INTERNATIONAL PROBIOTICS ASSOCIATION EUROPE[1]

CRITERIA TO QUALIFY A MICROORGANISM DESIGNATED AS 'PROBIOTIC' IN FOODS, BEVERAGES AND DIETARY SUPPLEMENTS

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In 2001, in a period that marked a rise in interest in probiotics among consumers and the clinical and scientific communities, experts convened by the Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) provided a scientific opinion on 'probiotics' (FAO/WHO 2001) and agreed on the following definition (later amended by an expert consensus group): "*live microorganisms that, when administered in adequate amounts, confer a health benefit on the host*" [2] (Hill C 2014)

This report was followed by the "Guidelines for the Evaluation of Probiotics in Food" (FAO/WHO 2002) where the FAO/WHO experts made several recommendations. One of these was to officially adopt the definition as well as more specific criteria as a prerequisite to qualify a microbial strain as a 'probiotic'.

While the definition of probiotics has been widely acknowledged by the scientific community and key players in the field of probiotics, the FAO/WHO guidelines have not been implemented. In Europe, there is neither regulatory status nor guidelines defining the probiotics category, nor a commonly acknowledged list of individual probiotic strains and/or species [3].

Therefore, it is essential that the industry clarifies specifications for probiotics in foods, in order to ensure the proper use of the term without contradicting national requirements or health claim provisions.

[1] IPA Europe is the European chapter of IPA, the International Probiotics Association; it was established in Brussels in 2015. The members of IPA Europe are Companies directly engaged in the manufacture of probiotic cultures or probiotic foods, supplements, nutritionals or therapeutic products: BioGaia, Chr. Hansen, Danone, DuPont, IPA, Lallemand, Lesaffre, Probi and Yakult. The IPA Europe mission is: to gain acceptance of the term "probiotic" throughout Europe as a defined category and to create a favourable environment for probiotics in Europe. For additional information on IPA Europe's activities see: http://ipaeurope.org

[2] Note: but restricted its scope to discussion of 'Live microorganisms which when consumed in adequate amounts as part of food confer a health benefit on the host.'

[3] Note: although some EU Member States have adopted such lists and others have developed certain conditions for qualifying specific strains as probiotic

Scope of the IPA Europe criteria

In accordance with the FAO/WHO guidelines, the scope of this document is limited to the use of probiotics in food, including food supplements (Chapter 3). Drug applications and animal feeds are excluded from the scope of these criteria.

Probiotic Criteria

There have traditionally been many products available in the marketplace carrying the label 'probiotic'. However, there are currently no defined criteria or guidelines accepted within Europe on what constitutes a 'probiotic' microorganism. IPA Europe recommends that the term 'probiotic' should only be used to describe microorganisms when a certain combination of requirements is met (IPA EU, 2015). No specific authorisation would be required as long as no reference to any specific health effect is made.

Probiotic Strains

1. Must be taxonomically characterized at the species level and identifiable at the strain level

- Probiotics are specific strains that need to be identified at the strain level, by using the most current, valid and internationally accepted techniques. This would require using a combination of the most appropriate molecular techniques, according to the LPSN list (List of prokaryotic names with standing in nomenclature http://www.bacterio.net/, see also http://ijs.sgmjournals.org/content/64/Pt_4/1434.full) or the International Committee on Systematics of Prokaryotes (http://icsp.org/).
- Probiotics are classified, as per reference nomenclature, at the species level (family, genus and species). IPA Europe recommends that probiotic strains are indicated in the ingredients list with their strain ID.
- IPA Europe recommends that probiotic strains are deposited in an internationally recognised culture collection (http://wfcc.info/collections).

2. Must be safe for the intended use (i.e. for the targeted consumer and in the conditions of recommended use)

- Species that are safe for human consumption are listed in the "Qualified Presumption of Safety" (QPS) EFSA reference documents (EFSA, 2007, Annon). The European Food Safety Authority (EFSA) has taken responsibility for this European initiative (Anon, 2005), which aims to allow strains with an established history and safety status to enter the market without further extensive testing requirements. The QPS concept is a fast track approach for species for which there is a sufficient body of knowledge, so that all strains within a species are presumed to be safe for human consumption (EFSA BIOHAZ, 2017).
- Safety assessment of strains of QPS-listed species can be limited to aspects that are relevant for the organism in question.

3. Must be scientifically documented

- FAO/WHO definition and guidelines (2001-2002), state that strains of micro-organisms should be considered as probiotic if these are scientifically documented. IPA Europe recommends that the probiotic status of strains should be characterized and documented by at least one human supportive clinical trial according to generally accepted scientific standards (http://www.consort-statement.org/).

4. Must be alive when consumed

- Probiotic strains must be alive in the product throughout shelf life and when consumed.
- The amount of live probiotic strain in the product should be consistent with the scientifically demonstrated amount required to achieve the desired effect up to the end of shelf-life[4].
- Any statements with regard to survival of the probiotic through the gastrointestinal tract should be demonstrated by human studies.

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[4] On the basis of available literature, it can be assumed that the sufficient amount to produce an effect is 10^9 live cells per daily portion. A different daily dose may be accepted if substantiated by specific studies that have shown the specific strain is effective in smaller amounts

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