

Country	Does exist Prebiotic definition in the regulation? (yes/no)	Prebiotic Definition	Is it possible to claim "Prebiotic" on labels?
Canada	yes	<p>The term "prebiotic(s)" and similar representations (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 to be implied health claims.</p> <p>These 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 and measurable health effect supported by scientific evidence and the overall impression created by the labelling and advertising of the food. For information on the scientific criteria to substantiate claims about "prebiotic(s)"</p>	yes, but is 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".
USA	no This type of claim is regulated as a structure-function claim. FDA guidance	A self substantiated "prebiotic" claim can be made if the totality of scientific evidence for the substance supports the claim. The 2017 ISAPP definition of the term "prebiotic" should be used as a basis for the 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.	yes, it is possible to make a "prebiotic" claim provided that the claim is truthful and not misleading. The conditions in column C must be met as well.

EU	<p>No</p> <p>However, there is guidance at EU level which clarifies that a claim of 'prebiotic' / 'prebiotic fibre' would be considered as a health claim under Regulation (EC) No 1924/2006.</p>	<p>All new health claims have to be reviewed by European Food Safety Authority (EFSA). EFSA guidelines set out the following criteria that they use:</p> <p>'In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:</p> <ol style="list-style-type: none"> 1. the food/constituent is defined and characterised; 2. the claimed effect is defined and is a beneficial physiological effect ("beneficial to human health"); 3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use). <p>Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.</p> <p>For a claim, each relationship between a food/constituent and a claimed effect is assessed separately and individual assessments are combined, as appropriate, to form coherent opinions.</p>	<p>Yes, in principle. EFSA has not yet approved any prebiotic claims due to the fact that submitted data has not met the criteria in column C.</p>
Central America (Guatemala, Costa Rica, Honduras, El Salvador & Nicaragua)	<p>yes</p>	<p>A prebiotic substance must:</p> <ol style="list-style-type: none"> a. Be preferred by one or more beneficial bacteria species in the gut or colon. b. Be resistant to gastric acids. c. Be fermented by gut flora. d. Be resistant to endogenous enzymatic hydrolysis. e. Selectively stimulate the growth and/or activity of bacteria associated to health and wellbeing. 	<p>yes</p> <p>Example of accepted health claim: "An adequate diet and regular consumption of food with prebiotics, promotes the growth of beneficial gut bacteria and improves the intestinal function and natural defenses".</p>
Colombia	<p>yes</p>	<p>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:</p> <ol style="list-style-type: none"> 1. Amount, to obtain the health effect, must be reasonable in the daily intake context. 2. Be preferred by one or more beneficial species from the gut flora. 3. Be resistant to gastric acids. 4. Be fermented by gut flora. 5. Be resistant to endogenous enzymatic hydrolysis. 6. Have the capability to produce lumen changes in the large intestine or in the host organism that shows the health benefit effects. 7. Selectively stimulates the growth and/or activity of bacteria associated with health. 	<p>yes</p> <p>Example of accepted health claim: "A balanced diet and regular consumption of X g per day of prebiotics Y, promotes a healthy/good/balanced gut flora" "Benefits gut flora" "Helps to improve intestinal / digestive function"</p>

Ecuador	yes	A prebiotic substance must have the next characteristics: 1. Amount, to obtain the health effect, must be reasonable in the daily intake context. 2. Be preferred by one or more benefic species from the gut flora. 3. Be resistant to gastric acids. 4. Be fermented by gut flora. 5. Be resistant to endogenous enzymatic hydrolysis. 6. Have the capability to produce lumen changes in the large intestine or in the host organism that shows the health benefit effects. 7. Selectively stimulates the growth and/or activity of bacteria associated with health.	yes Example of accepted health claim: "A balanced diet and regular consumption of X g per day of prebiotics Y, promotes a healthy/good/balanced gut flora" "Benefits gut flora" "Helps to improve intestinal / digestive function"
Argentina	yes	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	yes. The authorization of health claims for food requires evaluation by the "Evaluation Commission for the authorization of health claims in food" according to the protocol of Provision 7730/2011. The regulation contemplates the approval of health claims in advertising and promotion of food, not in labeling. However, there are numerous cases of companies that include them in the labeling of their products.
ISAPP	does not apply	ISAPP published a consensus statement updating the prebiotic concept – Expert consensus document: The International Scientific Association for Probiotics and Prebiotics (ISAPP) consensus statement on the definition and scope of prebiotics. Available open access from Nature Reviews in Gastroenterology and Hepatology, this paper offers a new definition of prebiotic: a substrate that is selectively utilized by host microorganisms conferring a health benefit. The consensus panel was led by Prof. Glenn Gibson, University of Reading, co-founder and past president of ISAPP. In 1995, Prof. Gibson, along with Professor Emeritus Marcel Roberfroid, first coined the term 'prebiotic'. This new definition embraces progress in microbiome science and prebiotic innovation. Publication of this consensus statement is just in time for the ISAPP 2017 annual meeting, which will be held June 27-29, 2017.	does not apply
Korea	No Remark: for Korean regulation, only definition of <u>Probiotic</u> is available.	No	Only materials with function of growth of beneficial bacteria(fructooliosaccharide, xyloigosaccharide,etc) can be advertised as 'prebiotic' In this case the materials should be recognized by Korean FDA for their functionality.
Vietnã	No		No
Japan	No	No	Yes. with condition on applying for "Foods for Specified Health Uses" or "Foods with Function Claims".

Legislation link

<https://www.inspection.gc.ca/food-label-requirements/labelling/industry/health-claims-on-food-labels/eng/1392834838383/1392834887794?chap=11>

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

Regulation (EC) No 1924/2006 Nutrition and Health Claims
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1924-20141213>
EFSA opinion on submitted prebiotic health claims
<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1809> EU guidance on health claims
https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf

<http://web-sieca.s3.amazonaws.com/actos%20administrativos/resoluciones/comieco/281-2012ANEXO.pdf?AWSAccessKeyId=AKIAQZBIU6IINLAVIAEJ&Expires=1601668486&Signature=1jUIFL4uP1EXv8dgle5RrFJArY%3D>

<https://extranet.who.int/nutrition/gina/sites/default/files/COL%202011%20RESOLUCI%C3%93N%200333%20%28etiquetado%20nutricional%29.pdf>

https://www.normalizacion.gob.ec/buzon/normas/nte_inen_1334-3.pdf

https://www.argentina.gob.ar/sites/default/files/anmat-capitulo_xvii_dieteticosactualiz_2018-12.pdf

[ISAPP published a consensus statement updating the prebiotic concept – Expert consensus document: The International Scientific Association for Probiotics and Prebiotics \(ISAPP\) consensus statement on the definition and scope of prebiotics. Available open access from Nature Reviews in Gastroenterology and Hepatology, this paper offers a new definition of prebiotic: a substrate that is selectively utilized by host microorganisms conferring a health benefit. The consensus panel was led by Prof. Glenn Gibson, University of Reading, co-founder and past president of ISAPP. In 1995, Prof. Gibson, along with Professor Emeritus Marcel Roberfroid, first coined the term ‘prebiotic’. This new definition embraces progress in microbiome science and prebiotic innovation. Publication of this consensus statement is just in time for the ISAPP 2017 annual meeting, which will be held June 27-29, 2017.](#)

https://www.caa.go.jp/policies/policy/food_labeling/information/pamphlets/pdf/151224_1.pdf

