

MERCOSUR/GMC/RES. Nº 30/07

MERCOSUR TECHNICAL REGULATION ON POLYETHYLENE TEREPHTHALATE (PET) POST-CONSUMER RECYCLED FOOD GRADE (PET-PCR FOOD GRADE) PACKAGING INTENDED TO COME IN CONTACT WITH FOOD

HAVING SEEN: The Treaty of Asunción, the Protocol of Ouro Preto and Resolutions Nos. 56/92, 38/98 and 56/02 of the Common Market Group.

WHEREAS:

Having determined in the point 9 of the General Provisions of Resolution GMC No 56/92, that special technological processes for obtaining of resins from recycled materials may be studied;

That the studies carried out confirm the inclusion of new technologies for post-consumer PET recycling and are based on the evaluation of the safety of the use of the mentioned material;

That it is advisable to have a common regulation on the packaging of PET post-consumer recycled food grade (PET-PCR food grade);

That, consequently, the States Parties agreed to regulate PET-PCR food grade packaging intended to come in contact with food;

That, the harmonization of Technical Regulations tends to remove trade barriers.

THE COMMON MARKET GROUP RESOLVES:

Article 1 - To approve the "MERCOSUR Technical Regulation on Polyethylene terephthalate (PET) Post-consumer Recycled Food Grade (PET-PCR food grade) Packaging intended to come in contact with food" which is included as an Annex and is part of this Resolution.

Article 2 - The national agencies authorized to implement this Resolution are:

Argentina: Ministerio de Salud
Secretaría de Políticas, Regulación e Institutos
Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT)
Ministerio de Economía y Producción
Secretaría de Agricultura, Ganadería, Pesca y Alimentos (SAGPyA)

Brazil: Ministerio da Saude
Agencia Nacional de Vigilância Sanitária (ANVISA)

Paraguay: Ministerio de Industria y Comercio (MIC)
Instituto Nacional de Tecnología, Normalización y Metrología (INTN)
Ministerio de Salud Pública y Bienestar Social (MSPyBS)

Instituto Nacional de Alimentación y Nutrición (INAN)

Uruguay: Ministerio de Salud Pública (MSP)
Ministerio de Industria, Energía y Minería (MIEM)
Laboratorio Tecnológico del Uruguay (LATU)

Article 3 – This Resolution shall be applicable in the territory of the States Parties, to trade among them and to extra-zone imports.

Article 4 – The States Parties shall incorporate this Resolution into their domestic body of laws before VII/01/2008.

LXX GMC – Montevideo, XII/11/07

ANNEX

MERCOSUR TECHNICAL REGULATION ON POLYETHYLENE TEREPHTHALATE (PET) POST-CONSUMER RECYCLED FOOD GRADE (PET-PCR FOOD GRADE) PACKAGING INTENDED TO COME IN CONTACT WITH FOOD

1. SCOPE

1.1. Objective.

To establish the general requirements and criteria for evaluation, approval/authorization and registration of PET packaging made of variable proportions of virgin PET (food grade) and post-consumer PET (food grade), intended to come in contact with food.

1.2. Scope of application. This technical regulation applies to final products (PET-PCR food grade packaging), its precursor articles and raw material (PET-PCR food grade).

2. DEFINITIONS

For purposes of applying this technical regulation, it is considered:

2.1. Industrial discard PET: is the discarded material from packaging or precursors of them, both of food grade, generated in the industrial establishment that manufactures packaging, precursor articles and/or foods, and which is not recovered from household solid waste. Scrap is not included.

2.2. Scrap (scrap resulting from manufacturing process): food grade PET which is not contaminated nor degraded, which can be reprocessed with the same processing technology that originated it, and which can be used for the manufacture of food contact packaging and materials.

2.3. Post-Consumer PET: is the material coming from used packaging or precursor articles, both of food grade, that is obtained from solid wastes for the purpose of applying the decontamination technologies.

2.4. Standardized validation procedure ("challenge test" or equivalent): analysis protocol to evaluate the pollutant removal efficiency model of the physical and/or chemical recycling technology used to process post-consumer and/or industrial discard PET. It is established or recognized by the USA Food and Drug Administration (FDA), the European Food Safety Authority (EFSA), the European Union Directorate General of Health and Consumer Protection, the Competent Health Authorities of Member States of the European Union, or that which in the future is to be agreed in the MERCOSUR sphere.

2.5. Surrogates (Model contaminants): substances used in the "challenge test" or equivalent of the physical and/or chemical recycling technologies to evaluate their decontamination efficiency and which are representative of the potential contaminants present in post-consumer and/or industrial discard PET.

2.6. Special Authorizations of use: are no objection letter or "NOL" for food grade PET-PCR, or the approvals or decisions related to its use, issued by the Food and Drug Administration (FDA) from the USA, the European Food Safety Authority (EFSA), the European Commission's Directorate-General for Health and Consumer Protection, the Competent Health Authorities of Member States of the European Union, or that which in the future to be agreed within the MERCOSUR sphere.

2.7. Food grade PET-PCR (decontaminated post-consumer recycled food grade PET):

- is the material coming from a source of post-consumer and/or industrial discard PET;

- obtained by means of a highly efficient decontamination chemical and/or physical recycling technology, which has been demonstrated by subjecting it to a challenge test or equivalent, and therefore has special validated by the Competent National Authority;
- and can be used in the preparation of food-contact packaging.

2.8. PET-PCR food grade packaging: packaging made from variable proportions of virgin PET and food grade PET-PCR, intended to come in contact with food.

2.9. Precursor articles for food grade PET-PCR packaging: semi-processed or intermediate materials (films, foils and preforms), made from variable proportions of virgin PET and food grade PET-PCR, from which food-contact packaging is made.

2.10. Food Grade: characteristics of the composition of the virgin plastic materials that determines their sanitary suitability according to the corresponding MERCOSUR Regulation. In the case of recycled materials it also implies the removal of contaminants potentially present in them, obtained by the application of the decontamination processes of the validated physical and/or chemical recycling technologies, to levels such that their use does not imply a health risk to the consumer, or modify the sensory quality of food. In both cases these characteristics allow the use of these materials in direct contact with food.

2.11. Raw Material: material destined to the production of PET-PCR, including food grade industrial discard and post-consumer PET.

3. BASIC CRITERIA FOR THE CONFORMITY OF THE SAFETY AND APPROVAL OF PACKAGING, PRECURSORS AND FOOD GRADE PET-PCR.

3.1. The proportion of food grade PET-PCR to be used in the preparation of food grade PET-PCR packaging shall be subject to the restrictions established in the special authorizations for use defined in item 2.

3.2. Food grade PET-PCR packaging must meet the sanitary suitability requirements established in the MERCOSUR Regulation on plastic packaging and must be compatible with the food that they will contain. In the event that this packaging is returnable and/or multilayer, it must also meet the requirements established for them in the corresponding MERCOSUR Regulation.

3.3. Food grade PET-PCR packaging and/or precursors must be approved/authorized and registered with the Competent National Sanitary Authority in accordance with established procedures and it must be declared, as appropriate, if they are multilayer or single-layer packaging (or precursors), of a single use or returnable, containing food grade PET-PCR.

3.4. PET-PCR Food Grade Packaging should not yield substances outside the composition of the plastic, in amounts involving a risk to human health or a modification of the sensory characteristics of the packaged products. The toxicological aspect is ensured when the technologies of physical and/or chemical recycling are duly validated, and therefore count with special authorizations of use defined in item 2.

For this purpose, in the standardized validation procedure (test challenge or equivalent), the compliance with the limit of concentration of model contaminants in the food grade PETPCR of 220 ppb ($\mu\text{g/kg}$) (for each contaminant) or of the limit of specific migration for model contaminants of 10 ppb ($\mu\text{g} / \text{kg}$) in packaging (for each contaminant) must be verified. For the case of food grade PET-PCR, these two limits derive from the maximum concentration of contaminants admitted in the human diet of 0.5 ppb ($\mu\text{g/kg}$ of food) (regulatory threshold).

The organoleptic aspect is ensured with the sensorial analysis program required in item 3.11.

3.5. In the case that food producers use PET-PCR food grade packaging or precursor articles, only those approved/authorized and registered by the Competent National Sanitary Authority (following the established procedures), and destined to contain only the specified foods and only in the conditions stipulated in said approval/authorization and registration should be used, based on the special authorizations of use defined in item 2.

3.6. Establishments producing food grade PET-PCR packaging or their precursor articles must be qualified and registered by the Competent National Sanitary Authority and must request the approval/authorization of said packaging or their precursor articles and their registration before the Authority, following the established procedures.

3.7. In order to be qualified and registered, establishments producing food grade PET-PCR packaging or its precursor articles will also be required to have:

- written procedures and its records of Good Manufacturing Practices application available to the Competent National Sanitary Authority;
- records of the origin and composition/characterization of food grade PET-PCR and virgin PET, with supporting documentation;
- adequate equipment for the conditioning and processing of food grade PET-PCR;
- control procedures for the process of manufacturing of the packaging or its precursor articles of food grade PET-PCR, allowing traceability;
- personnel for the operation of all the equipment and for the control of the process, specifically trained for this purpose;
- a quality assurance system to prevent contamination with other sources of recycled material for applications other than food grade.

3.8. Establishments authorized and registered to produce food grade PET-PCR packaging or precursor articles, shall use for this purpose, in addition to virgin PET resin, only food grade PET-PCR obtained using a physical and/or chemical recycling technology approved/authorized and registered by the Competent National Sanitary Authority and evaluated by its recognized Reference Laboratory.

3.9. Establishments authorized and registered to produce food grade PET-PCR packaging or precursor articles, must obtain the PET-PCR food grade of the producer (authorized and registered by the Competent National Sanitary Authority) and use it for the manufacture of packaging or its precursor articles intended to contain only the specified foods and only under the conditions stipulated in the approval/authorization and registration by the Competent National Sanitary Authority, based on the special authorizations of use defined in item 2.

3.10. In order for an establishment producing food grade PET-PCR to be qualified and registered by the Competent National Sanitary Authority, it will be required that:

- use food grade post-consumer PET and/or industrial discard as raw material, whose original source and application are subject to the restrictions established in the special authorizations of use defined in item 2 and the specifications thereon physical and/or chemical recycling technology used;
- use a physical and/or chemical recycling technology approved/authorized and registered in each particular case by the Competent National Sanitary Authority and evaluated by the Reference Laboratory recognized by the Competent National Sanitary Authority, based on: the detailed description of the technology involved, the international history of its use, the results of the challenge test or equivalent, the special use authorizations defined in item 2, and the health suitability assessment tests of packaging made of food grade PET-PCR;
- provide the PET-PCR food grade of the producer of PET-PCR packaging or precursor articles, intended only for the packaging of the specified foods and only under the conditions stipulated in the

approval/authorization and registration by the Authority National Competent Sanitary, based on the special authorizations of use defined in item 2;

- has written procedures and records of application of Good Manufacturing Practices available to the Competent National Sanitary Authority;
- keep records of origin and composition/characterization of the raw material from the physical and/or chemical recycling process of decontamination, i.e., of the post-consumer and/or industrial discard PET, both of food grade;
- keep records of destination and composition/characterization of food grade PET-PCR product of the process;
- have procedures to control the process of obtaining food grade PET-PCR that allows its traceability;
- has an analytical laboratory set up to carry out the test for contaminants characterization of the post-consumer and/or industrial discard PET, both of food grade, used as raw material of the physical and/or chemical recycling technology, as well as and of the PET-PCR obtained in order to determine its quality and the efficiency of the technology used;
- have personnel for the operation of all the equipment, for the control of the process, and to perform in the laboratory, trained specifically for this purpose;
- have a quality assurance system that prevents contamination with other sources of recycled material for non-food grade applications or non-decontaminated material.

3.11. Food grade PET-PCR producers should also have a quality assurance system that includes:

- Scope of the validation test. A challenge test or equivalent of the technology is valid as long as the parameters of the process are kept constant and the equipment involved to carry out the decontamination operations is the one corresponding to the technology originally approved/authorized and registered.

If there are changes, the PET-PCR producer must notify them to the Competent National Sanitary Authority and its Reference Laboratory, and if they compromise the quality of the obtained material, the efficiency of the process should be evaluated again by a new standardized validation procedure ("challenge test" or equivalent).

- Analytical monitoring programs that ensure the continuity of the quality of the food grade PET-PCR obtained over time.
- Sensory analysis. In order to ensure that the food grade PET-PCR does not alter the organoleptic properties of the foods, sensory analysis of the packaging, according to ISO 13302 "Sensor", must be carried out with appropriate frequency, analysis - Methods for assessing modifications to the flavor of foodstuffs due to packaging" or equivalent.

4. LABELING

The identification of the producer, the batch number or codification that allows its traceability and the expression "PETPCR" must be indicated in the final packaging in indelibly form.