PAKISTAN STANDARD GUIDELINE
FOR

MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODS

PAKISTAN STANDARDS AND QUALITY CONTROL AUTHORITY
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PAKISTAN STANDARD GUIDELINE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODS

0. FOREWORD

0.1 This Pakistan Standard was developed by the Pakistan Standards & Quality Control Authority Standards Development Centre on **16-08-2021** after the draft finalized by the Food Packaging Material Technical Committee, had been approved by the National Standards Committee for Agriculture & Food Products.

0.2 The Pakistan Standards and Quality Control Authority, under the Ministry of Science and Technology, is the national standardization body. In performing its duties and functions, PSQCA is governed by the PSQCA Act, 1996. PSQCA has also been established to advise the Government on standardization policies, program and activities to promote industrial efficiency and development, as well as for consumer protection.

0.3 The main function of the Department is to foster and promote standards and conformity assessment as a means of advancing the national economy, promoting industrial efficiency and development, ensuring the health and safety of the public, protecting the consumers, facilitating domestic and international trade and furthering international co-operation in relation to standards and conformity assessment.

0.4 PSQCA establishes Pakistan Standards as per mandate given in sub section (xvi) of section 8 of PSQCA Act VI of 1996 i.e. framing and publishing, amending, revising or withdrawal of Pakistan Standards in relation to any article, product, process and in accordance with Pakistan standard rules 2008.

0.5 The formulation and/ or adoption of Pakistan Standards is carried out in technical committees and recommended by national standards committee which include experts from public and private organizations, academia and consumers and from relevant production or service units. Standard development activity is based on consensus to make sure that Pakistan standards safeguard national interest, public tendencies keeping in view the concept of quality, safety, health efficiency as basic parameters for the sustainable development.

0.6 In the preparation of this standard the views of the Manufacturers, Scientist, Suppliers, Consumers, Food Technologist Academia, R & D organizations, Regulators and Testing Authorities have been taken into consideration.

0.7 The assistance has been derived from

i. EU REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food.

ii. COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

iii. COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with food.
and acknowledged with thanks.

iv. ISO 14021

0.8 For further information on Pakistan standards development, please visit PSQCA website: **www.psqca.com.pk.**

0.9 For the purpose of deciding whether a particular requirements of this standard is complied with final value observed or calculated expressing the result of test or analysis shall be rounded off in accordance with PS:103 for Methods of Rounding Off Numerical Value the number of significant places retained in the rounded off value, shall be the same as that of the specific value in the standard.

INTRODUCTION

The principle underlying this standard is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

Purpose of This Pakistan Standard Guideline

The purpose of this standard is to ensure that the materials and articles intended to come into contact directly or indirectly with food should be safe and ensure protection of human health.

This standard will be voluntary for 3 years and during the period the industry will check the compliance status.

The use of recycled materials and articles should be favoured in the country for environmental reasons, provided that strict requirements are established to ensure food safety and consumer protection. Such requirements should be established taking also into account the technological characteristics of the different groups of materials and articles established by U.S. FDA and EU Standards.

About Part-A

Plastic materials and articles may be composed of different layers of plastics held together by adhesives. Plastic materials and articles may also be printed or coated with an organic or inorganic coating. Printed or coated plastic materials and articles as well as those held together by adhesives should be within the scope of the Standard. Adhesives, coatings and printing inks are not necessarily composed of the same substances as plastics. Pakistan Standard on Material and articles intended to come into contact with Food foresees that for adhesives, coatings and printing inks specific measures can be adopted. Therefore, plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics.

About Part-B

1. It is necessary to lay down special requirements to ensure that materials and articles produced from recycled plastics and intended for food contact respect the requirements of Clause 4 General requirement of Standard as a guideline on Material and articles intended to come into contact with Food.

2. Plastic waste can be treated mechanically to produce recycled materials and articles or it can be broken down to monomers and oligomers by chemical depolymerisation. Monomers and oligomers resulting from chemical depolymerisation should not be treated differently from monomers manufactured by chemical synthesis.

3. The declaration of compliance and record keeping to ensure that relevant information on the safe use of the plastic material is passed on between business operators and to the competent authorities. Those general rules are also valid for recycled plastics; therefore, they should apply also to recycled plastic food contact materials and articles.

4. The safety of the recycled plastics can only be ensured if the recycling process is able to produce a reproducible quality of the recycled plastics. This can be controlled if an effective quality assurance system is applied. Therefore, only recycled plastics from a recycling process managed by an effective quality assurance system should be placed on the market.

5. Certain materials, such as polyolefines, due to their physico-chemical properties, 100 % sorting efficiency may be necessary to ensure recycled plastic that complies with the requirements of Clause 4. General requirement of the Standard as a guideline on Material and articles intended to come into contact with food. This sorting efficiency can be achieved in product loops which are in a closed and controlled chain. For other materials, for example, PET the safety of the recycled plastic can be ensured with a lower sorting efficiency as regards to its former use in food contact which is realistically achievable from kerbside collection systems. The sorting efficiency necessary for each material should be identified on a case by case basis.

6. In the mechanical treatment, in which the plastic waste is ground into small pieces and cleaned, special care has to be taken to remove these contaminations. The recycling process must demonstrate that it can efficiently reduce potential contamination to a level that does not pose a risk to human health. The contaminants should only migrate in levels comparable to or well below levels demonstrated in the challenge tests of that recycling process or in other appropriate analytical test and should comply with the requirements of Clause 4. General requirement of Standard as a guideline on Material and articles intended to come into contact with food. A safety assessment should verify that the recycling process fulfils these conditions. Alternatively, for non-fillable materials and articles, such as crates and pallets that are handled in product loops in a closed and controlled chain in which all steps of manufacture, distribution and use are controlled, it may be sufficient to prove that contamination can be excluded when they are only used in contact with dry food such as fruits and vegetable.

7. The safety assessment of the recycling process should be followed by a risk management decision as to whether this recycling process should be authorised.

8. Industry should be enabled to label that their packaging contains recycled plastics. However, consumers should not be misled by labelling as regards recycled content. Rules for labelling of recycled plastics in relation to the content of recycled plastics have been laid down in EN ISO 14021. To ensure adequate information of the consumer when recycled plastics are labelled, they should follow transparent rules as those laid down in EN ISO 14021 or equivalent.

9. Standard as a guideline on Material and Articles intended to come into contact with food requires a declaration of compliance for materials and articles. The converter of recycled plastic material and articles should declare that he is using only recycled plastic from an authorised process and that the final product respects Standard. The recycler should provide the converter with the information that the recycled plastic is produced by an authorised process and specify its field of application. Therefore, both the finished recycled plastic materials and articles and the recycled plastic should be accompanied by a declaration of compliance. General information to be provided in the declaration is already laid down in this Standard. Therefore, this Standard should only specify the additional information in relation to the content of recycled plastics in the recycled plastic materials and articles.

1. SCOPE

1.1 This Pakistan Standard Guideline applies to any material or article intended to come into contact directly or indirectly with food. This guideline on Material and articles intended to come into contact with food has two parts:

A. Plastic materials and articles intended to come into contact with food.
B. Recycled plastic materials and articles intended to come into contact with foods.

1.2. This guideline shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

(a) are intended to be brought into contact with food; or
(b) are already in contact with food and were intended for that purpose; or
(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

2. References:

i. EU REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food.

ii. COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

iii. COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with food.

iv. ISO 14021-2016 for Environmental labels and declarations — Self-declared environmental claims (Type-II environmental labelling)

3. DEFINITIONS

The following definitions shall also apply:

(a) 'active food contact materials and articles' (hereinafter referred to as active materials and articles) means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;

(b) 'intelligent food contact materials and articles' (hereinafter referred to as intelligent materials and articles) means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

4. General Requirements

4.1 Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) Endanger human health; or
(b) Bring about an unacceptable change in the composition of the food; or
(c) Bring about a deterioration in the organoleptic characteristics thereof.

4.2 The labelling, advertising and presentation of a material or article shall not mislead the consumers.

5. Special Requirements for Active and Intelligent Materials and Articles

5.1 In the application of 4(1)(b) and 4(1)(c), active materials and articles may bring about changes in the composition or organoleptic characteristics of food on condition that the changes comply with the referred documents' provisions applicable to food.

5.2 The adoption of additional rules in a specific measure on active and intelligent materials and articles, substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food shall be authorised and used in accordance with the relevant provisions applicable to food, and shall comply with the provisions of this standard and its implementing measures.

5.3 Active materials and articles shall not bring about changes in the composition or organoleptic characteristics of food, for instance by masking the spoilage of food, which could mislead consumers.

5.4 Intelligent materials and articles shall not give information about the condition of the food which could mislead consumers.

5.5 Active and intelligent materials and articles already brought into contact with food shall be adequately labelled to allow identification by the consumer of non-edible parts.

5.6 Active and intelligent materials and articles shall be adequately labelled to indicate e that the materials or articles are active and/or intelligent.

6. Specific Measures for Group of Material and Articles

6.1 For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended with the amendments in the reference documents.

Specific measures may include.

(a) A list of substances authorised for use in the manufacturing of materials and articles;

(b) list(s) of authorised substances incorporated in active or intelligent food contact materials and articles, or list(s) of active or intelligent materials and articles and, when necessary, special conditions of use for these substances and/or the materials and articles in which they are incorporated;

(c) Purity standards for substances referred to in (a);

(d) Special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used;

(e) Specific limits on the migration of certain constituents or groups of constituents into or on to food, taking due account of other possible sources of exposure to those constituents;

(f) An overall limit on the migration of constituents into or on to food;

(g) provisions aimed at protecting human health against hazards arising from oral contact with materials and articles;

(h) Other rules to ensure compliance with general and specific requirements;

(i) Basic rules for checking compliance with points (a) to (h);

(j) Rules concerning the collection of samples and the methods of analysis to check compliance with points (a) to (h);

(k) Specific provisions for ensuring the traceability of materials and articles including provisions regarding the duration for retention of records or provisions to allow, if necessary, for derogations from the requirements of Traceability.

(l) Additional provisions of labelling for active and intelligent materials and articles;

(m) Provisions of authorised substances, processes, or materials or articles as per Annex-1

(n) Specific procedural rules adapting, as necessary, or making it appropriate for the authorisation of certain types of materials and articles and/or processes used in their manufacture, including, where necessary, a procedure for an individual authorisation of a substance, process, or material or article through a decision addressed to.

7. LABELLING

7.1 Without prejudice to the specific measures referred to in Specific Measures for group of materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by:

(a) The words 'for food contact', or a specific indication as to their use, such as coffee machine, bottle, soup spoon, or the symbol reproduced in Annex II; and

(b) If necessary, special instructions to be observed for safe and appropriate use; and

(c) The name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community; and

(d) Adequate labelling or identification to ensure traceability of the material or article and

(e) In the case of active materials and articles, information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component so as to enable food business operators who use these materials and articles to comply with any other relevant provisions.

7.2 The information referred to in paragraph 1(a) shall not, however, be obligatory for any articles which, because of their characteristics, are clearly intended to come into contact with food.

7.3 The information required by paragraph 1 shall be conspicuous, clearly legible and indelible.

7.4 Retail trade in materials and articles shall be prohibited if the information required under paragraph (1)(a), (b) and (e) is not given in a language (English and/or Urdu) easily understood by purchasers.

7.5 Paragraphs 4 and 5 shall not preclude the labelling particulars from being indicated in several languages.

7.6 At the retail stage, the information required under paragraph 1 shall be displayed on:

(a) The materials and articles or on their packaging; Or

(b) Labels affixed to the materials and articles or to their packaging; Or

(c) A notice in the immediate vicinity of the materials and articles and clearly visible to purchasers; for the information referred to in paragraph 1(c), however, this option shall be open only if, for technical reasons, that information or a label bearing it cannot be affixed to the materials and articles at either the manufacturing or the marketing stage.

7.7 At the marketing stages other than the retail stage, the information required by paragraph 1 shall be displayed on:

(a) The accompanying documents; Or

(b) The labels or packaging; Or

(c) The materials and articles themselves.

7.8 The information provided for in paragraph 1(a), (b) and (e) shall be confined to materials and articles which comply with:

(a) The criteria laid down in Clause-4. General requirements and, where they apply, clause-5. Special requirement for active and intelligent materials and articles; `and

(b) The specific measures referred in clause-6 applicable to these materials and articles.

8. DECLARATION OF COMPLIANCE

8.1 The specific measures for group of materials and articles shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

8.2 Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

8.3 Materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

9. TRACEABILITY

9.1 The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

9.2 With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Standard Guideline and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

9.3 The materials and articles which are placed on the market shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

ANNEX-I

List of Groups of Materials and Articles Which May Be Covered By Specific Measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

Part-A Plastic Materials and Articles Intended To Come Into Contact With Food

This Pakistan Standard Guideline establishes specific requirements for the manufacture and marketing of plastic materials and articles:

(a) Intended to come into contact with food; or
(b) Already in contact with food; or
(c) Which can reasonably be expected to come into contact with food.

1. SCOPE

1.1 This Standard guideline shall apply to materials and articles which are placed on market and fall under the following categories:

(a) Materials and articles and parts thereof consisting exclusively of plastics;
(b) Plastic multi-layer materials and articles held together by adhesives or by other means;
(c) Materials and articles referred to in points a) or b) that are printed and/or covered by a coating;

(d) Plastic layers or plastic coatings, forming gaskets in caps and closures that together with those caps and closures compose a set of two or more layers of different types of materials;
(e) Plastic layers in multi-material multi-layer materials and articles.

1.2 This Standard guideline shall not apply to the following materials and articles which are placed in the market and are intended to be covered by other specific measures:

(a) Ion exchange resins;

(b) Rubber;

(c) Silicones.

1.3 This Standard guideline shall be applicable to printing inks, adhesives or coatings

2. DEFINITIONS

For the purpose of this Standard guideline, the following definitions shall apply:

2.1 'Plastic materials and articles' means**:**

(A) Materials and Articles Referred to in Points (a), (b) and (c)

(a) Materials and articles and parts thereof consisting exclusively of plastics;

(b) Plastic multi-layer materials and articles held together by adhesives or by other means;
(c) Materials and articles referred to in points a) or b) that are printed and/or covered by a coating;

And

(B) <u>Plastic Layers Referred to in (d) and (e)</u>

(d) Plastic layers or plastic coatings, forming gaskets in caps and closures that together with those caps and closures compose a set of two or more layers of different types of materials;
(e) Plastic layers in multi-material multi-layer materials and articles.

2.2 **'Plastic'** means polymer to which additives or other sub- stances may have been added, which is capable of functioning as a main structural component of final materials and articles;

2.3 **'Polymer'** means any macromolecular substance obtained by:

(a) A polymerisation process such as polyaddition or poly- condensation, or by any other similar process of monomers and other starting substances; or
(b) Chemical modification of natural or synthetic macro- molecules; or
(c) Microbial fermentation;

2.4 **'Plastic multi-layer'** means a material or article composed of two or more layers of plastic;

2.5 **'Multi-material multi-layer'** means a material or article com- posed of two or more layers of different types of materials, at least one of them a plastic layer;

2.6 **'Monomer or other starting substance'** means:

(a) A substance undergoing any type of polymerisation pro- cess to manufacture polymers; or
(b) A natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or
(c) A substance used to modify existing natural or synthetic macromolecules;

2.7 **'Additive'** means a substance which is intentionally added to plastics to achieve a physical or chemical effect during pro- cessing of the plastic or in the final material or article; it is intended to be present in the final material or article;

2.8 **'polymer production aid'** means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;

2.9 **'Non-intentionally added substance'** means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product;

2.10 **'Aid to polymerisation'** means a substance which initiates polymerisation and/or controls the formation of the macro- molecular structure;

2.11 **'Overall migration limit'** (OML) means the maximum permit- ted amount of non-volatile substances released from a material or article into food simulants;

2.12 **'Food simulant'** means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;

2.13 **'Specific migration limit'** (SML) means the maximum permit- ted amount of a given substance released from a material or article into food or food simulants;

2.14 **'Total specific migration limit'** (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;

2.15 **'Functional barrier'** means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with General requirements (clause 4 of Material and articles intended to come into contact with Food) and with the provisions of this Standard Guideline;

2.16 **'Non-fatty food'** means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table-2 of Annex-V to this Standard;

2.17 **'Restriction'** means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;

2.18 **'Specification'** means composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits.

2.19 **'Hot-fill'** means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.

2.2 Placing on The Market of Plastic Materials and Articles

Plastic materials and articles may only be placed on the market if they:

(a) Comply with the relevant requirements set out in General requirements of this guideline (clause 4 of Material and articles intended to come into contact with Food) under intended and foreseeable use; and

(b) Comply with the labelling requirements set out in Pakistan Standard Guideline on Material and Articles intended to come into contact with Food and

(c) Comply with the traceability requirements set out in Pakistan Standard Guideline on Material and Article intended to come into contact with food; and

(d) Are manufactured according to good manufacturing practice as set out in this Standard Guideline and

(e) Comply with the compositional and declaration requirements set out in this Standard Guideline Appendices A, B and C.

COMPOSITIONAL REQUIREMENTS

(APPENDIX-A)
AUTHORISED SUBSTANCES

1. Annex-1 (A) List of Authorised Substances

1.1 Only the substances included in the referred document's list of authorised substances set out in Annex-I(A) may be intentionally used in the manufacture of plastic layers in plastic materials and articles.

1.2 The list shall contain:

(a) Monomers or other starting substances;
(b) Additives excluding colorants;
(c) Polymer production aids excluding solvents;
(d) Macromolecules obtained from microbial fermentation

2. Derogations for Substances Not Included in the Referred Document's List

2.1 By way of derogation substances other than those included in the list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles.

2.2 By way of derogation, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles.

2.3 The following substances not included in the referred document's list are authorised subject to the rules set out in Section-2:

(a) All salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;

(b) Mixtures obtained by mixing authorised substances without a chemical reaction of the components;

(c) When used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, except macromolecules obtained from microbial fermentation, complying with the requirements of this Standard Guideline, if they

are capable of functioning as the main structural component of final materials or articles;

(d) When used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the referred document's list.

2.4 The following substances not included in the referred document's list may be present in the plastic layers of plastic materials or articles:

(a) Non-intentionally added substances;
(b) Aids to polymerisation.

2.5 By derogation, additives not included in the referred document's list may continue to be used until a decision is taken to include or not to include them in the referred document's list provided they are included in the provisional list referred to in Clause-3. Establishment and management of the provisional list.

3. ESTABLISHMENT AND MANAGEMENT OF THE PROVISIONAL LIST

3.1 The provisional list of additives that are under evaluation and so changed in the referred document's list shall be regularly updated.

3.2 An additive shall be removed from the provisional list:

(a) When it is included in the referred document's list set out in Annex I; or
(b) When a decision is taken not to include it in the referred document's list; or

Note-1: Referred document means the document mentioned in clause-2.Refrences of this Pakistan standard Guideline (Clause-2 Ref.1, 2 and 3).

Note-2: Annexure-1(A) includes authorized substances as per Commission Regulation (EU) No.10/2011 (Pages No.16 to 105)

(APPENDIX-B)

GENERAL REQUIREMENTS, RESTRICTIONS AND SPECIFICATIONS

1. General Requirement On Substances

1.1 Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

2. Specific Requirements on Substances

2.1 Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:

(a) The specific migration limit set out in this standard Guideline.
(b) The overall migration limit set out in this standard Guideline.
(c) The restrictions and specifications set out in column 10 of Table-1 of point 1 of Annex-I (A);
(d) The detailed specifications set out in point 4 of Annex-I.

2.2 Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex-I.

3. GENERAL RESTRICTIONS ON PLASTIC MATERIALS AND ARTICLES

3.1 General restrictions related to plastic materials and articles are laid down in Annex-II (A).

4. SPECIFIC MIGRATION LIMITS

4.1 Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex-I (A). Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

4.2 By derogation from paragraph 1, additives which are also authorised as food additives or as flavourings shall not migrate into foods in quantities having a technical effect in the final foods and shall not:

(a) Exceed the restrictions provided for in Standard or in Annex-I to this Standard Guideline for foods for which their use is authorised as food additive or flavouring substances; or

(b) Exceed the restrictions set out in Annex-I to this Standard in foods for which their use is not authorised as food additive or flavouring substances.

4.3 Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods.

4.3.1 For the purposes of the first subparagraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply.

5. OVERALL MIGRATION LIMIT

5.1 Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm 2 of food contact surface (mg/dm^2).

5.2 By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

6. Plastic multi-layer materials and articles

6.1 In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Standard Guideline.

6.2 By derogation from paragraph 1, a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may:

(a) not comply with the restrictions and specifications set out in this Standard Guideline except for vinyl chloride monomer as provided in Annex I (A); and/or

(b) be manufactured with substances not listed in the referred document's list or in the provisional list.

6.3 Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Specific migration limit sub clause (4). The detection limit set out in the second subparagraph of Specific migration limit shall apply to groups of substances if they are structurally and toxicologically related, including isomers or substances with the same relevant functional group, or to individual substances that are not related, and shall include possible set- off transfer.

6.4 The substances not listed in the referred document's list (Annex 1) or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:

(a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction
(b) substances in nanoform.

6.5 The final plastic multi-layer material or article shall comply with the specific migration limits set out in clause-4 and the overall migration limit set out in clause-5 of this Standard Guideline.

7. MULTI-MATERIAL MULTI-LAYER MATERIALS AND ARTICLES

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

7.2 By derogation from paragraph 1, in a multi-material multi-layer material or article a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances not listed in the referred document's list or the provisional list.

7.3 The substances not listed in the referred document's list or provisional list referred to in paragraph 2 shall not belong to either of the following categories:

(a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction
(b) substances in nanoform.

7.4 By derogation from paragraph 1, Clause 4 and 5 of this Standard Guideline do not apply to plastic layers in multi-material multi-layer materials and articles.

7.5 The plastic layers in a multi-material multi-layer material or article shall always comply with the restrictions for vinyl chloride monomer laid down in Annex I to this Standard Guideline.

7.6 In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.

(APPENDIX-C)

DECLARATION OF COMPLIANCE AND DOCUMENTATION

1. Declaration of Compliance

1.1 At the marketing stages other than at the retail stage, a written declaration in accordance with Clause-7 declaration of Compliance, Pakistan Standard Guideline on material and articled intended to come in contact with food shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

1.2 The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex-IV.

1.3 The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

2. Supporting Documents

2.1 Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Standard shall be made available by the business operator to the national competent authorities on request.

2.2 That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance as set out in Annexure-D

(APPENDIX-D)
COMPLIANCE

1. Expression of Migration Test Results

1.1 To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

1.2 By derogation from paragraph 1 for:

(a) containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,

(b) materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,

(c) sheets and films that are not yet in contact with food,

(d) sheets and films containing less than 500 millilitres or grams or more than 10 litres, the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm 2 per kg of food.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children.

1.3 By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:

(a) mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2; (b) mg/article if the intended use of the article is unknown.

1.4 For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:

(a) mg/dm 2 applying the total contact surface of sealing article and sealed container if the intended use of the article is known;
(b) mg/article if the intended use of the article is unknown.

2. Rules for Assessing Compliance with Migration Limits

2.1 For materials and articles already in contact with food verification of compliance with specific migration limits shall be carried out in accordance with the rules set out in Annex-V.

2.2 For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex-V.

2.3 For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Annex-V.

2.3.1 If a material or article fails to comply with the migration limits in the screening approach a conclusion of non- compliance has to be confirmed by verification of compliance in accordance with. Above paragraph 2.

2.4 For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants as set out in Annex-III in accordance with the rules set out in Annex-V

2.5 For materials and articles not yet in contact with food screening of compliance with the overall migration limit can be performed applying screening approaches in accordance with the rules set out in Annex-V.

2.5.1 If a material or article fails to comply with the migration limit in the screening approach a conclusion of non- compliance has to be confirmed by verification of compliance in accordance with above paragraph 4.

2.6 The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

2.7 Before comparing specific and overall migration test results with the migration limits the correction factors set out in Annex V shall be applied in accordance with the rules set out therein.

3. Assessment of Substances Not Included in the Annex-1(A)

3.1 Compliance with Clause-4. General requirement of Pakistan Standard Guideline on material and articles intended to come into contact with food of substances referred to in Derogations for substances not included in the Annex-1(A) sub clause-1, Sub clause-2, sub clause 4, Sub clause-5 and sub clause (2) of Multi-material multi-layer materials and articles of this Standard which are not covered by an inclusion in Annex-I to this Standard shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

ANNEX-I of PART-A

Substances

1. **EU list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids**

Table 1 contains the following information:

Table 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applies No (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance

Column-1 (FCM substance No): the unique identification number of the substance

Column-2 (Ref. No): the EEC packaging material reference number

Column-3 (CAS No): the Chemical Abstracts Service (CAS) registry number

Column-4 (Substance Name): the chemical name

Column-5 (Use as additive or polymer production aid (PPA) (yes/no)): an indication if the substance is authorised to be used as additive or polymer production aid (yes) or if the substance is not authorised to be used as additive or polymer production aid (no). If the substance is only authorised as PPA it is indicated (yes) and in the specifications the use is restricted to PPA.

Column-6 (Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)): an indication if the substance is authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes) or if the substance is not authorised to be used as

monomer or other starting substance or macromolecule obtained from microbial fermentation (no). If the substance is authorised as macromolecule obtained from microbial fermentation it is indicated (yes) and in the specifications it is indicated that the substance is a macromolecule obtained from microbial fermentation.

Column-7 (FRF applicable (yes/no)): an indication if for the substance the migration results can be corrected by the Fat Consumption Reduction Factor (FRF) (yes) or if they cannot be corrected by the FRF (no).

Column-8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND ('not detectable') if the substance is one in respect of which no migration is permitted, to be determined in accordance with 4. Specific migration limits (4).

Column-9 (SML(T) [mg/kg] (group restriction No)): contains the identification number of the group of substances for which the group restriction in Column 1 in Column 10 (Restrictions and specifications): contains other restrictions than the specific migration limit specifically mentioned and it contains specifications related to the substance. In case detailed specifications are set out a reference to Column 11 (Notes on verification of compliance): contains the Notes number which refers to the detailed rules applicable for verification of compliance for this substance included in Column 1 in Table 3 of this Annex.

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.

2. Group restriction of substances

Table-2 on Group restrictions contains the following information:

Table 2

(1)	(2)	(3)	(4)
Group Restriction No	FCM substance No	SML (T) [mg/kg]	Group restriction specification

Column-1 (Group restriction No): contains the identification number of the group of substances for which the group restriction applies. It is the number referred to in Column 9 in Table-1 of this Annex.

Column-2 (FCM substance No): contains the unique identification numbers of the substances for which the group restriction applies. It is the number referred to in Column 1 in Table 1 of this Annex.

Column-3 (SML (T) [mg/kg]): contains the total specific migration limit for the sum of substances applicable to this group. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column-4 (Group restriction specification): contains an indication of the substance whose molecular weight forms the basis for expression of the result.

3. Notes on Verification of Compliance

Table-3 on notes on verification of compliance contains the following information:

Table 3

(1)	(2)
Note No	Notes on verification of compliance

Column-1 (Note No): contains the identification number of the Note. It is the number referred to in Column 11 in Table 1 of this Annex.

Column-2 (Notes on verification of compliance): contains rules that shall be respected when testing for compliance of the substance with specific migration limits or other restrictions or it contains remarks on situations where there is a risk of non-compliance.

4. Detailed Specification on Substances

Table-4 on detailed specifications on substances contains the following information

Table 4

(1)	(2)
FCM substance No	Detailed specifications on the substance

Column-1 (FCM substance No): contains the unique identification number of the substances referred to in Column-1 in Table-1 of Annex-I to which the specification applies.

Column-2 (Detailed specification on the substance): contains the specification on the substance.

Note: For Annex 1 Current updated Tables of EU Regulations will be used for this standard

ANNEX-II of Part -A

RESTRICTIONS ON MATERIALS AND ARTICLES

1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

   Aluminium = 1 mg/kg food or food simulant.

   Barium = 1 mg/kg food or food simulant

   Cobalt = 0,05 mg/kg food or food simulant

   Copper = 5 mg/kg food or food simulant

   Iron = 48 mg/kg food or food simulant

   Lithium = 0,6 mg/kg food or food simulant

   Manganese = 0,6 mg/kg food or food simulant

   Nickel = 0,02 mg/kg food or food simulant

   Zinc = 5 mg/kg food or food simulant.

2. Primary aromatic amines which are not listed in Table-1 of Annex-I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant in accordance with clause-4 Specific migration limits (sub clause-4). The detection limit referred to in the second subparagraph of sub clause-4 of Clause-4 Specific migration limits applies to the sum of primary aromatic amines released.

ANNEX-III of Part-A
Food simulants

1. **Food Simulants**

For demonstration of compliance for plastic materials and articles not yet in contact with food the food simulants listed in Table-1 below are assigned.

Table 1

List of food simulants

Food simulant	Abbreviation

Note: For Annex-III Current updated Tables of EU Regulations will be used for this standard

ANNEX IV

DECLARATION OF COMPLIANCE

The written declaration shall contain the following information:

(1) the identity and address of the business operator issuing the declaration of compliance;

(2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;

(3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;

(4) the date of the declaration;

(5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this This Pakistan Standard Guideline and in clause-4. General requirements, , , Clause-7 Labelling and Clause-9 Traceability of Standard Pakistan as a guideline on Materials and articles intended to come into contact with food.

(6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes-I and

Annexes --II to this Standard to allow the downstream business operators to ensure compliance with those restrictions;

(7) 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 referred documents at clause-2 of Ref of this standard guideline to enable the user of these materials or articles to comply with this Pakistan standard Guideline.

(8) 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) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Expression of migration test results and Rules for assessing compliance with migration limits or equivalent information;

(9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Plastic multi-layer materials and articles Clause-2, 3 and 4 or Multi-material multi-layer materials and articles clause 3 and 4 of this Standard.

ANNEX-V

COMPLIANCE TESTING

Note: For testing compliance of migration from plastic food contact materials and articles the Annex-V Shall be used

PART B- Recycled plastic materials and articles intended to come into contact with foods

1. SUBJECT MATTER AND SCOPE

1.1 This Pakistan Standard Guideline shall apply to the plastic materials and articles and parts thereof intended to come into contact with foodstuffs as referred to in this Standard Guideline which contain recycled plastic (hereafter 'recycled plastic materials and article).

1.2 This Pakistan Standard Guideline shall not apply to the following recycled plastic materials and articles, provided that they have been manufactured according to good manufacturing practice :

(a) recycled plastic materials and articles made with monomers and starting substances, derived from chemical depolymerization of plastic materials and articles;

(b) recycled plastic materials and articles made from unused plastic production offcuts and/or process scraps in compliance with Standard, that are recycled within the manufacturing site or are used at another site;

(c) recycled plastic materials and articles in which the recycled plastic is used behind a plastic functional barrier, as specified in the Pakistan Standard Guideline.

2. DEFINITIONS

2.1 For the purposes of this Part, the definitions laid down in Pakistan Standard Guideline on Materials and articles intended to come into contact with food shall apply.

2.2 The following definitions shall also apply:

(a) **'recycling process'** means a process in which plastic waste is recycled ;for the purpose of this Standard, this term is limited to processes, in which a recycled plastic is produced;

(b) **'plastic input'** means collected and sorted post-use plastic materials and articles used as input into a recycling processes

(c) **'product loops which are in a closed and controlled chain'** means manufacture and distribution cycles in which products circulate with a controlled reuse and distribution system, and in which the recycled material originates only from these entities in the chain, so that the unintentional introduction of external material is just the minimum technically feasible;

(d) **'challenge test'** means a demonstration of the effectiveness of a recycling process to remove chemical contamination from plastic materials or articles;

(e) **'converter'** means the natural or legal person responsible for ensuring that the requirements of this Standard, as regards the recycled plastic materials and articles are met within the business under their control;

(f) **'recycler'** means the natural or legal person responsible for ensuring that the requirements of this Standard, as regards the recycling process are met within the business under their control.

(g) **chemical feedstock recycling** means the conversion of waste plastics into a light fuel like mixture (e.g. naphta), light alkenes, and/or synthesis gas in a thermal cracking process by means of pyrolysis; the substances thus obtained are after further processing used as feedstock for traditional monomer production

3. Requirements for Recycled Plastic Materials and Articles

3.1 Recycled plastic materials and articles shall only come from authorized recycling processes.

3.2 The authorised recycling process shall be managed by an appropriate quality assurance system that ensures that the recycled plastic complies with the requirements set out in the authorisation.

However, the following recycled plastic materials and articles may be placed on the market if obtained from a recycling process without authorization:

- Recycled plastic materials and articles made from unused and unprinted production offcuts and/or process scraps from plastic materials;
- Recycled plastic materials and articles made with plastic input originating from a product loop which is in a closed and controlled chain ensuring that only materials and articles which have been intended for food contact are used and any contamination can be ruled out;
- Recycled plastic and articles in which the recycled plastic is used behind a plastic functional barrier
- Plastic materials and articles manufactured in accordance with this Standard using starting substances obtained from chemical feedstock recycling

4. Conditions for the Authorisation of Recycling Processes

In order to be authorised, a recycling process shall comply with the following conditions:

(a) the quality of plastic input must be characterised and controlled in accordance with pre-established criteria that ensure compliance of the final recycled plastic material and article with clause 4. General requirement of Pakistan Standard Guideline on Materials and articles intended to come into contact with food.

(b) the plastic input must originate from plastic materials and articles that have been manufactured

(c) (i) either the plastic input must originate from a product loop which is in a closed and controlled chain ensuring that only materials and articles which have been intended for food contact are used and any contamination can be ruled out; or

(ii) it must be demonstrated in a challenge test, or by other appropriate scientific evidence that the process is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health;

(d) the quality of the recycled plastic must be characterised and controlled in accordance with pre-established criteria that ensure compliance of the final recycled plastic material and article with clause-4. General requirement of Pakistan Standard Guideline on Materials and articles intended to come into contact with food;

(e) there must be established conditions of use of the recycled plastic whereby it can be ensured that the recycled plastic materials and articles comply with clause 4. General requirement of Pakistan Standard as a guideline on Materials and articles intended to come into contact with food.

5. Labelling of recycled plastic materials and articles

5.1 Voluntary self-declaration of the recycled content in recycled plastic materials and articles shall follow the rules laid down in ISO 14021:2016 or equivalent.

6. Declaration of compliance and record keeping

6.1 The declaration of compliance of recycled plastic materials and articles shall contain the information laid down in Part A of Annex I to this Standard.

6.2 The declaration of compliance of recycled plastic shall contain the information laid down in Part B of Annex I to this Standard

ANNEX-I of PART- B

A. Additional information in the declaration of compliance for recycled plastic materials and articles

The written declaration shall contain the following additional information:

a declaration that only recycled plastic from an authorised recycling process has been used.

B. Additional information in the declaration of compliance for recycled plastic

The written declaration shall contain the following additional information:

1. The declaration that the recycling process is authorised recycling process;
2. The declaration that the plastic input, the recycling process and the recycled plastic meet the specifications for which the authorisation has been granted;

1. The declaration that a quality assurance system is in place.

ANNEX-V
COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

1. CHAPTER

Testing for specific migration of materials and articles already in contact with food

1.1. Sample Preparation

The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety.

1.2. Conditions of Testing

The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

1.3. Analysis of Migrated Substances

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004. ▼**M7**

1.4. Account of substances originating from other sources

In case there is evidence linked to the food sample that a substance partially or wholly originates from a source or sources other than the material or article for which the test is being carried out, the test results shall be corrected for the amount of that substance originating from the other source or sources before comparing the test results to the applicable specific migration limit. ▼B

2. CHAPTER

Testing for specific migration of materials and articles not yet in contact with food

2.1. Verification Method

Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests according to the rules set out in paragraphs 2.1.1 to 2.1.7. ▼B

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2.1.1. Sample Preparation

The material or article shall be treated as described by accompanying instructions or by provisions given in the declaration of compliance.

Migration is determined on the material or article or, if this is impractical, on a specimen taken from the material or article, or a specimen representative of this material or article. For each food simulant or food type, a new test specimen is used. Only those parts of the sample which are intended to come into contact with foods in actual use shall be placed in contact with the food simulant or the food.

2.1.2. Choice of Food Simulant

Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.

Materials and articles intended only for specific types of foods shall be tested with the food simulants indicated for the food types in Annex-III.

2.1.3. Conditions of Contact when using Food Simulants ▼M7

The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table-1 and as regard contact temperature in Table-2.

By way of derogation to the conditions set out in Tables-1 and 2, the following rules apply:

(i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 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;

(ii) if the material or article during it intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;

(iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour 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 or below, the test conditions set out in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage. **▼B**

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If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are not technically feasible in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a migration test shall be done using food simulant E if the temperature under the worst foreseeable conditions of intended use exceeds 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation. **▼B**

Table-1 ▼M7

Selection of test time **▼B** Contact time in worst foreseeable use **►M7** Time to be selected for testing **◄**

t ≤ 5 min 5 min
5 min < t ≤ 0,5 hour 0,5 hour
0,5 hours < t ≤ 1 hour 1 hour
1 hour < t ≤ 2 hours 2 hours
2 hours < t ≤ 6 hours 6 hours
6 hours < t ≤ 24 hours 24 hours
1 day < t ≤ 3 days 3 days
3 days < t ≤ 30 days 10 days
Above 30 days See specific conditions
▼M7

Table-2

Selection of test temperature Worst foreseeable contact temperature Contact temperature to be selected for testing

T ≤ 5 °C 5 °C
5 °C < T ≤ 20 °C 20 °C
20 °C < T ≤ 40 °C 40 °C
40 °C < T ≤ 70 °C 70 °C
70 °C < T ≤ 100 °C 100 °C or reflux temperature
100 °C < T ≤ 121 °C 121 °C (*)
121 °C < T ≤ 130 °C 130 °C (*)
130 °C < T ≤ 150 °C 150 °C (*)
150 °C < T < 175 °C 175 °C (*)
175 °C < T ≤ 200 °C 200 °C (*)
T > 200 °C 225 °C (*)

(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table-1.
▼M7

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2.1.4. Specific conditions for contact times above 30 days at room temperature and below

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C (1).

(a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above – 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.

(b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T- 70)/10) minutes.

(c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T- 70)/10) minutes.

(d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T- 70)/10) minutes.

(e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

(f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

$t2 = t1 * Exp (9627 * (1/T2 – 1/T1))$
t1 is the contact time
t2 is the testing time
T1 is the contact temperature in Kelvin. For room temperature storage this is set at 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (– 15 °C).
T2 is the testing temperature in Kelvin.

▼M7 (1) When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.

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2.1.5. **Specific Conditions for Combinations of Contact Times and Temperature ▼M7**

If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence. **▼B**

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, 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.

2.1.6. **Repeated use Articles**

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant 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 limits are not exceeded on the first test, no further test is necessary. **▼M7**

The material or article shall respect the specific migration limit already in the first test for substances that are prohibited from migrating or from being released in detectable quantities under Article 11(4). **▼B**

2.1.7. **Analysis of Migrating Substances**

At the end of the prescribed contact time, the specific migration is analysed in the food or food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

2.1.8. **Verification of Compliance by Residual Content per Food Contact Surface Area (QMA)**

For substances which are unstable in food simulant or food or for which no adequate analytical method is available it is indicated in Annex-I that verification of compliance shall be undertaken by verification of residual content per 6 dm 2 of contact surface. For materials and articles between 500 ml and 10 l the real contact surface is applied. For materials and articles below 500 ml and above 10 l as well as for articles for which it is impractical to calculate the real contact surface the contact surface is assumed to be 6 dm 2 per kg food.

2.2. **Screening Approaches ▼M7**

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.

▼B

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2.2.1. **Replacing specific Migration by overall Migration**

To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.

2.2.2. **Residual Content**

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration. **▼M7**

2.2.3. **Migration Modelling**

To screen for specific migration, the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.

2.2.4. **Food Simulant Substitutes**

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2.

2.2.5. **Single test for Successive Combinations of Time and Temperature**

If the material or article is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature from Section 2.1.3 and/or 2.1.4 by using the equation as described in point (f) of Section 2.1.4. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation provided for in Article 16. ▼B

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3. CHAPTER

Testing for Overall Migration

Overall migration testing shall be performed under the standardised testing conditions set out in this chapter.

3.1. Standardised Testing Conditions

3.1.1 The overall migration test for materials and articles intended for the food contact conditions described in column 3 of Table-3 shall be performed for the time specified and at the temperature specified in column 2. For test OM5 the test can be performed either for 2 hours at 100 °C (food simulant D2) or at reflux (food simulant A, B, C, D1) or for 1 hour at 121 °C. The food simulant shall be chosen in accordance with Annex III. ▼B

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3.1.2 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. ▼M7

Table-3

Standardised Conditions for Testing the Overall Migration Column-1 Column-2 Column-3

Test number Contact time in days [d] or hours [h] at contact temperature in [°C] for testing Intended food contact conditions

OM1 10 d at 20 °C Any food contact at frozen and refrigerated conditions.

OM2 10 d at 40 °C Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.

OM3 2 h at 70 °C Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by long term room temperature or refrigerated storage.

OM4 1 h at 100 °C High temperature applications for all types of food at temperature up to 100 °C.

OM5 2 h at 100 °C or at reflux or alternatively 1 h at 121 °C High temperature applications up to 121 °C.

OM6 4 h at 100 °C or at reflux Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex-III assigns simulants A, B, C or D1.

OM7 2 h at 175 °C High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM7 also covers food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents the worst case conditions for food simulant D2 in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in Section 3.2.

Test OM6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B, C and D1 in contact with non-polyolefins. **▼B**

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Test OM5 covers also food contact conditions described for OM1, OM2, OM3, and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins. Test OM2 covers also food contact conditions described for OM1 and OM3.

3.2. **Substitute Overall Migration Tests for Tests with Food Simulant D2**

If it is not technically feasible to perform one or more of the tests OM1 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2 the test can be replaced by either test OM8 or test OM9 as appropriate given the intended or foreseeable

use. Both tests involve testing at two test conditions for which a new test sample shall be used for each test. The test condition that results in the highest overall migration shall be used to establish compliance with this Regulation. Test number Test conditions Intended food contact conditions Covers the intended food contact conditions described in OM8 Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C High temperature applications only OM1, OM3, OM4, OM5 and OM6 OM9 Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C High temperature applications including long term storage at room temperature OM1, OM2, OM3, OM4, OM5 and OM6

3.3. **Verification of Compliance**

3.3.1. **Single Use Articles and Materials**

At the end of the prescribed contact time, to verify compliance the overall migration is analysed in the food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

3.3.2. **Repeated use Articles and Materials**

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test. **▼M7**

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If it is not technically feasible to test the same sample three times, such as when testing in oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time.

The difference between the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, it shall not be higher than the first result and the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration does not increase in the second and third tests and if the overall migration limit is not exceeded in the first test, the first test alone shall be sufficient. **▼B**

3.4. **Screening Approaches ▼M7**

To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as the verification method described in Sections 3.1 and 3.2. **▼B**

3.4.1. **Residual Content**

To screen for overall migration the migration potential can be calculated based on the residual content of migratable substances determined in a complete extraction of the material or article. ▼M7

3.4.2. **Food Simulant Substitutes**

To screen for overall migration, food simulants can be replaced if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex-III. ▼B

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4. CHAPTER

Correction factors applied when comparing migration test results with migration limits

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

For lipophilic substances for which in Annex I it is indicated in column-7 that the FRF is applicable the specific migration can be corrected by the FRF. The FRF is determined according to the formula FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100.

The FRF shall be applied according to the following rules.

The migration test results shall be divided by the FRF before comparing with the migration limits.

The 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 intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC; ▼M7

(b) 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. ▼**M7**

The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.

When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table-2 of Annex-III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table-2 of Annex-III exceeds 5.

▼**B**