A CLOSER LOOK AT BIOTHERAPEUTIC AGENTS

WHAT IS A POSTBIOTIC?

A new consensus definition provides the response...

The International Scientific Association of Probiotics and Prebiotics (ISAPP) **consensus statement on the definition and scope of POSTBIOTICS**

(Nature Review 2021)

ISAPP
International Scientific Association for **PROBIOTICS** and **PREBIOTICS**

If you're interested in knowing more about postbiotics, scan the QR code to see interviews with experts from ISAPP

Salminen *et al.* The International Scientific Association for Probiotics and Prebiotics (ISAPP) consensus statement on the definition and scope of postbiotics. *Nature Rev Gastroenterol Hepatol* (2021).

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POSTBIOTICS: the need for a clear definition

The microbiome and biotherapeutics

Interest in the role of biotherapeutic products for health is increasing as the knowledge about the pivotal role of the microbiome evolves. ISAPP consensus wants to learn more about the potential benefits of these microbe-based 'biotic' compounds and to understand how they differ from one another.

Introducing postbiotics

The term 'postbiotic' appears more and more frequently in both the scientific literature and in the public domain. However, until now there has been confusion as to what exactly constitutes a postbiotic.

The ISAPP consensus

ISAPP*, an International Scientific Association focused on the science around 'biotics', has now addressed the challenge of defining this new 'biotic'.

The ISAPP consensus statement on the definition and scope of postbiotics was published in the *Nature Review of Gastroenterology and Hepatology* (May 2021).

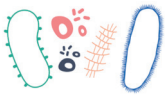
A postbiotic is...

'A preparation of inanimate micro-organisms and/or their components that confers a health benefit on the host'

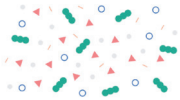
ISAPP consensus 2021

Components of postbiotics:

Postbiotics may contain intact inanimate microbial cells...



And/or microbial cell Fragments/ structures...



With or without Metabolites/ endproducts

*The International Scientific Association of Probiotics and Prebiotics

What's different about POSTBIOTICS?

ISAPP based its definition on the following criteria :

- Evidence of a health benefit in the host based on data from high quality, placebo-controlled, clinical trials
- Proven safety record in the target group for a specific indication
- Clear identification of the original bacterial strain
- Detailed description of all the components of the postbiotic
- Description of how the compound has been inactivated
- Confirmation of inactivation

NOT included in the Postbiotic definition

- viruses (including bacteriophages)
- vaccines
- filtrates without cell components
- purified microbial components such as SCFAs*
- purified microbial metabolites

The advantages of postbiotics compared to other biotics

Postbiotics have

INHERENT STABILITY

Advantages of long shelf-life, room temperature storage & transport

GOOD SAFETY PROFILE

They cannot cause bacteraemia or fungaemia, risks that are associated with probiotic administration

*Short chain fatty acids

Beneficial health effects of POSTBIOTICS

All 'Biotics' offer health benefits

As for probiotics and prebiotics, postbiotics, by definition, must have a positive action on health.

Postbiotics work with the microbiome to improve health

ISAPP suggest that there are five main mechanisms of action:

1. Modulation of the resident microbiota
2. Enhancement of epithelial barrier functions
3. Modulation of local and systemic immune responses
4. Modulation of systemic metabolic responses
5. Systemic signaling via the nervous system

Proven efficacy of postbiotics

Clinical studies have shown that postbiotics can offer benefits across several therapeutic areas that include:

- ✓ digestive health
- ✓ dermatology
- ✓ allergy
- ✓ respiratory disease
- ✓ mental health
- ✓ infectious disease

Good safety profile

'Postbiotics could reasonably be expected to have a better safety profile than probiotics, because the micro-organisms they contain have lost the capacity to replicate.'

ISAPP consensus 2021

POSTBIOTICS for treatment & prevention

The ISAPP Consensus highlights the fact that postbiotics can be used to both treat and prevent a range of health problems in patients of all ages.

Examples of postbiotic use in adults and children

Therapeutic Area	Postbiotic	Indication
Digestive problems in adults	Inactivated *Lactobacillus* LB plus fermented culture medium	Alleviation of symptoms in patients with Irritable Bowel Syndrome (IBS), diarrhea, and improvement of quality of life
	Inactivated *Lactobacillus* LB plus fermented culture medium	Reduction in stool frequency in patients with chronic diarrhea
	Bifidobacterium bifidum	Alleviation of IBS symptoms; abdominal discomfort, bloating and abnormal bowel habits
Gastroenteritis in infants & children	Inactivated *Lactobacillus LB* plus fermented culture medium	Reduction in duration of acute diarrhea
	Lactobacillus casei	Clinical recovery from rotavirus diarrhea
Respiratory disease in adults	*Mycobacterium phlei*	Improvement in symptoms and spirometry in moderate, persistent asthma
	Haemophilus influenzae	Reduction of severe exacerbations of COPD*
Prevention of common infectious diseases in children	*Lactobacillus paracasei*	Reduction in risk of gastroenteritis, respiratory tract infections and other common infections such as otitis media

*Chronic obstructive pulmonary disease

Summary of the POSTBIOTIC consensus

Main conclusions from the panelists:

- **Postbiotics are deliberately inactivated microbial cells with or without metabolites or cell components that:**
  - Remain stable for several years and offer reproducible results.
  - Offer greater convenience than probiotics in terms of storage and transportation with no need of refrigeration.

- **Purified microbial metabolites and vaccines are not postbiotics.**

- **Postbiotics have proven health benefits in the target host as demonstrated in controlled studies**
  - Proven efficacy in adults and children across a range of indications in digestive health.

- **Postbiotics do not have to be derived from a probiotic**
  - They do not depend on viable micro-organisms to convey their health benefits.

- **The site of action is not limited to the gut**
  - Postbiotics can play a role in improving both intestinal and systemic health.

- **By definition, a postbiotic must be safe for its intended use**
  - They have an good safety record in clinical practice and offer safety benefits in comparison to live micro-organisms.

‘Several clinical indications could benefit from the availability of effective postbiotics… they could have a valuable role in clinical medicine.’

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