Lex Mundi
World Ready

Global Practice Guide

Differences and Similarities in Food Supplement Regulations

A Global Practice Guide prepared by the
Lex Mundi Life Sciences Practice Group

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series at: www.lexmundi.com/GlobalPracticeGuides.

Lex Mundi is the world's leading network of independent law firms with in-depth experience in 100+ countries. Through close collaboration, our member firms are able to offer their clients preferred access to more than 21,000 lawyers worldwide – a global resource of unmatched breadth and depth.

Lex Mundi – the law firms that know your markets.

About this Guide

This Guide provides business information necessary to estimate the possibility of selling a given product on a certain market as well as the time and cost related to administrative procedures and preparation of labeling.

Table of Contents

© 2012 Lex Mundi

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Austria

Prepared by Lex Mundi member firm CHSH Cerha Hempel Spiegelfeld Hlawati

1. What is the definition of a food supplement in your jurisdiction?

Pursuant to Article 3 clause 4 of the Austrian Food Safety and Consumer Protection Act, food supplement means foodstuff the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

A Food supplement must have the following characteristics:

a. marketed as foodstuff and presented as such;
b. delivered to the ultimate consumer only in a pre-packaged form;
c. concentrated of sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination;
d. supplementing the normal diet.

2. Are the ingredients of food supplements regulated?

Food supplement may contain only those vitamins and minerals mentioned in Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and Council Regulation (EC) No 1925/2006 of the European Parliament and Council on lists of vitamins and minerals and their forms that can be added to foods, including food supplements.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

For food supplements it is the same procedure for launching the product which applies to all food products. For launching the product, several requirements must be fulfilled. The product must not be unsafe, adulterated, debased or contrarious to the regulation. In addition, the product must not mislead the consumer. If it turns out that the food supplement does not meet the requirements, administrative and criminal sanctions may be imposed

It is not necessary to notify any authority of the launching of the product.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

The general rules of food labeling also apply to labeling of food supplements (Article 1 Austrian Food Labeling Act). There are some specific regulations for supplements, which are also presented in the table below.

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	Austria
Source/ origin	Label must indicate: – the name or business name and address of the manufacturer or packager or of a seller established within the Community; – particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff.
Name	The term "dietary supplement" must be placed near the name under which the product is sold. Name, net weight and the date of minimum durability must be in the same view.
Ingredients	The list of ingredients, which must be placed on labeling, shall include all the ingredients of the foodstuff, in descending order of weight, as recorded at the time of their use in the manufacture of the foodstuff. It shall appear preceded by a suitable heading which includes the word "ingredients". Allergy causing ingredients must be explicit declared.
Amount of the product	The net quantity of prepackaged foodstuff shall be expressed: - in units of volume in the case of liquids, - in units of mass in the case of other products, using the liter, centiliter, milliliter, kilogram or gram, as appropriate.
Obligatory information, warnings or statements	– Lot number; – Date of minimum durability; – Quantity of certain ingredients; – Labeling as licorice; – Labeling as dietary supplement.
Optional statements	– Alcoholic strength, if the product contains more than 1.2 percent. – Special storage conditions or conditions of use, if necessary; – Warning of increased caffeine concentration, if more than 150g/l;
Language	German language is obligatory and the language must be easily understood by the consumer. Exceptions are allowed to general known terms (e.g. "made in", "Cornflakes", "Chewing Gum", "Energy Drink").
General features of a label	The label and information thereon must be affixed to the product, be clear, legible, and easily understandable and cannot be covered by any other prints or designs.

© 2012 Lex Mundi

Other remarks	**-**

Contact Information

Dr. Thomas Zivny, LL.M.
Thomas.zivny@chsh.com

CHSH Cerha Hempel Spiegelfeld Hlawati
Parkring 2
A-1010 Vienna, Austria

Tel 43.1.514.35.0 Fax 43.1.514.35.35
www.chsh.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Barbados

Prepared by Lex Mundi member firm Clarke Gittens Farmer

1. **What is the definition of a food supplement in your jurisdiction?**

   Food supplements are not specifically defined, but are treated as “Foods” meaning “any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.”

   [See Barbados National Standard Specification for Labelling of Prepackaged Foods BNS 5: Part 2:2004]

2. **Are the ingredients of food supplements regulated?**

   Labelling requirements under the above Standard Specification require that a list of ingredients be declared on the label (except for single ingredient foods and food or drink for which there is some other mandatory standard), in descending order of ingoing weight at the time of manufacture. Foods and ingredients which are known to cause hypersensitivity (e.g. crustacean, eggs, nuts, milk and sulphite) must be declared. The Standard also specifies certain other substances which must be declared on the labelof all foods including food supplements.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   The procedure is the same as for launching food products generally.

   However, since on arrival in Barbados a Standards Inspector may be invited by the Customs Department to inspect the shipment before release into the market, it is recommended that before launching a food supplement, a sample is provided to the Barbados National Standards Institution (BNSI) for approval.

   If the claims or ingredients listed lend themselves to being classified as a drug, a Drug Inspector may be consulted to analyse the compound and the manufacturer must produce a certificate of analysis. If classified as a drug, different standards will be applicable.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   The requirements are the same as for all food products.

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Country of origin shall be declared.
Name	• The name shall indicate the true nature of the food and normally be specific and not generic. • The name of a food established in a Barbados National Standard, if existing, must be used. If no such name is established, a common or usual name approved by the BNSI may be used. • Near to the name of food, there must appear additional words indicating the true nature and physical condition of the food e.g. dried, concentrated, reconstituted, smoked. • A trademark or brand name may also appear on the label.
Ingredients	• Required except for single ingredient foods. List shall be preceded by a title such as Ingredients ---, Contents ---, Prepared from --- • Shall be listed in descending order of ingoing weight (m/m) at the time of manufacture; compound ingredients must be accompanied by a list (in brackets) of their ingredients;
Amount of the product	Net weight in the metric system: Liquids – by volume – specify drained weight Solids – by weight
Obligatory information, warnings or statements	• Name of the food • List of ingredients • Net contents and drained weight (metric system) • Name and address of manufacturer, packer, distributor, importer, exporter or vendor of the food • Country of origin (if processed in a second country which changes the nature of the food, the second country becomes the country of origin) • Lot identification • Date marking and storage instructions • Instructions for use • Statement if food is artificial, imitation, substitute or synthetic • Statement of irradiation
Optional statements	• Graphic material, provided that it does not conflict with the Standard • Grade designations, if they are readily understandable and not misleading or deceptive in any way. • Nutrition information conforming to BNS 5: Part 2:2004 - Appendix D
Language	English is obligatory Numbers relating to net contents and drained weights must be in Arabic numerals

© 2012 Lex Mundi

	[BNS 5: Part 2:2004 – 7.2 Language]
General features of a label	A label may be any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of food.
Other remarks	• Items may not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect. [BNS 5: Part 2:2004 - 3. General Principles] • Claims must comply with BNS 5: Part 2:2004 - Appendix A • Required elements of a label must be clear, prominent, indelible and readily legible under normal conditions of purchase and use • Size of information must be not less than 1.6 mm in height

Contact Information

Rosalind Smith Millar
rsm@clarkes.com.bb

Clarke Gittens Farmer
Parker House
Wildey Business Park, Wildey Road
St. Michael, BB14006 Barbados

Tel 1.246.436.6287 Fax 1.246.436.9812
www.clarkes.com.bb

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Bolivia

Prepared by Lex Mundi member firm C.R. & F. Rojas - Abogados

1. What is the definition of a food supplement in your jurisdiction?

Currently, food supplements are not widely regulated under Bolivian law; however, the law does regulate matters related to maternal lactation and its supplements. To this effect, Law Nº 3460, The Promotion of Maternal Lactation and Sale of Supplemental Products, in pursuance to Article 6, food supplements related to maternal lactation are defined as any supplement for maternal milk, including the product per-se, its presentation and/or its explicit or implicit offer as a partial or whole supplement of maternal milk, intended or not for such purpose, independent of its nutritional values, including infant formulas, follow-up or continuing formulas, special formulas and others. Products intended for sale, presented or offered to children aged 2 or older, are not considered substitutes for maternal milk.

2. Are the ingredients of food supplements regulated?

Prior to entering the market, maternal milk supplements and related medical devises require a sanitary registration that is issued by the Medical Branch of the Ministry of Health and Sports in accordance with Law Nº 1737, its Regulation and Manual on Sanitary Registration among other norms related to pharmaceutical regulation. The entity in charge of supervising for the safety of product supplements for maternal milk is the Agency for Quality Control and Food Safety ("INLASA") and Food Safety Unit ("SEDES") in coordination with local Municipal Government Authorities. Every semester the National Agency for Agricultural and Health Services ("SENASAG") issues a report for the Ministry of Health and Sports of all the registered food supplements, which details their main characteristics (name, producer, and registration number, country of origin).

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

The promotion and advertisement of maternity milk supplement products bars producers, importers and/or distributors, institutions, commercial pharmaceutical establishments, to directly or indirectly promote or advertise any supplemental product, to stores, health centers, shopping centers and/or any other place of expenditure.

Furthermore, the following advertising practices for maternal milk supplements are prohibited:

a) Advertising of the products;
b) Selling the products, special presentations, discount coupons, sales subject to conditions, gifts, prizes, etc;
c) Free distribution of products;
d) Promotions for financial benefits, distribution of gifts with the names or logos of the mentioned products;
e) Distribution and showcase of printed, audio and/or visual materials, targeting pregnant woman, woman in lactation stage, and general public;

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

The labels of any maternal milk supplement product, and special or follow-up infant formula, must contain the following:

© 2012 Lex Mundi

a) A warning message "AVISO IMOPRTANTE" that is visually notorious which indicates that maternal milk feeding is superior to any other option at least for the first six months of the child's age, i.e., "MATERNAL MILK IS THE BEST OPTION TO FEED YOUR BABY, IT IS RECOMMENDED TO BE USED EXCLUSIVELY DURING THE FIRST SIX MONTHS OF FEEDING" (this statement must be printed close to the product name, in big and notorious font letters).
b) Inform about the analytical composition, ingredients, including the use of additives, preservatives, among others, and directions on the proper use of the product;
c) Label must be printed in Spanish;
d) It must contain the name and address of the producer;
e) The label must be designed with a purpose to NOT TO DISCOURAGE the use of maternal milk;
f) The package must contain the expiration date, prohibiting its sale and use after it is expired, must also include the lot number, and the conditions to dispense after opening, if any;
g) It must contain a photograph, design or graphic to illustrate the correct preparation of the product;
h) Preparation instructions, additional appropriate hygiene measures, and the age of the intended user.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Mexico
Name	NAN PRO1
Ingredients	Lacteal formula powder based de with iron and pro-biotic for lactates
Amount of the product	900 grams
Obligatory information, warnings or statements	FOR BOLIVIA: IMPORTANT MESSAGE: MATERNAL MILK IS THE BEST FOOD FOR YOUR BABY
Optional statements	Prior to using the infant formula, consult with your health physician
Language	Spanish
General features of a label	Any color permitted
Other remarks	

Contact Information

Antonio Sanjinez
antonio@rojas-lawfirm.com

C.R.& F Rojas – Attorneys
Calle Federico Zuazo 1598
Edif. Park Inn - Piso 11 - P.O. Box 662
La Paz, Bolivia

Tel 591.2.231.3737 Fax 591.2.211.2775
www.rojas-lawfirm.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Brazil

Prepared by Lex Mundi member firm Demarest e Almeida

1. What is the definition of a food supplement in your jurisdiction?

Food supplements are food products made with food ingredients and can be added either synthetic nutrient identical to the present in foods.

The ANVISA ordinance Nº 222 of March 24, 1998, brings the following definitions:

Hydroelectrolitic reposition: Products formulated from varied concentration of electrolytes, associated with varying concentrations of carbohydrates, with the objective of fluid and electrolyte reposition from physical activity.

Repositories of Energy: These products are formulated with nutrients that enable the achievement and maintenance of appropriate level or energy for athletes.

Protein foods: These are products with a predominance of protein(s), hydrolyzed(s) or not, in its composition, formulated with the aim of increasing the intake of nutrient(s) or supplement the diet of athletes, whose protein needs are not being satisfactorily met by the usual food sources.

Food Compensators: These products are formulated in different ways for use in the nutrient adequacy of the diet of physically active.

Branched chain amino acids: These are products made from varying concentrations of branched chain amino acids, with the objective of providing energy for athletes.

Other foods with specific purposes to practitioners of physical activity: These products are formulated in different ways with specific metabolic purposes, to physical activity.

2. Are the ingredients of food supplements regulated?

The ingredients used in these dietary supplements must comply with regulations brought in ANVISA item 4 of Ordinance No. 222, as the amount of vitamins and minerals, based on daily values optimal nutrition.

Some of these supplements can contain carbohydrates and fats, if the sum of percentages of total caloric value of both does not exceed the percentage of protein.

In Branched Chain Amino Acid (valine, leucine and isoleucine), singly or in combination, should be at least 70% of energetic nutrients in the formulation, providing the recommended daily intake of up to 100% of the daily needs of each amino acid.

It allowed the use of additives in the same limits for conventional food, provided they are not going to change the purpose for which the feed is proposed.

© 2012 Lex Mundi

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

According to the ANVISA Ordinance Nº 222, these Food for Physical Activity Practitioners are subject to the same administrative procedures for registration of food in general.

For Hydroelectrolitic Reposition, the company must submit a declaration that the product is compatible with the purpose of use to which it proposes, demonstrating by calculation and/or laboratory analysis.

There is a tendency to become more exigent the requirements for trading these products. It was found a Public Consultation by ANVISA on 2008, suggesting a regulation that restricts the use of dietary supplements to professional athletes only, which would reduce drastically the possibility of trading these products.

Given the rejection of the considerable number of consumers of those products, besides the companies related to this area, the regulation change did not succeed, remaining the effect of what is stipulated in ANVISA Ordinance Nº 222.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

The labeling of products classified by ANVISA Ordinance Nº 222, in addition to the words required for foods in general, should include:

In the main panel:

Appropriate designation among the items: Hydroelectrolitic Reposition, Repositories of Energy, Protein foods; Food Compensators; Branched chain amino acids, or other foods with specific Purposes to practitioners of physical activity.

In the other panels:

For the Repositories of Energy, the guidance highlighted and bold: "Children, pregnant women and elderly consume preferably under the guidance of a nutritionist and/or doctor."

Protein foods and for the Branched Chain Amino Acids, the recommendation highlighted and bold: "Children, pregnant women, elderly and patients with any illness should consult their doctor and/or nutritionist".

For Hydroelectrolitic Reposition the recommendation highlighted and bold: "It is recommended that patients with diseases to consult a doctor or nutritionist before consuming this product."

It is required the nutritional information in accordance with the Rules of Nutritional Labeling on binding.

Are prohibited expressions such as "steroids", "body building", "muscle hypertrophy", "fat burners", "increase in sexual ability," or equivalent.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	ANVISA Ordinance Nº 222
Ingredients	Vitamins, Minerals, Carbohydrates, Protein, Fats, Branched chain amino acids
Amount of the product	These products above might be on stipulated proportions according

© 2012 Lex Mundi

	to the Designation on ANVISA Ordinance Nº 222. Hydroelectrolitic reposition must have varied concentrations of sodium, chloride and carbohydrates. Optionally, these products may contain potassium, and vitamins or minerals. On Repositories of Energy, carbohydrates should constitute at least 90% of energetic nutrients in the formulation. Optionally, these products may contain vitamins and or minerals. Protein foods should be composed of at least 65% protein nutritional quality equivalent to proteins of high biological value, which are made from the intact or hydrolyzed protein. The addition of specific amino acids is permitted to restore the concentrations of the same levels of the original food, lost function in the processing, or to address specific limitations of formulated products based on incomplete proteins, in an amount sufficient to achieve high biological value. Optionally, these products may contain vitamins and or minerals. They may also contain carbohydrates and fats, provided that the sum of the percentage of total caloric value of both does not exceed the percentage of protein. Food Compensators must contain varied concentrations of nutrients, according to the following requirements: Carbohydrates below 90%, Protein at least 65% should correspond to the high biological value protein, fats, with a ratio of one third saturated fat, 1/3 monounsaturated and 1/3 polyunsaturated, optionally, these products may contain vitamins and/or minerals. Branched Chain Amino Acids (valine, leucine and isoleucine), singly or in combination, should be at least 70% of energetic nutrients in the formulation, providing the recommended daily intake of up to 100% of the daily needs of each amino acid.
Obligatory information, warnings or statements	Appropriate designation among the items: Hydroelectrolitic Reposition, Repositories of Energy, Protein foods; Food Compensators; Branched chain amino acids, or other foods with specific Purposes to practitioners of physical activity. Are prohibited expressions such as "steroids", "body building", "muscle hypertrophy", "fat burners", "increase in sexual ability," or equivalent.
Language	Portuguese
General features of a label	The same requirements for foods in general, according to ANVISA.
Other remarks	For the Repositories of Energy, the guidance highlighted and bold:

© 2012 Lex Mundi

	"Children, pregnant women and elderly consume preferably under the guidance of a nutritionist and/or doctor." Protein foods and for the Branched Chain Amino Acids, the recommendation highlighted and bold: "Children, pregnant women, elderly and patients with any illness should consult their doctor and/or nutritionist". For Hydroelectrolitic Reposition the recommendation highlighted and bold: "It is recommended that patients with diseases to consult a doctor or nutritionist before consuming this product."

Contact Information

Renato Poltronieri
da.sp@demarest.com.br

Demarest e Almeida
Av. Pedroso de Moraes, 1201
Centro Cultural Ohtake
Sao Paulo, 05419-001 Brazil

Tel 55.11.3356.1800 Fax 55.11.3356.1700
www.demarest.com.br

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Costa Rica

Prepared by Lex Mundi member firm Facio & Cañas

1. **What is the definition of a food supplement in your jurisdiction?**

   A food supplement is every food product that supplies vitamins, minerals, proteins, carbohydrates or some other nutritional ingredient destined to complement the normal diet. It is not a common food product, and it has a nutritional or physiological effect that aims to enrich the nutrients that a person's body needs.

   A food supplement normally follows the same registration procedure that a regular food product requires, but there are some exceptions. If the food supplement contains some kind of plant among its ingredients, it should be registered as a natural product. On the other hand, if it supplies a bigger dose than the fifty percent of nutrients required in a normal daily diet, it should be recorded as a medicine product. The range used in Costa Rica to measure the normal daily diet is the one provided by the World Health Organization.

2. **Are the ingredients of food supplements regulated?**

   Yes. They are ruled by the same stipulations established for ordinary food, natural or medicine products in each case.

   When there is no enacted rule on some matter, the Costa Rican Health Ministry applies the regulations adopted by the Codex Alimentarius Commission. On the matter, the Codex Commission has enacted the Guidelines for Vitamin and Mineral Food Supplements, in which they provide criteria for establishing the maximum amounts of vitamins and minerals that should be consumed on a daily basis.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   The procedure for launching the product is the same procedure for introducing any other food product to the market. It can be registered directly at the Costa Rican Health Ministry webpage. The person responsible for the registration process is given a user password. This information system is controlled by the Registries and Controls Division of the mentioned ministry. They have to file for the Sanitary Permits before starting the process online.

   A product can be registered by a physical person or a legal entity. For doing it for the first time, a legal statement should be filed at Customer Service.

   Only products that have been manufactured in establishments with the necessary operation permit can be registered. In case of an imported product, it must be traded freely in its country of origin.

   To start the process online, you have to give certain information such as name, brand, description of the product, country of origin, etc.

© 2012 Lex Mundi

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

They are the same for all food products. However, the products that have been registered as a medicine or natural product are regulated differently.

The table below shows the legislation established for the nutritional labeling of different types of food:

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Name of the laboratory or company and country of origin. In case that the product is manufactured by a third party, it should include the name and country of origin of the labs involved in the process.
Name	Commercial, brand name or drug denomination.
Ingredients	List of ingredients specifying its quality and quantity in percentages and in descending order. Active ingredients full name. Every product that contains some kind of nutrient must provide this quantity information: a) Energetic value. It must be calculated using the following formula: (4,189 kJ = 1 kcal), and the unit of the International System must be used. b) Proteins. c) Carbohydrates. d) Fat. e) Total amount of specific nutrients and other components. This declaration must be shown numerically; however, that does not exclude any other kind of presentation. f) Total amount of sugars. The complementary nutritional information looks forward to facilitate the consumer comprehension of the nutritional value of the product. This is facultative and complementary to the main information about the amount of nutrients.
Amount of the product	Quantity or net volume of the product in the package.
Obligatory information, warnings or statements	Registration number. Lot number. Expiration date. Dose. Sanitary number (medicinal products). Storage conditions and use indications are obligatory for products registered as medicine. Every product must contain the following statements: - Keep out of children reach. - If the symptoms continue, ask your doctor or pharmacist. - Do not use in pregnant or breastfeeding women.

© 2012 Lex Mundi

	- The Costa Rican Health Ministry does not support indications other than those approved for this specific product. Any other warning a specific product may have.
Optional statements	Use indications. Storage conditions, if they are needed. The information must be placed near the expiration date.
Language	Labeled in Spanish. Labels in other languages are accepted if they contain the same information than the one duly translated into Spanish.
General features of a label	The label and information must be clear, legible and easily understandable.
Other remarks	

Contact Information

Kathya Araya
karaya@fayca.com

Milagro Chaves
mchaves@fayca.com

Facio & Cañas
Apartado 5173
1000 San Jose, Costa Rica

Tel 506.2256.5555 Fax 506.2255.2510
www.fayca.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Cyprus

Prepared by Lex Mundi member firm Dr. K. Chrysostomides & Co LLC

1. What is the definition of a food supplement in your jurisdiction?

'Food supplement' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional and physiological effect, alone or in combinations, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

2. Are the ingredients of food supplements regulated?

A food supplement may contain only those vitamins and minerals mentioned in Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and Council Regulation (EC) No 1925/2006 of the European Parliament and Council on lists of vitamins and minerals and their forms that can be added to foods, including food supplements.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

There is a specific procedure established in relation to food supplements. The food supplements which are legally marketed in a Member State of the EU, other than the Republic of Cyprus, are put on the Cypriot market after notification to the Director of the Department of Medical Services and Public health Services of the Ministry of Health, provided that they exclusively contain vitamins and minerals that are set out in the Regulations on Food Supplements of 2004 and only if the recommended dose:

a) (i) covers not less than 15% of the recommended daily dose;
   (ii) does not exceed the maximum security limit
b) is in accordance with the manufacture guidelines of the manufacturing Member State or the Member State marketed first.

The said notification must include the following information:

a) details of the person making the notification and of the person responsible for the marketing of the product;
b) name of the product;
c) a sample of the labeling of the product.

The food supplements which do not fall under the above category, are subject to an approval procedure by the Director of the Department of Medical Services and Public health Services of the Ministry of Health, with the issuance of a five-year, renewable license for the marketing of the product. The issuance of the said license is subject to, among others, the existence of a certificate for the lawful marketing of the product at the manufacturing country or Member State and a license for the manufacture or packaging for the products manufactured in the Republic of Cyprus or in a third country.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

The packaging, labeling and presentation of the food supplements must comply with the general

© 2012 Lex Mundi

requirements which apply for all food products under Labeling, Presentation and Advertising (General) Regulations. Additionally, the labeling of the food supplements must also include the following:

a) the name of the product which is going to be sold as a 'food supplement';
b) the name of the categories of the nutrients or substances which characterize the product or a denotation relevant to the nature of the said nutrients or substances;
c) the quantity of the nutrients or substances with nutritional or physiological effects, which are included in the product, in numbered form and in the units which are used regarding vitamins and minerals;
d) the portion of the product recommended for daily consumption;
e) a statement to the effect that food supplements should not be used to substitute for a varied died;
f) a warning not to exceed the stated recommended daily dose;
g) a statement to the effect that the products should be stored out of the reach of young children.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	required
Name	the name of the product which is going to be sold as a 'food supplement'
Ingredients	the name of the categories of the nutrients or substances which characterize the product or a denotation relevant to the nature of the said nutrients or substances
Amount of the product	Net weight
Obligatory information, warnings or statements	(a) the portion of the product recommended for daily consumption; (b) a statement to the effect that food supplements should not be used to substitute for a varied died; (c) a warning not to exceed the stated recommended daily dose; (d) a statement to the effect that the products should be stored out of the reach of young children
Optional statements	NA
Language	Greek obligatory; any out of the official EU languages
General features of a label	NA
Other remarks	-

Contact Information

Alexandros Georgiades
a.georgiades@chrysostomides.com.cy

Maria Pilikou
m.pilikou@chrysostomides.com.cy

Dr. K. Chrysostomides & Co LLC
1, Lampousas Street
P.O. Box 22119
1095 Nicosia, Cyprus

Tel 357.22.777000 Fax 357.22.779939
www.chrysostomides.com.cy

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Czech Republic

Prepared by Lex Mundi member firm PRK Partners

1. **What is the definition of a food supplement in your jurisdiction?**

   The definition is in line with definition used in EU Directives. Food supplements are foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, contained in the foodstuff alone or in combination, designed to be taken in measured small unit quantities.

2. **Are the ingredients of food supplements regulated?**

   The ingredients of food supplements are regulated in Public Notice No. 225/2008 Coll., setting out the requirements for food supplements and foodstuff upgrading. Use of vitamins and minerals other than those listed in the Public Notice is possible based on prior consent of the Ministry of Healthcare of the Czech Republic.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   Before setting afloat a food supplement the producers and distributors are obliged to send to the Ministry of Healthcare of the Czech Republic (with a copy to the Ministry of Agriculture of the Czech Republic) a notification with the Czech labeling text which will be stated on the packaging of the product.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   In addition to general requirements regarding packaging, labeling and presentation of food products, the following specific requirements apply to food supplements:
   - Packaging is mandatory;
   - Advertisements must contain the clearly visible and legible designation “food supplement;

   For specific labeling requirements please see the table below.

   Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	General requirements for food products apply.
Name	The word “food supplement” must be stated in the name of the product.
Ingredients	- The names of vitamins, minerals and other substances that characterize the product must be stated; - Amounts of vitamins, minerals and other substances related to the recommended daily dose must be declared in numerical form; - Amounts of vitamins and minerals must be declared as percentage of the recommended daily dose as well.
Amount of the product	General requirements for food products apply.

© 2012 Lex Mundi

Obligatory information, warnings or statements	- Recommended daily dose and other conditions of usage; - Warning against exceeding the recommended daily dose; - Notice that the products should be stored out of reach of children,; - Warning that food supplements do not substitute for a varied diet; - Warning "Not suitable for pregnant women" if the food supplement contains more than 800 micrograms of vitamin A in the daily dose; - Labeling of products containing Cimicifuga racemosa must contain a warning to interrupt consumption of the product and seek a physician's advice in case of suspicion of liver disease.
Optional statements	No special optional statement for food supplements.
Language	Czech language is mandatory.
General features of a label	Labeling must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.
Other remarks	Labeling must not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Contact Information

Jan Kohout
jan.kohout@prkpartners.com

Mgr. Monika Mašková
monika.maskova@prkpartners.com

PRK Partners
Jáchymova 2, 110 00 Prague 1
Czech Republic

Tel 420.221.430.111 Fax 420.224.235.450
www.prkpartners.com/en/

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Estonia

Prepared by Lex Mundi member firm LAWIN

1. What is the definition of a food supplement in your jurisdiction?

A food supplement is food the purpose of which is to supplement regular food and which is a concentrated source of nutrients or other substances with nutrient or physiological effect for humans. Such substances may be presented individually or in combinations and are placed on the market in sales packaging and in specified doses, such as capsules, pastilles, tablets and other similar products, as well as sachets of powder, ampoules with liquid, drop-bottles, etc., designed for using liquid or powder in small measured quantities. (Article 14^1(1) of Food Act)

Food supplements should be distinguished from pharmaceuticals products – i.e. any substance or combination of substances intended for the prevention, diagnosis or treatment of a disease or disease symptom, for the relief of a disease condition in a human or animal, or for the restoration or alteration of vital functions in a human or animal through pharmacological, immunological or metabolic effect (Article 2(1) of Pharmaceuticals Act). Pharmaceuticals can be sold only through pharmacies in Estonia. It is up to the State Agency of Medicines to classify the status of substances and products as pharmaceuticals.

2. Are the ingredients of food supplements regulated?

Food supplements may contain only such vitamins and minerals which are mentioned in the Regulation No. 165 of 30 April 2004 of the Government of the Republic of Estonia “Content and quality requirements for food supplements and special requirements for labeling and other means of presentation of information” and Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

Upon the first placing on the market of a nutritional supplement, the person responsible for placing it on the Estonian market (i.e. manufacturer or importer) is required to inform the Veterinary and Food Board no later than on the day when it is placed on the market by delivering by post the specimen of labelling to be used with the food supplement, together with the notice. The notification must include at least following information: name, place of residence and contact details of the supplier; name of the food supplement; date of placing the food supplement on the market.
Further to receiving the notification, Veterinary and Food Board will review the notification and register the food supplement in its data base. There is no need to obtain an approval from Veterinary and Food Board or wait until the registration is done before launching the food supplement.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General rules of food labeling apply also to labeling of food supplements. However, there are some regulations specific for supplements. The below table presents elements of the food supplement’s label (resulting from both general and specific rules).

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	Estonia
Source/ origin	Label must indicate: • producer or packing entity or entity launching the supplement into the market; • place or source of origin, if lack of such information may mislead the consumer.
Name	• The trade name of the product and the term "food supplement" must be used.
Ingredients	List of ingredients which should contain the following: • names of ingredients, • name of the group of the nutritional substance or other substance characterizing the product or a reference to their characteristics; The content of nutrient or other substance having nutritional or physiological effect is shown on the labeling in numbers by using the units set forth in the regulation establishing the labeling requirements. The said content is shown per recommended daily dosage and it should be an average value, which is received during the chemical analysis of the nutritional supplement conducted by the manufacturer. Information regarding the content of vitamins and mineral nutrients is reflected also as a percentage of the recommended daily dosage for an adult. Such percentage can be shown also graphically.
Amount of the product	Net weight
Obligatory information, warnings or statements	• Shelf life; • Lot number; • Usage instructions, if the right use of the product would not be procured in the case of the lack of such information; • Recommended daily dosage; • Warning that the recommended daily dosage should not be exceeded; • Warning that the food supplement should not be used as substitute for diverse diet, • Warning that the product should be kept out of the reach of the children.
Optional statements	• Recommendations for use, if necessary. • Storage instructions, if necessary. The information must be placed in the proximity of period of use. • If applicable, relevant statements regarding sweeteners, liquorices etc. must be placed.
Language	Estonian is obligatory; other language versions may be added.
General features of a label	The label and information on it must be fixed with the product, must be clear legible, easily understandable, wear proof and cannot be covered by any other prints or designs.
Other remarks	It is not allowed to refer on labeling or upon providing information in any other way with regard to the nutritional supplement that a balanced and diverse diet does not ensure required amount of nutrients.

© 2012 Lex Mundi

Contact Information

Pirkko-Liis Harkmaa
pirkko-liis.harkmaa@lawin.ee

Katri Paas
katri.paas@lawin.ee

Erik Lepik
erik.lepik@lawin.ee

LAWIN
Niguliste 4
10130 Tallinn, Estonia

Tel 372.630.6460 Fax 372.630.6463
www.lawin.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Finland

Prepared by Lex Mundi member firm Roschier, Attorneys Ltd.

1. What is the definition of a food supplement in your jurisdiction?

A food supplement is defined in Section 1 of the Decree on Food Supplements (78/2010, in Finnish: *Maa- ja Metsätalousministeriön asetus ravintolisistä*) as a pre-packaged product marketed as a foodstuff and sold in the form of a pellet, capsule, pastille, tablet, pill, powder, concentrate, extract, liquid or some other form, the purpose of which is to supplement the diet through the nutrients or other substances it contains or influence the nutritional or physiological functions of people in some other way. Food supplements are to be taken in small doses and the amount of energy obtained from them shall be insignificant.[1]

Products classified as medicinal products under the Medicines Act (395/1987, in Finnish: *Lääkelaki*) are not considered as food supplements. Medicinal products are defined in Section 3, Chapter 1 of the Medicines Act as products, substances and combinations thereof intended for internal or external use to treat, alleviate or prevent a disease or its symptoms in humans or animals, or to establish the state of health or the cause of a disease or to restore, alter or modify physiological functions in humans or animals through pharmacological, immunological or metabolic effect. Medicinal products must, as a rule, have a marketing authorization or be registered by the Finnish Medicines Agency Fimea.

2. Are the ingredients of food supplements regulated?

According to Section 3 of the Decree on Food Supplements, food supplements may contain only those vitamins and minerals listed in the Commission Regulation (EC) 1170/2009 (EC) amending Directive 2002/46/EC of the European Parliament and Council and Council Regulation (EC) 1925/2006.

There are currently no detailed provisions with regard to other substances used in food supplements, including plants, plant extracts, herbs, bee products, microbes, bone meal, dolomite, ashes, horn powder and organic matter. Food supplements may therefore contain such substances subject to general food safety requirements as laid down in the Food Act (23/2006, in Finnish: *Elintarvikelaki*) and relevant EC food safety law (in particular, Council Regulation(EC) 178/2002 laying down the general principles and requirements of food law).

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

By virtue of Section 7 of the Decree on Food Supplements, the manufacturer and importer of a food supplement is required to file a notification with the Finnish Food Safety Authority Evira ("Food Supplement Notification"). A Food Supplement Notification must also be filed if the ingredients of the food supplement with regard to its characteristic substances are altered, and when the food supplement is withdrawn from the market. The label and package design must be attached to all of the above notifications.

Evira has issued more detailed guidelines regarding the contents of a Food Supplement Notification. The Notification must be filed no later than in connection with the launching of the food supplement on the

[1] The Finnish Food Safety Authority Evira has taken the view that the amount of energy obtained from a food supplement is insignificant for the purposes of the Decree on Food Supplements if it does not exceed 200 kJ (50 kcal) per day.

© 2012 Lex Mundi

Finnish market. According to the guideline, the Notification must include, *inter alia*, the following information: name and contact details of the supplier, name and trade name(s) of the food supplement, information on the characteristics substances as well as a list of ingredients, country of origin, intended use, recommended dosage and minimum shelf life.

Evira reviews the Food Supplement Notification and, provided that the Notification contains all of the required information, forwards the Notification to the relevant municipal authorities for supervisory purposes. Evira does not, however, assess the compliance of the food supplement or the labeling and packaging with applicable laws and regulations – this is the responsibility of the manufacturers and importers within the context of the mandatory in-house control procedures set forth in the Food Act.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

The general rules applicable to packaging, labeling and presentation apply also to food supplements. In addition, some further requirements related to packaging and labeling specific to food supplements are set forth in Section 5 of the Decree on Food Supplements. These specific requirements are included in the below table.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Label must indicate: • Name, trade name or secondary trade name and address of the manufacturer, packager or a seller operating in the EU • Source and country of origin, if the lack of said information may mislead the consumer
Name	The name must: • Briefly and accurately state what foodstuff is are contained in the package (*e.g.* calcium tablet, oat shoot extract). Note that the term 'food supplement', which must also be indicated, does not by itself constitute sufficient information. • A trademark or trade name cannot be used to replace the name of the food product. • The trade name(s) or part of the name must not be the same as a name of a medicinal product or a herbal medicinal product.
Ingredients	An ingredient means a substance or product, including additives, that have been used in the manufacture of a foodstuff and that remain in the final foodstuff in one form or another. With regard to ingredients, the following information must be included: • All ingredients must be listed by weight from heavier to lighter in accordance with the formula. • Names of the group of nutritional substances or other substances that are characteristic to the food supplement in question. • Vitamins and minerals should, in the interest of conformity and clarity, be declared in the list by their chemical name (e.g. ascorbic acid or thiamine hydrochloride) (opinion of Evira). • Any substances potentially causing hypersensitivity (e.g. grains and cereals containing gluten (wheat, rye, barley, oats, spelt, kamut), eggs and egg products, fish and fish products, peanuts and peanut products) must always be included in the list of ingredients.
Amount of the product	Net weight
Obligatory information,	The following information and warnings must be included: • Term 'food supplement' • Names of characteristic nutrients or substances, or an indication of the nature

© 2012 Lex Mundi

warnings or statements	of these nutrients or substances • Quantities of characteristic substances in a daily dose of food supplement • Best before marking or last date of use • Identification code of the foodstuff batch • Recommended daily dose Warnings • Recommended daily dose must not be exceeded • Food supplement must not be used as a substitute for a varied diet • Product must be kept out of reach of small children Evira publishes an updated list of warning requirements for specific products at http://www.evira.fi/attachments/elintarvikkeet/valvonta_ja_yrittajat/pakkausmerkinnat/varoitusmerkinnat_taulukko.pdf (in Finnish)
Optional statements	• Storage instructions if necessary • Instructions of use if necessary • Alcohol content of drink and solid food if necessary
Language	All mandatory information must be included on the packaging/label in Finnish and Swedish (both are official languages in Finland). Alternatively, labeling in Swedish may be replaced with Danish or Norwegian labeling, if said labeling is understandable and clear to Swedish speaking consumers.
General features of a label	Labelling in general, and warnings in particular, must be • easily visible; • in sufficiently large print; • easily readable; • understandable; and • made in a permanent manner. Labelling must not be untruthful or misleading.
Other remarks	According to Section 5 of the Decree on Food Supplements, the labeling and/or packaging of food supplements may not contain statements to the following effect: • That a balanced and varied diet does not ensure a sufficient amount of nutrients. • That the food supplement may be used for the treatment, prevention or cure of diseases in humans.

Contact Information

Mikael Segercrantz
mikael.segercrantz@roschier.com

Rasmus Sundström
rasmus.sundstrom@roschier.com

Roschier, Attorneys Ltd.
Keskuskatu 7 A
Helsinki, 00100 Helsinki, Finland

Tel 358.20.506.6000 Fax 358.20.506.6100
www.roschier.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Greece

Prepared by Lex Mundi member firm Zepos & Yannopoulos

1. What is the definition of a food supplement in your jurisdiction?

Under Ministerial Decision ΥΑ Υ1/Γ.Π. 127962/03 (Government Gazette B 395/27.02.2004) (hereinafter referred to as "the Ministerial Decision") implementing in Greece Directive 2002/46, "food supplements" are the foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect (edible extracts of vegetables or other substances of plant origin with nutrient ingredients such as vitamins, metals, amino acids, proteins, antioxidant substances), alone or in combination, which are marketed in dose forms, such as capsules, pastilles, tablets, pills and other similar forms as well as in sachets of powder, ampoules or liquid drops, drop dispensing bottles and other similar forms of liquids and powders designed to be taken in small unit quantities.

The Ministerial Decision is not applicable on pharmaceutical products.

It is worth mentioning that under the Ministerial Decision, food supplements may be only sold through pharmacies. Although the relevant provision setting forth the said restriction has been challenged, the Council of State (i.e. the Supreme Administrative Court) has recently held that this restriction is not in breach of EU Law and that it is fully justified. It should be stressed however, that the relevant restriction has never been fully enforced in practice.

2. Are the ingredients of food supplements regulated?

Food supplements may only contain the vitamins and minerals which are set forth in Annex I of the Ministerial Decision ΥΑ Υ1/Γ.Π. 127962/03 and only in the form set forth in Annex II of the Ministerial Decision.

The relevant list has been amended by virtue of Commission Regulation (EC) 1170/2009 which has entered into force on 21.12.2009.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

The placing of food supplements in the Hellenic market is not subject to a special licensing procedure nor does it require the prior approval of the Hellenic Medicines Organization ("EOF"). However, the entity manufacturing or placing in the Hellenic market food supplements is required to directly notify EOF of such placement in the market.

The notification is effected by submitting to EOF an application which must contain specific information on the product (such as, indicatively, the trade name of the product, the particulars of the applicant, the composition of the product, any ingredients which are not included in Annex II of the Ministerial Decision ΥΑ Υ1/Γ.Π. 127962/03 or exceed the limits set by Annex II of the said Ministerial Decision, a description of the product's packaging and labelling etc).

The applicant must also pay a special notification fee and submit the product's instruction of use, if such instructions are available.

© 2012 Lex Mundi

In case it results from the notification that the product under consideration does not meet the requirements set forth by the pertinent legal framework, EOF informs the applicant that: (i) the product does not qualify as a "food supplement" and thus it may not be placed in the market as such or (ii) that the product under consideration does qualify as a "food supplement", but its presentation does meet the requirements set forth by the Ministerial Decision.

The entity which is responsible for placing the product in the market is required to comply with the Decision sent by EOF within 60 days; otherwise sanctions in the form of fines are imposed. The compliance of the food supplement traders with this obligation is not strictly monitored by EOF, save on a case by case basis.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

As a general rule, the labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing human disease, or refer to such properties.

Further, the labelling must include the following information:

a) the names of the categories of nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances;
b) the daily recommended dose;
c) a warning not to exceed the daily recommended dose;
d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
e) a statement to the effect that the products should be stored out of reach for young children.

Finally, the labelling, presentation and advertising of food supplements must not explicitly state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

For more information on the labelling of food supplements, please refer to the table below.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Particulars of the place of origin or provenance, in case failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the food supplement under consideration.
Name	▪ The products under consideration must be sold under the name "food supplement". ▪ The name or business name and address of the manufacturer or packager, or of a seller established within the Community must be indicated.
Ingredients	List of the ingredients should be included. Further, the amount of nutrients or substances with a nutritional or physiological effect shall be declared on the labelling in numerical form. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.
Amount of the product	Net weight
Obligatory information,	▪ The name "food supplement";

© 2012 Lex Mundi

warnings or statements	▪ The names of the categories of nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances; ▪ The net weight; ▪ Shelf Life; ▪ Lot Number; ▪ Existence of allergens, if any; ▪ The name or business name and address of the manufacturer or packager, or of a seller established within the Community; ▪ Particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the food supplement under consideration; ▪ Instructions of use when it would be impossible to make appropriate use of the food supplement in the absence of such instructions; ▪ The daily recommended dose; ▪ A warning not to exceed the daily recommended dose; ▪ A statement to the effect that food supplements should not be used as a substitute for a varied diet; ▪ A statement to the effect that the products should be stored out of reach for young children.
Optional statements	Optional statements are allowed, in case they do not breach the rules set forth by the pertinent legal framework, i.e. in case they are not misleading for the consumer as to the characteristics of the product and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production, when they do not attribute to the food supplement effects or properties it does not posses and when they do not suggest that the product under consideration possesses special characteristics, when in fact all similar products possess such characteristics. Further any statements included must not explicitly state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.
Language	Greek is obligatory both for the labelling as well as for the instructions of use, if any.
General features of a label	-
Other remarks	**-**

© 2012 Lex Mundi

Contact Information

Marina Kolia
m.kolia@zeya.com

Sofia Chatzigiannidou
s.chatzigiannidou@zeya.com

Zepos & Yannopoulos
75 Katehaki & Kifissias Ave.
Athens, 115 25 Greece

Tel 30.210.6967000 Fax 30.210.6994640
www.zeya.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Hungary

Prepared by Lex Mundi member firm Nagy és Trócsányi

1. **What is the definition of a food supplement in your jurisdiction?**

   According to **Section 2. point a) of Ministry of Health, Social and Family Affairs Decree 37/2004[2] on food supplements**, the definition of a food supplement is the following:

   Food supplement: Food which serves as supplement of standard food, and contains nutriments or other substances with dietetic or physiological effect, in concentrated form, and released in portions, or in dividable form (e.g.: capsule, pastille, tablets, sachet that contains powder, dividable powder, ampoule, dropper bottle or other similar powder or liquid form, that fits for dosing small amounts).

2. **Are the ingredients of food supplements regulated?**

   Ministry of Health, Social and Family Affairs Decree 37/2004 on food supplements Annex 1. list the vitamins and mineral compounds that can be used for the manufacture of food supplements.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   Ministry of Health, Social and Family Affairs Decree 37/2004 on food supplements *fixes, that in the* Republic of Hungary, food supplements shall be launched in accordance with the regulations of this decree. These regulations prescribe the followings:

   The manufacturer or importer is obliged to report the product by the Országos Élelmezés-és Táplálkzástudományi Intézet (National Institute for Food and Nutrition Science) (OÉTI), by informing it about the data listed in Annex 4. of the Decree. If necessary, OÉTI can request further data related to the product. If the product is already in commerce in any member state of the European Economic Area, the manufacturer or the importer shall submit the data presented, when the product was reported for the first time, in English or Hungarian to OÉTI, and shall name the institution to which the first report was submitted.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   According to **Ministry of Health, Social and Family Affairs Decree 37/2004 on food supplements,** all regulations regarding food products apply for food supplement also, but there are special requirements that food supplements have to fulfill. These are the followings:

   a) Food supplements shall be launched to consumers exclusively in pre-packed form.
   b) It is forbidden to declare, that a food supplement is capable of preventing or healing disease when advertising, portraying or denoting it.

[2] 37/2004. (IV. 26.) ESzCsM rendelet az étrend-kiegészítőkről

© 2012 Lex Mundi

c) Besides the general rules concerning the denotation of food products, the denotation of food supplements shall include the followings:
    i. The names of the characteristic nutriments or components of the food supplement, or reference to them.
    ii. The daily amount of the food supplement recommended.
    iii. Warning to the consumer to not to exceed the recommended daily amount.
    iv. Notice to the consumer that the food supplement does not replace the diverse nutrition.
    v. Warning, that the product shall be stored locked from children.
d) It is forbidden to declare, that divers, balanced nutrition is not eligible to gain the necessary nutriments when advertising, portraying or denoting the food supplement.
e) The amount of nutriments or other substances with dietetic or physiological effect in the food supplement shall be indicated numerically on the denotation of the product.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	It is necessary to indicate on the package the place of origin and the name of the manufacturer, or the distributor, if it has its seat in one of the member states of the European Economic Area.
Name	The name of the product has to be indicated also.
Ingredients	On the package it is necessary to list the names and amounts of the ingredients the product consists of.
Amount of the product	The amount of the product also has to be indicated.
Obligatory information, warnings or statements	Warning to the consumer to not to exceed the recommended daily amount, notice to the consumer that the food supplement does not replace the diverse nutrition and warning, that the product shall be stored locked from children shall be indicated on the package.
Optional statements	The law regulates no optional statements regarding food supplements
Language	These peaces of information shall be indicated in Hungarian language
General features of a label	The label of a dietary supplement is required to indicate extra information compared to ordinary food products, as summarized in the answer to question 4.
Other remarks	The recommended daily amount shall be indicated in percentage also. We note that labeling issues are priority matters for the National Consumer Protection Agency (NFH).

Contact Information

Dr. Orsolya Kovács
kovacs.orsolya@nt.hu

Nagy és Trócsányi
Ugocsa utca 4/B
Budapest, 1126 Hungary

Tel 36.1.487.8700 Fax 36.1.487.8701
www.nt.hu

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Ireland

Prepared by Lex Mundi member firm Arthur Cox

1. What is the definition of a food supplement in your jurisdiction?

The legal definition of a food supplement in Ireland is found in The European Communities (Food Supplements) Regulations 2007, S.I. No. 506 of 2007 (the "Irish Food Supplement Regulations") This legislation gives effect to Directives 2002/46/EC and 2006/37/EC (the "Food Supplement Directives"). A food supplement is defined by the Irish Food Supplement Regulations as: "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities "

Food supplements are distinguished from medicinal products. A medicinal product is defined in Directive 2001/83/EC as: "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis".

2. Are the ingredients of food supplements regulated?

In Ireland, food supplements and their ingredients are subject to general food law as well as additional specific rules for vitamins and minerals used as ingredients in food supplements. A food supplement may only contain such vitamins and minerals listed in the annexes to the Directives as amended by Regulation 1170/2009/EC, and Schedule 1 and 2 of the Irish Food Supplement Regulations. Regulation 1170/2009/EC amends Directive 2002/46/EC as regards the lists of vitamins and minerals and their forms which can be added to food. Other substances used as ingredients must be safe, and food business operators should ensure they are not considered medicinal products or novel foods. Food supplements with vitamin and mineral levels at, or above, prescription levels are considered medicinal products and are under the remit of the Irish Medicines Board.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

Yes, there is a specific procedure in place for the launch of a food supplement on the Irish market. Any person placing a food supplement on the market in Ireland for the first time must notify the Food Safety Authority of Ireland. The obligation to notify is dependant upon the method of introduction to Ireland. If the product is manufactured in Ireland, the duty to notify falls on the manufacturer. If, however, the product is imported, it is the importer who must make the notification. This requirement applies irrespective of product country of origin. A separate notification must be made in respect of each product and indeed each flavour of product, for products which come in different flavours. The notification must be accompanied by a model of the product label and accompanying product literature.

Additional notification and registration requirements apply with respect to imports of supplements containing products of animal origin. The regulatory body with control over this area is the Department of Agriculture and Food ("DAF"). Importers of animal products into Ireland must be registered with the DAF

© 2012 Lex Mundi

and provide notice in advance of their intended imports. Different procedures apply depending on whether the product is being imported from an EU country or a non EU country.

4. Are there any specific food supplement requirements regarding packaging, labelling and presentation or are they the same for all food products?

In addition to general labeling requirements for pre-packaged foods, there are specific rules relating to the labelling of food supplements set out in the Irish Food Supplement Regulations and summarised as follows:

Information	
Source/ origin	The place of origin must be stated if its absence might mislead the consumer to a material degree.
Name	The product must: be sold under the name "Food Supplement"; state the product name with a product description; and state the name or business name and address of the manufacturer or packager or seller within the EU.
Ingredients	The label must include: the list of ingredients; the quantity of each ingredient; the amount of the nutrients/substances with a nutritional or physiological effect in numerical form and the amount should be per portion of the product as recommended for daily consumption; and information on vitamins and minerals as a percentage of the reference values outlined in the nutrition labelling legislation.
Amount of the product	The net quantity should be stated.
Obligatory information, warnings or statements	The label must contain the following statements: the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances; the portion of the product recommended for daily consumption; a warning not to exceed the stated recommended daily dose; a statement to the effect that food supplements should not be used as a substitute for a varied diet; a statement to the effect that the products should be stored out of the reach of young children; The date of minimum durability; and Storage instructions. The labelling, presentation and advertising must also not attribute to food supplements the property of preventing, treating or curing disease, or refer to such properties and must not mention, state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients.
Optional statements	
Language	Food products, including food imports sold in Ireland, must be labelled in English, or in Irish and English. The food product may also be labelled in other languages, but only in addition to English.
General features of a label	The information provided on the label must be easy to understand

© 2012 Lex Mundi

	and be clearly legible. It must also be indelible, easy to see and not obscured in any way.
Other remarks	There is no prescribed font or text size for the labels.

Contact Information

Lisa Kinsella
Lisa.Kinsella@arthurcox.com

Arthur Cox
Earlsfort Centre, Earlsfort Terrace
Dublin 2, Ireland

Tel 353.1.618.0000 Fax 353.1.618.0618
www.arthurcox.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Japan

Prepared by Lex Mundi member firm Nishimura & Asahi

1. What is the definition of a food supplement in your jurisdiction?

In Japan, there are no regulations which define a food supplement itself.

There are only two categories of things subject to regulations that people ingest, “food” and “medicine”. Food supplements fall under the category of “food” and are regulated in the same way as food products.

In general, food supplements are thought to contribute to promoting and maintaining health as so-called “health food.”

2. Are the ingredients of food supplements regulated?

There are no additional regulations for health food products, and the general regulations on food products (Food Sanitation Act) are applied.

Under the Pharmaceutical Affairs Act, substances which are designated as medicine may not be contained in health food products, or any other food products.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

The same procedure is applied to health food products as with other food products.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General regulations on food labeling (Food Sanitation Act and Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products) are applied to the labeling of health food products, the same as other food products.

Also, under the Health Promotion Act, health food products which comply with the specifications and standards established by the Minister of Consumer Affairs Agency of the Government of Japan and are labeled with certain nutritional or health functions can be labeled as “Food with Health Claims.”

These food products are categorized into two groups, according to differences in purpose and function:

a) Foods with Nutrient Function Claims (FNFC):
Foods that are labeled with the functions of nutritional ingredients (vitamins and minerals)

b) Foods for Specified Health Uses (FOSHU):
Foods which are officially approved to claim physiological effects on the body and approved by the Minister of Consumer Affairs Agency of the Government of Japan.

© 2012 Lex Mundi

In addition, food products which are approved or permitted by the Minister of Consumer Affairs Agency of the Government of Japan as appropriate for specified dietary uses can be labeled as “Food for Special Dietary Uses (FOSDU)” under the same act.

The categories of “Food for Special Dietary Uses” are as follows:

a) Formulas for pregnant or lactating women
b) Infant Formulas
c) Foods for the elderly with difficulty masticating or swallowing
d) Medical foods for the ill
e) Foods for Specified Health Uses (FOSHU)
(“Foods for Specified Health Uses (FOSHU)” overlap this category and “Food with Health Claims” above)

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Name and address of manufacturer must be labeled. In addition, country of origin must be labeled for imported products.
Name	Name must be labeled.
Ingredients	Ingredient lists must be labeled.
Amount of the product	Net weight must be labeled.
Obligatory information, warnings or statements	Other obligatory statements: ・ Expiration date ・ Storage instructions ・ Food additives (if contained) ・ Food allergens (if contained) ・ Genetically-modified food (if contained) General rules on food labeling obligations are applied to health food products, and additional information may be necessary for some food products.
Optional statements	If they meet the requirements, health food products can be indicated and labeled as follows: ・ Food for Special Dietary Uses ・ Food for Specified Health Uses ・ Food with Nutrient Function Claims ・ Organic Food
Language	Japanese is obligatory; other languages may be added.
General features of a label	The information shall be labeled collectively on a conspicuous part of the containers or packaging in legible form.
Other remarks	Health foods shall not be indicated to have any effect or efficacy of medicine. False advertising is prohibited. Labels which lead to customer misinterpretation are prohibited.

© 2012 Lex Mundi

Contact Information

Alvin H. Shiozaki
h_shiozaki@jurists.co.jp

Yumi Ueda
y_ueda@jurists.co.jp

Nishimura & Asahi
Ark Mori Building 28th Floor
1-12-32 Akasaka
Tokyo, 107-6029 Japan

Tel 81.3.5562.8500 Fax 81.3.5561.9711
www.jurists.co.jp/en/

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Latvia

Prepared by Lex Mundi member firm LAWIN

1. What is the definition of a food supplement in your jurisdiction?

According to clause 4 of the Regulation of Cabinet of Ministers Cabinet of Ministers Regulations No725, adopted on September 20, 2005 „Regulations on Mandatory Harmlessness and Labelling Requirements of Nutritional Supplements and Procedure for Registration of Nutritional Supplements" food supplements are the food products for supplementation of normal nutrition. They are concentrated nutrients (vitamins and minerals) or other substances which have a nutritional value or a physiological effect individually or in combinations, and they are distributed and marketed in dosages – in capsules, pastilles, tablets, drops and in other ways, in powder bags, ampoules and other packaging that is intended for the use in small and measured quantities.

2. Are the ingredients of food supplements regulated?

Latvia does not have a separate list for prohibited substances. In turn Latvian authorities stick to the regulation of EU (Regulation No 1170/2009 of 30 November 2009 as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements). This means that in Latvia it is allowed to distribute the nutritional supplements which consist of vitamins and minerals listed in this regulation. In contrast if the vitamin or mineral is not mentioned in the Regulation distribution of nutritional supplement which consist of such vitamin or mineral is prohibited.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

It is mandatory to register every nutritional supplement which is distributed in Latvia. Obligation to register a nutritional supplement would lie on the person who imports the particular nutritional supplement in Latvia. The registrations must take place with the Food Veterinary Service. The notice shall include the following data: name of the product, name, country and address of the manufacturer, type of preparation (for example, pill, capsule, etc.), amount of the unit of pre-packaging, amount of the unit of package, recommended daily dose, components, name, address of the applicant and the distributor, registration number, bank requisites, food company registration certificate issued by the FVS (number of acknowledgement certificate), data of a contact person. There are also certain documents which must be attached to such notice.

Besides Every person who distribute nutritional supplement (title from this persons is transferred to customers in Latvia) must register himself or herself with the Food Veterinary Service.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General rules of food labeling apply also to labeling of food supplements. However, there are some regulations specific for supplements. The below table presents elements of the food supplement's label (resulting from both general and specific rules).

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Label must indicate: • name (firm name) and address of the producer, packager or vendor registered in the member state of the European Economic Area; • data on the place of origin of a product, if the lack of such information may result in misperception of the consumer regarding the actual place of origin of the product.
Name	• The trade name of the product and the term "food supplement" must be used.
Ingredients	List of ingredients of a product must include all ingredients of a product in decreasing mass sequence, as they are registered in the process of production of a good. Net weight or volume of certain ingredients or groups of ingredients of the product ingredients must be indicated. The content whereof in the end product is less than 2%, may be specified in another sequence, but after the rest of the ingredients. The reference containing the word "Ingredients" ("Composotion") shall precede the list of ingredients of a product. According to the respective regulation an ingredient is any substance (including food additive), used within the process of production or preparation of a product and contained in the end product, also in transformed form.
Amount of the product	net mass or volume (liters, centiliters, milliliters, kilograms or grams)
Obligatory information, warnings or statements	The labeling must contain the following information: • recommendation not to use the nutritional supplement as a replacement for a full-fledged and balanced nutrition; • warning that the nutritional supplement is to be kept in a place unavailable for children; • warning not to exceed the recommended daily dosage; • minimum term of validity of the product, or, in case of a short-life product – final term of validity; • energetic value of a product; • batch of the product (lot No); • nutrition value for albuminous substances, hydrocarbons, fats, sodium, fibrous matters; • nutrition value for vitamins and mineral substances, if the quantity thereof per 100 grams or 100 milliliters of a product or in one packaging, if it contains a single portion, is at least 15% of the recommended daily dosage; • recommended daily dosage; • quantity of ingredients (for nutritive substances or substances with nutritive value or physiological effects) in mass or volume units per daily dosage; • quantity of vitamins or mineral substances in one prepackaging per unit in percentage of the daily dosage, prescribed by laws and regulations on labelling of Food Products.
Optional statements	• detailed instructions or use of a product, if necessary;

© 2012 Lex Mundi

	• special terms of storage or use of a Food Product, if it is necessary to comply with such terms, in order to ensure the correct use of the Food Product.
Language	Latvian is obligatory; other language versions may be added.
General features of a label	The label and information on it must be fixed with the product, must be clear legible, easily understandable, wear proof and cannot be covered by any other prints or designs.
Other remarks	NA

Contact Information

Ivo Maskalans
ivo.maskalans@lawin.lv

Liga Hartmane

LAWIN
Elizabetes 15, LV-1010 Riga, Latvia

Tel 371.6781.4848 Fax 371.6781.4849
www.lawin.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

Differences and Similarities in Food Supplement Regulations

Lebanon

Prepared by Lex Mundi member firm Moghaizel Law Office

1. **What is the definition of a food supplement in your jurisdiction?**

   There is no specific definition for food supplements in our jurisdiction. But it is considered to be a substance with nutritive values that has the purpose of supplementing regular food ("nutritive complements") and is distinguished from pharmaceutical products.

2. **Are the ingredients of food supplements regulated?**

   No, the ingredients of food supplements are not regulated yet.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   Decree no 11710 institutes a committee with the Ministry of Public Health which receives and approves all the requests relating to importing, manufacturing and marketing natural medical products and nutritive complements. None of these products can be introduced on the Lebanese Market before obtaining the approval of the Committee at the Ministry of Public Health.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   There are no specific food supplement requirements regarding packaging, labeling and presentation.

Contact Information

Hala Tyan
mlo@mlof.com

Moghaizel Law Office
Ashrafieh 5585 Building
Pierre Gemayel Avenue
Beirut 2066 7113, Lebanon

Tel 961.1.425222 Fax 961.1.424366
www.mlof.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Lithuania

Prepared by Lex Mundi member firm LAWIN

1. What is the definition of a food supplement in your jurisdiction?

Food supplement is food product intended to supplement regular food ration and which individually or in combination with other substances is a concentrated source of nutrients or other substances with nutrient or physiological effect for humans. Food supplements are marketed in specific doses, such as capsules, pastilles, pills, tablets and other similar products as well as sachets of powder, ampoules, bottles with drop dosators and other similar liquid or powder forms designed for using liquid or powder in small measured quantities (Item 4 of Lithuanian Hygiene Norm 17:2010 “Food Supplements” approved by 13 May 2010 order No V-432 of Health Ministry).

Medicinal product is a substance or combination of substances manufactured and presented for treating or preventing disease in humans as it meets at least one of the following criteria: 1) has properties which make it suitable for treating or preventing human diseases; 2) due to pharmacological, immunological or metabolic action may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions or to making a medical diagnosis (Part 50 of Art. 2 of Law on Pharmacy). State Medicines Control Agency qualifies substances as medicinal products. Medicinal products could be sold to ultimate consumers only in licensed pharmacy stores by licensed pharmacists.

Lithuanian law does not explicitly provide criteria that could serve as the basis to attribute particular products to the category of food supplements and to discern them from medicinal products. However, competent authority in charge of control of marketing of food supplements (State Food and Veterinary Service) tend to treat products consisting of substances enlisted in the annex No 1 to Commission Regulation (EC) No 1170/2009 as food supplements. If particular product in its composition has other substances, such product can not be treated as food supplement and thus can not be marketed as such.

2. Are the ingredients of food supplements regulated?

Item 11 of Hygiene Norm 17:2010 „Food Supplements“ approved by 13 May 2010 order No V-432 of Health Ministry expressly specifies that only those vitamins and mineral substances that are listed in Annex No 1 to Commission Regulation (EC) No 1170/2009 in the form of Annex No 2 of the same regulation could be used for manufacturing food supplements. This leads to conclude that components other than those expressly listed in Annex No 1 or such products but in other form than indicated in Annex No 2 can not be used for manufacturing food supplements.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

The supply of nutritional supplements to Lithuanian market may be conducted only following notification to authorized public authority – State Public Health Service under the Ministry of Health. The following food supplement must be notified: 1) manufactured (in part or entirety) in non-EU member states, excluding Norway, Lichtenstein, Iceland, and/or; 2) imported from non-EU member states, excluding Norway, Lichtenstein, Iceland.

Notification must be filed by persons supplying food supplements to the market. Current legislation is unclear as to subjects having an obligation to notify. Following the literal interpretation of law, notification must be filled by all subjects who place food supplement on the market. Thus, literal interpretation of law

© 2012 Lex Mundi

requires notification on all stages of “placement on the market”, including wholesale and retail. Nevertheless, in practice, notification pursued only by subjects placing food supplements on Lithuanian market for the first time is considered sufficient by competent authority.
Notification is submitted to the State Public Health Service under the Ministry of Health. Notification is be included into public register within 3 business days; however supply of food products could be commenced immediately after having filled the notification. Notification includes the following information: 1) specimen of label; 2) details on subject supplying the product to the market (e.g. name, address, telephone number, e-mail). Notification could be submitted by letter, e-mail with electronic signature, by fax or via special form provided on website of the authority.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

In addition to general food labeling requirements, specific labeling requirements apply for food supplements. Both general and specific requirements are outlined below.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Labeling must contain: 1. Name and address of manufacturer, packing entity or supplier established in the EU; 2. Place of source of origin, if lack of such information may mislead consumer.
Name	Name of food supplement; Statement that product is classified as “nutritional supplement”.
Ingredients	List of ingredients: 1. Names of ingredients; 2. Names of categories of nutritional or other substances characterizing the product, or the reference to their characteristics. Quantities of ingredients contained in nutritional supplement and having nutritional value or physiological impact in the recommended daily intake of particular food supplement as well as percentage of such quantities in relation to recommended daily dosage must be provided (the latter information can be provided in graphical form). Quantities of ingredients contained in nutritional supplement and having nutritional value or physiological impact must be indicated in numbers. Measurement units applicable for vitamins and mineral materials are provided in Annex 1 to Regulation (EC) No 1170/2009.
Amount of the product	Net weight
Obligatory information, warnings or statements	Labeling must contain: 1. recommended daily dosage of food supplement; 2. warning not to exceed the recommended daily intake; 3. warning not to use nutritional supplement as a replacement of wholesome and balanced nutrition; 4. warning that nutritional supplements must be kept out of reach of children; 5. lot number; 6. shelf life; 7. all special storage and consumption conditions; 8. usage instructions if the right use of the product would not be possible without such instructions;

© 2012 Lex Mundi

	Labeling must not include: 1. reference that nutritional supplement prevents illness, treats or cures illness, or references to such a possibility; 2. references that balanced and varied nutrition cannot provide sufficient amount of nutrients.
Optional statements	Specific labeling requirements apply for food supplements containing particular ingredients (e.g. sweeteners, caffeine); In particular instances, nutritional information (energetic value, fat, carbohydrates, etc.).
Language	Lithuanian language must be used for obligatory labeling information; other languages may be also used.
General features of a label	Obligatory information must be presented in visible place, clearly legible, unequivocal and inerasable. Information must not be hidden or covered with other text or pictures.
Other remarks	Only packed food supplements can be supplied to ultimate consumers.

Contact Information

Rūta Pumputienė
ruta.pumputiene@lawin.lt

Liudas Karnickas
liudas.karnickas@lawin.lt

LAWIN
Jogailos 9/1
LT-01116 Vilnius, Lithuania

Tel 370.5.268.18.88 Fax 370.5.212.55.91
www.lawin.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Malaysia

Prepared by Lex Mundi member firm Skrine

1. What is the definition of a food supplement in your jurisdiction?

In Malaysia, there is no specific definition of a food supplement in Malaysia. Food supplement products have been considered by health authorities as being part of health supplement products, which have been defined as "*products that are intended to supplement the diet taken by mouth in forms such as pills, capsules, tablets, liquids or powders and not represented as conventional food/sole item of a meal or diet*" (para 9.1 Guidance Notes for Health Supplement Products, Drug Registration Guidance Document, August 2010, issued by the National Pharmaceutical Control Bureau, Ministry of Health, Malaysia).

Health supplement products may include active ingredients such as vitamins, minerals, amino acids, natural substances of plant/animal origin, enzymes, and substances with nutritional/physiological function.

2. Are the ingredients of food supplements regulated?

There are no specific statutory provisions governing this, but all health supplement products may contain only those active ingredients that are specified in the Drug Registration Guidance Document. The Drug Registration Guidance Document also requires that the maximum daily levels of vitamins and minerals in health supplements for adults be specified.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

The procedure to be adopted before launching of food supplement (which are treated as health supplements) products is generally regulated in a manner similar to that of pharmaceutical products. However, there may be a need to identify certain supplements as "pharmaceutical" or "food" products due to the presence of multiple ingredients. In light of this, the Committee for the Classification of Food-Drug Interface Products has developed a classification system to determine whether the launch of a product in question is to be regulated by the Drug Control Authority ("DCA") of the National Pharmaceutical Control Bureau or the Food Quality Division ("FQD").

If a product contains 80% or more of food-based ingredients, singly or in combination, with equal to or less than 20% of biologically active ingredients (such as vitamins, minerals, amino acids), the product is considered as a food product and shall be regulated by the FQD. Food products do not have to be registered but the products must comply with the standards and the labeling requirements under the Food Act 1983 and the Food Regulations 1985.

If a product contains less than 80% of food-based ingredients, with more than 20% of the active ingredients, the product is considered as pharmaceutical product and shall be regulated by the DCA. A product which contains solely natural ingredients that are not traditionally used as food and possesses medicinal value such as alfalfa, spirulina, royal jelly, noni juice, rooibos tea, pegaga tablet and other herbal products, is regulated by the DCA. In the event of any uncertainty about the classification of the products, the applicant can always submit the documentation showing the intended use and formulation of the product to the DCA to be evaluated.

© 2012 Lex Mundi

For health supplement products that are regulated by the DCA, the products must be registered with the DCA prior to being manufactured, sold, supplied, imported, possessed or administered in Malaysia, unless an exemption applies.

All applications for registration must be submitted online through DCA's website at http://www.bpfk.gov.my/. If the applicant is a foreign company wishing to bring the product into Malaysia, the foreign company would have to first appoint a local agent (a company registered in Malaysia) to be the holder of the registration certificate. The applicant (or the appointed local agent) shall be responsible for the product and all information supplied in support of its application for registration of the product as well as the quality, safety and efficacy of its products.

The applicant is required to submit a letter of intent containing certain particulars relevant to the product and a sample(s) of the product for laboratory analysis. Thereafter, the applicant is also required to submit all documentation pertaining to the product for full evaluation. A regulatory decision will be made by the DCA as to whether or not to approve or reject the application within six (6) months of the date of final and complete submission of all the relevant documents to the DCA.

After a product is registered, the applicant must apply for a manufacturer/import/wholesale license. A registration number will be given when a product application is deemed to have satisfied the registration requirements of quality, safety and efficacy in which the registration number must be printed on product's label or packaging. A certificate of registration with the provisions, conditions, limitations etc shall also be issued for the registered product. The registration of a product shall be valid for five (5) years or such period as specified in the certificate of registration. This period may be renewed upon fresh application. Separate applications are required for each of the products that contains same ingredients but made to different specifications (in terms of strength, dosage form, description etc) or by a different manufacturer.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

There are some labeling requirements specifically provided for health supplement products.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	• Name and business address of manufacturer • Name and business address of marketing authorization (product licence) holder • Name and business address of packer (if applicable) • Name of the country of origin
Name	• Product name • Product name must not contain any words or phrases that is misleading, improper or not factual • Product must contain one of the following indications:- - Used as Health Supplement - Used as Dietary Supplement - Used as Food Supplement - Used as Nutritional Supplement - Vitamins and mineral supplements for pregnant and lactating women

© 2012 Lex Mundi

Ingredients	• Nutrient function claims of the individual vitamins or minerals are allowed. For e.g. Vitamin A helps to maintain growth, vision and tissue development etc. • Name and strength of active substances • Name and content of preservative (where present) • Name and content of alcohol (where present) • Source of ingredients (active, excipient, and/or capsule shell) – derived from animal origin
Amount of the product	• Net Weight
Obligatory information, warnings or statements	• Registration Number. For e.g. MAL 12345678HN • Batch Number • Manufacturing Date • Expiry Date • Route of administration / dose / use instruction • Dosage form • Pack size • Storage condition • The words “Keep out of reach of children” or words bearing similar meaning in both Bahasa Malaysia (national language of Malaysia) and English
Optional statements	• Recommended daily allowance (RDA) for vitamins/multivitamins/minerals preparation used as Health Supplements • Other country specific labeling requirements
Language	• Bahasa Malaysia (national language of Malaysia) is obligatory, English, other language versions may also be added.
General features of a label	• The particulars on a label must appear conspicuously and prominently and the label must be legibly and durably marked on the material of the package.
Other remarks	• If the product is without an outer carton, the inner label should bear all the information that is required • Batch number, manufacturing date, expiry date can be stated on label, on top of cap or bottom of bottle • All health supplement products registered with the DCA must be affixed with a hologram label as a form of security device. The hologram label shall be affixed onto the outer packaging of the product, or if there is no outer packaging, it shall be affixed on the immediate packaging i.e. the bottle label. The hologram label cannot be applied onto the outer shrink wrap.

Contact Information

KHOO Guan Huat
kgh@skrine.com

Skrine
Unit.No. 50-8-1, 8th Floor
Wisma UOA Damansara
50, Jalan Dungun
Damansara Heights
50490 Kuala Lumpur, Malaysia

Tel 60.3.2081.3999 Fax 60.3.2094.3211
www.skrine.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

New Zealand

Prepared by Lex Mundi member firm Simpson Grierson

1. What is the definition of a food supplement in your jurisdiction?

Food supplements are split into two categories: supplemented foods and dietary supplements.

Supplemented foods are governed by the New Zealand Food (Supplemented Food) Standard 2010 (**Standard**). A supplemented food is a product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement.

A product is not a supplemented food if it is-

a) a dietary supplement (as defined in the Dietary Supplement Regulations 1985); or
b) a medicine (as defined in the Medicines Act 1981); or
c) a controlled drug or restricted substance (as defined in the Misuse of Drugs Act 1975); or
d) a formulated meal replacement or a formulated supplementary food (as defined in standard 2.9.3 of the Australia New Zealand Food Standards Code (**Code**)); or
e) a formulated caffeinated beverage (as defined in standard 2.6.4 of the Code).

Dietary supplements are governed by the Dietary Supplement Regulations 1985 (**Regulations**). Dietary supplements are defined as something to which the following apply:

a) It is an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin.
b) It is sold by itself or in a mixture.
c) It is sold in a controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet).
d) It is intended to be ingested orally.
e) It is intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food.

2. Are the ingredients of food supplements regulated?

The ingredients of supplemented foods are regulated by the Standard and to some degree by the Code.

The ingredients of dietary supplements are regulated by the Regulations.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

No. The procedure is essentially the same as that which applies to food products.

4. Are there any specific food supplement requirements regarding packaging, Labeling and presentation or are they the same for all food products?

The Regulations provide for specific requirements for the packaging and labelling of dietary supplements.

The Standard provides specific requirements for the packaging and labeling of supplemented foods.

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for supplemented foods:

Information:	
Source/ origin	Not required.
Name	Product name or a description sufficient to indicate the true nature of the food, and the words "supplemented food".
Ingredients	As per food and clauses 14 to 16 of the Standard.
Amount of the product	Weight/volume as per food.
Obligatory information, warnings or statements	As per food. If there is a risk to a person in consuming more than an appropriate daily consumption of a supplemented food, the label on the package must specify the appropriate daily consumption, and include an advisory statement to the effect that exceeding that daily consumption may cause harm.
Optional statements	
Language	
General features of a label	Font sizes as per food.
Other remarks	

Contact Information

Peter Stubbs
peter.stubbs@simpsongrierson.com

Simpson Grierson
Level 27 Lumley Centre
88 Shortland Street
Private Bag 92518
Auckland, New Zealand 1141

Tel 64.9.358.2222 Fax 64.9.307.0331
www.simpsongrierson.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Norway

Prepared by Lex Mundi member firm Advokatfirmaet Thommessen AS

1. What is the definition of a food supplement in your jurisdiction?

The Norwegian Regulation on Food Supplements defines food supplements in Article 3 as foodstuff intended to supplement the diet *and* which are being concentrated sources of vitamins and minerals or other substances with a nutritional or physiological effect, alone or in combination, *and* which are traded in a pre-packaged and dosed form intended to be taken in small measured quantities, such as capsules, pastilles, tablets, pills, powder bags, vials, drop dispensing bottles, and other similar forms for liquids and powders.

According to the labeling and marketing requirements, food supplements cannot be presented as treating or preventing diseases, disease symptoms or pain (Art. 6 Regulation on Food Supplements). If a product can be classified as a medicinal product, the stricter rules governing medicinal products under the Norwegian Act on Pharmaceuticals will apply.

2. Are the ingredients of food supplements regulated?

A food supplement may contain only those natural or added vitamins and minerals mentioned in Appendix 1 to the Norwegian Regulation on Food Supplements which to a large extend is aligned with relevant EU/EEA regulation (directive 2002/46/EC). Appendix 1 also lists applicable minimum and maximum limits for content of vitamins and minerals in food supplements..

Further, section 5 of the Norwegian Regulation on Food Supplements makes an unspecific reference to the applicability of EEA regulation concerning purity, which presumably is to be interpreted as a reference to the Norwegian Regulation on Food Additives section 4 regarding the composition of vitamins and minerals in order to be qualified as pure. The latter refers to directives 78/663/EEA, 2008/84/EU as amended by directive 2009/10/EU and 2008/128/EU as incorporated under the EEA agreement.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

Notification requirements to the Norwegian Food Safety Authority (the “FSA”) are laid down in Article 10 to the Norwegian Regulation on Food Supplements. When food supplements are traded on the Norwegian market, the producer/importer has to submit the following information to the FSA:

1. Name and address of the notifying party and the producer (if they are not the same)
2. All ingredients, including compounds of added vitamins and minerals,
3. Total content (sum of naturally occurring and added quantities) of all vitamins and minerals per recommended daily dose.

Any changes to the submitted information and any withdrawal of products from the market must be reported to the FSA. In addition, the FSA may require further information and documentation.

© 2012 Lex Mundi

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

Food supplements shall be labeled in accordance with the general rules for foodstuff. These contain relatively detailed requirements. In addition, certain labeling requirements apply specifically to food supplements. These specific requirements will be specified in the table below.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Name	• Must be labeled with the trade designation "food supplement"
Ingredients	The ingredient list must contain: • Name of the categories of nutrients or other substances with nutritional or physiological effects characterizing the product, or a statement of the nature of these • Amount of content of nutrients or other substances with nutritional or physiological effect in terms of numbers per recommended daily dose (stated in accordance with the units specified in Appendix 1 to the Norwegian Regulation on Food Supplements)
Obligatory information, warnings or statements	• Recommended daily dose • A warning not to take more than the recommended daily dose • Information that food supplements should not be used as a substitute for a varied diet • Information that the product should be stored out of reach of children
Other remarks	• It is not permitted in labeling or marketing of food supplements to claim or give the impression that a balanced and varied diet generally does not provide adequate supply of vitamins and minerals. • It is not permitted in labeling or advertising to claim or give the impression that a food supplement treats or prevents diseases, disease symptoms or pain**.**

Contact Information

Advokat Kirti Mahajan Thomassen
kmt@thommessen.no

Advokatfirmaet Thommessen AS
Haakon VII's gate 10
P.O. Box 1484 Vika
N-0161 Oslo, Norway

Tel 47.23.11.11.11 Fax 47.23.11.10.10
www.thommessen.no/en/

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Pakistan

Prepared by Lex Mundi member firm RIAALAW

1. What is the definition of a food supplement in your jurisdiction?

In the event the food supplement falls within the definition of a "drug", it will be regulated in accordance with the provisions of the Drugs Act, 1976 (the "Drugs Act"). Pursuant to the Drugs Act, a "drug" includes:

a) any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof in human beings or animals, or the restoration, correction, or modification or organic functions in human beings or animals, not being a substance exclusively used for ayurvedic, unani, homeopathic or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed;

b) any substance mentioned as monograph or as preparation in the Pakistan Pharmacopoeia or Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States, whether alone or in combination with any substance exclusively used in the unani, ayurvedic, homeopathic or biochemic system of treatment, and intended to be used for any of the purposes mentioned in sub-clause a) above;

c) or any other substance with the Federal Government may, by notification in the Official Gazette, declare to be a "drug" for the purposes of the Drugs Act.

2. Are the ingredients of food supplements regulated?

If the food supplement falls within the above-mentioned definition of a "drug", it has to be registered in accordance with The Drugs (Licensing, Registering and Advertising) Rules, 1976 (the "Rules"). Pursuant to the Rules, the application for the registration of the drug has to be in either Form 5 or 5-A. Both of the aforementioned forms require the ingredients of the drug to be disclosed. Furthermore, after the registration, the ingredients of the registered drug can only be altered with the prior approval of the Ministry of Health.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

If the food supplement falls within the definition of a drug, it has to be launched in accordance with the provisions of the Drugs Act and the Rules. Pursuant to the Drugs Act, a drug can only be made available for sale after it has been registered in accordance with the Rules.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

The labeling and packaging requirements of all drugs are given in The Drugs (Labeling and Packaging) Rules, 1986 (the "Labeling Rules"). If the food supplement falls within the abovementioned definition of a "drug", it will be subject to the Labeling Rules.

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Yes
Name	If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner.
Ingredients	Each active ingredient of a drug with weight or measures in metric system, or the number of units of activity as the case may be, expressed
Amount of the product	Yes
Obligatory information, warnings or statements	The following obligatory information must be provided on the label (in the manner specified below): a) The name and principal place of business of the manufacturer; b) The drug manufacturing license number; c) The drug registration number; d) The date of expiry; e) The letters “P.P”, “Ph.I”, “Eur.P”, “B.P”, “B.P.C” and “U.S.N.F” shall be printed or written in indelible ink on the label to indicate so that the drug is manufactured in accordance with the specifications set out in the Pakistan Pharmacopoeia, international Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, British Pharmacopoeia, British Pharmaceuticals Codex or the United States National Formulary, as the case may be; and f) The distinctive batch number date of manufacture and the maximum retail price.
Optional statements	
Language	The Urdu version of the following must appear on the label: (i) Name of drug; (ii) dosage; and (iii) Instructions.
General features of a label	The abovementioned particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on a label of the innermost container of drug and also on the in which such container is packed.

© 2012 Lex Mundi

	In the case of a drug packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more that two milliliter or in an ampoule containing a sterile suture or ligature and such strip foil blister or ampoule is placed in other package and also in the case of printed collapsible tubes it shall be sufficient to give the information on the outer packing containing such strips, foils, blister or ampoule.
Other remarks	If the food supplement is not a “drug” as defined, none of the above will apply to it.

Contact Information

Mubariz Siddiqui
Karachi@riaalaw.com

RIAALAW
RIAALAW Chambers
D-67 Block 4, Clifton
Karachi 75600, Pakistan

Tel 92.21.3583.6308 Fax 92.21.3587.0014
www.riaalaw.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Poland

Prepared by Lex Mundi member firm Wardyński & Partners

1. What is the definition of a food supplement in your jurisdiction?

Food supplement means foodstuff to supplement the normal diet in which sources of vitamins and minerals or other substances with a nutritional or physiological effect are concentrated alone or in combination, which is marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids as well as powders to be taken in measured small unit quantities (Article 3 item 3 point 39 of the Food and Nutrition Safety Act of 25 August 2006).

A food supplement cannot meet requirements of a medicinal product, which means that it may not have pharmacological features and cannot be presented as treating or preventing diseases. If a product can be classified as a food supplement and medicinal product at the same time, stricter rules governing medicinal products apply.

2. Are the ingredients of food supplements regulated?

A food supplement may contain only those vitamins and minerals mentioned in Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and Council Regulation (EC) No 1925/2006 of the European Parliament and Council on lists of vitamins and minerals and their forms that can be added to foods, including food supplements.
Other substances, i.e. food additives, herbal substances, can also be added, unless prohibited by general food safety rules, or may cause classification of a food supplement as a medicinal product due to its composition.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

An entity that is about to launch or which is launching a foodstuff for particular nutritional use, foodstuffs containing certain vitamins and minerals, or a food supplement must notify the General Sanitary Inspector thereof. The notification must include information on the producer, launching entity, ingredient list and ingredients amounts. A label design must be attached to the notification. If the food supplement has been reported in another EU-country, such notification also should be provided. On-line notification is possible for those entrepreneurs with a certified electronic signature.

Upon notification the General Sanitary Inspector may commence an inspection in which it will be verified whether the composition of the food supplement (as well as its labelling) comply with health, nutrition and labeling regulations and, especially, if the supplement is not a medicinal product. The Inspector may demand a scientific opinion regarding the food supplement. The food supplement cannot be sold or must be withdrawn from the market during the inspection.

If, as a result of these proceedings, it turns out that the food supplement meets requirements of medicinal products and therefore pharmaceutical law shall apply, administrative and criminal sanctions may be imposed for introducing a medicinal product to the Polish market without complying with the pharmaceutical procedure.

© 2012 Lex Mundi

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General labeling rules apply toward labeling of food supplements, but there are some regulations specific for supplements. The table below presents elements of a food supplement label (under general and specific rules).

Please fill in the table regarding labeling requirements for dietary supplements:

Information	Poland
Source/ origin	Label must indicate: • producer or packing entity or entity launching the supplement onto the market, • and place or source of origin if lack thereof may mislead the consumer.
Name	• The wording "dietary supplement" must be placed near a trade name. • Name, net weight and period of use must be in the same view.
Ingredients	An ingredient list must be placed on labeling. It shall contain the following: • name of ingredient, also the name of ingredient causing allergic reactions, • names of allowed food additives, • amounts of vitamins, minerals and amounts nutrients or substances with a nutritional or physiological effect per product portion as recommended for daily consumption. Additionally, if the name of an ingredient is present in the name of a dietary supplement (or if labeling refers to an ingredient) its amount also must be indicated.
Amount of product	Net weight
Obligatory information, warnings or statements	• Period of use, • Lot number, • Recommended daily portion, • „More than the recommended daily amount should not be taken" • "Dietary supplements are no substitute for a balanced varied diet." • "Keep out of reach of young children".
Optional statements	• Recommendations for use, if necessary. • Storage instructions, if necessary. The information must be place near the period of use. • If applicable, relevant statements regarding sweeteners, liquorice etc. must be placed.
Language	Polish is obligatory; other language versions may be added.
General features of a label	The label and information thereon must be affixed to the product, be clear and legible and cannot be covered by any other prints or designs. The font size must be adjusted to the size of packaging in compliance with relevant regulations.
Other remarks	**-**

© 2012 Lex Mundi

Contact Information

Ewa Butkiewicz
ewa.butkiewicz@wardynski.com.pl

Wardyński & Partners
Aleje Ujazdowskie 10
Warsaw 00-478, Poland

Tel 48.22.437.82.00 Fax 48.22.437.82.01
www.wardynski.com.pl

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Portugal

Prepared by Lex Mundi member firm Morais Leitão, Galvão Teles, Soares da Silva & Associados

1. What is the definition of a food supplement in your jurisdiction?

"Food supplements" are foodstuffs the purpose of which is to complement and or supplement the normal diet and which are concentrated sources of certain nutrient substances or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. This definition is given in Decree-Law nº 136/2003 of 28 June 2003, which implemented Directive 2002/46/EC of 10 June 2002 (this decree-law was further amended by Decree-law n.º 296/2007 of 22 August 2010, which implemented Directive 2006/37/CE of 30 March 2006).

Food supplements should be distinguished from medicinal products (defined as any substance or combination of substances presented for treating or preventing diseases or their symptoms in human beings or which may be administered to human beings with a view to making a medical diagnosis or to restore, correct or modify physiological functions in human beings by way of a pharmacological, immunological or metabolic action) and cannot be presented has having prophylactic properties that enable to prevent or treat diseases.

2. Are the ingredients of food supplements regulated?

The ingredients of food supplements are regulated, in particular, in what concerns the vitamins and minerals that can be used in the production of food supplements, which are limited to those specified in Regulation (EC) n.º 1170/2009 of the European Commission of 30 November 2009.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

Previously to the commercialization of the product, the manufacturer or the person or entity responsible for placing the food supplement on the market must notify the competent authority (at present, the *Gabinete de Planeamento e Políticas* of the Ministry of Agriculture, Rural Development and Fisheries) that said commercialization will occur, by forwarding to that entity a model of the label used for the product at stake. This is a mere notification procedure and thus there is no requirement for a preliminary approval as a pre-condition for commercialization to occur.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

Alongside with the rules on the labeling of food products in general (Decree-law n.º 560/99 of 18 December, as amended by subsequent legislation), which apply to food supplements as well, the latter must comply with a set of specific rules regarding labeling, presentation and publicity of food supplements, which are set forth in Decree-law n.º 136/2003 (see table below, which incorporates not only information resulting from specific rules but also some information based on the general rules).

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Label must indicate: • the name or trade name and address of the producer or of the packaging entity or of the EU-established sales entity; • place or source of origin if lack of such information may mislead the consumer.
Name	The term "food supplement" must be used. Name, net quantity and minimum durability date or maximum consumption date must be in the same view.
Ingredients	A list of ingredient must be placed on the labeling. In the particular case of food supplements, the following must be observed: • the list of ingredients must include the name of the categories of nutrients or substances characterizing the products or a specific reference to the nature of those nutrients or substances; • the amount of the nutrients or substances with a nutritional or physiological effect present in the products must be declared in the label in numerical form by reference to the daily consumption portion recommended by the manufacturer and indicated on the label. • Information on vitamins and minerals must be expressed as a percentage of the reference values mentioned, in particular those contained in the legislation in force regarding the nutritional labeling of food stuffs.
Amount of the product	Net quantity
Obligatory information, warnings or statements	• Recommended daily dosage; • Warning that the recommended daily dosage must not be exceeded; • Statement that the food supplement should not be used as substitute for a varied diet; • Statement to the effects that the products should be stored out of the reach of young children.
Optional statements	Not expressly ruled. General provisions regarding the prohibition of use of misleading information in the labeling of foodstuffs (see below) should apply.
Language	Mandatory information must be presented in Portuguese; other language versions can be added.
General features of a label	Label's mandatory information must be in indelible writing, easily visible and legible, written in correct, clear and precise manner and placed in a notorious spot and can not be disguised, covered or separated by other mentions or images. Information in the label can not be presented or described (by words, images or other means) in a way that misleads the consumer in what concerns the characteristics of the product at stake, its properties and effects (namely by referring to properties and effects which it does not have) nor suggesting that it has

© 2012 Lex Mundi

	special features when all other similar products have those same features.
Other remarks	The labeling, presentation and advertising of food supplements can not include: • any mention that attributes prophylactic properties to the food supplements in what concerns the treatment of human diseases or any reference to those properties; • any mention that states or implies that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Contact Information

Constança Carrington
ccarrington@mlgts.pt

Morais Leitão, Galvão Teles, Soares da Silva & Associados
Rua Castilho, 165
1070-050 Lisbon, Portugal

Tel 351.213.817.400 Fax 351.213.817.499
www.mlgts.pt

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Romania

Prepared by Lex Mundi member firm Nestor Nestor Diculescu Kingston Petersen

1. What is the definition of a food supplement in your jurisdiction?

In line with the provisions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, Romanian legislation defines food supplements as to the foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities (art. 2 letter a) of Order 1069/2007 for the approval of the norms regarding food supplements issued by the Ministry of Health).

The regulations concerning food supplements clearly differentiate such foodstuffs from the medicines, and expressly provide that the labeling, presentation and advertising of food supplements must not attribute such the property of preventing, treating or curing a human disease, or refer to such properties (similar to food products).

In order to ensure clear differentiation between these type of products, when filing the required notification form with the competent authority, the applicant must declare that the respective food supplement has not been authorized / registered in any country as OTC medicinal product.

2. Are the ingredients of food supplements regulated?

Yes. Food supplements may only contain the vitamins and minerals exhaustively listed in Order 1069/2007 or Commission Regulation (EC) no. 1170/2009 of 30 November 2009 amending Directive 2002/46/EC and Council Regulation (EC) no. 1925/2006 of the European Parliament and Council on lists of vitamins and minerals and their forms that can be added to foods, including food supplements.

In addition, the botanicals that may be used as ingredients of food supplements are separately listed in the common Order no. 244/401/2005 on the processing and trading of medicinal and aromatic plants used as such, partially processed or processed as pre-dosed food supplement, issued by the Ministry of Agriculture together with the Ministry of Health. The inclusion as ingredient of a food supplement of a plant which is not listed in the aforementioned piece of legislation is subject to the prior approval of the Foodstuff Bio-Resources Institute.

Other substances (e.g., food additives) may also be added, unless prohibited by applicable legislation and unless such addition may transform the food supplement into a medicinal product.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

The placing on the market of the food supplements
a) including botanicals processed in pre-dosed food supplements or
b) of animal and vegetal origin
is subject to the submission with the Foodstuff Bio-Resources Institute of a notification file, containing data on the respective food supplement and the composition thereof, as well as the standard artwork

© 2012 Lex Mundi

under which such is going to be sold on the Romanian market. In principle, the authority shall grant a registration number to the notification file and shall issue its approval within 30 days as of the submission of all documents as concerns the food supplements including botanicals or within 10 days as concerns the food supplements of animal and vegetal origin.

For the food supplements which do not contain either vegetal or animal components, the placing on the market is allowed after the notification of the Public Health Ministry, upon the submission of a standard application filled in by the applicant and the standard label. Within 48 hours as of the receipt of all documents, the Public Health Ministry will issue a registration of the notification document, on the basis of which the food supplement may be commercialized.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General rules concerning food labeling, packaging and presentation apply also to food supplements, save for certain particular requirements applicable only for these types of products. The table below summarizes both the general and particular requirements in the legislation in force:

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	• For the EU products, the label shall indicate the name or commercial name and the headquarters of the manufacturer, packager or of the distributor registered in the European Union. For the non-EU products, the label shall include the name and headquarters of the importer or of the distributor registered in Romania. • Place of origin shall be included on the label insofar the omission thereof may be confusing for the consumers with respect to the actual origin of the product.
Name	The name under which the products may be sold is “food supplements”. The commercial name of the product shall be placed in the same view with the quantity and expiry date information.
Ingredients	The ingredients shall be listed on the label in the decreasing order of their quantities. Vitamins and minerals shall be also listed in the ingredients list. In case of ingredients which are (i) listed together with the name under which the product is sold or which are regularly associated with the name of the product by the consumers; (ii) highlighted in labeling upon words, drawings or graphics or (iii) giving the product special characteristics, differentiating the product, such will be included in the ingredient list jointly with the quantity thereof expressed in percentages.
Amount of the product	Net weight

© 2012 Lex Mundi

Obligatory information, warnings or statements	• Name of the product; • Ingredient list; • Quantities for certain ingredients, as case may be; • Net weight; • Validity term; • Name or commercial name and the headquarters of the manufacturer, packager or of the distributor registered in the European Union (for EU products) or name and headquarters of the importer or of the distributor registered in Romania (for non-EU products). • Origin, label insofar the omission thereof may be confusing for the consumers with respect to the actual origin of the product; • Recommended use instructions; • Lot number; • The names of the categories of nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances; • The portion of the product recommended for daily consumption; • A warning not to exceed the stated recommended daily dose; • A statement to the effect that food supplements should not be used as a substitute for a varied and balanced diet; • A statement to the effect that the products should be stored out of the reach of young children. • If applicable, relevant statements regarding sweeteners, liquorices, etc. • If applicable, storage and use conditions
Optional statements	Any statement not mandatory to be included, which represent correct information that might be useful to consumers
Language	Romanian language is mandatory. Other language versions may be included as well.
General features of a label	The label must include correct, complete and precise information of the product.
Other remarks	N/A

Contact Information

Ana-Maria Baciu
Ana-Maria.Baciu@nndkp.ro

Anca Melinte
Anca.Melinte@nndkp.ro

Nestor Nestor Diculescu Kingston Petersen
Bucharest Business Park
1A Bucuresti-Ploiesti National Road
Entrance A, 4th floor, 1st District
Bucharest 013681, Romania

Tel 40.21.201.1200 Fax 40.21.201.1210
www.nndkp.ro

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Slovenia

Prepared by Lex Mundi member firm Odvetniki Šelih & Partnerji

1. What is the definition of a food supplement in your jurisdiction?

The Rules on food supplements of 21 August 2003 as amended ("the Rules") define food supplements as foodstuffs the purpose of which is to supplement regular diet. They are concentrated sources of individual or combined nutrients or other substance with a nutritious or physiological effect that are placed on the market in the form of capsules, pastilles, tablets and other similar forms, sachets of powder, ampoules of liquid, drop dispensing bottles and other similar forms of liquid and powder that are formed so as to be able to be consumed in measured small quantity units.

A different set of rules applies to food supplements exceeding the highest allowed daily quantities of vitamins and minerals, and vitamin and mineral products and plants and plant extracts that fulfill the criteria for the classification among pharmaceutical products.

2. Are the ingredients of food supplements regulated?

The Rules contain information on the vitamins and minerals that may be used for the production of food supplements, as well as information on the chemical forms in which they may be placed on the market. The Rules also list chemical forms of amino acids, carnitine and taurine, nucleotids and choline and inositol that are allowed to be used for the production of food supplements.

Food supplements may also contain amino acids, fatty acids, roughage, plants and plant extracts, microorganisms and other substances with a nutritious or physiological effect, provided that their safety in the human diet is scientifically founded.

Food supplements containing plants and plant extracts must comply with the rules regulating the classification of medicinal plants.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

When a food supplement is first placed on the market in Slovenia, its manufacturer, supplier or importer is required to inform thereof the Ministry of Health. The first notification must consist of an accompanying letter and the following documentation: (i) original packaging, if the product is not manufactured in Slovenia, or a product specification, if the product is manufactured in Slovenia; (ii) proposed label in Slovenian language prepared in accordance with the rules of labeling set forth by the Rules; (iii) a confirmation that the product is a food supplement, if the product is not manufactured in Slovenia, and (iv) proof of payment of the administrative fee.

4. **Are there any specific food supplement requirements regarding packaging, labelling and presentation or are they the same for all food products?**

Food supplements may only be placed on the market as prepackaged foodstuffs. In addition to the general rules of labeling prepackaged foodstuffs, certain specific requirements pursuant to the Rules apply to food supplements.

© 2012 Lex Mundi

When labeling, presenting and marketing food supplements, the characteristic of preventing treatment or healing diseases in humans must not be attributed to food supplements. Only effects confirmed by scientific proof may be alleged. Labeling, presentation and marketing of food supplements must not contain statements that would allege or mean that a balanced and varied diet cannot ensure an adequate quantity of nutrients.

Food supplements must be explicitly marked as such. In addition to the general rules of labeling prepackaged foodstuffs, the label of a food supplement must contain the following data: (i) name of type of nutrients or substances characteristic of the food supplement, or data on the nature of nutrients or substances; (ii) recommended daily quantity or dose of food supplement; (iii) warning: "The recommended daily quantity or does must not be exceeded."; (iv) statement: "The food supplement is not a substitute for a balanced and varied diet."; (v) warning: "Store out of reach of children!".

The food supplement label must also designate the quantity of an individual nutrient or substance with a nutritious or physiological effect. These quantities are to be expressed per recommended daily quantity or dose of the product. When designating vitamins and minerals, their quantity must also be expressed as a percentage of the recommended daily intake.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Label must indicate the manufacturer, the entity packaging the goods or the seller based in the EU, as well as the place of origin, if omission of information on origin may mislead the consumer.
Name	Trade name must be included. Food supplements must explicitly be marked as a "food supplement". Name, net quantity and the expiry term should be placed in the same visual field.
Ingredients	An ingredient list must be placed on the label and must contain the name of the ingredient, including names of ingredients that may cause allergic reactions.
Amount of the product	Net weight
Obligatory information, warnings or statements	Label must contain the following obligatory information: - trade name; - list of ingredients (name of type of nutrients or substances characteristic for the food supplement or data on the nature of nutrients or substances); - the quantity of an individual nutrient or substance with a nutritious or physiological effect. These quantities are to be expressed per recommended daily quantity or dose of the product. When designating vitamins and minerals, their quantity must also be expressed as a percentage of the recommended daily intake; - net quantity; - expiry date; - lot number; - recommended daily quantity or dose of food supplement; - special storage or use conditions; - name and address/seat of manufacturer, the entity packaging the goods or the seller based in the EU; - information on place of origin, if omission of this information could mislead the consumer with regards to the true origin of the product; - instructions for use if the product cannot be used adequately without such instructions;

© 2012 Lex Mundi

	- warning: “The recommended daily quantity or does must not be exceeded.”; - statement: “The food supplement is not a substitute for a balanced and varied diet.”; - warning: “Store out of reach of children!”
Optional statements	No optional statements are regulated.
Language	Slovenian is obligatory, other languages may be added.
General features of a label	Label in Slovenian language must be placed at a visible spot on the packaging, so that it is easily visible, understandable, unambiguous, clearly legible, and indelible and must not be unclear, hidden behind or interrupted by other text or pictures. Name, net quantity and the expiry term should be placed in the same visual field. Labels on the product must not mislead the end consumer and must not attribute to the product healing characteristics.
Other remarks	**-**

Contact Information

Nina Šelih
nina.selih@selih.si

Odvetniki Selih & Partnerji
Komenskega ulica 36
1000 Ljubljana, Slovenia

Tel 386.1.300.76.50 Fax 386.1.433.70.98
www.selih.si/eng/

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

South Africa

Prepared by Lex Mundi member firm Bowman Gilfillan

1. What is the definition of a food supplement in your jurisdiction?

The Foodstuff Cosmetics and Disinfectants Act No. 54 of 1972 regulates the sale, manufacture, importation and exportation of foodstuffs, cosmetics and disinfectants in South Africa. This Act has no separate definition for a food supplement. A food supplement falls into the broader category of foodstuff, which is inclusive of supplements.

A foodstuff is defined as any article or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) ordinarily eaten or drunk by a person or purporting to be suitable, or manufactured or sold, for human consumption, and includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance.

A medicine is defined as any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man or restoring, correcting or modifying any somatic or psychic or organic function in man. The definition is inclusive of veterinary medicine.

2. Are the ingredients of food supplements regulated?

Since food supplements are considered to be foodstuffs the regulation of ingredients included in food supplements is the same as that of foodstuffs and hence various regulations apply which deal with the amounts of various substances, such as mineral hydro carbons, antioxidants and so on apply.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

Food supplements are dealt with under the definition of foodstuff and hence the procedure for launching a food supplement is the same as the procedure for launching a foodstuff.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

A food supplement falls under the definition of foodstuff and, as such, the requirements regarding the packaging, labeling and presentation of foodstuff apply. There are certain requirements in the case of fortified foodstuffs but these are dealt with in further detail below.

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	Label must indicate: • The name and business address of the manufacturer or seller or person on whose behalf such product was prepacked.

© 2012 Lex Mundi

Name	The trade name or brand used to identify the product must be presented on the main panel of the label such that the brand and/or trade name are indentified associated with the product type in equal prominence. There are no special requirements in terms of specifying that the foodstuff is a dietary supplement, but where the foodstuff is fortified, as explained below, the logo and the words "fortified for better health" may be added.
Ingredients	The list of ingredients should contain the following: • The names and amounts of the ingredients in the product. The ingredients are listed alphabetically. Where the ingredients are seasonal and as such where there are possible variations in the ingredient this ingredient and its possible replacement ingredient are qualified by and/or. Where water is one of the ingredients in the product it must be specified. • In the case of fortified foodstuffs (i.e. foodstuffs fortified with nutrients or micronutrients) which are fortified in accordance with the regulations the words "fortified for better health" and the fortification logo (which is set out in the Act) may also be added to the label. This generally applies to fortified maize and wheat. • Where additional nutrients are added in the fortification step and are nutrients which are not included naturally in the foodstuff, these nutrients should be listed and it should state on the label that the foodstuff is fortified with this nutrient. The amount of each nutrient must be presented as a mass of that nutrient and should be reflected in a tabular form.
Amount of the product	Net weight of the Product in SI (Systeme International) units
Obligatory information, warnings or statements	• Instructions for the use of the foodstuff where it would be difficult to make use of the foodstuff without such instructions • Special storage conditions (if applicable) • The name of the country of origin in terms of the production and processing of the product • Batch number • Best before, Use by or Sell by dates followed by the relevant date • Where the foodstuff is stored in a pressurized container it must be marked with the words, "warning pressurized do not puncture." • Where the product contains allergens or could contain allergens by cross contamination this must be specified • The serving size is included (this must be substantiated by scientific evidence if questioned)
Optional statements	• The country of origin in terms of the packaging of the product • Where the foodstuff is free of a particular additive the foodstuff can be marked as additive free and the particular additive(s) that it is free of can be referred to.
Language	English and at least one other official language

© 2012 Lex Mundi

General features of a label	The label clearly visible, easily legible and indelible. The legibility of the label shall not be affected by pictorial or any other matter, printed or otherwise. The labels of pre-packaged foodstuffs shall be applied in such a manner that it cannot be separated from the container at point-of sale.
Other remarks	Inclusion of the following on a label is not permitted: • Endorsements that the foodstuff has been approved or has been manufactured in accordance with recommendations by a health practitioner • Endorsements that the foodstuff is approved by an organization, including a religious organization unless this organization and its practices have been preapproved by the Minister. • Endorsement of a nutritional claim by an individual or an endorsement that the foodstuff provides complete and balanced nutrition. • Laudatory descriptions of the foodstuff which precede the trade name, for example, healthy, wholesome or nutritious. There are various draft regulations under discussion that are going to change some of the aspects relating to the labeling of foodstuffs. However, these draft regulations have not, as yet, been enacted into law and hence do not apply at this stage.

Contact Information

Llewellyn Parker
l.parker@bowman.co.za

Bowman Gilfillan
165 West Street, Sandton
Sandton, Johannesburg, South Africa

Tel 27.11.669.9000 Fax 27.11.669.9001
www.bowman.co.za

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Sweden

Prepared by Lex Mundi member firm Advokatfirman Vinge KB

1. What is the definition of a food supplement in your jurisdiction?

A food supplement is defined as a concentrated source of nutrients or other substances with nutrient or physiological effect for humans. Such substances can *inter alia* contain vitamins, minerals or different kinds of herbal extracts and are placed on the market in sales packaging and in specified doses, such as capsules, pastilles or tablets. (Section 2 of the Swedish National Food Administration's Code of Statues LIVSFS 2003:9).

Food supplements should be distinguished from pharmaceuticals products, i.e. any substance or combination of substances intended for the prevention, diagnosis or treatment of a disease or disease symptom, for the relief of a disease condition in a human, or for the restoration or alteration of vital functions in a human through pharmacological, immunological or metabolic effect. It is up to the Swedish Medical Products Agency to classify the status of substances as pharmaceuticals.

2. Are the ingredients of food supplements regulated?

As a starting point, only substances that supposedly are safe and that can be assimilated by the human body are permitted. Food supplements may explicitly contain such vitamins and minerals which are mentioned in Supplement 1 and 2 to the Swedish National Food Administration's Code of Statues LIVSFS 2003:9. Food supplements may also contain vitamins and minerals that can be found in ordinary foodstuffs (provided that they are safe and can be assimilated by the human body, also in the form of a food supplement).

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

A provider of a food supplement does not have to obtain any authorization from the Swedish National Food Administration. However, a manufacturer, importer, or retailer must register with the relevant authority at the municipality where it carries out its business.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General rules of food labeling apply also to labeling of food supplements. In addition there are specific regulations for food supplements (which are principally described in the below table).

Please fill in the table regarding labeling requirements for dietary supplements:

Information	
Source/ origin	The label must indicate: • name and address of manufacturer, packing entity or retailer, within the European Economic Area ("EEA"); • place of origin, if lack of such information may mislead the consumer.
Name	The product name established in EU regulations or generally

© 2012 Lex Mundi

	recognized in Sweden or EEA and the term “kosttillskott (*Eng.* “food supplement”) must be used.
Ingredients	List of ingredients setting out the following: • the established names of the ingredients (in order of magnitude); • name of the group of the nutritional substance or other substance characterizing the product; • Information regarding the content of vitamins and mineral nutrients reflected as a percentage of the recommended daily intake for an adult.
Amount of the product	Net weight (or volume if liquids). If tablets or capsules, set out number of tablets/capsules.
Obligatory information, warnings or statements	• Best before date; • Storage instructions; • Recommendations for use, if necessary; • Recommended daily intake; • Warning that the recommended daily intake should not be exceeded; • Warning that the food supplement should not be used as a substitute for a diverse diet; • Warning that the product should be kept out of reach of small Children; • If applicable, relevant statements regarding e.g. sweeteners.
Optional statements	For example brand name.
Language	Swedish is obligatory; other language versions may be added.
General features of a label	The label must be provided with the product, be clearly visible, easily understandable and thus cannot be covered by any other prints or designs.
Other remarks	Only generally applicable rules on food supplements are set out above. Launching a food supplement on the Swedish market may require further analyses.

Contact Information

Per Eric Alvsing
per_eric.alvsing@vinge.se

Adam Weissbach
adam.weissbach@vinge.se

Advokatfirman Vinge KB
Smålandsgatan 20
PO Box 1703
S-111 87 Stockholm, Sweden

Tel 46.10.614.30.00 Fax 46.10.614.31.90
www.vinge.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Switzerland

Prepared by Lex Mundi member firm Pestalozzi

1. **What is the definition of a food supplement in your jurisdiction?**

   Food supplements are defined as essential or physiologic useful substances, such as vitamins, minerals or other substances whose purpose is to supplement the normal foodstuff.

2. **Are the ingredients of food supplements regulated?**

   Yes, only permitted substances in the permitted concentration can be added to foodstuff (legal provisions are contained in the "Verordnung des EDI über den Zusatz essenzieller oder physiologisch nützlicher Stoffe zu Lebensmitteln" enacted on 23 November 2005)

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   In principle, the same procedure applying to all food products also apply to the launch of a product containing food supplements. However, if foodstuff contains a food supplement which is not already permitted, a marketing authorization by the Federal Office for Public Health (BAG) shall be requested.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   The added food supplements must be expressly mentioned in the list of the substances contained in the foodstuff. Moreover, the nutritional relevance of vitamins, mineral and other substances shall be indicated. For salt and vitamins specific label requirements apply.

Contact Information

Dr. Lorenza Ferrari Hofer
lorenza.ferrari@pestalozzilaw.com

Pestalozzi
Loewenstrasse 1
CH-8001 Zurich, Switzerland

Tel 41.44.217.91.11 Fax 41.44.217.92.17
www.pestalozzilaw.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

LexMundi
World Ready

Differences and Similarities in Food Supplement Regulations

Taiwan

Prepared by Lex Mundi member firm Tsar & Tsai Law Firm

1. What is the definition of a food supplement in your jurisdiction?

A food supplement is generally considered as “food” under the Food Sanitation Act. The term "food" is defined as goods provided to people for eating, drinking, or chewing, and the raw materials of such goods. There is no particular definition for a food supplement except for “special dietary foods” and “health foods” which are regulated separately.

According to the Food Sanitation Act, “special dietary foods” mean the following formulas that are nutritionally balanced or added with nutrients, to be consumed by people with special nutrient requirements:

a) Infant formula and follow-up formula;
b) foods for special medical purposes to be provided to patients with certain disease and with nutritional needs, and to be consumed under the instruction of a doctor, pharmacist or dietitian, with the purpose to sustain the health of the patients; and
c) other foods designed for special subjects designated by the Department of Health (the “DOH”).

According to the Health Food Control Act, “health foods” mean foods with health protection effect (i.e. the effect of advancing health and decreasing the risk of disease, as opposed to pharmacological effect) as designated by the DOH.

A food supplement, like other general foods, may not have pharmacological features and cannot be presented (including labeled, promulgated, and advertised) as having medical effect.

2. Are the ingredients of food supplements regulated?

The uses of food additives are regulated and the Standards of Usage Scope and Quantity Limitation of Food Additives (the ”Standards”) issued by the DOH provide the details, including the names of permitted food additives, specifications, scope of use, limit of quantity, etc.

3. Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?

There is no specific food supplements procedure for launching the product since food supplements are generally treated as general food products. To launch a food product designated by the DOH, such as special dietary foods, foods in forms of tablet or capsule, foods qualified as “health food”, it would require registration with and license from the DOH.

4. Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?

General labeling rules apply to the labeling of food supplements, but there are also special rules applied to the labeling of food supplements as well. The table below presents elements of a food supplement label (under both general and specific rules).

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

Information	Taiwan
Source/ origin	˙Name, telephone number, and address of the manufacturer, packager, importer, exporter, or distributor, as applicable. ˙Country of origin.
Name	˙Name of the food supplement. ˙Where a food product is a mixture of two or more product, they must be identified individually.
Ingredients	˙List of ingredients ˙Names of allowed food additives and warning language if there is side effect.
Amount of the product	Net Weight/Quantity/Number
Obligatory information, warnings or statements	˙Expiration date; if required by the DOH, manufacturing date, period of storage and/or storage instructions. ˙Nutrition facts. ˙For food supplements in capsulate or tablet form, “food” must be clearly labeled. ˙For food supplements in capsulate or tablet form which contain certain vitamins designated by the DOH, “no benefit for excessive use” must be labeled.
Optional statements	
Language	˙Chinese labeling is obligatory. ˙Maybe supplemented by English or other foreign languages if needed.
General features of a label	˙Labeling must be clear and consistent. ˙Labeling must not have contents of the following nature: (1) containing incorrect, false and/or misleading information or claims; (2) in violation of the mandatory and/or prohibitive legal regulations; (3) contrary to public order or good morals.
Other remarks	˙Unless qualified as health food with DOH license, no indication of health food or with health protection effect (such as reducing cholesterol level) is permitted. ˙No indication of pharmacological effect or misleading statement with similar effect

Contact Information

Sophia Hsieh
SophiaHsieh@tsartsai.com.tw

Tsar & Tsai Law Firm
8th Floor, 245, DunHua S. Road, Section 1
Taipei 106, Taiwan

Tel 886.2.2781.4111 Fax 886.2.2721.3834
www.tsartsai.com.tw/eng/

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

Differences and Similarities in Food Supplement Regulations

USA, Arkansas

Prepared by Lex Mundi member firm Rose Law Firm, a Professional Association

Note: This response is specific to the laws of the State of Arkansas and does not address any applicable laws of the United States.

1. **What is the definition of a food supplement in your jurisdiction?**

   No definition.

2. **Are the ingredients of food supplements regulated?**

   Not specifically. Regulations apply generally to all food products.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   Same for all food products.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   Same for all food products.

© 2012 Lex Mundi

Please fill in the table regarding labeling requirements for dietary supplements:

No labeling requirements for dietary supplements other than as required for food products generally**.**

Information	
Source/ origin	
Name	
Ingredients	
Amount of the product	
Obligatory information, warnings or statements	
Optional statements	
Language	
General features of a label	
Other remarks	

Contact Information

Kevin R. Burns
kburns@roselawfirm.com

Rose Law Firm, a Professional Association
120 East Fourth Street
Little Rock, Arkansas 72201

Tel 1.501.375.9131 Fax 1.501.375.1309
www.roselawfirm.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi

Differences and Similarities in Food Supplement Regulations

USA, South Carolina

Prepared by Lex Mundi member firm Wyche, P.A.

1. **What is the definition of a food supplement in your jurisdiction?**

   Food supplements are not regulated by the State of South Carolina. As a result, there is no statutory definition of food supplements.

2. **Are the ingredients of food supplements regulated?**

   Not by the State of South Carolina.

3. **Is there a specific food supplement procedure for launching the product or is it the same procedure which applies to all food products?**

   Not applicable.

4. **Are there any specific food supplement requirements regarding packaging, labeling and presentation or are they the same for all food products?**

   Not applicable.

The answers above are based solely on the laws of the State of South Carolina. There may be and likely are applicable US federal laws that apply, but the answers above do not include any such federal laws.

Contact Information

Terrell W. Mills
TMills@wyche.com

Wyche, P.A.
44 East Camperdown Way
Greenville, South Carolina 29601-3512

Tel 1.864.242.8200 Fax 1.864.235.8900
www.wyche.com

This guide is part of the Lex Mundi Global Practice Guide Series which features substantive overviews of laws, practice areas, and legal and business issues in jurisdictions around the globe. View the complete series of Lex Mundi Global Practice Guides at: www.lexmundi.com/GlobalPracticeGuides

© 2012 Lex Mundi