unknown, such articles shall be tested in a separate test and the result be expressed in mg/article. The value obtained shall be added, if appropriate, to the quantity migrated from the container for which it is intended to be used.

Special provisions relating to overall migration

9. 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 8, 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.

10. 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:
(a) 20 mg/kg or 3 mg/dm^2 in migration tests using rectified olive oil or substitutes,
(b) 12 mg/kg or 2 mg/dm^2 in migration tests using the other simulants referred to in the Sixth and Seventh Schedules.

11. 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/dm^2, 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:
(a) substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture macromolecules,
(b) 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,
(c) 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:
(i) impurities in the substances used,
(ii) reaction intermediates,
(iii) 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:

(a) column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,

(b) column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,

(c) column 3 (Name): the chemical name,

(d) column 4 (Restrictions and/or specifications):
These may include:
(i) specific migration limit (SML),
(ii) maximum permitted quantity of the substance in the finished material or article (QM),
(iii) 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),
(iv) any other restriction specifically mentioned,
(v) 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 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;

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)
4. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within 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)
4. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within 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:
      (i) impurities in the substances used,

(ii) reaction intermediates,
(iii) 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:
(a) column 1 (Ref. No): the EEC packaging material reference number of the substances on the list,
(b) column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
(c) column 3 (Name): the chemical name,
(d) column 4 (Restrictions and/or specifications). These may include:
(i) specific migration limit (SML),
(ii) maximum permitted quantity of the substance in the finished material or article (QM),
(iii) 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),
(iv) any other restriction specifically mentioned,
(v) 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)
4. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within the Malta Standards Authority.

Section B

Incomplete list of additives referred to in paragraph 11 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)
4. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within 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 above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within the Malta Standards Authority.

PART IVa

LIPOPHILIC SUBSTANCES FOR WHICH THE FRF APPLIES

As stipulated by Annex IVa of Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17).

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within the Malta Standards Authority.

PART V

SPECIFICATIONS

Part A: General Specifications

Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL = 0,01 mg/kg of food or food simulant). The migration of the primary aromatic amines appearing in the lists in Parts II and III of this Schedule is 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)
4. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within 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)
4. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within the Malta Standards Authority.

PART VIa

DECLARATION OF COMPLIANCE

The written declaration referred to in paragraph 37 of this Schedule shall contain the following information:

(1) the identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing of those materials and articles;

(2) the identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles;

(3) the date of the declaration;

(4) confirmation that the plastic materials or articles meet relevant requirements laid down in this Schedule and Regulation (EC) No 1935/2004;

(5) adequate information relative to the substances used for which restrictions and/or specifications are in place under this Schedule to allow the downstream business operators to ensure compliance with those restrictions;

(6) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with the Sweeteners for use in Foodstuffs Regulations, 2005, the Use of Colours in Foodstuffs Regulations, 1995 and the Permitted Food Additives Regulations, 2005, to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food;

L.N. 30 of 2005
L.N. 107 of 1995
L.N. 54 of 2005

(7) specifications on the use of the material or article, such as:
- (i) type or types of food with which it is intended to be put in contact;
- (ii) time and temperature of treatment and storage in contact with the food;
- (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;

(8) when a plastic functional barrier is used in a plastic multi-layer material or article, the confirmation that the material or article complies with the requirements of paragraphs 27, 28 and 29 of this Schedule.

The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.”.

4. For the Seventh Schedule to the principal regulations, there shall be substituted the following:- Amends the Seventh Schedule to the principal regulations.

"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), as amended by the Directive/s mentioned hereunder:

    1. Commission Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17)

    Copies of the above mentioned Annex shall be made available to the general public by the Directorate responsible for Foodstuffs within 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.".