

*The purpose of this paper is to serve as a summary of the discussions from the panel convened at the 2018 ISAPP meeting (Singapore). It is intended to provide perspective to local regulators for discussions on this topic at the Codex Alimentarius meeting.*

## **ISAPP position statement on minimum criteria for harmonizing global regulatory approaches for probiotics in foods and supplements.**

### **Background and aim**

The annual meeting of the International Scientific Association of Probiotics and Prebiotics (ISAPP) took place June 5th and 6th 2018 in Singapore. A discussion forum on harmonizing global probiotic and prebiotic food/supplements regulations was held June 7<sup>th</sup>. The forum was attended by 30 participants (see list of participants below) from 13 countries and had the following objectives:

1. To promote understanding of current probiotic and prebiotic regulations in different countries;
2. To discuss how to make progress on global harmonization of regulatory approaches to probiotics and prebiotics;
3. To agree on minimum standards.

The final goal of the discussion forum is to provide regulators guidance derived from this panel of experts regarding the minimum criteria a probiotic food or supplement should meet.

During the thirty-ninth session of the *Codex Alimentarius* (CA) Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) held in Berlin (Germany) from December 4<sup>th</sup> to 8<sup>th</sup> 2017, the International Probiotic Association (IPA) presented a proposal for new work on harmonized probiotic guidelines for use in foods and dietary supplements. The full IPA proposal can be read [here](#).

The CA accepted the proposal and requested the Argentinian regulatory authority, the National Food Institute (Spanish acronym: INAL), to prepare of a draft of guidelines on probiotics to be discussed in the 2018 session of the CCNFSDU. This position statement is intended to be provided to the CCNFSDU through country representatives, in order to contribute to the CCNFSDU discussion on the construction of a guideline for probiotics.

### **Rationale**

An increasing number of people worldwide are eager to maintain their health with evidence-based dietary and lifestyle solutions. This trend has led to the

development of a diverse market of foods and food supplements to address these needs. Among them, food and food supplements with probiotics are gaining broader appeal. On a regular basis new products labeled as containing probiotics are launched, including ice creams, juice drinks, hot beverages, flavored waters, fruit and cereal snacks, chocolate bars, breakfast cereals, snacks for kids (Markets & Markets, 2018). Indeed, the probiotic food sector is experiencing a dynamic growth, with claims of projected retail value from 50 to 64 billion dollars by 2022, depending on the source (Euromonitor, 2018; Markets & Markets, 2018). In Asia Pacific, the market for dietary supplements with probiotics is valued at US\$3.08B as of retail year 2017 and is projected to grow to US\$6.56B in retail year 2020, with a compounded annual growth rate in 2017-2022 of 6.9% (Euromonitor, 2018). Market research shows that of new products launched in the waters, soft drinks, tea and traditional beverages category, those with probiotics accounted for 39% and 28% of in US and UK markets, respectively, during 2015-2017 (Markets & Markets, 2018). In this expanding, worldwide market, different local rules and lack of clarity on what constitutes a probiotic for operators and regulators are likely to confuse the consumer. The term “probiotics” is used more and more, with a risk of no or limited adherence to scientifically accepted criteria for probiotics. The absence of formal criteria leaves the door wide open for misuse of the “probiotic” denomination and misinterpretation of the probiotic concept. The global array of products labeled as ‘probiotic’ raise important concerns on the identity, safety and efficacy of the probiotic microorganisms they claim to deliver (Toscano et al., 2013; de Simone, 2018). All of these factors establish the basis for consumer confidence if presented in an evidence-based manner.

### **The role of *Codex Alimentarius* in improving probiotic foods globally**

The CA is a collection of food standards, guidelines and codes of practice that contribute to the safety, quality and fairness of the international food trade. International food trade has existed for thousands of years but until recently food was mainly produced, sold and consumed locally. Over the last century the amount of food traded internationally has grown rapidly, and a quantity and variety of food never before possible travels the globe today, including probiotic supplements and foods. Food operators can use established good food manufacturing practices, consumers can trust the safety and quality of the food products they buy and importers can trust that the food they ordered will be in accordance with their specifications. Since its foundation in 1963, the Codex system has evolved in an open, transparent and inclusive way to meet emerging challenges. Public concerns about food supply issues such as security, safety, quality, nutrition and labeling often place CA at the center of global debates. Codex standards are based on sound science provided by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO.

In relation to probiotics, a joint FAO/WHO expert consultation on the [Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live](#)

[Lactic Acid Bacteria](#) was held in the city of Córdoba (Argentina), 1-4 October 2001. This expert consultation resulted in a definition of probiotics. [Guidelines](#) for the evaluation of probiotics in food were developed the following year. These guidelines provided the first minimum criteria for meeting the definition of 'probiotic'. Today, 16 years later, considering the growth and development of the science, commercialization and regulation of the probiotic field, it is worthwhile to revisit this guideline to assess its continued relevance.

Today's market of probiotic foods and supplements creates a pragmatic example of a topic that should be considered in the framework of the CA. While being recommended for voluntary application by members, Codex standards serve in many cases as a basis for national legislation. In this context, out of the 189 members of the *Codex Alimentarius*, local regulation of probiotic in foods and supplements, yet inspired by the [FAO/WHO 2002](#) guidelines, can be found in fewer than one third of these countries.

### **ISAPP position statement on minimum criteria for probiotics**

During the ISAPP discussion forum, the participants agreed that probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host ([Hill et al., 2014](#)). From this definition, and informed by the 2002 FAO/WHO guidelines, participants derived minimum criteria that should be met for a microorganism to be legitimately called a 'probiotic' food or food supplement. From a scientific point of view, meeting these criteria would constitute a truthful and not misleading use of the term 'probiotic' to describe the microbe in commerce. The minimum criteria are:

1. Characterization sufficient to identify the probiotic to the genus, species and strain level.
2. Probiotic named according to scientifically valid nomenclature.
3. Probiotic name includes a strain designation.
4. Safety of probiotic demonstrated for intended use.
5. Probiotic strain deposited in an international culture collection.
6. Probiotic has health benefit demonstrated from at least one human study.
7. Products using the probiotic provide until the end of shelf life sufficient level of live microbes to deliver a health benefit.

For criterion 7, if a health benefit is claimed, the level of probiotic provided in the product must be sufficient to deliver the claimed benefit.

[Similar criteria](#), in the spirit of the FAO/WHO 2002 guidelines, were published by trade associations of the probiotic sector, to promote the correct use of the term ‘probiotic’ among interested parties.

In addition, it was agreed that accurate labelling should be defined and provided for foods and food supplements containing probiotics, but this was not comprehensively discussed. In principle, labels of probiotic products should display the genus, species and strain designation of each probiotic in the product, as well as the count of live microbes through the end of shelf life.

The scope of the discussion group also included minimum criteria for prebiotics. The definition of prebiotics was accepted as “A substrate that is selectively utilized by host microorganisms conferring a health benefit” ([Gibson et al., 2017](#)). Since prebiotics are not part of the proposal made by the International Probiotic Association to the CA for the production of a harmonized codex standard in the 2017 meeting in Berlin, they will not be included in this initial action. A different and new action must be taken for prebiotics.

#### **List of participants that attended the discussion panel (in alphabetical order)**

Akihito Endo, Tokyo University of Agriculture, Hokkaido, Japan  
Anadi Nitithamyong, Food Science and Technology Association of Thailand  
Anders Henriksson, DuPont Nutrition and Health, Australia  
Carlos Gómez Gallego, Functional Foods Forum, University of Turku, Finland  
Caroline Gray, DuPont Nutrition and Health, Singapore  
Charmaine Ng, National University of Singapore  
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Fei Li, Abbott Nutrition Research & Development, Singapore  
Gabriel Vinderola, Instituto de Lactología Industrial (CONICET-UNL), Argentina  
Hani El-Nezami, University of Hong Kong, Hong Kong SAR  
Jasvir Singh, DuPont Nutrition & Health, Gurgaon, India  
Jinzhong Xiao, Morinaga Milk Industry, Zama, Japan  
Karen Wong, National Pharmaceutical Regulatory Agency, Malaysia  
Le Thi Hop, Vietnam Nutrition Association  
Malee Jirawongsy, Thai Food and Drug Administration  
Margriet Schoterman, FrieslandCampina, Amersfoort, The Netherlands  
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Maria Stolaki, Winclove Probiotics, The Netherlands  
Martijn Bekker, NIZO, Ede, The Netherlands  
Mary Ellen Sanders, Executive Science Officer, ISAPP, USA

Nana Bartke, Danone Nutricia Research, Singapore  
Neerja Hajela, Yakult Danone India Pvt. Ltd, New Delhi, India  
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