DIFFERENCES AND SIMILARITIES IN FOOD SUPPLEMENT REGULATIONS

BRAZIL
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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 food is proposed.

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 became 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:

<table>
<thead>
<tr>
<th>INFORMATION</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source/origin</td>
<td>ANVISA Ordinance Nº 222</td>
</tr>
<tr>
<td>Ingredients</td>
<td>Vitamins, Minerals, Carbohydrates, Protein, Fats, Branched chain amino acids</td>
</tr>
<tr>
<td>Amount of the product</td>
<td>These products above might be on stipulated proportions according to the Designation on ANVISA Ordinance Nº 222.</td>
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<tr>
<td></td>
<td>Hydroelectrolitic reposition must have varied concentrations of sodium, chloride and carbohydrates. Optionally, these products may contain potassium, and vitamins or minerals.</td>
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<td></td>
<td>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.</td>
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<td>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.</td>
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<td>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.</td>
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<tr>
<td></td>
<td>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.</td>
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<td>Food Compensators must contain varied concentrations of nutrients, according to the following requirements:</td>
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<tr>
<td>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.</td>
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<tr>
<td><strong>Obligatory information, warnings or statements</strong></td>
<td>Appropriate designation among the items: Hydroelectrolytic 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 &quot;steroids&quot;, &quot;body building&quot;, &quot;muscle hypertrophy&quot;, &quot;fat burners&quot;, &quot;increase in sexual ability,&quot; or equivalent.</td>
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<tr>
<td><strong>Language</strong></td>
<td>Portuguese</td>
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<tr>
<td><strong>General features of a label</strong></td>
<td>The same requirements for foods in general, according to ANVISA.</td>
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<tr>
<td><strong>Other remarks</strong></td>
<td>For the Repositories of Energy, the guidance highlighted and bold: &quot;Children, pregnant women and elderly consume preferably under the guidance of a nutritionist and/or doctor.&quot; Protein foods and for the Branched Chain Amino Acids, the recommendation highlighted and bold: &quot;Children, pregnant women, elderly and patients with any illness should consult their doctor and/or nutritionist&quot;. For Hydroelectrolytic Reposition the recommendation highlighted and bold: &quot;It is recommended that patients with diseases to consult a doctor or nutritionist before consuming this product.&quot;</td>
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