

MERCOSUR/GMC/RES. Nº 32/10

**MERCOSUR TECHNICAL REGULATION ON MIGRATION FROM PLASTIC MATERIALS, PACKAGING AND EQUIPMENT INTENDED TO COME INTO CONTACT WITH FOODS
(REPEAL OF RES. Nº 30/92, 36/92, 10/95, 11/95, 15/97, 32/97 and 33/97)**

HAVING SEEN: The Treaty of Asunción, the Protocol of Ouro Preto and Resolutions Nº 30/92, 36/92, 10/95, 11/95, 15/97, 32/97, 33/97, 38/98 and 56/02 of the Common Market Group.

WHEREAS:

The harmonization of Technical Regulations tends to remove trade barriers created by the different national regulations in force, complying with the provisions set forth under the Treaty of Asunción.

That the States Parties, due to the advances in the matter, understood it necessary to update the corresponding regulations.

That plastic materials, packaging and equipment, under the foreseeable conditions of use, should not yield to foodstuffs substances that represent a risk to human health, in quantities greater than the limits of total and specific migration.

That the plastic materials, packaging and equipment referred to in this Technical Regulation must be manufactured following Good Manufacturing Practices, compatible with their use for food contact.

THE COMMON MARKET GROUP RESOLVES:

Article 1 - To approve the "MERCOSUR Technical Regulation on Migration from Plastic Materials, Packaging and Equipment intended to come into contact with Foods" 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
Ministerio de Agricultura, Ganadería y Pesca
Secretaría de Agricultura, Ganadería y Pesca

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

Paraguay: Ministerio de Salud Pública y Bienestar Social (MSPyBS)
Instituto Nacional de Alimentación y Nutrición (INAN)
Ministerio de Industria y Comercio (MIC)

Instituto Nacional de Tecnología, Normalización y Metrología (INTN)

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 – To repeal GMC Resolutions Nº 30/92, 36/92, 10/95, 11/95, 15/95, 32/97 and 33/97.

Article 5 – The States Parties shall incorporate this Resolution into their domestic body of laws before XII/15/2010.

LXXX GMC – Buenos Aires, VI/15/10

ANNEX

MERCOSUR TECHNICAL REGULATION ON MIGRATION FROM PLASTIC MATERIALS, PACKAGING AND EQUIPMENT INTENDED TO COME INTO CONTACT WITH FOODS (REPEAL OF RES. Nº 30/92, 36/92, 10/95, 11/95, 15/97, 32/97 and 33/97)

1. SCOPE

This Technical Regulation establishes the general criteria for the determination of the overall and specific migration, and applies to the following food contact plastic packaging and equipment:

- a) those composed exclusively of plastic;
- b) those composed of two or more layers of materials, each of them consisting exclusively of plastic;
- c) those composed 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 of plastic or polymeric coating. In this case, all layers of plastic or polymer coating must comply with the Resolutions of the Common Market Group regarding materials, packaging and plastic equipment, as regards migrations and inclusion of components in positive lists.

2. BASIC CRITERIA FOR THE CONDUCT OF MIGRATION TESTS

2.1 Introduction

2.1.1 Verification of compliance with the overall and specific migration limits shall be carried out through migration or assignment tests, the basic criteria of which are detailed in this section.

2.1.2 In the migration tests, the plastic materials and simulants shall be contacted under the appropriate time and temperature conditions in order to reproduce normal or foreseeable conditions of processing, fractionation, storage, distribution, commercialization and consumption of food, namely:

- a. Elaboration: conditions that are verified by generally short periods, such as pasteurization, sterilization, hot filling, etc.
- b. Storage: prolonged contact throughout the shelf life of the product, at room temperature or in refrigeration.
- c. Consumption: heating the food inside the same container before its intake; use of plastic utensils in contact with food; preparation of food inside domestic utensils, with or without heating; use of plastic wrappers for food protection.

2.2 Classification of Foods

For the purposes of these Technical Regulation, foods and beverages (hereinafter "foods") are classified according to the following categories:

- aqueous and non-acidic foods (pH > 4.5)
- aqueous and acidic foods (pH < 4.5)
- fatty foods (containing fats or oils among its components)

- alcoholic foods (alcohol content $\geq 5\%$ (v/v))
- dry foods

2.3 Food Simulant Assignment

2.3.1. Food simulants to be used in the migration tests are:

Simulant A (simulant for aqueous and non-acidic foods ($\text{pH} > 4.5$)): distilled or deionized water;

Simulant B (simulant for aqueous and acidic foods ($\text{pH} \leq 4.5$)): 3% (v/v) acetic acid solution in distilled or deionized water;

Simulant C (simulant for alcoholic foods): 10% (v/v) ethanol solution in distilled or deionized water, concentration to be adjusted to the actual ethanol content of the product if it exceeds 10% (v/v);

In case of simulant C being used in the migration tests, it will correspond:

- for foods containing from 5% (v/v) alcohol to 10% (v/v): 10% (v/v) ethanol solution in distilled or deionized water;
- for foods with an alcohol content greater than 10% (v/v): ethanol solution in distilled or deionized water, in the same concentration as the food.

Simulant D (simulant for fatty foods): 95% (v/v) ethanol solution in distilled or deionized water, or isooctane, or MPPO (modified polyphenylene oxide), as appropriate;

Simulant D' (equivalent to simulant D): edible oils (olive oil, sunflower oil, corn oil) or mixture of synthetic triglycerides.

In the case of use fatty food simulants in the migration tests, the following shall apply:

- for the tests of overall migration: simulant D (the one that corresponds), or simulant D'.
- for the specific migration tests: simulant D (which corresponds), or simulant D'.
- for tests on the migration of substances which impart color to materials, packaging and plastic equipment containing coloring agents in their formulation: coconut oil.

For the products mentioned in items 07.01, 07.02, 07.03 and 07.06 of Table 2 (whole milk, condensed milk, skimmed or partially skimmed milk, fermented milks such as yogurt and similar products, cream milk, sour cream and chilled dairy desserts) the fatty simulant used should be a 50% (v/v) ethanol solution in distilled or deionized water.

2.3.2. The following simulants correspond to the food categories listed in item 2.2 and their combinations:

Table 1: Selection of Simulants for Different Kinds of Food

Kind of food	Simulant
Only aqueous non-acidic foods	A

Only aqueous acidic foods (pH <4.5)	B
Only alcoholic foods	C
Only fatty foods	D or D'
aqueous non-acidic alcoholic foods	C
aqueous acidic alcoholic foods	B and C
aqueous non-acidic foods containing fats and oils	A and D or D'
aqueous acidic foods containing fats and oils	B and D or D'
aqueous, non-acidic, alcoholic, fatty foods	C and D or D'
aqueous, acidic, alcoholic, fatty foods	B, C and D or D'
Non-fatty dry foods	migration test not necessary
Fatty dry foods	D or D'

2.3.3. Table 2 details, non-exhaustively, various foods or food groups, with the assignment of corresponding simulants to be used in the overall and specific migration tests. For each food or food group, the simulants indicated with an "X" will be used, using virgin samples of the material being evaluated for each simulant. When no "X" is indicated, no migration testing is required.

In the case of foods to which simulant D or D' is assigned, when the symbol "X" followed by "/" and a number "n" ("X/n") appears, the results of the migration tests has to be divided by this number (n). The number "n" is the reduction factor of the simulator D or D', used conventionally to take into account the greater extractive capacity of the simulant D or D' compared to the extractive capacity of the food in question.

Table 2. Assignment of Food Simulants for Overall and Specific Migration Tests.

Reference Number	Description of the Food	Simulants			
		A	B	C	D or D'
01	BEVERAGES				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength < 5% (v/v): water, ciders, clear fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and others	X(a)	X(a)		
01.02	Alcoholic beverages of an alcoholic strength ≥ 5% (v/v): beverages of an alcoholic strength ≥ 5% (v/v) listed in 01.01; wines, alcoholic beverages and spirits		X(1)	X(2)	
01.03	Undenatured ethyl alcohol		X(1)	X(2)	
02	CEREALS AND FARINACEOUS PRODUCTS				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes, popcorn, cornstarch (foods with fatty substances on the surface, see 08.10)				

02.03	Cereal flour and meal				
02.04	Food Pastas				
	A. dry				
	B. fresh with fatty substances on the surface	X			X/5
	C. fresh without fatty substances on the surface	X			
02.05	Pastry, bakery products, cakes and other bakery products, dry:				
	A. with fatty substances on the surface				X/5
	B. without fatty substances on the surface				
02.06	Pastry, confectionery products, cakes and other bakery products, fresh:				
	A. with fatty substances on the surface				X/5
	B. without fatty substances on the surface				
03	CHOCOLATE, SUGAR AND CONFECTIONERY PRODUCTS				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				
	A. In solid form:				
	I. with fatty substances on the surface				X/3
	II. without fatty substances on the surface	X			
	B. In paste form				
	I. with fatty substances on the surface				
	II. moist	X			
03.03	Sugar and sugar products				
	A. in solid form				
	B. honey and similar	X			
	C. molasses, sugar syrups	X			
04	FRUIT, VEGETABLES AND PRODUCTS THEREOF				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit:				
	A. Dried or dehydrated fruits, whole, flour or powder				
	B. Sliced, purée or paste	X(a)	X(a)		
	C. Fruit preserved in a liquid medium (jams and the like, whole or sliced fruit or in form of powder or flour preserved in a liquid medium)				
	I. In an aqueous medium	X(a)	X(a)		
	II. In an oily medium	X(a)	X(a)		
	III. In an alcoholic medium (≥ 5% (v/v))		X(1)	X(2)	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels, etc.).				
	A. shelled, dried,				X/5 (3)
	B. shelled and roasted				X/5 (3)
	C. in paste or cream form	X			X/3 (3)

04.04	Whole vegetables, fresh or chilled				
04.05	Processed vegetables:				
	A. dried or dehydrated vegetables whole or in the form of flour or powder				
	B. sliced vegetables or in the form of purée	X(a)	X(a)		
	C. preserved vegetables:				
	I. in an aqueous medium	X(a)	X(a)		
	II. in an oily medium	X(a)	X(a)		X
	III. in an alcoholic medium (≥ 5% (v/v))		X(1)	X(2)	
05	FATS AND OILS				
05.01	Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, rendered lard, pork fat)				
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				
06	ANIMAL PRODUCTS AND EGGS				
06.01	Fish:				
	A. fresh, chilled, salted, smoked	X			X/3(3)
	B. in form of paste	X			X/3(3)
06.02	Crustaceans and mollusks (including oysters, mussels, snails), shell removed	X			
06.03	Meat of all zoological species (including poultry and game):				
	A. fresh, chilled, salted, smoked	X			X/4
	B. in the form of paste, creams	X			X/4
06.04	Processed meat products (ham, salami, bacon, sausages, etc.)	X			X/4
06.05	Preserved and semi-preserved meat or fish				
	A. in an aqueous medium	X(a)	X(a)		
	B. in an oily medium	X(a)	X(a)		X
06.06	Shelled eggs				
	A. powdered or dried				
	B. in other form	X			
06.07	Egg yolks				
	A. liquid	X			
	B. dried or frozen				
06.08	Dried egg white				
07	MILK PRODUCTS				
07.01	Milk				
	A. whole				X(b)
	B. condensed				X(b)
	C. skimmed or partly skimmed				X(b)
	D. powdered whole milk				X/5
	E. powdered skimmed or partly skimmed				

07.02	Fermented milk such as yoghurt or similar products		X		X(b)
07.03	Cream and sour cream		X(1)		X(b)
07.04	Cheeses				
	A. whole, with not edible rind				
	B. all other types of cheese				X/3(3)
07.05	Rennet:				
	A. powdered or dried	X(a)	X(a)		
	B. liquid or viscous				
07.06	Chilled dairy desserts:				
	A. non-fatty	X			
	B. fatty				X(b)
08	MISCELLANEOUS PRODUCTS				
08.01	Vinegar		X		
08.02	Fried or roasted foods:				
	A. fried potatoes, fritters and the like				X/5
	B. of animal origin				X/4
08.03	Preparations for soups and broths, in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes:				
	A. powdered or dried:				
	I. with fatty substances in the surface				X/5
	II. without fatty substances in the surface				
	B. liquid or paste:				
	I. with fatty substances in the surface	X(a)	X(a)		X/3
	II. without fatty substances in the surface	X(a)	X(a)		
08.04	Yeast and raising agents:				
	A. paste	X(a)	X(a)		
	B. dried				
08.05	Salt				
08.06	Sauces:				
	A. without fatty substances in the surface	X(a)	X(a)		
	B. mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions	X(a)	X(a)		X/3
	C. sauces containing oil and water forming two separate phases	X(a)	X(a)		
08.07	Mustard (except powdered mustard under heading 08.17)	X(a)	X(a)		X/3(3)
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff				
	A. with fatty substances on the surface				X/5
	B. without fatty substances on the surface				
08.10	Edible ices:				
	A. non-milk based (water or fruit juice)		X		

	B. milk based edible ices				X/5
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength $\geq 5\%$ (v/v)				X/5
08.13	Cocoa:				
	A. powder				X/5(3)
	B. paste				X/3(3)
08.14	Coffee, whether or not roasted, decaffeinated, soluble, coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			
08.16	Aromatic herbs and other herbs, tea				
08.17	Spices and seasonings in the natural state, powdered mustard				

(a): Use only one of the two food simulants:

- Simulant A if the food has a pH > 4.5

- Simulant B if the food has a pH ≤ 4.5

(b): This test shall be performed with 50% (v/v) ethanol solution in distilled or deionized water as simulant.

(1): This test shall be performed only if the food pH ≤ 4.5 .

(2): This test shall be performed in the case of liquids or beverages of alcoholic strength greater than 10% (v/v) with aqueous solutions of ethanol of similar alcoholic content.

(3): If it is demonstrated by some suitable test that there is not a fat contact with the plastic sample, it is not necessary to perform the D or D' simulant test.

2.3.4. Time and Temperature for Specific and Overall Migration Tests.

2.3.4.1. Migration tests in food simulants A, B, C and D' will be performed in the time and temperature conditions set in Table 3, and those set in Table 4 in the case of use of simulant D, equivalent to the most foreseeable conditions of contact of materials, packaging and plastic equipment with the food, or at the maximum temperature and time of use shown on its labeling or in the instructions for use, if any.

For those materials, packaging and plastic equipment intended to come into contact with food in two or more time and temperature conditions in series, the sample should be subjected to migration test successively to the two or more equivalent test conditions corresponding to the most severe predictable contact conditions using the same portion of the simulant.

2.3.4.2. If there is no indication of the maximum recommended temperature for use under the foreseeable conditions of processing, storage and consumption in the plastic material, packaging or equipment or in the instructions for use, the migration test shall be carried out for 4 hours at 100 °C (or at reflux temperature) with the simulants A, B or C, and for 2 hours at 175 °C with the simulant D', or in the equivalent conditions for the simulant D (Table 4).

2.3.4.3. When it is indicated on the plastic material, packaging or equipment or in the instructions for use that it may be used in contact with food at or below ambient temperature, or when, by its nature, the material, packaging or equipment is clearly intended for use in contact with food at room temperature or lower, the migration test will be carried out for 10 days at 40 °C.

2.3.4.4. For a set contact time, if the material, packaging or plastic equipment meets the migration limits at a given temperature, it is not necessary to repeat the migration test at a lower temperature.

2.3.4.5. For a set contact temperature, if the material, packaging or plastic equipment meets the migration limits at a given time, it is not necessary to repeat the migration test in a shorter time.

2.3.4.6. For determining the specific migration of volatile substances, simulant tests must be conducted in closed systems in such a way as to avoid loss of volatile substances likely to migrate, which may occur under the most severe foreseeable contact conditions with food (Annex A to EN 13130-1: 2004 - "Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 1: Guide to the test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants").

2.3.4.7. For materials, packaging and equipment intended for use in microwave ovens, both a conventional oven and a microwave oven may be used to maintain the test time and temperature conditions set out in Tables 3 and 4. To determine the test temperature, the method described in Standard EN 14233 - "Materials and articles in contact with foodstuffs - Plastics - Determination of temperature of plastics materials and articles at the plastics / food interface during microwave and conventional oven heating in order to select the appropriate temperature for migration testing".

2.3.4.8. If it is found that, during the migration test under the contact conditions set in Tables 3 or 4, the sample undergoes physical or other changes which do not occur under the most severe foreseeable conditions of real contact with food, the test will be performed under the most severe real conditions.

2.3.4.9. If the material, packaging and plastic equipment is intended to be used for periods of time of less than 15 minutes at temperatures between 70 °C and 100 °C (e.g. during hot filling of food) and this is indicated in the label or in the instructions for use, the test shall be carried out for 2 hours at 70 °C, and not under the conditions set out in Table 3.

Table 3: Conventional Conditions for Migration Tests in Food Simulants A, B, C and D'

Contact time in worst foreseeable use	(Food Simulants A, B, C and D'; see Table 4 for Food Simulant D)
Constant Time (t)	Test Time
$t \leq 5 \text{ min}$	(1)
$5 \text{ min} < t \leq 30 \text{ min}$	30 min
$30 \text{ min} < t \leq 1 \text{ h}$	1 h
$1 \text{ h} < t \leq 2 \text{ h}$	2 h
$2 \text{ h} < t \leq 6 \text{ h}$	6 h
$6 \text{ h} < t \leq 24 \text{ h}$	24 h
$t > 24 \text{ h}$	10 days

Contact Temperature (T)	Test Temperature
$T \leq 5 \text{ °C}$	5 °C
$5 \text{ °C} < T \leq 20 \text{ °C}$	20 °C
$20 \text{ °C} < T \leq 40 \text{ °C}$	40 °C
$40 \text{ °C} < T \leq 70 \text{ °C}$	70 °C

70 °C < T ≤ 100 °C	100 °C
100 °C < T ≤ 121 °C	121 °C (2)
121 °C < T ≤ 130 °C	130 °C (2)
130 °C < T ≤ 150 °C	150 °C (2)
T > 150 °C	175 °C (1) (2)

min: minutes; h: hour

(1): in those cases where the real contact conditions of the plastic material and the food are not adequately covered by the test conditions in this table (e.g. contact times less than 5 minutes or contact temperatures greater than 175 °C), other more appropriate contact conditions may be used in each case under evaluation, provided that the conditions chosen represent the most severe foreseeable contact conditions.

(2): this temperature corresponds only in the case of use simulant D'.

See Table 4 for Simulants D.

For Simulants A, B and C the temperature of the migration test shall be 100 °C (or reflux temperature) for a time equal to 4 (four) times the time selected, according to the general rules established above in 2.3.4.1 . (i.e. the test time equivalent to the most severe foreseeable contact time in this Table or the recommended usage time in the labeling of the plastic material, packaging or equipment, if any).

2.3.4.10. Migration Testing in Food Simulant D

Table 4 sets some of the examples of migration test conditions which are considered conventionally the most usual with simulant D' and those corresponding to simulant D.

To set other migration test conditions not contemplated in Table 4, Table 4 will be used as a guiding example, as well as information on existing experience for the type of polymer under evaluation. For the calculation of the migration test results, the reduction factors ("n") per fat simulant D or D' set out in Table 2 as explained in section 2.3.3, should be used.

Table 4: Time and Temperature Conditions for Migration Test in Food Simulant D

Time and Temperature Conditions in Food Simulant D'	Time and Temperature Conditions in Food Simulant D		
	Isooctane	95% (v/v) ethanol water solution	MPPO (modified polyphenylene oxide)
10 d at 5 °C	12 h at 5 °C	10 d at 5 °C	--
10 d at 20 °C	1 d at 20 °C	10 d at 20 °C	--
10 d at 40 °C	2 d at 20 °C	10 d at 40 °C	--
2 h at 70 °C	30 min at 40 °C	2 h at 60 °C (1)	--
30 min at 100 °C	30 min at 60 °C (1)	2.5 h at 60 °C (1)	30 min at 100 °C
1 h at 100 °C	1h at 60 °C (1)	3 h at 60 °C (1)	1 h at 100 °C
2 h at 100 °C	1.5 h at 60 °C (1)	3.5 h at 60 °C (1)	2 h at 100 °C
30 min at 121 °C	1.5 h at 60 °C (1)	3.5 h at 60 °C (1)	30 min at 121 °C
1 h at 121 °C	2 h at 60 °C (1)	4 h at 60 °C (1)	1 h at 121 °C
2 h at 121 °C	2.5 h at 60 °C (1)	4.5 h at 60 °C (1)	2 h at 121 °C
30 min at 130 °C	2 h at 60 °C (1)	4 h at 60 °C (1)	30 min at 130 °C
1 h at 130 °C	2.5 h at 60 °C (1)	4.5 h at 60 °C (1)	1 h at 130 °C
2 h at 150 °C	3 h at 60 °C (1)	5 h at 60 °C (1)	2 h at 150 °C

2 h at 175 °C	4 h at 60 °C (1)	6 h at 60 °C (1)	2 h at 175 °C
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min: minutes; h: hour; d: days

(1): volatile simulants are used up to a temperature of 60 °C. A requirement for the use of simulant D, instead of using the simulant D', is that the plastic material, packaging or equipment in contact supports the test conditions. A test piece must be immersed in the simulant D' under the conditions selected from Table 4, and if the physical properties of the sample change (for example, if softening or melting, or deformation, etc.), then the material is considered unsuitable for use at that temperature. If the physical properties do not change, then the migration test will be carried out with the simulant D.

2.3.5. Overall Migration Testing

2.3.5.1. Methodology with Food Simulants A, B, C and D

The methods described in EN 1186 (EN 1186-1 "Materials and articles in contact with foodstuffs - Plastics - Part 1: Guide to the selection of conditions and test methods for overall migration" and complementary) should apply.

2.3.5.2 Methodology with Food Simulant D'

In the case of carrying out the overall migration tests with food simulant D', the different methods described in the EN 1186 Series Standards corresponding to tests with edible oils and mixtures of synthetic triglycerides should apply.

2.3.6. Specific Migration Testing

The methods described in the EN Standards 13130 Series should apply (EN 13130-1 "Materials and articles in contact with foodstuffs - Plastics substances subject to limitation - Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants" and complementary).

After the contacts between the samples and the corresponding simulants in Tables 1 and 2, in the conditions set in Tables 3 and 4 of this Technical Regulation, the specific migration of substances in the extracts, according to the methodology referred to in the preceding paragraph, will be obtained with the methods available in the EN Standard 13130 Series. If analytical methods are not covered by this standard, instrumental analytical techniques with adequate sensitivity shall be used (e.g. absorption or emission spectrometry, gas chromatography, high performance liquid chromatography, etc.).

2.3.7 Overall and specific migration testing in repeated use plastic materials, packaging and plastic equipment, including returnable packaging, shall be carried out three times on the same sample, using virgin simulant at each occasion (except in the case of simulant D', in which case simulant D must be used).

The conformity of the material, packaging or equipment with the migration limits shall be established on the basis of the level of migration determined in the three tests. If there are conclusive evidence that for certain materials the level of migration does not increase in the second and third tests, it is not necessary to carry out these last two tests.

On the other hand, if there is evidence that repeated use and washing degrades material, packaging or equipment, leading to increased overall and specific migration, relevant assessments shall be carried out to ensure conformity with this Regulation.

3. Overall Migration Limits

Overall migration limits of components of plastic materials, packaging and equipment are those established in the Resolution of the Common Market Group on "General Provisions for Plastic Packaging and Equipment in Contact with Foods".

4. Specific Migration Limits

Specific migration limits of components of plastic materials, packaging and equipment are those established in the Resolutions of the Common Market Group on plastic materials:

- for monomers: MERCOSUR Technical Regulation on Positive List of Polymers Intended to Come into Contact with Food;
- for additives: MERCOSUR Technical Regulation on Positive List of Additives for the Manufacture of Plastic Materials Intended to Come into Contact with Food;
- for substances that confer color, heavy metals and other elements, from colored and/or printed materials, packaging and equipment: MERCOSUR Technical Regulation on Colorants for Plastic Packaging and Equipment Intended to Come into Contact with Food.