

Regulatory Committee

July 2024



AGENDA

REGULATORY UPDATE

- Argentina
- Brasil
- Colombia
- El Salvador
- Panama

ALANUR ACTIVITIES

- Colombia
- Peru



ARG. CONAL launches public consultation on projects to include dietary supplements in the Argentine Food Code

Regulatory
impact :

Product/Company/Authority

Action
required :

To implement/ Follow up/ None

Executive summary:

- **EX-2022-136576887.** The project proposes to incorporate basic methacrylate copolymer and anionic methacrylate copolymer as dietary supplements in the Argentine Food Code. It also proposes to prohibit their use in supplements intended for infants and young children.
- **EX-2024-63045112.** The bill proposes to incorporate ferric glycinate and ferrous glycinate in the Argentine Food Code as an ingredient for use in dietary supplements and fortified foods.
- **EX-2024-30902015.** The bill proposes to incorporate in the Argentine Food Code the hydroelectrolytic supplement understood as that non-alcoholic beverage intended for hydroelectrolytic replacement, carbonated or not, containing in its composition certain concentrations of sodium and potassium.



Country comments: N/A

BRA. *Anvisa modifies authorized lists of constituents, limits of use and labeling indications for dietary supplements*

Regulatory impact :

Product/Company/Authority

Action required :

To implement/ Follow up/ None

Executive summary:

The new rule amends IN 28/2018 to update the list of constituents authorized for use in dietary supplements contained in Annexes I and II, the list of minimum and maximum limits of nutrients, bioactive substances, enzymes and probiotics that must be provided by supplements, in the daily recommendation of consumption per indicated population group provided in Annexes III and IV and the list of supplemental labeling requirements provided in Annex VI.



Country comments: N/A

COL. *MinSalud publishes for consultation draft decree on sanitary conditions and requirements for dietary supplements*

Regulatory impact :

Product/Company/Authority

Action required :

To implement/ Follow up/ None

Executive summary:

The draft decree provides that natural and legal persons engaged in manufacturing, marketing, labeling, advertising and other activities related to dietary supplements,.

Country comments: The items with the highest risk for the category are: definition, good manufacturing practices, sanitary notification vs. sanitary registration, advertising, implementation times.

The international consultation has not yet been notified in WTO.



ELS. Executive enacts initiative that eliminates for 10 years tariffs on products in the expanded basic food basket, including supplements

Regulatory impact :

Product/Company/Authority

Action required :

To implement/ Follow up/ None

Executive summary:

Publication of the Special Law to Promote Competitiveness and Facilitate Access to Products of the Expanded Basic Food Basket, which eliminates tariffs for 10 years on 120 products of the expanded basic food basket, including powdered food supplements.

Exonerates from the Import Tariff Duty (DAI) 120 food products and inputs for agricultural production, including powdered food supplements, until July 31, 2034.



Country comments: No prior permits are required for the importation of these products.

ELS. *Executive enacts reform to the Superintendency of Health Regulation Law*

Regulatory impact :

Product/Company/Authority

Action required :

To implement/ Follow up/ None

Executive summary:

On July 16, the Executive Branch published the amendment to the Law that creates the Superintendence of Sanitary Regulation. This amendment establishes the new organizational structure of the institution, eliminating the pharmaceutical and food product intendancies in favor of the new Intendancy of Registrations and Registrations; the attributions of the entity on medicines, supplements and food; the transition process for the dissolution of the National Directorate of Medicines (DNM).



Country comments: This regulation will become effective on December 13, 2024.

PAN. President Mulino announces the beginning of Panama's integration process into Mercosur

Regulatory impact :

Product/Company/Authority

Action required :

To implement/ Follow up/ None

Executive summary:

President José Raúl Mulino informed that he accepted the proposal to initiate the integration process of Panama to the Southern Common Market (Mercosur). This announcement was made in the framework of the Panamanian president's participation as a guest at the meeting of the presidents of the bloc, which is being held in Asuncion, Paraguay. In this sense, Mulino asked Mercosur for a road map for the country to fully integrate, a process which he assured "will be based on consensus and coordination with the private sector".

Country comments: N/A





ALANUR ACTIVITIES

COLOMBIA

- Actualización de la normativa vigente de forma general

PERÚ

Reunión del grupo de trabajo DIGESA/DIGEMID/Industria

ALANUR está elaborando un documento de postura que contrarreste la postura de las autoridades peruanas sobre la implementación del FOP en suplementos alimenticios.

¡THANKS!