Probiotic definition and elements of the proposal on harmonised Codex approach

THE GLOBAL VOICE OF PROBIOTICS

IPA/IPA EUROPE SESSION

How to define a comprehensive approach for the definition of the probiotic category (nutrition relevance and scientific requirements)

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Chair of the Standing Committee

on Microbiological Hygiene

International Dairy Federation

- Founded in 1903
- Providing expertise and scientific knowledge in support of the development and promotion of quality milk and milk products, to offer consumers nutrition, health and well-being.
- Best practice at international level in order to guide the dairy sector and to harmonize members' work on a variety of issues along the dairy production chain including animal health and welfare, protection of the environment, nutrition, food safety and hygiene and food standards.
- http://www.fil-idf.org

FAO / WHO (Draft) Guidelines 17 years after. Time to update ?

Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food
London, Ontario, Canada, April 30 and May 1, 2002

1. Introduction

The Joint FAO/WHO Expert Consultation on **Evaluation of Health and Nutritional Properties of Probiotics in Food** held in Córdoba, Argentina from 1-4 October, 2001 recognized that there is a need for guidelines to set out a systematic approach for the evaluation of probiotics in food leading to the substantiation of health claims. Consequently, a Working Group was convened by FAO/WHO to generate guidelines and recommend criteria and methodology for the evaluation of probiotics, and to identify and define what data need to be available to accurately substantiate health claims. The aims of the Working Group were to identify and outline the minimum requirements needed for probiotic status. Consequently, guidelines were prepared to meet this objective.

Report of CCNFSDU #40 (2018/11)

Discussion: Those delegations in support of the work noted that harmonized global guidelines would benefit the Codex community in light of the significant increase in global trade of probiotics for use in foods and dietary supplements in recent years and would assist national authorities in evaluating foods/supplements containing probiotics. **One observer also supported new work on harmonized guidelines which would establish a definition with minimum characterization requirements as well as quality and labelling criteria for probiotics for use as an ingredient in foods and dietary supplements.**

Those delegations and **an observer not in favour** of starting new work at this point, expressed the following view or concerns:

- There was no perceived need for such work.
- This work might not have the priority taking into account the current heavy workload of the Committee.
- **The paper needed to be revised to provide more clarity especially on the scope of the work.**
- Collection of information and data from Members should be first conducted to identify a globally applicable definition of probiotics.
- Infant foods should be excluded since safety was of concern due to a limited number of studies.

Conclusion: The Committee agreed that Argentina should redraft the discussion paper for consideration at its next session elaborating further on the sections on **scope**, **definition** as well as health and trade concerns in particular.

IDF comments to CX/NFSDU 18/40/12 Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements

- In principles, **IDF supports the proposal** of Argentina to establish guidelines for the use of probiotics in foods and dietary supplements
- Subject to approval by the committee to develop guidelines for the use of probiotics in foods and dietary supplements, **IDF would like to offer its participation in the work** as it is believed modifications are needed to the proposed document
- It should be more explicit on its scope, purpose, and limits. **The definition of a probiotic strain, inactivated or not, a probiotic food product should be established for food and not medical purpose.** IDF would like to see the focus on the labelling rules regarding the use of "probiotic"
- Safety and health benefit demonstration guidelines should not be detailed in the document but referred to scientific evidence presently available. **Of note, a positive list approach such as IDF's one for food culture, does not apply to probiotic strain candidates**.

ISDI position CCNFSDU40 Agenda Item 11: Proposal for New Work *Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Dietary Supplements*

However, ISDI calls the attention of CCNFSDU members on the following elements:

- Several Codex texts, elaborated by various codex committees (e.g. CCFH, CCCF, CCFL) along with the guidance provided by the FAO/WHO guidelines are already addressing this topic
- **The safety and manufacturing requirements** of probiotics as a food/food ingredient **are elements already covered** by several horizontal Codex-Standards, including among others:
  - the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) or
  - the General Principles of Food Hygiene (CXC 1-1969) and other relevant Codex texts.
- **Communication on the health benefit of probiotics is already covered** by a Codex document "Guidelines for Use of Nutrition and Health Claims – CAC/GL 23-1997" along with its annex regarding "Recommendations on the scientific substantiation of health claims"
  - The specific need for efficacy studies are clearly described in the FAO/WHO-guidelines (2002)
- A number of countries have already developed national provisions based on the FAO/WHO guidelines *(IDF Note: but some of them are conflicting nevertheless)*

Definition of Probiotic Strain

- IDF is aligned on the FAO/WHO 2001 and 2002 proposal, Nutrition Paper #85-2006
- "**Live** microorganisms which when administered in **adequate amounts** confer a **health benefit** on the **host**"
- Revised in 2014, Hill *et alii*, as "Live microorganisms **that**, when administered in adequate amounts, confer a health benefit on the host"
- Harmonization is indeed required since other definitions are applied in some countries or in the literature

Because too many definitions do no help (*at all*)

- De Vrese and Schrezenmeier, 2008, in Food Biotechnology pp 1-66
  - « According to the **German definition**, probiotics are defined viable microorganisms, sufficient **amounts of which reach the intestine in an active state** and thus exert positive health effects. »

(So long for vaginal probiotics strains…)

Growing scientific evidence when deciphering the mechanism of action (**another**) definition needed

Research-Article

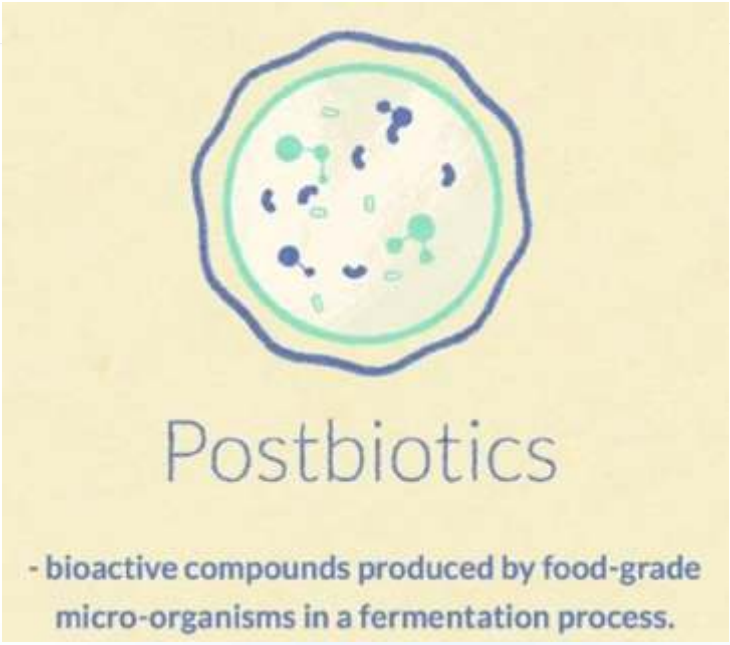
Postbiotics: what else?

K. Tsilingiri , M. Rescigno

Beneficial Microbes: 4 (1)- Pages: 101 - 107

https://doi.org/10.3920/BM2012.0046

Published Online: December 27, 2012



Recent work on relevant probiotic strains has also led to the isolation and characterisation of certain probiotic-produced, soluble factors, here called **postbiotics**, which were sufficient to elicit the desired response.

Wanted: Probiotics – Dead or Alive

(could it be acceptable?)

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Probiotic microbes: do they need to be alive to be beneficial?

Jasmeet Kataria, Nan Li, James L Wynn, Josef Neu ✉

Nutrition Reviews, Volume 67, Issue 9, 1 September 2009, Pages 546–550, https://doi.org/10.1111/j.1753-4887.2009.00226.x

Published: 01 September 2009

What does alive mean ? “cultivable” ?

Food or Drug ?

2. Scope

The report of the **Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food** addressed probiotics in food, and excluded reference to the term biotherapeutic agents, and beneficial microorganisms not used in food (http://www.fao.org/es/ESN/Probio/probio.htm). The Working Group adopted the same scope as the Expert Consultation, and specifically excluded genetically modified organisms (GMOs).

The US FDA refers to Probiotic also as biotherapeutic agents, and specify the classification, in case of use for specific purpose, of the product as a drug

(and therefore cannot be classified as a food: a benefit / risk assessment is required – PROPATRIA Study 2008)

Case report of opportunistic infection following consumption of a probiotic food product

To cite: Pararajasingam A, Uwagwu J. *BMJ Case Rep* Published Online First: [*please include* Day Month Year]. doi:10.1136/bcr-2016-218423

CASE REPORT

Lactobacillus: the not so friendly bacteria

Abirami Pararajasingam,[1] Juliet Uwagwu[2]

Summary: We present a 65-year-old diabetic patient with a complex liver abscess and bacteraemia from *Lactobacillus paracasei*. The abscess resulted in a prolonged hospital stay due to ongoing sepsis despite ultrasound-guided drainage and broad-spectrum antibiotics. Furthermore, the patient developed several secondary complications including a right-sided pleural effusion, an inferior vena cava thrombus and septic lung emboli. The abscess was eventually managed successfully with a prolonged course of antibiotics and multiple ultrasound-guided drainage procedures.

To our knowledge, this is the first reported case of probiotic consumption, confirmed by strain identification, as the likely source of a liver abscess. Probiotic products have been widely used for many years and are advocated to the general public for their health benefits with no warning of side effects. Lactobacilli are one group of bacteria commonly used in these products. Although rare, complications have been reported. Susceptible patients, such as those who are immunocompromised, should be advised against excessive consumption.

Take home message

- The information of the FAO/WHO Nutrition paper #85 - 2006, compendium of Cordoba – Argentina 2001 and London, Ontario – Canada 2002 workshops, has been used by the scientific and industrial communities for almost two decades.

- While an upgrade is needed (e.g. ongoing work of IDF – SCAMDAM Action team on updating the IDF Bulletin for Identification of a probiotic at the strain level), most of the information available in these draft guidelines for recommendation are still valid (*yet not always applied*).

- **A reinforcement of the recommendations,** based on the updated scientific evidence, is welcome. **Not a change for another set of propositions.**

Thank you
for your attention

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