

ABIAD

Associação Brasileira da Indústria de Alimentos para Fins
Especiais e Congêneres

GT PREBIÓTICOS

1ª reunião: 22/09/2020

PREBIÓTICOS – “DEFINIÇÃO”

De acordo com a legislação Brasileira não há definição do **termo Prebiótico** para uso em alimentos.

Nos Estados Unidos, Canadá e em vários outros países já existe uma definição do termo “prebiótico” nas legislações locais, sendo que muitos deles adotaram a definição do ISAPP como oficial.

AGENDA REGULATÓRIA 2021 - 2023



Documento Orientador



AGENDA REGULATÓRIA

OUT 2020

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA | ANVISA

Agenda regulatória

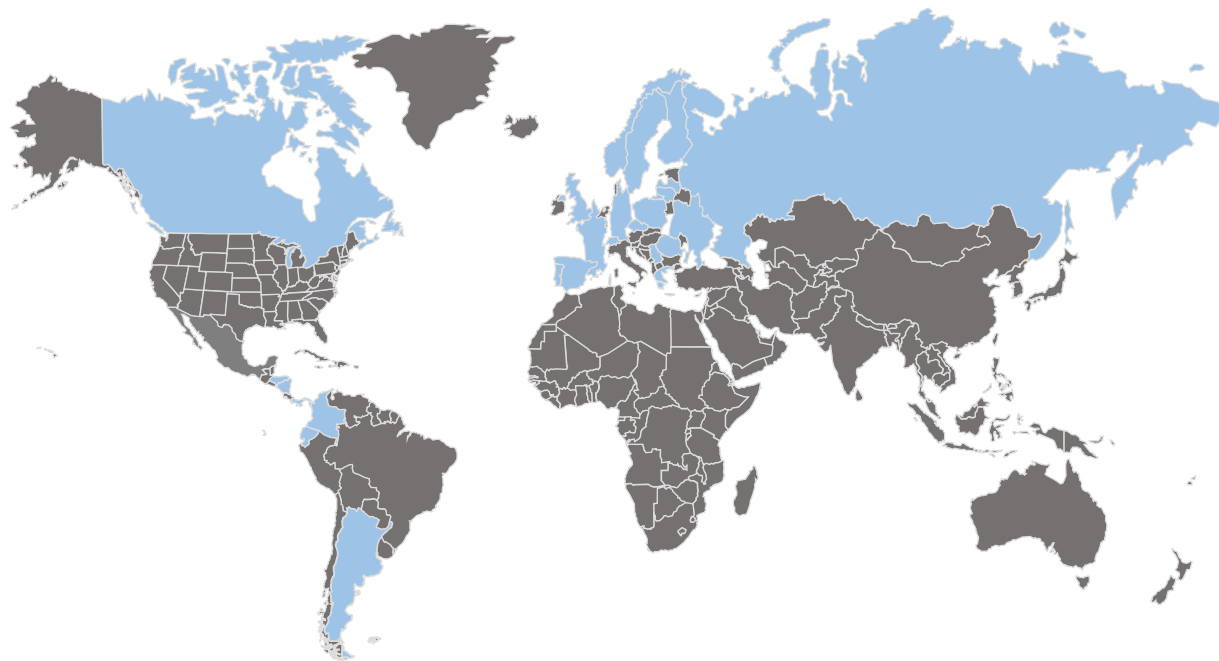
Atualmente não existe na legislação brasileira uma definição do termo “prebiótico”

Assimetria nas informações presentes no mercado nacional sobre o uso do termo prebiótico pelas empresas

Convergência regulatória internacional sobre o termo “prebiótico” no mercado local facilitará a inovação e lançamento de novos produtos

CENÁRIO INTERNACIONAL

- Europa
- US
- Canada
- Guatemala
- Costa Rica
- Honduras
- El Salvador
- Nicaragua
- Colombia
- Equador
- Argentina





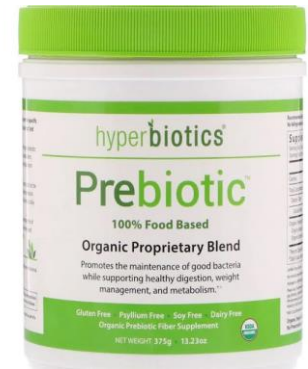
Government
of Canada

Gouvernement
du Canada



Use of the Term “Prebiotic”- Canada

- The term "prebiotic(s)" and similar statements (for example, "stimulates the growth of friendly intestinal microflora", "promotes healthy/beneficial bacteria in the large intestine") on food labels and in advertising that suggest a food confers a health benefit are considered implied health claims
- Such implied health claims are only acceptable when accompanied by a statement of the specific and measurable health benefit conferred by the prebiotic substance, as demonstrated in humans, for example "Prebiotic X increases calcium absorption"
- Whether the use of the term "prebiotic(s)" is assessed as a function claim, disease risk reduction claim or therapeutic claim depends on the specific, measurable health effect supported by scientific evidence and the overall impression created by the labelling and advertising of the food





Label Claims for Foods and Dietary Supplements - USA

- A self-substantiated structure/function claim, including “prebiotic,” can be made if the totality of scientific evidence, demonstrated in humans, supports the claim

<https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements>

- The 2017 ISAPP definition of the term "prebiotic" should be used as a basis for a prebiotic claim since this definition is based on current scientific consensus
- Among other requirements, the ISAPP definition requires that the prebiotic substance must have a measurable beneficial physiologic effect, demonstrated in humans



Guidance on Scientific Requirements for Specific Health Claims - EU

- All new health claims must be reviewed by the European Food Safety Authority (EFSA)

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4369>

- EFSA guidance uses the following criteria to assess each specific food/health relationship that forms the basis of a health claim, considering the extent to which:
 - the food/constituent is defined and characterised;
 - the claimed effect is defined and is a beneficial physiological effect; and
 - a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group, under proposed conditions of use).
- Of 30 submitted health claim petitions for “prebiotic,” none have been favorably reviewed by EFSA



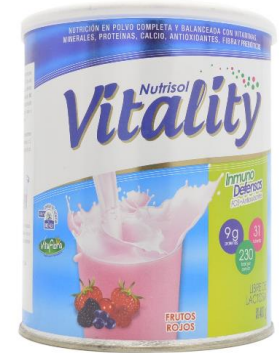
SIECA
SECRETARÍA DE INTEGRACIÓN
ECONÓMICA CENTROAMERICANA



Central America (Guatemala, Costa Rica, Honduras, El Salvador & Nicaragua)

A prebiotic substance must:

- Be preferred by one or more benefic bacteria species in the gut or colon.
- Be resistant to gastric acids.
- Be fermented by gut flora..
- Be resistant to endogenous enzymatic hydrolysis.
- Selectively stimulate the growth and/or activity of bacteria associated to health and wellbeing.



Contiene **IMMUNODEFENSAS** que consiste en una mezcla de prebióticos (Fructooligosacáridos) y antioxidantes (Vitamina C, Vitamina E y Selenio) que contribuyen a balancear el sistema digestivo y fortalecer el sistema inmunológico.

A prebiotic substance must have the next characteristics:

- Amount, to obtain the health effect, must be reasonable in the daily intake context.
- Be preferred by one or more benefic species from the gut flora.
- Be resistant to gastric acids.
- Be fermented by gut flora.
- Be resistant to endogenous enzymatic hydrolysis.
- Have the capability to produce lumen changes in the large intestine or in the host organism that shows the health benefit effects.
- Selectively stimulates the growth and/or activity of bacteria associated with health.



Colombia

Prebiotics definition: non-digestible oligosaccharides or polysaccharides that favor the selective growth of beneficial gut bacteria, modifying favorably the microbial balance. Also, it must comply with the next characteristics:

- Amount, to obtain the health effect, must be reasonable in the daily intake context.
- Be preferred by one or more benefic species from the gut flora.
- Be resistant to gastric acids.
- Be fermented by gut flora.
- Be resistant to endogenous enzymatic hydrolysis.
- Have the capability to produce lumen changes in the large intestine or in the host organism that shows the health benefit effects.
- Selectively stimulates the growth and/or activity of bacteria associated with health.



Argentina

Prebiotic is understood the food ingredient or part of it (indigestible) that has a beneficial effect for the recipient organism, stimulating the selective growth and / or activity of one or a limited number of bacteria in the colon and which confers benefits for your health. For a compound to be used as a prebiotic ingredient for food, it must comply with the protocol for Evaluation of a Prebiotic as an ingredient for Food



Obrigada