

<b>Title:</b>	RDC Resolution No. 344 of December 13, 2002
<b>Unofficial agenda:</b>	Approve the Technical Regulations for the Wheat Flour and Corn Flour Fortification with Iron and Folic Acid, found in the annex to this Resolution.
<b>Publication:</b>	Official Federal Gazette (D.O.U. - Diário Oficial da União) - Official Federal Gazette; Executive Power, on December 18, 2002
<b>Issuing agency:</b>	ANVISA - National Health Surveillance Agency.
<b>Scope of the act:</b>	Federal - Brazil
<b>Area of operation:</b>	Food
<b>Relationship (s):</b>	
	<b>Related acts:</b>
	<input type="checkbox"/> <a href="#">Law No. 6437 of 20 August 1977</a>
	<b>repeals:</b>
	<input type="checkbox"/> <a href="#">RDC Resolution No. 15 of 21 February 2000</a>

**RDC (Board of Directors Resolution) RESOLUTION No. 344 OF 13 DECEMBER 2002**

**Commented [H1]:** Acronyms have been defined in their first appearance, but kept in the original form.

The Chief Executive Officer of National Health Surveillance Agency in exercise of the powers conferred to him by section IV of art. 13 of the ANVISA Regulation approved by Decree No. 3029 of April 16, 1999,

considering the need for constant improvement in prevention and sanitary control actions in the food sector, aiming at the health of the population;

considering the recommendations from the World Health Organization-WHO and the Pan American Health Organization-PAHO for fortification of food products with iron and folic acid;

considering the attribute issued by the Inter-institutional Commission for Conducting and Implementing Actions to Fortify Wheat Flours and Corn Flours, coordinated by the Ministry of Health;

considering the benefits that come from the practice of adopting flour fortification, as proven in scientific studies;

considering that iron deficiency is a major nutritional problem in Brazil, with severe economic and social consequences;

considering that folic acid reduces the risk of disorders of the neural tube and in the myelomeningocele;

considering that the wheat and corn flours are widely consumed by the Brazilian population;

considering the urgency of the matter,

adopt, by referendum, following the resolution by the Board of Directors and determine its publication:

Art. 1 Approve the Technical Regulations for the Wheat Flour and Corn Flour Fortification with iron and folic acid, found in the annex to this Resolution.

Art. 2 Businesses have a term of 18 (eighteen) months from the date of publication of this Regulation to adapt their products.

Art. 3. Failure to fulfill the terms of this Resolution constitutes a health violation subject to the penalties set forth in Law No. 6437 of August 20, 1977 and other applicable provisions.

Art. 4 RDC Resolution No. 15 of 21 February 2000, Official Gazette of February 25, 2000 is revoked.

Art. 4 This Resolution enters into effect on the date of its publication.

Commented [H2]: I assume this should be 5?

GONZALO VECINA NETO

ANNEX

Technical Regulation for the fortification of Wheat and Corn Flours with iron and folic acid

## 1. SCOPE

### 1.1. Objective

Mandating wheat flour and corn flour fortification with the iron and folic acid.

### 1.2. Scope of Application

This Technical Regulation applies to the mandatory fortification of wheat flour and corn flour with the iron and folic acid. Excluded from this regulation, due to technological processing, are the following products: tapioca flour or corn flower obtained by maceration; flakes; whole wheat flour and durum wheat flour.

## 2. DEFINITIONS

2.1. For the purpose of this Technical Regulation, the following definitions apply to corn flour: cornmeal and corn flakes.

## 3. REFERENCES

3.1. BRAZIL. Decree-Law No. 986 of October 12, 1969. Establishing Standard Regulations on food. Official Gazette, Brasília, October 21, 1996.

3.2. BRAZIL. SVS (Health Surveillance Service)/ MS (Ministry of Health) Ordinance No. 540 of October 27, 1997. Approves the Technical Regulation: Food additives - Definitions, Classification and Employment. Official Gazette, Brasília, October 28, 1997.

3.3. BRAZIL. SVS / MS Ordinance No. 27 of January 14, 1998. Technical Regulation concerning Complementary

Nutritional Information. Official Gazette, Brasilia, January 16, 1998.

3.4. BRAZIL. SVS / MS Ordinance No. 31 of January 13, 1998. Technical Rules for Identity and Quality Setting for Essential Nutrients Added to Foods. Official Gazette, Brasilia, March 30, 1998.

3.5. BRAZIL. SVS / MS Ordinance No. 33 of January 13, 1998. Recommended Daily Intake (RDI) Tables. Official Gazette, Brasilia, January 16, 1998.

3.6. BRAZIL. SVS / MS Ordinance No. 27 of January 14, 1998. Technical Regulation for Packaged Food Labeling. Official Gazette, Brasilia, January 16, 1998.

3.7. BRAZIL. Resolution No. 23 of March 15, 2000. Technical Regulation on the Basic Procedures Manual for the Registration and Exemption of Obligatory Product Registration Relevant to the Food Sector. Official Gazette, Brasilia, March 16, 2000.

3.8. BRAZIL. RDC Resolution No. 39 of March 21, 2001. Reference Values Table for portions of Packaged Food and Beverages for the purpose of Nutritional Labeling. Official Gazette, Brasilia, March 22, 2001.

3.9. BRAZIL. RDC Resolution No. 40 of March 21, 2001. Technical Regulation on Mandatory Nutrition Labeling on Packaged Food and Beverages. Official Gazette, Brasilia, March 22, 2001.

3.10. BRAZIL. Resolution No. 385 of August 5, 1999. Technical Regulation that approves the use of food additives, establishing their functions and Maximum Levels for Category 6 Foods - Cereals and Cereal Products or Cereal based products. Official Gazette, Brasilia, August 9, 1999.

3.11. ATA of the I Regular Meeting of the Inter-institutional Commission for Conducting and Implementing the fortification of Wheat and Corn Flour and their by-products. Brasilia, April 19, 2002. Typed document.

3.12. BRAZIL. MS / GM Ordinance No. 14, of January 3, 2002. Establishing the Inter-institutional Commission for Conducting and Implementing Actions to Fortify Wheat and Corn Flours and their by-products. Official Gazette, Brasilia, January 08, 2002.

3.13. BRAZIL. MS Ordinance No. 291, February 8, 2002. Included in art. 2 of MS / GM Ordinance No. 14. Official Gazette, Brasilia, February 13, 2002.

3.14. Manual for Fortification of Wheat Flour with Iron. Rio de Janeiro: Embrapa Food Agribusiness, 2001, p. 56. Documents, ISSN 0103-6068; 46.

3.15. Manual for fortification of cornmeal and corn flakes with iron. Rio de Janeiro: Embrapa Food Agribusiness, 2001, 56p. Documents, ISSN 0103-6068; 47.

3.16. BRAZIL. MS Ordinance No. 710 of June 10, 1999. Approves the National Policy on Food and Nutrition. Official Gazette, Brasilia, June 11, 1999.

3.17. BRAZIL. CNNPA (National Commission on Food Regulations and Standards) Resolution No. 12 of 1978. Approves Identity and Quality Standards for food (and drinks) found in this Resolution. Official Gazette, Brasilia, July 24, 1978.

3.18. The Prevention of Neural Tube Defects with Folic Acid. Pan American Health Organization / World Health

Organization, Division of Health Promotion and Protection, Food and Nutrition Program. Centers for Disease Control and Prevention, Birth Defects and Pediatric Genetics- CDC. P. 5-15.

3.19. Iron Fortification: Where Are We in Terms of Iron Compounds PAHO / FNP / USAID Technical Consultation. Nutrition Reviews, Vol. 60, No. 7 (part II), July. 2002 p.61.

#### 4. GENERAL PRINCIPLES

4.1. The addition of iron and folic acid in wheat flour and the corn meal that is pre-packaged in the customer's absence and ready to offer to the consumer, those for industrial use, including baking and flour added to pre-mixtures is mandatory, and each 100g of wheat flour and corn flour should provide at least 4.2 mg (four point two milligrams) of iron and 150 micrograms (one hundred fifty micrograms) of folic acid.

4.2. Fortified wheat flours and corn flours used as ingredients in industrialized food products, where iron and folic acid are proven to cause interference, may be exempted from the addition of iron and/or folic acid. The company shall keep available to the Health Surveillance Agency, the studies that prove this interference.

4.3. The choice of iron compounds for fortification is the responsibility of the industries, which should guarantee their stability in wheat and corn flours within the period of validity of the same.

4.4. Companies should ensure that the food grade iron compounds are bioavailable.

4.5. Companies may use the following food-grade iron compounds: dehydrated iron sulfate (dry); ferrous fumarate; reduced iron - 325 mesh Tyler; electrolytic iron - 325 mesh Tyler; Sodium and iron EDTA (NaFeEDTA); and iron glycinate chelate.

Other compounds may be used provided that the bioavailability is not inferior to the compounds listed.

4.6. Companies should use food-grade folic acid, ensuring the stability of the wheat flour and the corn flour within the period of validity of the same.

#### 5. LABELLING

5.1. Wheat flours and corn flours should be designated using the conventional name of the product according to the specific legislation, followed by one of the following expressions: Fortified with iron and folic acid, enriched with iron and folic acid or rich in iron and folic acid.

5.2. Fortified wheat flours and corn flour used as ingredients must be stated on the label in the list of ingredients with the following expressions: fortified wheat flour or enriched or rich in iron and folic acid; and fortified corn flour or enriched or rich in iron and folic acid.

5.3. Processed products that contain wheat flours and or corn flour fortified with iron and folic acid as ingredients that want to use the names mentioned in the previous item, must meet the requirements set out in the Technical Regulation for Identity and Quality Setting for Essential Nutrients Added to Foods.

#### 6. ADDITIVES

The use of food additives and supporting technology provided by specific legislation is permitted.

