

MERCOSUR/GMC/RES No 56/92 General provisions for Plastic packaging and food contact equipment

(SWG No3 * - CA)

SEEN: Article 13 of the Treaty of Asuncion, Article 10 of the No4 / 91 Decision of the Common Market Council and Recommendation No 4/92 of WSG No. 3 - Technical Standards and

CONSIDERING

Who, having set the general criteria of containers and equipment in contact with food in

Resolution GMC No 3/92, it is necessary to harmonize the technical specifications for the material classification agreed in the resolution mentioned;

That according to these criteria, it is considered desirable to have common rules on general provisions for packaging and plastic food contact equipment;

THE COMMON MARKET GROUP

RESOLVED

Article 1. - The plastic packages and equipment that come into contact with foods that are traded between MERCOSUR States Parties shall comply with the requirements set out in the attached Annex to this Resolution "General provisions for plastic containers and equipment in contact with food ".

Article 2. - The provisions of Article 1. do not apply compulsorily to packaged foods for export to third countries.

Article 3. - The competent authorities of States Parties shall take appropriate measures in order to comply with the provisions above.

GENERAL PROVISIONS FOR PLASTIC CONTAINERS AND EQUIPMENT IN CONTACT WITH FOOD.

1. This resolution applies to packaging and equipment, including coatings and accessories intended to come into contact with food, raw materials for food and mineral water and table, as well as finished or coated plastic household items. It does not apply to fixed water supply facilities, whether public or private.

2. This Resolution applies to the following packaging and equipment:

- a. Plastic compounds exclusively.
 - b. The compounds of two or more layers of materials, each of them consisting exclusively of plastic.
 - c. The compounds of two or more layers of materials, one or more of which may not be exclusively of plastic, provided that the layer in contact with the food is plastic. In this case, all the plastic layers should comply with the MERCOSUR Resolutions concerning plastic packaging and equipment, with regards to migration and inclusion of their components in positive lists.
3. Only the substances included in the positive list of components (polymers, additives, etc.) to which this resolution is concerned having fulfilled the conditions, limitations and tolerances of the uses specifically indicated in the details of the corresponding MERCOSUR Resolutions and grade purity is compatible with its use, can be used in the manufacture of plastic packaging and equipment.

4. The lists of components (polymers, additives, etc.) may be modified:

- a. For the inclusion of new components it must be shown that the new component does not represent a significant risk to human health, and technological need for its use is justified.
- b. If new technical and scientific knowledge indicate a significant risk to human health, then the component can be excluded from the list.

The criteria and mechanisms for inclusion and exclusion of components (polymers, additives, etc.) and for the harmonization of MERCOSUR positive lists are described in Appendix "Criteria for Harmonization of Positive Lists".

5. Plastic containers and equipment in the foreseeable conditions of use, will not yield to food undesirable, toxic or polluting substances that pose a risk to human health, in excess of the limits of total and specific migration amounts.

The total migration limits to be met by all plastic containers and equipment in contact with food are:

- 50 mg/kg simulant, in the case of packaging and equipment exceeding 250 ml capacity, and in the case of packaging and equipment that is not possible to estimate the surface area in contact with food, and in the case of closure elements or objects of small area.

- 8 mg/dm² of surface area of the container, in the case of packaging and equipment with less than 250 ml capacity, and in the case of generic plastic material.

The analytical methodology of total migration tests is set in MERCOSUR Resolutions No /92 and No / 92.

The specific migration limits and analytical methodology are set out in the relevant MERCOSUR Resolutions.

6. Plastic containers and equipment shall not cause unacceptable changes in the composition of food or sensory characteristics thereof.

7. To color plastic packaging and equipment that come into contact with food all types of dyes and pigments may be used that meet the following requirements:

a. They must not migrate to food;

b. Not contain metals in higher amounts than the following percentages:

Arsenic (soluble in 1N NaOH) -----0.005% m/m

Barium (soluble in 0.1N HCl) ----- 0.01% m/m

Cadmium (soluble 0.1N HCl) ----- 0.01% m/m

Zinc (soluble in 0.1N HCl) ----- 0.20% m/m

Mercury (soluble 0.1N HCl) ----- 0.005% m/m

Lead (soluble in 1N HNO₃) ----- 0.01% m/m

Selenium (soluble 0.1N HCl) ----- 0.01% m/m

c. The content of aromatic amines should not exceed 0.05% m/m.

The analytical methodology for the determination of these metals in the dyes and pigments is described in the corresponding Resolution MERCOSUR.

8. Plastic containers and equipment that come into contact with food having dyes or pigments in their formulation, in addition to the requirements of this Resolution, must meet the corresponding specific migration in other MERCOSUR resolutions.

9. In the development of plastic packaging and equipment that come into contact with food, the use of plastic packaging materials from fragments of objects, plastics and recycled or used, is prohibited and must therefore be virgin material of first use.

This prohibition does not apply to reprocessed material in the same process of transformation that originated (scrap) from non-contaminated or degraded plastics.

The Commission of MERCOSUR specialists can study special technological processes for obtaining resins from recyclable materials.

10. The containers, intermediate products (intermediates) and plastics equipment intended to come into contact with food, must be registered by the competent authority.

11. All changes of composition of plastic packaging and fittings shall be communicated to the competent authority for approval.

12. Users of plastic containers and equipment intended to come into contact with food, may use only those approved by the competent authority.

13. Plastic containers intended for oral contact must ensure adequate protection against risks that may arise from this contact at the time of consumption.

14. The use of returnable plastic containers for foods such as carbonated soft drinks bottles, is permitted, provided that, in addition to this, the plastic material complies with the specific MERCOSUR Resolution for that plastic.

APPENDIX

CRITERIA FOR MATCHING OF SCHEDULES POSITIVE

1. Considering the need for continuous updating of the positive lists, it is recommended to the Common Market Group, that a Commission of Experts be created to which performs this task.

2. If a substance is included in the positive list of laws in force in the States, the substance will be incorporated, without discussion in the positive list of MERCOSUR.

3. If a substance is included only in the positive list of the laws of one of the States Parties and there is a consensus of the other States Parties to incorporate, it will be included in the positive list of MERCOSUR. In the event that no agreement would be drawn to the positive list of directives and documents to EC Directives that are not yet and secondarily to the positive list of Italian law and FDA U.S.A. If the substance is included in one of these lists will be incorporated into the positive list of MERCOSUR, with restrictions on use and/or corresponding limits.

4. In the event that a State Party intends to include or exclude a component of the positive list, it must show a justifiable history to the corresponding MERCOSUR commission of experts.

5. With regard to the limitations of use of the substances listed in the positive list, it shall be fixed, as the case composition limits, specific migration and employment restrictions, applying the same harmonization criteria, after a proper study of the substance's background.

In the case of set specific migration limits or composition there must be established corresponding analytical methods.

Approved by Government Representatives on December 4, 1992; by:

ARGENTINA, Lic. Marta Galak, National Institute of Industrial Technology -----

BRAZIL Farm. Maria L. S. Albuquerque, Ministerio da Saude -----

PARAGUAY, Honorina Marsal, Coordinator Paraguay. -----

URUGUAY, Dra. Teresita Villar, Uruguayo Institute of Technical Standards.