Regulatory Committe

Sep 2024

ALANUR
Alianza Latinoamericana de Nutrición Responsable

AGENDA

REGULATORY UPDATE

- Argentina
- Brasil
- Nicaragua
- Peru

ARG. Minister of Economy confirms PAÍS tax reduction

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

The Minister of Economy, Luis Caputo, confirmed that as from Monday, September 2, the rate of the PAÍS Tax will be reduced from 17.5% to 7.5% for the import of goods and freight.

It should be recalled that this measure had been previously announced by President Javier Milei on June 28. The President had anticipated that this reduction would take place as soon as “the regulation of the Tax Measures Law is completed and the new tax revenues start to flow”.

Country comments: N/A

ARG. The 155th Ordinary Meeting of the National Food Commission took place

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

The Food Additives Working Group expressed that there is insufficient evidence to incorporate chia mucilage as a food additive in the Argentine Food Code (AAC). However, given that chia mucilage is derived from chia seeds already included in the FAC, it was concluded that there is no objection to allowing the incorporation of chia mucilage with alternative uses other than as an additive. Nor was there any endorsement for incorporating the gum exuded from the white carob tree as an additive.

Importance in the incorporation of fortified beverages and water and electrolyte supplements to the FAC. The agency took note of the comments received during the public consultation on this incorporation and agreed not to accept those comments referring to changing the word “beverage” to “product” and the incorporation of other ingredients to water-electrolyte supplements..

Country comments: N/A

ARG. Executive would be evaluating modifications to labeling regulations

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

Various government sources stated that these portfolios are looking into different modalities to modify the design of the black octagons established by law, with the aim of making them “less invasive” on the packaging of the products. The Ministry of Health and the Ministry of Deregulation, together with other state agencies such as the National Administration of Medicines, Food and Medical Technology (ANMAT), are evaluating the possibility of modifying the existing regime of Front Food Labeling (regulated by the Healthy Food Law and Decree 151/2022 that regulates it).

Country comments: There are no stipulated dates for these eventual changes to be implemented.

ARG. CONAL launches public consultation on draft resolutions to amend the FAC regarding enzymes and dietary supplements

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

EX-2024-99286304. Proposes to incorporate new enzymes in Article 1263 of Chapter XVI on Correctives and Adjuvants of the Argentine Food Code (CAA).

EX-2023-129487245. Seeks to amend Articles 1381 and 235 of the CAA regarding the incorporation of Health Claims in the labeling of dietary supplements.

Country comments: comentarios 23 de octubre

BRA. E-Notivisa will receive notifications of adverse events and food technical complaints.

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

From now on, the system will be able to receive notifications of adverse effects and technical claims related to food products regulated by the Agency. Among the products that can be notified are foods intended for infants and young children or the elderly, foods with functional and/or health claims, infant formulae, enteral nutrition, food supplements, probiotics, among others.

Country comments: N/

BRA. Anvisa amends regulations on food supplement labeling

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

The instruction makes amendments to Regulatory Instruction 28 of 2018 to modify annexes such as Annex I which includes the list of constituents authorized for use in food supplements, except for infants (0 to 12 months) or early childhood children (1 to 3 years), Annex II on the list of constituents authorized for use in food supplements indicated for infants (0 to 12 months) or early childhood children (1 to 3 years) and Annex VI on the list of supplemental labeling requirements for food supplements. In addition to changes to Annexes III, IV and V.

Country comments: N/

HON. ARSA opens public consultation to regulate sale and advertising of energy drinks

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

The proposal aims at establishing the parameters for the sale of energy drinks and products. It would reach private companies and individuals involved in the whole production chain, from its elaboration to its sale and advertising. The document has a section on vitamins and other ingredients that allow classifying a drink as an energizing drink: caffeine, sugar, taurine, vitamin B or other substances such as ginseng, guarana and yerba mate, among others. It would also require the consumer to be notified of the inclusion of these ingredients in the product.

The regulation under consultation establishes that products may contain various vitamins and other components that may endanger the physical integrity of consumers. It also proposes a maximum content in the inclusion of caffeine, taurine, inositol and glucuronolactone, prohibiting the commercialization of those products that exceed it, in order to protect the population under 18 years of age.

Country comments: The public consultation will be open until November 11th.

NI. Executive updates regulation on requirements and procedures for import and export of medicines and supplements

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

The National Health Regulation Authority (ANRS) updated the administrative resolution on Requirements and Procedures for Import and Export Authorization of Products Regulated by the entity, including changes in over-the-counter medicines and supplements. The modifications include provisions on maximum import limits for sample products, requirements for special import permits for the public sector and requirements for export for commercial purposes.

The resolution establishes that products imported as samples for sanitary registration must not exceed certain quantities required by the ANRS. In the case of medicines and supplements, the Directorate of Pharmacy establishes a maximum of 3 units according to commercial presentation.

Country comments: Among the requirements for exporting products for commercial purposes, the obligation to present the original toxicological review letter signed and sealed by the company's accredited regent is eliminated. In addition, the requirement that established the presentation of a sworn statement by the applicant to commit that the country would not be out of supply of the product to be exported for a period of not less than 6 months has been eliminated. This new regulation is already in force, repealing its previous version.

PE. MEF evaluates updating the regulations of the Law for the Promotion of Healthy Eating

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

The Ministry of Economy and Finance (MEF) communicated that it is evaluating the feasibility of issuing a new version of the Regulation for Law 30021 on the Promotion of Healthy Food for Children and Adolescents. Unicef representatives have stressed the urgency of approving this update.During the Meeting of Milk Banks, an event promoted by Congresswoman Milagros Jáuregui Martínez de Aguayo (Renovación Popular - opposition), Unicef representatives, Javier Álvarez and María Elena Ugaz, highlighted the need to implement the new regulation. This would propose the use of warnings in the form of octagons indicating 'High in sugars, sodium and saturated fats' on infant formulas and foods, in accordance with the standards of the Pan American Health Organization (PAHO).

Country comments: N/A

PE. Congressman presents his project to create a Health Registry for food supplements before the Health Commission

Regulatory impact : Product/Company/Authority

Action required : To implement/ Follow up/ None

Executive summary:

Alejandro Soto Reyes, congressman of Alianza para el Progreso (opposition), appeared before the Health Commission to explain the provisions of his bill proposing the creation of a sanitary registry for food supplements.

The bill contemplates the creation of a registry for the importation and commercialization of supplements that improve, complement or fortify food. It also grants the General Directorate of Environmental Health and Food Safety (DIGESA) the responsibility of certifying these products at national level, by issuing a registration certificate to authorize their commercialization.

Country comments: N/A

¡THANKS!