

# CHANGES IN THE BRAZILIAN LAW OF POLYMERIC PACKAGES FOR CONTACT WITH FOODSTUFFS

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On June 15, 2010, the *Grupo do Mercado Comum* [Common Market Group] published two Technical Regulations, GMC no. 15/10 and GMC no. 32/10, revoking the Mercosur Technical Regulations GMC no. 28/93 and GMC no. 30/92, 36/92, 10/95, 11/95, 15/97, 32/97 and 33/97. In Brazil, the Technical Regulations revoked comprise the attachments I, IV, V, VI, X, XIII and XIV of the Resolution 105, dated May 19, 1999, published by *Agência Nacional de Vigilância Sanitária* [National Health Surveillance Agency] (ANVISA). In Brazil, the Technical Regulations GMC no. 15/10 and GMC no. 32/10 were published by the National Health Surveillance Agency, of the Ministry of Health, in the Federal Official Gazette on November 30, 2010, as the Resolution RDC no. 52/10, dated November 26, 2010, and as the Resolution RDC no. 51/10, dated November 26, 2010, respectively.

The Resolution RDC no. 52/10 applies to the plastic equipment and packages containing colorants and pigments in its formulation, destined to contact with foods, as well as the colorants used to dye the packages. This regulation changes the analytical methodologies of metals and aromatic amines in pigments and colorants, defines the methodologies for assessment of the carbon black pigment and changes the specific migration limits of metals for colored polymeric packages.

The organic pigments and colorants must comply with the limits for sulfonated and non-sulfonated aromatic amines by using the methodologies DIN 55610 (1986) and the Resolution AP (89). In quantification of the non-sulfonated aromatic amines, the content of the amines benzidine,  $\beta$ -naphthylamine and 4-aminobiphenyl is determined, however, no methodology was defined for this.

The limits of metals for organic and inorganic colorants and pigments were not changed; however, the limits for the elements chromium and antimony were determined. The reference methodologies are the Resolution AP (89) 1 (1989) and DIN 53770-1 (2007).

The limits of the aromatic amines and metals for pigments and colorants are described in Table 1.

**TABLE 1.** Limits of aromatic amines and metals for pigments and colorants.

Parameters	Limits
Sulfonated aromatic amines	500 mg/kg
Non-sulfonated aromatic amines	500 mg/kg
Amines; benzidine, $\beta$ -naphthylamine and 4-aminobiphenyl	The sum of the contents of three amines must be < 10 mg/kg
Antimony	0.05%
Arsenic	0.005%
Barium	0.01%
Cadmium	0.01%
Lead	0.01%
Chrome	0.10%
Mercury	0.005%
Selenium	0.01%
Zinc	0.20%

The carbon black pigment must comply with the limits of metals and amines, as well as the requirements set forth in the Resolution RDC no. 17/08, as per Table 2, using the reference analytical methodologies: ISO 6209 (2009) for extractable in toluene and German BfR, BIII, Reinheitsprüfung von Rußen, Stand 1.7.1972 for extractable in cyclohexane. No methodologies were defined for quantification of benzo(a)pyrene.

**TABLE 2.** Requirements and limits for carbon black.

Parameters	Limits
Carbon black in polymers	2.5%
Extractable in toluene	0.1%
Extractable in cyclohexane at 386 nm	< 0.02 UA (OP = 1 cm) < 0.10 UA (OP = 5 cm)
Benzo(a)pyrene	0.25 mg/kg

AU = absorbance unit

OP = optical path

The specific migration of metals applies to the colored polymeric packages and the limits for metals are described in Table 3. The methodology for extraction is the same used in overall migration, however, it uses only the simulant for aqueous acid foods (aqueous solution of acetic acid at 3% m/v), even if the food in contact with the colored package is not an aqueous acid one.

**TABLE 3.** Limits of specific migration for the metals antimony (Sb), arsenic (As), barium (Ba), boron (B), cadmium (Cd), zinc (Zn), copper (Cu), chromium (Cr), tin (Sn), fluorine (F), mercury (Hg), silver (Ag) and lead (Pb).

Parameters	Limits of specific migration (mg/kg)
Antimony (Sb)	0.04
Arsenic (As)	0.01
Barium (Ba)	1
Boron (B)	0.5
Cadmium (Cd)	0.005
Zinc (Zn)	25
Copper (Cu)	5
Chromium (Cr)	0.05
Tin (Sn)	1.2
Fluorine (F)	0.5
Mercury (Hg)	0.005
Silver (Ag)	0.05
Lead (Pb)	0.01

The Resolution RDC no. 51/10 applies to the plastic equipment and packages destined to contact with foods. This regulation changes the classification of foods, the simulants and the analytical methodology of overall and specific migration.

The methodology for quantification of overall and specific migration consist of the contact of the sample with food simulants, with times and temperatures which simulate their actual condition of use. For the overall migration assay, the methods described in the Regulations EN Series 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 supplementary regulations) must be applied, and for specific migration the methods described in Regulations EN Series 13130 (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 supplementary regulations) must be applied.

In case the analytical methods are not addressed in the concerned regulation, instrumental analytical techniques with appropriate sensitivity must be used (e.g., absorption or emission spectrometry, gas chromatography, high-performance liquid chromatography, etc.).

The simulants show similar characteristics to the foods, requiring, in some cases, the use of one or more simulants to represent a given group of foods. Table 4 shows the simulants used in the migration assays.

For aqueous acid and/or alcoholic foods the assay using simulant A is not required, since it will be performed with the simulants B and/or C. In case of dry and fatty foods, the migration assay will be performed with the simulants D or D', requiring no migration assay if the dry food is not fatty as well.

Other change proposed by the regulation RDC 51/10 (GMC 32/10) is the use of aqueous solution of ethanol at 50% (v/v) as a fatty simulant for assessment of materials destined to the contact with milk products.

Type of food	Simulant	
Aqueous non-acid foods (pH > 4.5)	A	distilled or deionized water
Aqueous acid foods (pH ≤ 4.5)	B	acetic acid solution at 3% (m/v) in distilled or deionized water
Alcoholic drinks (alcohol content between 5% and 10%) <sup>(1)</sup>	C	ethanol solution at 10 % (v/v) in distilled or deionized water
Fatty foods	D	ethanol solution at 95% (v/v) in distilled or deionized water or Isooctane or MPPO (modified polyphenylene oxide) or ethanol solution at 50 % (v/v) in distilled or deionized water <sup>(2)</sup>
	D'	Comestible oils (olive-oils, sunflower oil, corn oil) or synthetic triglycerides mixtures

(1) For drinks with alcohol content above 10% (v/v): ethanol solution in distilled or deionized water, with concentration equal to that of the drink.

(2) Fatty simulant for milk products