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Septiembre de 2019

NEW PUBLIC CONSULTATION: AMENDMENTS TO THE SANITARY FOODS REGULATIONS REGARDING DIETARY SUPPLEMENTS AND OTHER MATTERS

The Ministry of Health has recently published a new public consultation process regarding proposed amendments to Titles: Preliminary; II "Of Foods"; XXVII "Of Non-Alcoholic Beverages, Fruit and Vegetable Juices and Bottled Waters"; and XXIX "Of Dietary Supplements and Foods for Athletes" of Decree No. 977/1997 which sets forth the Sanitary Food Regulations (herein, "**RSA**").

This public consultation process will open for comments until**October 5, 2019**.

Among the most relevant aspects of this public consultation are important modifications to the regulation applicable to food supplements in Chile, regarding which we can highlight the following:

•**Limitation of the concept of "Product for Athletes"**: The new proposed article 537 bis provides a closed list of foodstuff that may use the denomination "Product for Athletes" and**all of the provisions that currently regulate "Foods for Athletes" in the RSA are eliminated**.

According to said article, the denomination "Product for Athletes" can only be used for foodstuff that qualifies as:**Isotonic beverages, protein supplements, amino acid supplements or creatine supplements**. Hence, the use of the concept "Product" or "Food" for athletes would be forbidden for any product which does not fulfill the regulatory requirements for such categories.

•**New category of "Supplemented Foods"**: The proposal replaces Paragraph II of Title XXIX of the RSA, currently referred to "Foods for Athletes", creating a new category, "Supplemented Foods" (art. 538 and subsequent). Thus, proposed article 538 defines "Supplemented Foods" as "**foods that do not have a pharmaceutical presentation**, which have one or more added vitamins or minerals in supplement

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Carey y Cía. Ltda.
Isidora Goyenechea 2800, Piso 43.
Las Condes, Santiago, Chile.
www.carey.cl

concentrations, or that have addition of other substances naturally present in foodstuff".

In this context, the proposal sets forth that the compounds or ingredients used in order to add vitamins, minerals or other substances to this type of food shall be those indicated in document CAC/GL 10-1979 of the Codex Alimentarius.

Additionally, the proposal establishes the prohibition to formulate foodstuff that qualify as "High in" one or more critical nutrients as "Supplemented Foods".

Advertisement of "Supplemented Foods": The proposal provides that healthy nutritional declarations may be used for this type of products insofar as they comply with the corresponding requirements for such use (Resolution No. 860/2017).

These foods shall indicate, on the main face or panel of their labeling or in a visible part thereof, "SUPPLEMENTED FOOD WITH …", followed by the corresponding nutrient or substance, in compliance with the graphic requirements set forth therein. Also, the proposal includes the obligation to incorporate the following caption on the label and advertisement of these products: "FOR CHILDREN AND PREGNANT WOMEN OR WHILE BREASTFEEDING, THIS PRODUCT SHALL BE RECOMMENDED BY A HEALTH CARE PROFESSIONAL", as well as the application of the same requirements set forth regarding the nutritional information table for dietary supplements.

•**Change of the definition of "dietary supplements"**: The proposal contains an amendment of the definition of dietary supplements contained in article 534 of the RSA. Although the new proposed definition contains all of the elements of the currently applicable definition, it includes certain new aspects, mainly, the requirement that, in order to be qualified as a dietary supplement, products, "**shall have presentations for oral consumption exclusively, such as powder, liquids, granulates, tablets, capsules or similar, of conventional liberation**."

In this context, the proposed new second paragraph of article 535 restricts the compounds or ingredients that may be used to add vitamins, minerals or other substances to those indicated in document CAC/GL 10-1979 of the Codex Alimentarius.

Moreover, the definitions of supplementation and complementation, currently contained in numbers 5 y 6 of article 106 of the RSA are eliminated.

•**Rules regarding advertisement**: The proposal includes a change in the drafting of the first paragraph of article 537, clarifying that the labeling and advertisement of dietary supplements must comply, both with the general rules applicable to all foodstuff, as well as with the special rules applicable to this particular category.

Further, new proposed article 537 provides the graphic requirements applicable to the denomination "Dietary Supplements" and modifies the warning messages that said products must include in their label and advertisement.

Also, this proposal incorporates**a new obligation with regard to advertisement**of dietary supplements, setting forth the obligation to include the message,**"Supplements do not replace a balanced diet in accordance with the Dietary Guidelines"**, in all advertisement of these products made through means of mass communication.

•**Nutritional Information Table**: On the other hand, the new drafting of article 537 includes the obligation of incorporating the content of the nutrients or other especial substances that have been used with supplementation purposes, in the nutritional information table of the product, for every 100 g y and per serving. Moreover, the proposal sets forth the obligation to label the maximum amount of daily servings of the product.

Finally, the proposal sets forth that dietary supplements shall always be sold packed from the manufacturing facility, forbidding sales of these products in other formats (e.g., fractionated or in bulk).

•**Modification of the exceptions to the obligation of labeling the**

descriptor "High in": Lastly, the consultation modifies the exceptions to the obligation of labeling the nutritional descriptor "High in", set forth in article 120 bis of the RSA, by eliminating, "foods for athletes", which, "comply with the requirements established in letters a), b), c) and d) of article 540." from such exemption. It is worth noting that the proposal does not incorporate "Supplemented Foods" within the exempt categories.

Finally, the public consultation also includes three additional documents to the proposed amendments to the RSA, regarding supplementation levels and declarations that can be made regarding dietary supplements. These supplementary documents are:

a) Resolution that, "Sets forth the Guidelines for the Declaration of Nutritional Properties in Dietary Supplements";

b) Resolution that, "Sets forth Authorized Nutritional Properties for Dietary Supplements"; and

c) Resolution that, "Sets Forth Nutritional Guidelines for Dietary Supplements and Supplemented Foods and their content of Vitamins, Minerals and other substances".

Please find more information and the complete text of the public consultationhere.

Autores: Ignacio Gillmore; Alejandra Del Rio; Cristina Busquets; Javiera Péndola