



POSITION PAPER

Food supplements products for self-care.

- ILAR highlights the importance of including food supplements as self-care products within the framework of public health and wellness policies, thus improving and maintaining people's health outcomes. To this end, ILAR supports the development of regulatory frameworks that allow safe and responsible access to these products to the population.
- ILAR supports updating food supplement regulations in Latin America, aimed at post-marketing surveillance by National Regulatory Authorities (NRAs), thus guaranteeing user safety.
- The update of the regulation of food supplements in Latin American countries includes the following aspects: i) definition of supplements as food, ii) notification mechanism and risk approach, iii) expansion in the use of health and nutritional claims for communication to users, iv) establishment of safety-based vitamin and mineral levels, and v) definition of the mechanism for updating the list of permitted ingredients dynamically.

Food supplements and self-care

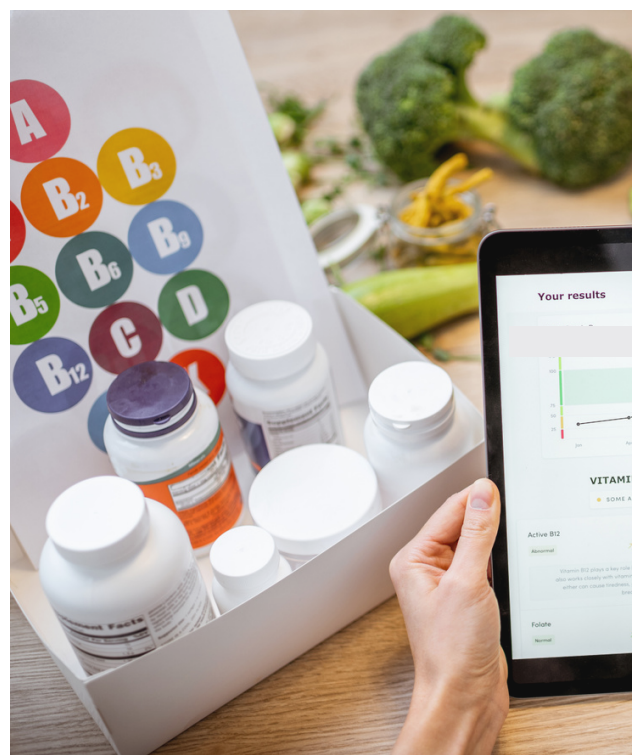
Self-care is "the ability of individuals, families, and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health professional" (WHO, 2022).¹ This strategy allows individuals to move towards improving diverse health outcomes, increasing responsibility for their own health and awareness through health education. Additionally, it allows optimizing the human and economic resources of health systems, reducing the risk of disease in the future.

According to the World Health Organization - WHO, "to provide quality health services and achieve universal health coverage, nutrition must be one of the cornerstones of essential health services". Similarly, WHO experts refer to this challenge, in that "essential health services in all settings must contain solid components of nutrition, but countries will have to decide which interventions best support their national health policies, strategies, and plans".² "We also need better feeding environments that allow everyone to eat healthy diets" says Dr Naoko Yamamoto, Assistant Director-General for Improving Population Health at WHO. In practice, it is evident that self-care is vital for Latin Americans, according to the survey conducted by ILAR in 2021, on healthy habits during the COVID-19 pandemic, **the activities most related to self-care included: "Healthy eating and physical activity" supported by 73% of interviewees**".³

Food supplements help to complement a healthy diet, so they should be used to provide additional nutrients, which people acquire through food. According to the Codex Alimentarius, "in cases where the intake of nutrients with food is insufficient or users consider that their diet requires supplements, food supplements of vitamins and / or minerals will be used to complete the daily diet".⁴

Additionally, **food supplements help maintain a balanced diet throughout the stages of life**, due to natural conditions or growth processes, associated with particular requirements. For example, food supplements help minimize or manage discomfort during climacteric, menstrual cycle, pregnancy, slight memory loss due to age, hair loss due to age or even acne; Conditions in which a balanced diet allows to strengthen the functioning of the healthy body and maintain the structural functions of the organism.⁵

A healthy diet helps protect us from malnutrition in all its forms, as well as reduce the risk of factors associated with chronic diseases, including diabetes, heart disease, stroke and cancer (WHO, 2018).⁶ Micronutrient deficiencies can lead to poor eye health, low birth weight, and a negative impact on children's physical and cognitive development, and increase the risk of chronic disease in adults.⁷



Non-communicable diseases represent a significant mortality rate in the world, 41 million people each year, equivalent to 71%. In the Region of the Americas, 5.5 million NCD deaths each year (WHO, 2022).⁸

Studies have been developed around the world to show the relationship between the use of key ingredients in food supplements and the reduction of risk factors for chronic diseases. A study by the Council for Responsible Nutrition (CRN) developed in the United States in 2022, shows that the use of certain food supplements by specific populations can reduce direct and indirect medical costs associated with several common conditions such as: coronary artery disease, age-related cognitive decline disorders, age-related eye disease, diabetes, osteoporotic fractures, irritable bowel syndrome, and inadequate choline intake. The research

concludes that "many disease events require expensive treatments, especially those associated with chronic diseases, and prevention of at least one of these would necessarily have an impact on future health care spending."⁹

In that sense, for the World Health Organization - WHO, "strategies focused on the intake of varied and nutrient-rich foods, fortified foods and vitamin supplements can help prevent micronutrient deficiencies."¹⁰ The latter, usually derived from food intake, are small amounts of vitamins and minerals required by the body for most cellular functions.¹¹



In the international environment, supplements are regulated as food

According to Codex, food supplements or supplements "are concentrated sources of nutrients, minerals and/or vitamins, alone or in combination, which are marketed in forms such as capsules, tablets, powder, solutions, which are intended to be taken in small, measured unit quantities and not as conventional foods. Its purpose is to complement the intake of these nutrients in the daily diet".¹² The risk associated with the use of food supplements is lower than other products for human consumption monitored by National Regulatory Authorities (NRAs). In the United States and the European Union, food supplements are products intended to supplement the diet and are not intended to treat, diagnose, mitigate, prevent, or cure diseases. Nor are they aimed at restoring, correcting, or exerting a pharmacological, immunological, or metabolic action; Food supplements have no therapeutic indications. For this reason, the NRAs of these countries do not have sanitary registration for food supplements but concentrate on post-marketing surveillance. In this way, food supplement manufacturers are responsible for having proof that their products are safe and that the information on the label is not false or misleading. When the authority finds a supplement that is unsafe, it can take it off the market or ask the supplement manufacturer to remove it.

In Latin America, several countries recognize supplements as products within the food category, in line with most countries in the world (all of Europe, some countries in Asia and in America: United States, Mexico, Chile, Argentina, Brazil, Ecuador, among others). However, some countries in Central and South America have yet to update their definition of food supplements, in line with the trend in international regulation, to classify them as

foods and seek their scope in such a way that: i) recognizes the value of food supplements for self-care, ii) allows more ingredients to be incorporated, iii) is based on a risk and confidence analysis and (iv) is suitable for different target populations.

It is necessary for NRAs in Latin America to implement a risk approach in the surveillance of health care products, which allows balancing in practice, regulation based on risk management with preventive measures to reduce it and in this way, it is possible to guarantee the protection of people's health and safety.

With the aim of enhancing the impact of Self-Care, there are other regulatory aspects, related to the health management of food supplements, that require updating in Latin America. From ILAR, the following are identified with their respective objective, as well as some international references for each of them:

i. Definition:

Ensure that within the updated definition of food supplements the following aspects related to the physiological effect of supplements, their content and form of presentation are incorporated.

- The definition agreed by the NRAs of the Pacific Alliance "defines as food supplements to products that: i) Are specially developed to increase, add or complement normal or daily food with nutritional or physiological effect, ii) They can use vitamins, minerals and other food ingredients and substances with pharmacological or therapeutic action may not be used according to their dose and iii) Are for oral consumption only and may be presented in pharmaceutical form."

- The same NRAs agreed that physiological effect will be understood as "the effect of the intake of an ingredient or nutrient that contributes to the maintenance or improvement of a physiological function of the different systems of the organism".¹³

ii. Notification:

Implement a post-marketing surveillance mechanism based on a risk approach, to monitor food supplements available in the market.

- The Spanish Agency for Food Safety and Nutrition has a database of the General Sanitary Registry of Food and Food Companies (RGSEAA), in which companies with registered office in Spain or any other Member State of the European Union, notify / communicate their responsibility for the marketing of the supplement / food supplement.¹⁴

iii. Approval of Ingredients:

Establish clear mechanisms for evaluating ingredients and their combinations for each NRA and base acceptance of a new ingredient on: i) safety information provided, ii) "case-by-case" and, iii) use of international references and trust mechanisms.

- There are positive lists of vitamins and minerals and lists of plants in Europe.¹⁵ Brazil, for example, has a publicly available database of ingredients authorized for use in food supplements.¹⁶

iv. Use of claims:

Maximize the use and number of claims allowed in food supplements, to give the user the ability to make informed decisions when using these personal care products.

- The labelling, presentation and advertising of an increasing number of foods contain nutrition and health claims. Therefore, the main objective of NRAs is to guarantee a high level of protection for users and make it easier for them to choose the healthiest option among different foods (AESAN, Spain).¹⁷
- EFSA has a harmonized database for the countries of the European Union of the claims that were approved or are in the process of evaluation.¹⁸ In Latin America, countries like Brazil¹⁹ and Colombia,²⁰ already have separate positive lists for food and food supplements.

vi. Definition of vitamin and mineral levels:

Update regulation by expanding knowledge of safety-based methodologies for establishing maximum vitamin and mineral levels.

- At the international level, there are widely recognized safety levels supported by the Codex²¹ criteria on the values of reference intake of the population or recommended daily intake and the maximum levels (Tolerable Upper Intake Level - UL) of FDA in the United States.



Regulatory convergence for food supplements in Latin America

To make self-care a reality in the health continuum, in addition to other strategies, it is necessary to have a regulatory environment conducive to innovation and access to safe and low-risk self-care products, through convergence and the implementation of trust mechanisms between NRAs, which allows people to practice self-care and thus reduce the economic limitations of health systems (GSCF, 2022).

In the region, negotiations have been established between National Regulatory Authorities (NRAs), to seek the convergence of their regulations for food supplements, which will lead in the future to progress as a region in the surveillance of these products; with greater emphasis on the evaluation of new products

are a global trend in updating, and at the same time, facilitating access to products that have already demonstrated their technical and scientific support to generate benefits to people's health. **This allows the regulatory framework to contribute to the practice of self-care in society, under the safe use by users of food supplements, as over-the-counter products.** These initiatives have been established between countries belonging to the Pacific Alliance; Colombia, Chile, Mexico and Peru; and for their part, Central American countries; through the Central American Standardization or Technical Regulation Bodies.



CONCLUSION

- **Improving health outcomes through the appropriate use of food supplements** will reduce micronutrient deficiency and risk factors for certain chronic diseases, which are currently the leading cause of death and disability in the world, and bring future benefits for people and health systems economic sustainability.
- **Developing an enabling environment for innovation and access to low-risk self-care products**, such as food supplements, will require Latin American NRAs:
 - I. In the short term: reference to good regulatory practices of other NRAs of international reference; in terms of risk approach, post-marketing surveillance, safety-based methodologies, among others, to advance in the updating of national regulations.
 - II. In the medium term: seek the convergence of its regulations with the regulations of other countries in the region, to achieve a risk approach in post-marketing surveillance that guarantees the safety of users of food supplements in the region.
- **ILAR supports regulatory convergence initiatives around food supplements**, such as Pacific Alliance and initiatives at Central American convergence mechanisms that allow:
 - I. Define clear rules for access to self-care products and innovation.
 - II. Improve the surveillance of food supplements in the market and strengthen the surveillance network of these products, collaborating with other NRAs in the region.
 - III. Empower users to practice self-care based on the proper use of food supplements, within the framework of healthy eating habits.



ILAR Resources

In line with the objectives established by the NRA group that participates in the ILAR platform - Latin American Association of Responsible Self-Care, we launched a new regulatory tool for the category of Food Supplements: "Database for the Regulation of Food Supplements". This interactive query database allows you to visualize the different existing regulations for food supplements in Latin America, and compare the regulatory aspects of each country; for example, permitted ingredients and their corresponding maximum levels.

See at: <https://foodsupplementsdb.infoilar.org/en/>

ILAR Asks:

- **ILAR calls on governments to recognize the economic impact of food supplements** on health systems and improved health outcomes.
- To achieve this objective, **ILAR suggests strengthening regulatory convergence processes** and advancing the negotiations that have already begun. These initiatives should consider the implementation of reliance, the empowerment of the user to practice self-care, and the updating or development of regulations that allow greater safe, and responsible access to food supplements.
- **ILAR supports the development and updating of regulations for food supplements in Latin America**, focused on modernizing the definition of food supplements according to international references, their classification and regulatory treatment as food, independent of other products of higher risk, the establishment of agile processes and referenced in other NRAs for sanitary notification, approval of ingredients and property claims, and definition of vitamin and mineral levels, according to safety-based methodologies.



REFERENCE LIST:

- 1.WHO 2022. Guideline on self-care interventions for health and well-being. Available at: <https://www.who.int/publications>
- 2.WHO, 2019. Según la OMS, un mayor énfasis en la nutrición en los servicios de salud podría salvar 3,7 millones de vidas para 2025. Available at: <https://www.who.int/es/news/>
- 3.ILAR, 2021. Covid-19 Impact on self-care in Latin America. Available at: <https://www.infoilar.org/es/publicaciones>
- 4.Codex. 2005. Available at: [Microsoft Word - cxg_055s.doc \(fao.org\)](#).
- 5.FDA, USA. Small Entity Compliance Guide on Structure/Function Claims. Available at: <https://www.fda.gov>
- 6.WHO, 2018. Alimentación sana. Available at: <https://www.who.int/es/news-room/fact-sheets/>
- 7.WHO, 2023. Micronutrientes. Available at: <https://www.paho.org/es/temas/micronutrientes>
- 8.PAHO. [Economía de las ENT - OPS/OMS | Organización Panamericana de la Salud \(paho.org\)](#).
- 9.CRN_Overview-Supplements-to-Savings.pdf. 2022. Available at:crnusa.org.
- 10.WHO, 2023. Micronutrientes. Available at: <https://www.paho.org/es/temas/micronutrientes>
- 11.WHO, 2023. Micronutrientes. Available at: <https://www.paho.org/es/temas/micronutrientes>
- 12.Codex. 2005. Available at: [Microsoft Word - cxg_055s.doc \(fao.org\)](#).
- 13.DECISIÓN No. 9 Anexo Suplementos Alimenticios Eliminación de Obstáculos Técnicos – Alianza del Pacífico. (alianzapacifico.net).
- 14.[Aesan - Agencia Española de Seguridad Alimentaria y Nutrición](#)
- 15.EFSA. Europe. Available at: [Food supplements | EFSA \(europa.eu\)](#).
- 16.ANVISA. 2023. [painel de constituintes autorizados para uso em suplementos alimentares. Disponible en: https://app.powerbi.com/](#)
- 17.AESAN, Spain. [Aesan - Agencia Española de Seguridad Alimentaria y Nutrición](#)
- 18.EFSA, UE- [Food and Feed Information Portal Database | FIP \(europa.eu\)](#).
- 19.ANVISA, Brazil. 2021. LISTA DE ALEGAÇÕES AUTORIZADAS PARA USO NA ROTULAGEM DOS SUPLEMENTOS ALIMENTARES. Available at: <http://antigo.anvisa.gov.br/documents/>
- 20.INVIMA, Sala especializada. Octubre, 2021. Available at: <https://www.invima.gov.co/documents>
- 21.Codex, Directrices para complementos alimentarios de vitaminas y/o minerales 2005. Available at: <https://www.fao.org>

ABOUT ILAR:

ILAR is the **Latin American Association of Responsible Self-Care**, leader in promoting responsible self-care as the best way of being and staying healthy, as well as guaranteeing access to self-care products, such as over-the-counter (OTC) medications and food supplements. ILAR is a member of the Global Self-Care Federation (GSCF), an international non-governmental association in an official relationship with the World Health Organization (WHO).



www.infoilar.org