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Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: Brazil If applicable, name of local government involved (Article 3.2 and 7.2):

2. Agency responsible: Brazilian Health Surveillance Agency - ANVISA Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: National Institute of Metrology, Quality and Technology - INMETRO

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3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:

- 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Recognized sources of food allergies or food intolerances in sensitive persons.
- **5. Title, number of pages and language(s) of the notified document:** Draft Resolution n° 29, June 5th 2014, that adopts provisions on the mandatory declaration in the label of packaged food, of recognized sources of food allergies or food intolerances in sensitive persons. (6 pages, in Portuguese)

6. Description of content:

Draft resolution that adopts provisions on the mandatory declaration in the label of packaged food, of recognized sources of food allergies or food intolerances in sensitive persons.

This resolution applies to food, ingredients, food additives, technological coadjuvants and raw materials which are packaged in the absence of consumers, including those intended to be used exclusively for industrial processing and at food establishments.

This resolution is complementary to the Resolution number 259, of September 20 2002, which approves the technical regulation for labelling packaged food, and to the Law 10.674, of May 16 2003, which establishes mandatory providing information on the presence of gluten in marketed food products.

The following are recognized sources of food allergies or food intolerances in sensitive persons:

I. Cereals containing gluten, namely wheat, rye, barley, oats and their hybridised strains;

II. Crustaceans;

III. Eggs;

IV. Fish;

V. Peanut;

VI. Soy;

VII. Milk;

VIII. Almond (Prunus dulcis);

IX. Hazelnut (Corylus spp.);

X. Cashew nut (Anacardium occidentale);

XI. Brazil nuts (Bertholletia excelsa);

XII. Macadamia (Macadamia spp.);

XIII. Nut (Juglans spp.);

XIV. Pecan (Carya illinoensis);

XV. Pistachio (Pistacia vera L.);

XVI. Sulphites (sulphur dioxide and its salts) in concentration equal to or greater than 10 (ten) parts per million (ppm), expressed in sulphur dioxide.

Alterations in the list provided here within can be made upon updates on Codex Alimentarius guidelines or scientific evidences showing the cause-effect of the food consumption and adverse events, its epidemiological magnitude and its severity.

The food, ingredients, additives, technological coadjuvants and raw materials which are packaged in absence of consumers, including those intended to be used for manufacturing and for food establishments must contain the declaration: Contains Gluten or Gluten Free, as appropriate.

Food that are, derives from or have been intentionally added of ingredients, food additives, technological coadjuvants or raw materiasl from recognized sources of food allergies or food intolerances described in sections II to XVI of article 4, in any quantity, must bring the declaration: Allergic: Contains (source names), or Allergic: Contains derivatives of (source names), as appropriate.

In cases that food, ingredients, food additives, technological coadjuvants or raw materials have risks of causing incidental contamination from recognized sources of food allergies or food intolerances described in sections II to XV of article 4, must inform in its label the declaration: Allergic: May Contain (source names).

Declarations required at articles 6, 7 and 8 of this Resolution must be grouped near the ingredients list on the label, in a white background frame and in black characters of the same type, complying with height requirements established in the annex of this Resolution.

This Resolution revokes Resolution RDC number 40 of February 8 2002 which approves the technical regulation on labelling of packed food and beverage that contain gluten.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health

8. **Relevant documents:** Brazilian Official Journal (Diário Oficial da União), June 9th 2014; Section 1, p. 76, Draft Resolution (Consulta Pública) number 29, June 5th 2014, issued by Brazilian Health Surveillance Agency – Anvisa. When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.

Proposed date of adoption: To be determined after the end of the consultation period.
Proposed date of entry into force: To be determined after the end of the consultation period.

10. Final date for comments: 18 August 2014

11. Texts available from: National enquiry point [] or address, telephone and fax numbers email and website addresses, if available, of other body: Brazilian Health Surveillance Agency – ANVISA

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