Decree No Regulation on Health Registration, Importation, Customs Clearance, Labelling and Verification of Dietary Supplements

EXECUTIVE DECREE No

THE PRESIDENT OF THE REPUBLIC

AND THE MINISTER OF HEALTH

On the basis of the powers vested in them by Articles 50, 140(3) and (18) and 146 of the Political Constitution; Articles 27(1) and 28(2)(b) of Act No 6227 of 2 May 1978 and the *Ley General de la Administración Pública* (General Public Administration Act) and in accordance with the provisions of the *Ley General de Salud* (General Health Act) and its amendments, Act No 5395 of 30 October 1973

WHEREAS

1. It is an essential function of the State to ensure that public health is protected.

2. The State is also responsible for ensuring citizens' welfare without unnecessary impairment of the competitiveness needed for development of the national economy.

3. There are a growing number of products marketed as foodstuffs that contain high concentrations of nutrients and other ingredients and are intended to supplement the ingestion of such substances as part of a normal diet.

4. It is necessary for health registration purposes to classify such products as dietary supplements and also to set requirements regarding their composition, labelling and marketing in such a way as to promote the correct use of such products by the general public.

THEREFORE

DECREE

Article 1 That they approve the following Regulation:

COSTA RICAN TECHNICAL REGULATION (RTCR) NO 436:2009: DIETARY SUPPLEMENTS. REQUIREMENTS PERTAINING TO HEALTH REGISTRATION, IMPORTATION, CUSTOMS CLEARANCE, LABELLING AND VERIFICATION

1. Purpose and area of application

The purpose of this Regulation is to lay down the conditions and requirements for the health registration, importation, customs clearance, labelling and verification of food supplements.

This Regulation shall apply to all dietary supplements that are marketed in this country.

2. References

This Regulation is complemented by:

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1. *Decreto Ejecutivo* (Executive Decree) No 26012-MEIC, Costa Rican Technical Regulation (RTCR) No 100:1997: *Etiquetado de los Alimentos Preenvasados* (Labelling of pre-packaged foods), published in *La Gaceta* (Official Gazette) of 16 April 1997.

2. Executive Decree No 30256-MEIC-S, RTCR No 135:2002: *Etiquetado Nutricional de los Alimentos Preenvasados* (Nutrition labelling of pre-packaged food), published in the Official Gazette of 15 April 2002.

3. Executive Decree No 34728-S, *Reglamento General para el Otorgamiento de Permisos de Funcionamiento por parte del Ministerio de Salud* (General regulations governing the issuing of operating permits by the Ministry of Health), published in the Official Gazette of 9 September 2008.

4. Executive Decree No 33724, Central American Technical Regulation (RTCA) No 67.01.30:06: *Alimentos Procesados. Procedimiento para otorgar la licencia sanitaria a fábricas y bodegas* (Processed foods. Procedure for granting health licences to factories and warehouses), published in the Official Gazette of 30 April 2007.

3. Definitions

The following definitions shall apply for the purposes of implementing this Regulation:

3.1 Energy drinks: Non-alcoholic drinks marketed as such that contain any of the following ingredients: taurine, glucuronolactone, caffeine, inositol, carbohydrates, vitamins, minerals or other ingredients added to this list by means of an administrative decision taken by the Ministry and published in the Official Gazette.

3.2 Certificate of good manufacturing practice: The document issued by the health authority of the country of origin certifying that the manufacturer of the supplement in question duly meets the good manufacturing practice requirements applicable to dietary supplements.

3.3 Free sale and consumption certificate: The document issued by the competent authority of the country of origin and duly certified by the Consulate, stating that the sale of the food supplement is legally authorised for human consumption in that country and indicating the date up to which the registration or authorisation remains in force.

3.4 Confiscation: Loss of ownership to the State by the owner of products that have caused or resulted in a health infringement or are harmful or hazardous to human health. The health authorities will, on their own authority, confiscate dietary supplements that are obviously spoiled, contaminated, adulterated or counterfeited.

3.5 Special health measures: Measures that may be taken by the health authorities in order to effectively protect public health by preventing the appearance of hazards and the exacerbation and spread of damage and the continuation or recurrence of legal or regulatory infringements that impair human health. Withholding and withdrawing from the market or circulation, confiscation, denaturing, destruction of assets, closure of establishments and the cancellation of permits and registrations are deemed to be special measures.

3.6 Ministry: Ministry of Health.

3.7 Sampling: Procedure for taking the dietary supplement samples necessary to verify compliance with the provisions of this Regulation.

3.8 Sample of no commercial value: Substances or products that do not exceed the total import amount for customs purposes specified in the customs legislation in force and are generally intended for product promotion purposes are regarded as samples of no commercial value.

3.9 Customs clearance permit: Authorisation granted by the competent goods clearance authority.

3.10 Health permit: Advance administrative authorisation granted by the Ministry of Health to any natural or legal person importing, manufacturing or dealing in dietary supplements under a particular name and trademark into or in the territory of this country in accordance with the provisions of the General Health Act and the regulations applicable to the various economic activities.

3.11 Health registration: The process by which the Health Authority authorises the marketing of a dietary supplement in response to an application submitted together with the documentation necessary for its assessment, statistical registration and subsequent monitoring.

3.12 Legal representative: The natural or legal person resident in Costa Rica, designated by the owner of the dietary supplement by means of a power of attorney, who is responsible to the regulatory authority.

3.13 Withholding: Keeping dietary supplements of doubtful composition or condition in a safe environment under the seal of the health authority where there are grounds for suspecting that their use or consumption might be harmful or hazardous to health, and in so doing prohibiting their transportation, use or consumption until the corresponding tests to determine their composition or condition have been carried out.

3.14 Withdrawal from the market or circulation: The full or partial withdrawal of consignments or batches of dietary supplements found to be in contravention of the regulatory requirements they need to meet in order to be marketed or the use or consumption of which has been found to be harmful or hazardous to public health, such withdrawal being incumbent on the owner, director or legal representative of the company, who must duly and scrupulously carry it out.

3.15 Dietary supplement: A product intended to supplement the diet for health reasons, to help to maintain and protect certain physiological states. It is presented as a concentrated source of nutrients and other substances or plants, including ingredients such as vitamins, minerals, proteins, amino acids and other nutrients and substances derived from them. It must have only a physiological or nutritional, not a therapeutic, effect and its consumption must not constitute a health hazard. It may be marketed in pharmaceutical form (pills, capsules, syrup, etc.), in measured doses and for oral use only. Energy drinks shall be deemed to be dietary supplements for the purposes of this Regulation. Foods for special diets shall not be deemed to be covered by this Regulation.

3.16 Charge: Amount officially established to meet the duties payable to enable processing, registration and verification to be carried out.

3.17 Product owner: The natural or legal person who owns the dietary supplement.

4. Symbols and abbreviations

4.1 mg: milligram

4.2 ml: millilitre

4.3 • g ER: microgram of retinol equivalent

4.4 • g: microgram

4.5 NOAEL: No observable adverse effect level

5. Administration of the health registration of dietary supplements

The Ministry, through the *Dirección de Atención al Cliente* (Customer Service Department), shall be responsible for granting, refusing and cancelling the registration of dietary supplements.

6. General aspects of the health registration of dietary supplements

Dietary supplements must undergo health registration in accordance with the requirements of this Regulation before they can be marketed, imported or distributed.

Registration shall not preclude the full liability of the natural or legal persons who have manufactured, produced or imported the food supplement for giving a health guarantee in respect of the product and ensuring its nutritional value and safety. The Ministry shall register a dietary supplement when it has decided in to approve it after having analysed the legal, technical and scientific information required in each case.

Dietary supplement samples of no commercial value are exempted from the registration requirement.

7. Requirements for the health registration of dietary supplements. Persons wishing to effect the health registration of dietary supplements must submit the following information to the Ministry in a ring file containing numbered sheets and marked with the name of the supplement:

7.1 Registration application form completed and signed by the applicant or the company's legal representative.

7.2 Copy of the operating permit in force. If the products are to be imported, the duly authenticated free sale and consumption certificate duly issued by the competent authority in the country of origin. It may cover one or more products but must have been issued within the past two years. If the certificate is written in a language other than Spanish, it must be accompanied by the respective official translation.

7.3 Certificate of good manufacturing practice in the case of imported products. This must be duly authenticated and have been issued by the competent authority in the country of origin. It must have been issued within the past two years. If the certificate is written in a language other than Spanish, it must be accompanied by the respective official translation.

7.4 Valid confirmation of legal status in the case of legal persons, which must have been issued within the past three months.

7.5 Qualitative and quantitative formula of the product expressed in units in accordance with the *Ley del Sistema Internacional de Medidas* (International Measurement System Act). In the case of plants, the scientific species name and the part of the plant being used must be indicated. If the supplements contain probiotics, the scientific name and registration code of the bacteria and the dose contained in the supplement must be shown.

7.6 Original label or label design in accordance with Regulation (RTCR) No 100:1997: Labelling of pre-packaged foods and its amendments. If this is written in a language other than Spanish, the official translation must also be provided.

7.7 Evidence published in scientific journals of the use(s) of the supplement, unless its uses are included in the list of permitted uses of dietary supplements, to be confirmed by the Ministry at a later date.

7.8 Reference to the analysis methodology used to verify the presence of nutrients or ingredients of the dietary supplement.

7.9 Payment of the fixed registration charge according to the provisions of Executive Decree No 32468 published in Official Gazette No 137 of 15 July 2005.

8. Minimum and maximum concentrations of vitamins, minerals and other ingredients

a) The concentrations of the vitamins and minerals contained in the dietary supplements must be not less than the levels specified in Annex 1, which correspond to 20% of the RDI in the United States of America.

b) Dietary supplements may not exceed the maximum concentrations of vitamins, minerals and other ingredients respectively specified in Annexes 2 and 3.

9. Completion deadlines

When the full correct documentation has been received, it will be assessed by the Customer Service Department within one calendar month.

If the information that has been supplied needs to be clarified, corrected or supplemented, the Authority shall, before the end of the one-month period, issue a single administrative decision, duly substantiated in technical and legal terms, requesting the person concerned to submit the necessary information within ten (10) working days. The completion period for the public authority shall be extended by the same amount of time. If the person concerned fails to submit the requested information within this period, the application shall be deemed to have been abandoned and the Ministry shall issue a substantiated decision declaring discontinuation of the application, which shall then be placed on file. The respective payment shall not be refunded as a result of this.

The Ministry shall resume processing the application as soon as the applicant provides the requested information.

10. Validity of health registration

Health registration shall remain valid for five (5) years and shall be repeatedly renewable on expiry unless the owners are guilty of infringements that justify its immediate cancellation or the registered food supplement constitutes a hazard for public health in the opinion of the health authority.

11. Renewal of health registration

Health registration shall be renewed by the same procedure as for initial registration and subject to the same requirements, except for the need to submit studies to substantiate the uses of the product shown by the labels, unless there has been a change to the use originally approved.

12. Changes to health registration

If there are changes to the information or the features of a dietary supplement, the person responsible must apply to the authority for approval of the changes, enclosing the items needed for the changes to be processed as listed below. All the documentation must be submitted in Castilian Spanish and official documents written in other languages must be submitted with the respective official translation.

12.1 Change of name of applicant's company

12.1.1 Legal document certifying the change

12.1.2 Original legal status of the applicant's company under its new name, which must have been issued within the past three months.

12.2 Change of manufacturer

12.2.1 In the case of products manufactured in this country, the Public Authority shall verify the validity of the health operating permit of the new manufacturer.

12.2.2 If the product is manufactured outside this country, the person concerned must submit the Certificate of good manufacturing practice.

12.2.3 New label design or original label.

12.3 Change in the list of ingredients (excipients only)

12.3.1 Qualitative and quantitative formula.

12.4 Transfer of registration

12.4.1 Legal document certifying transfer.

12.5 Change in or extension of the product name or trade mark

12.5.1 New label design or original label.

12.6 Change in or extension of the use of the product

12.6.1 New label design or original label.

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12.6.2 Scientific studies supporting the proposed claim (in accordance with section 7.7 if applicable).

13. Labelling requirements

13.1 Labels for dietary supplements must comply with the provisions of Executive Decree No 26012 Technical Regulation on the labelling of pre-packaged foods, published in Official Gazette No 91 of 14 May 1997 and of Executive Decree No 30256 Technical Regulation on nutrition labelling of pre-packaged food, published in Official Gazette No 71 of 15 April 2002. They must also:

13.1.1 contain true information about the product, which must not be described or presented using words, illustrations or other graphical representations that might be misleading about the nature, origin, composition or quality of the dietary supplement.

13.1.2 provide details of the composition in dose form. If it includes plants, their common and scientific names and the parts of the plants used must be indicated. If the supplements contain probiotics, the scientific name and registration code of the bacteria and the dose contained in the supplement must be shown. The appropriate measurement units according to the International Measurement System Act must be used to declare ingredient quantities.

13.1.4 show the recommended maximum daily consumption of the dietary supplement in its commercial form.

13.1.5 include the following statements or equivalent phrases:

a) "THIS PRODUCT MUST NOT BE USED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY ILLNESS NOR AS A SUBSTITUTE FOR A BALANCED DIET";

b) "NOT FOR USE BY PREGNANT OR BREASTFEEDING WOMEN OR BY CHILDREN", except in the case of products specially intended for such persons, which must then bear the statement: "USE UNDER MEDICAL SUPERVISION";

c) "KEEP OUT OF THE REACH OF CHILDREN";

d) Dietary supplements that contain tartrazine or FD&C Yellow No 5 must indicate that they contain this colouring and bear the statement: "CONTAINS TARTRAZINE OR FD&C YELLOW NO FIVE, WHICH MAY CAUSE ALLERGIC REACTIONS IN SENSITIVE PERSONS";

e) Dietary supplements containing the sweetener aspartame must bear the statement: "PHENYLKETONURICS – CONTAINS PHENYLALANINE";

f) Energy drinks containing caffeine must show the quantity of this ingredient they contain and bear the statement:

"CONSUMPTION OF THIS PRODUCT BY PERSONS SENSITIVE TO CAFFEINE IS NOT RECOMMENDED";

g) In addition, labels for energy drinks must bear the following statements:

"CONSUMPTION OF THIS DRINK MIXED WITH ALCOHOL IS HARMFUL TO HEALTH".

If the original labels of imported products do not include the compulsory statements, it is acceptable for the importer to include them in an additional label.

14. Importation and customs clearance

Dietary supplements can be cleared through customs only after verification that the product is duly registered with the Ministry.

15. Verification

The Ministry shall be the body responsible for enforcement and verification of this Technical Regulation and may therefore carry out inspections and take samples for quality analysis and control purposes on the market, at customs points and on the premises of domestic manufacturers and other authorised establishments. If the product contains an ingredient or additive that cannot be analysed in this country, the manufacturer or importer must furnish a product analysis certificate issued by the health authority in the country of origin or a laboratory recognised by it.

16. Application of special measures

If statements made for the purposes of registration with the Ministry are shown not to have been complied with or to be incorrect, the health authority shall withhold or confiscate the product in question or withdraw it from circulation or its registration shall be cancelled as appropriate, after notification of the legal representative, who must pay the costs of the health measures taken.

The Ministry, under the legislation in force and the principles of fundamentally guaranteeing due process, may cancel registration or authorisation for customs clearance, particularly in the following cases:

a) existence of domestic or international health warnings justifying such action;

b) failure to comply with the requirements shown on the label;

c) if it is shown that the conditions under which health registration was granted have not been complied with.

The health authority shall apply these special measures on the basis of the provisions of Article 386 of the General Health Act without prejudice to the civil or criminal liability incurred by the natural or legal persons responsible for such non-compliance or to any other penalties applicable under the legislation in force.

17. CONFORMITY

This Regulation does not conform with any other standards or regulations.

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Annex 1

Minimum daily concentrations of vitamins and minerals in dietary supplements

(Regulatory standards)

Vitamin	Units	Quantity
A	• g ER	300
	UI	1 000
C	mg	12
D	• g	2
	UI	80
E	mg	4
	UI	6
K	• g	16
Thiamine (B1)	mg	0.3
Riboflavin (B2)	mg	0.34
Niacin	mg	4
Pyridoxine (B6)	mg	0.4
Folic acid	• g	80
Cyanocobalamin (B12)	• g	1.2
Biotin	• g	60
Pantothenic acid	mg	2

Mineral	Units	Quantity
Calcium	mg	200
Iron	mg	3.6
Phosphorus	mg	200
Magnesium	mg	80
Zinc	mg	3
Iodine	• g	30
Selenium	• g	14
Copper	• g	0.4
Manganese	mg	0.4
Chromium	• g	24
Molybdenum	• g	15

Source: Electronic Code of Federal Regulations. RDI's for vitamins and minerals. Available at http://www.gpoaccess.gov/ecfr/. Consulted in October 2008.

Annex 2

Maximum daily concentrations of vitamins and minerals in dietary supplements

(Regulatory standards)

Vitamin	Units	NOAEL
A	• g	3 000
	UI	10 000
Beta-carotene	mg	25
C	mg	2 000
D	• g	60
	UI	2 400
E	mg	1 000
	UI	1 490
K	mg	10
Thiamine (B1)	mg	100
Riboflavin (B2)	mg	200
Niacin	mg	35
Pyridoxine (B6)	mg	100
Folic acid	• g	1 000
Cyanocobalamin (B12)	• g	3 000
Biotin	mg	2.5
Pantothenic acid	mg	1 000

Mineral	Units	NOAEL
Calcium	mg	2 500
Phosphorus	mg	4 000
Magnesium	mg	400
Potassium	mg	1 500
Boron	mg	20
Chromium	• g	1 000
Copper	mg	10
Fluoride	mg	10
Iodine	• g	1 100
Iron	mg	60
Manganese	mg	10
Molybdenum	• g	2 000
Selenium	• g	400
Zinc	mg	40
Selenium	• g	400

Source: John N. Hathcock, Ph.D. Safety of vitamin and mineral supplements. Safe levels identified by risk assessment. April 2004.

Annex 3

Maximum concentrations by volume of a number of substances normally contained in energy drinks

(Regulatory standards)

TAURINE: 400 mg/100 ml
GLUCURONOLACTONE: 250 mg/100 ml
CAFFEINE: 35 mg/100 ml
INOSITOL: 20 mg/100 ml

Source: National Health Surveillance Agency (ANVISA). Technical Regulation for identifying and determining the quality of liquid substances ready for consumption. Ordinance No 868 of 3 November 1998. (DOU. DE 05/11/98). Available at http://www.anvisa.gov.br/legis/portarias/868_98.htm, Consulted on 21 July 2008.

Article 2. This Decree shall enter into force six months after publication.

Done by the President of the Republic at San José, on the ___ day of the month of _____ in the year two thousand and nine. **TO BE PUBLISHED.**

OSCAR ARIAS SÁNCHEZ

MARÍA LUISA ÁVILA AGÜERO

Minister of Health