



LifeSciences in Brazil

No. 8

Food, Drug, Agriculture, Health Care, Biotechnology and Biodiversity at a glance

August 2006

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This is the eighth edition of **Life Sciences in Brazil**, an electronic newsletter with information and rules on the regulations recently issued and/or proposed, which include the relevant aspects related to Food, Drug, Agriculture, Health Care, Biotechnology and Biodiversity.

This is a periodical publication prepared in the English and Portuguese languages by the LifeSciences practice group of Pinheiro Neto Advogados. We hope this publication is informative.

If you have any requests or believe this publication will also be useful to others, we will be glad to add their contact information to our mailing. Please send their names and e-mail address to (camila@pinheironeto.com.br).

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BRAZILIAN COMMON DENOMINATION

ANVISA updated the 2004 Brazilian Common Denomination (DCB) to reflect the number of some active ingredients as ascribed by the Chemical Abstracts Services (CAS) (Resolution RDC 112/06, published in the Official Gazette of the Federal Executive – DOU on July 4, 2006).

Companies have 360 days to conform to these changes.

ACTIVE INGREDIENTS

ANVISA has changed the classification of some active ingredients, as follows:

- M42 – METHYLEUGENOL was added to the compendium of codes for active ingredients of pesticides, household cleaning products and wood preservers. (Resolution RE No. 2053 of July 4, 2006)
- D36 – DIFENOCONAZOLE had its toxicity classification changed from III to I. (Resolution RE No. 2054 of July 4, 2006)
- I22 – IODOSULFURON-METHYL had its common name, chemical name, CAS systematic number, molecular formula and structure changed. (Resolution RE No. 2216 of July 14, 2006)
- D24 – DITHYANON had its toxicity classification changed from II to I. (Resolution RE No. 2217 of July 22, 2006)
- A07 – ALDICARB was removed from banana cultures (Resolution RE No. 2311 of July 24, 2006)

MEDICATIONS

ANVISA published the preliminary results of the Notification Document (*Edital de Notificação*) relating to ownership of trade names of medications. (Resolution RE No. 2207 of July 14, 2006)

The full list is available at www.anvisa.gov.br.

Sale of Medications by Mail

Under Law 5991/73, the dispensation of medication is restricted to pharmacies, drugstores, medication units, mobile units, and medication dispensers.

Bill 3324/2000 aims to expand this list set out in Law 5991/73 by allowing pharmaceutical companies to sell directly to consumers by mail. ANVISA and the Brazilian mail service (ECT) should enter into an agreement to that effect.



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Bill 3324/2000 is under review of the House of Representative's Social Security Committee.

HEALTHCARE ORGANIZATIONS

ANVISA has released the Brazilian Manual for Accreditation of Healthcare Organizations (Resolution RDC No. 93 of May 26, 2006), introducing a periodical process for assessment of healthcare institutions to check whether they meet a specific set of standards designed to improve the quality of healthcare services.

The quality standards and levels defined in the Manual should be followed by the National Organization of Accreditation (ONA) and by the Accrediting Institutions designated by it in Brazil.

The Manual is available at www.anvisa.org.br.

FOOD

Meat and Poultry

MAPA disclosed a list of countries that posed restrictions to import of Brazilian meat and poultry because of the Newcastle disease focus in the State of Rio Grande do Sul. The European Union and Argentina officially imposed restrictions on imports of poultry and byproducts.

Nutrition Labeling

The deadline for packaged food producers to conform to the new nutritional labeling rules as per the Technical Regulation on Packaged Food Labeling (approved by Resolution RDC No. 360 of December 23, 2003) ended on July 31, 2006.

However, ANVISA clarified that the products manufactured, packaged or imported by July 31st could be traded under the past labels until the inventory is cleared out.

Nonconforming companies from August 1 to December 31, 2006 will be notified by ANVISA to adapt themselves to the new nutritional labeling rules.

As from January 1, 2007, noncompliant companies will be held liable for sanitary offenses. (Resolution RE No. 2313 of July 26, 2006)

Edulcorant Substances

In July 2006, the São Paulo State Legislative Assembly proposed a Bill providing for compulsory display of the quantity of edulcorant substances on the label of all foods containing such products, coupled with information on the Acceptable Daily Intake (ADI). The Bill also states that a fine will be meted out on noncompliant companies.



In the statement of reasons for the Bill, the State Executive explains that such measure aims at warning consumers about the health risks posed by the excessive intake of edulcorant substances. This is not an usual practice in Brazil, as only the labels of soft drinks and powder juice preparations state the quantity of these substances as required by Law 8918/94 and Decree 2314/97.

ANIMALS

In an effort to develop regional cattle-breeding activities and increase the presence of member countries in the international trade arena, MERCOSUR approved the Action Plan for Eradication of Hoof-and-Mouth Disease in Mercosur (PAMA) as per Decision MERCOSUR/CMC/DEC No. 25 of December 8, 2005. This program aims to eradicate this disease within MERCOSUR and other member states by December 31, 2009.

MAPA, through Normative ruling No. 16 of July 13, 2006, added PAMA to the Brazilian legal system, repealing Normative Ruling No. 8 of April 7, 2006.

Bovine Traceability

MAPA has recently issued an Operational Rule for Traceability of the Production Chain of Bovine and Bubaline Animals (SISBOV), applying to production, transformation, distribution and services in the agricultural and stockbreeding industries (Normative Ruling No. 17 of July 13, 2006).

The identification of bovine and bubaline animals for traceability purposes will occur under a number code of up to 15 digits, controlled by the Agricultural and Stockbreeding Development and Cooperative Office (SDC).

Rural and other producers in the production chain of bovine and bubaline animals may adhere to SISBOV by filling out the corresponding Adhesion Form.

Transit of Animals

MAPA approved the model Animal Transit Form (GTA) for use in the transit of livestock, fertile eggs and other animal reproduction materials throughout the Brazilian territory (Normative Ruling No. 18 of July 18, 2006).

No GTA is required for cats and dogs, which must be accompanied by a health certificate issued by a veterinary.



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Ordinance No. 22 of January 13, 1995 was repealed by Normative Ruling No. 18 of July 18, 2006.

SOIL CONDITIONERS

MAPA approved rules on specifications, warranties, tolerance levels, registration, packaging and labeling of soil conditioners and correctives for acidity, alkalinity and sodium levels intended for agriculture use (Normative Ruling No. 35 of July 4, 2006).

Besides other requirements, the new regulation establishes that prior registration with MAPA is required for production, import, sale and use of these soil amendments and conditioners in the Brazilian territory.

Normative Ruling No. 4 of August 2, 2004 was expressly repealed.

IMPORT OF SEEDS

MAPA approved the phytosanitary requirements for imports of canola seed (Normative Ruling No. 36 of July 18, 2006) and *Daucus carota* seed (carrot) under category 4, class 3 (Normative Ruling No. 39 of July 25, 2006) when produced in Chile.

These seeds must be accompanied by the Phytosanitary Certificate issued by the National Organization for Phytosanitary Protection in the Republic of Chile (ONPF), plus Additional Statements relating to the place and conditions for production of seeds and to the nonexistence of fungi or weed. At the point of entry in the Brazilian territory, these seeds will be inspected and subject to sampling for phytosanitary assay by accredited establishments.

BIOSAFETY

On July 17, 2006, Ordinances MS Nos. 1598 and 1599 changed the structure envisioned in internal rules of the Health Biosafety Commission (CBS), as well as Ordinance No. 1683/GM of August 20, 2003, which had instituted CBS.

The innovations brought about by Ordinances 1598 and 1599 encompass the use of advisory activities when preparing the MS official stances addressed to National Technical Committee on Biosafety (CTNBio); follow-up on biosafety activities in the national and international spheres; and assistance to activities relating to formulation, updating and implementation of the National Biosafety Policy (PNB).



PUBLIC CONSULTATIONS

Before a regulation comes into force, MS, ANVISA or MAPA publishes the proposed regulation for “Public Consultation”. Comments and suggestions can be submitted by any interested party within a certain period of time as from the publication date of the Public Consultation at the Official Gazette of the Federal Executive. During such period, the Public Consultations are available at www.anvisa.gov.br or at www.agricultura.gov.br, the ANVISA and MAPA websites, respectively. A regulation only comes into force after it is published as a “Resolution”, “Normative Ruling”, “Ordinance” or the like.

No.	Subject Matter	Publication Date	Term
CP No. 38	Active Ingredients Proposed Technical Regulation for Active Ingredient B27 – BROMADIOLONE, contained in the Compendium of Active Ingredients of Pesticides and Wood Preservers.	July 26, 2006	60 days
CP No. 39	Active Ingredients Proposed Technical Regulation for Active Ingredient A53 – AMINOPIRALYD, contained the Compendium of Active Ingredients of Pesticides and Wood Preservers.	July 26, 2006	30 days
CP No. 40	Blood Banks Proposed Resolution stipulating the technical rules for the operation of de Human Skeletal Muscle Tissue Banks and Human Skin Banks.	July 26, 2006	45 days
CP No. 42	Medications Proposed Resolution providing for the Statement of Information subject to ANVISA Validation, for medication imports.	July 28, 2006	20 days

GLOSSARY

ANVISA – National Health Surveillance Agency

CNTBio – National Technical Committee on Biosafety

MAPA – Ministry of Agriculture, Cattle Breeding and Supply

MS – Ministry of Health

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