



# Biotic Industry Challenges: An IPA Perspective

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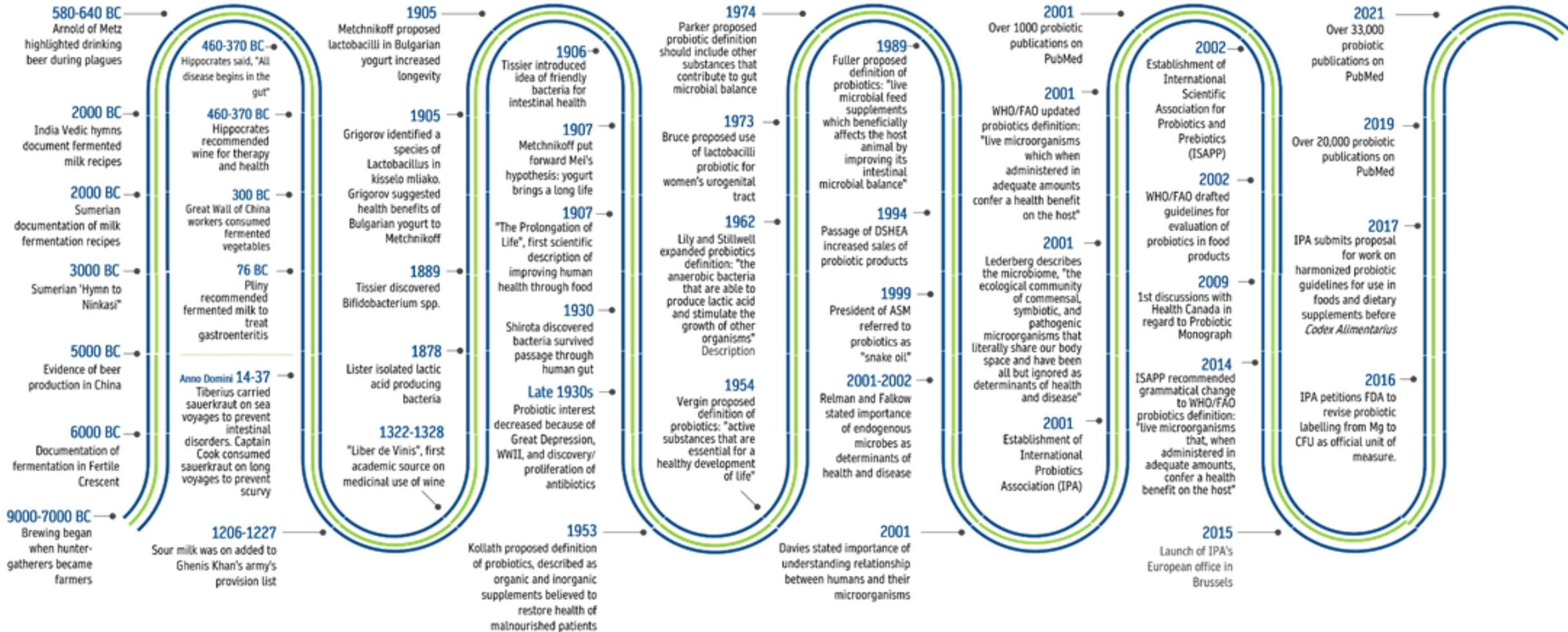
Democritus Univ.  
Alexandroupolis  
Feb 14 2025



# Setting the Scene



# Highlights from the History of Probiotics





2001-2002

FAO/WHO DEFINITION FOR PROBIOTICS

“LIVE MICROORGANISMS WHICH WHEN ADMINISTERED IN ADEQUATE AMOUNTS CONFER A HEALTH BENEFIT ON THE HOST”

IPA FOUNDED 1999

REGISTERED AS A 501C IN THE US



# Who is the IPA?

- Global **Non-profit** organization
- **International** Membership
- Bringing together the **biotic sector's stakeholders**
- **NGO** status before *Codex Alimentarius*
- **ISO** observer status
- We are the **Biotic industry's Voice**

## Regional Impact. Worldwide Reach.

As of December 1, 2024, IPA's community is 122 member companies strong.



# The Next Chapter of IPA



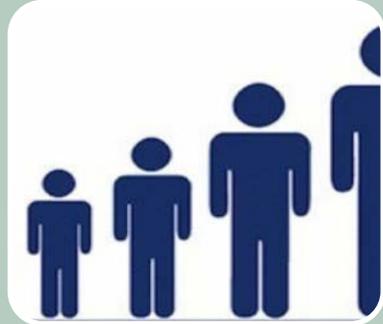


## IPA's Mission Statement

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IPA is a global non-profit organization that advocates for the safe and efficacious use of pre-, pro- and post-biotics.

# IPA Goals & KPIs



Expand geographical and category representation



Support Expanded Scope



Educate Health Care Practitioners



Drive Global Regulations



Advance technology and quality best practices

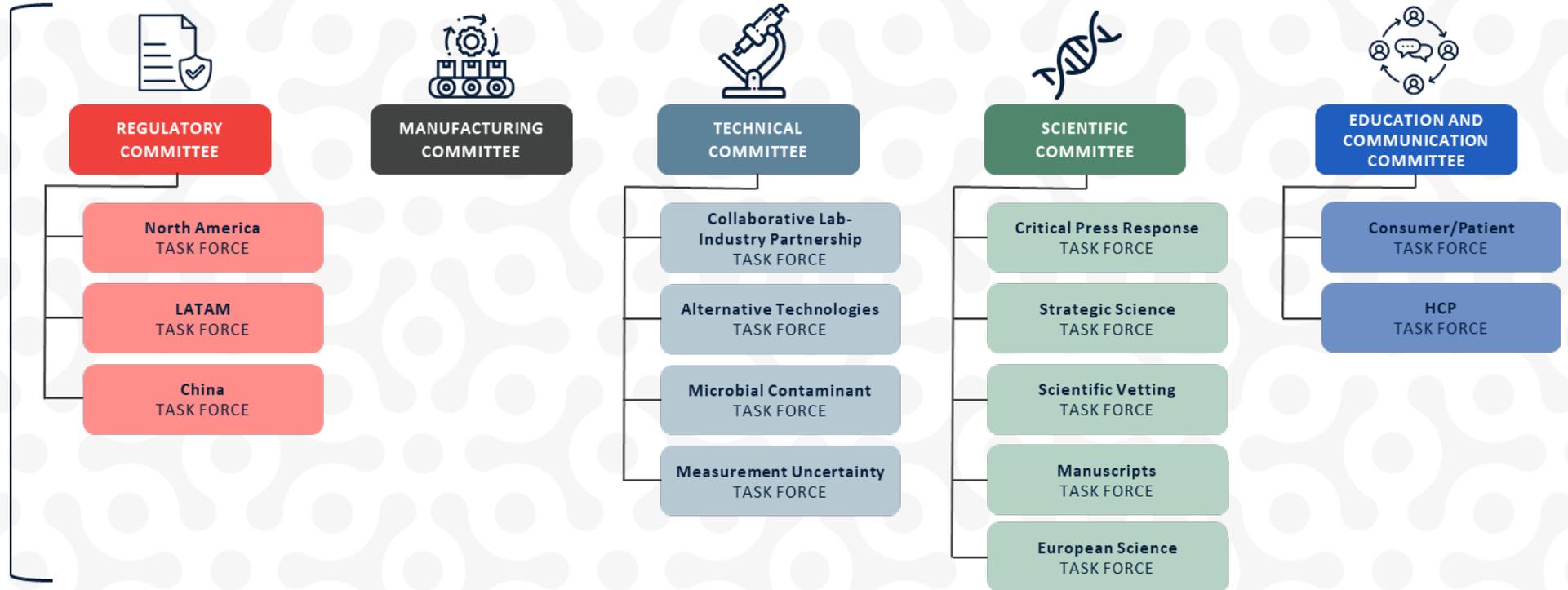


# **A Powerful Voice Through IPA Membership**

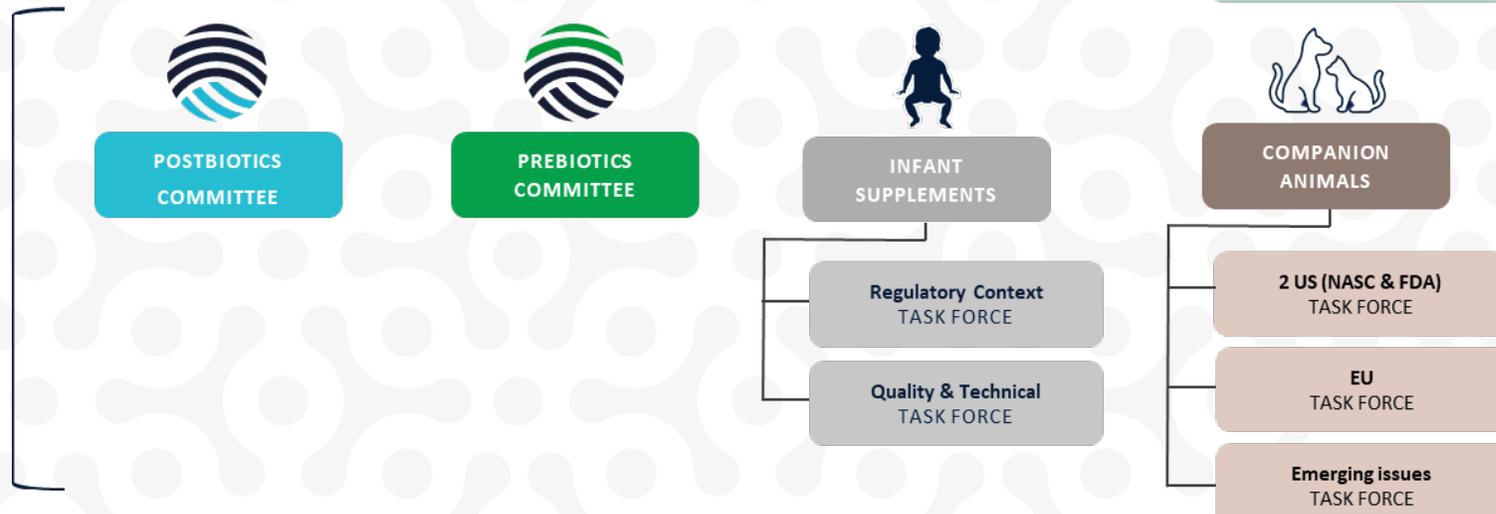
# COMMITTEES ORGANIZATION CHART



## IPA LEGACY COMMITTEES



## IPA NEW COMMITTEES





Align IPA Position  
on 'Pre-biotic'  
definition



Align IPA Position  
on 'Post-biotic'  
definition

# NEW IPA Committees!

## Infant Supplements

- Creation of quality and technical supplement guidelines
- Identify gaps and industry best practices

## Companion Animals

- Develop strategic collaborations with various stakeholders
- Identify gaps and industry best practices



# Regulatory Affairs



## Global DIVERGANCE in regulating probiotics

- Lack of specific considerations for probiotics
- Interpretations and grey zones – no clear expectations
- Communication barriers and unclear returns on investments
- Science and regulations not moving at the same speed
- Consumer awareness and confusion

## Some Highpoints

- ✓ 65 Government contacts
- ✓ Recognized at Codex
- ✓ Regional Task Forces
- ✓ 4 Planned Regulatory workshops in 2025



# Regulatory differences globally

Product classification



Permitted probiotic  
microorganisms



Definition



Labelling  
requirements



Conditions of use



Nutrition and health claims:

Market access



**FOOD, SUPPLEMENT,  
MEDICAL DEVICE, DRUG**



# What's in a name?

## Regional names for supplements with claims



**Complimentary Medicine**



**Natural Health Product**



**Health Food**



**Food Supplement**



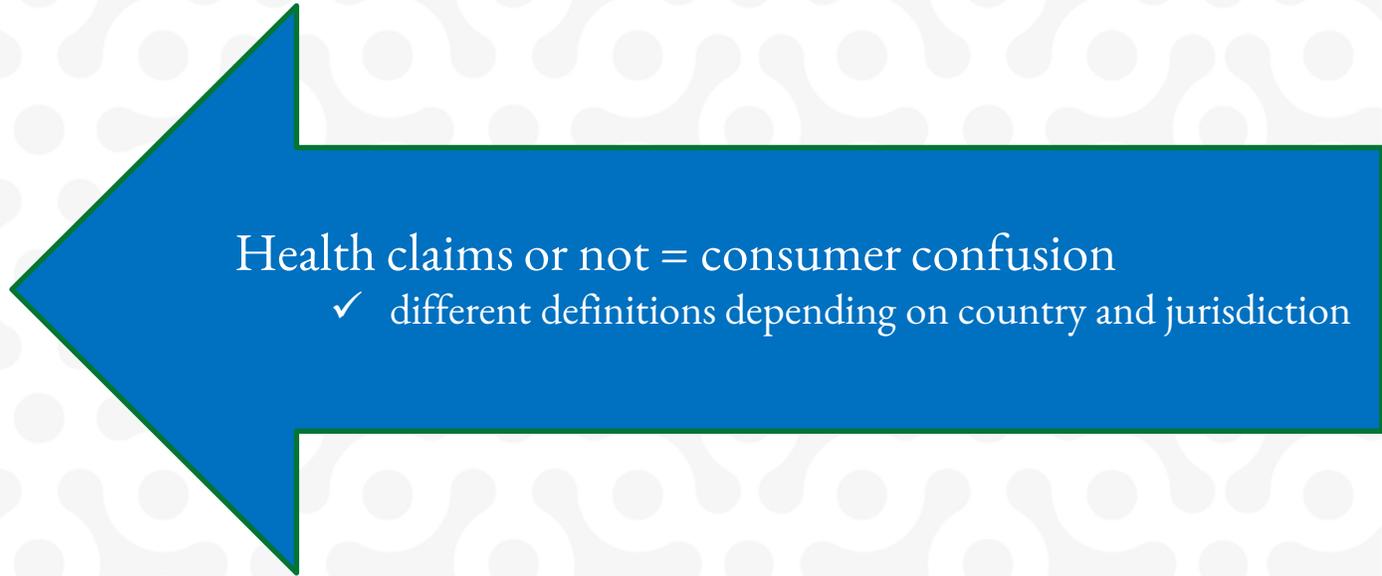
**Food with Health Claim**



**Health Functional Food**



**Dietary Supplement**



Health claims or not = consumer confusion

✓ different definitions depending on country and jurisdiction



# Release & Regulatory Considerations

## Label and Health Claims



APPROVAL REQUIRED	APPROVAL NOT REQUIRED
Specific health Claim General health claim Disease risk reduction	Structure function claim only* <b>(Must be truthful, not misleading and substantiated)</b>

### Two varying approaches

- **NNHPD** – Probiotic Monograph, Application process, Dependent on approach 60 to 270 days to market
- **FDA** - Wording cannot imply disease claim or statement
- **FTC** – Expressed and Implied Claims need to be Substantiated

**AS NUTRITIONAL /PHYSIOLOGICAL EFFECTS AND/OR AS A CATEGORY**  
**Bulgaria, Czech Republic, Cyprus, Denmark, France, Greece, Italy, Malta, The Netherlands, Poland, Portugal (MRP) and Spain.**  
**WITH THE AUTHORISED HEALTH CLAIM ON 'LACTOSE DIGESTION'**  
**Portugal, Belgium and the United Kingdom.**



**ASEAN food safety harmonisation: Codex standards best way forward for region to reach consensus – UNFAO expert**



# Global Harmonization A Codex Standard

## CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 11

NFSDU/39 CRD/3

Original language only

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

**Thirty-ninth Session**

**Berlin, Germany  
4 - 8 December 2017**

**OTHER BUSINESS AND FUTURE WORK**

*Comments of International Probiotics Association (IPA)*

**INTERNATIONAL PROBIOTICS ASSOCIATION (IPA)**

**Proposal for New Work on Harmonized Probiotic Guidelines for Use in Foods and Dietary  
Supplements**



# Why Public Standards are a Must!

Traditional



Non - Traditional





# Why Public Standards are a Must!



# IPA Manufacturing Guidelines

## Dietary Supplements



The dietary supplements audit standards contain the following GMP regulations as normative references:

- 21 CFR 111
- 21 CFR 117 (HACCP)
- 21 CFR 1.906
- 21 CFR 1.908
- 21 CFR 11
- 21 CFR 1.511
- IPA Manufacturing Guideline (for Probiotic Dietary Supplements)
- *Plus 14 additional best practices*

- IPA manufacturing guidelines adopted as a normative reference to regulations and part of a public standard
- Guidelines now part of the ANSI 455-2 as an addendum
- Recognized also within global harmonized GFSI DS program



# ISO & IPA - Standards for our Industry

- Voted 100% from ISO member states
- IPA is now an ISO observer at the TC34/SC9
- Currently at WG11 (Food and Feed Cultures)
- Working towards an ISO method for probiotics supplements
- Initiated from IPA's technical committee interlaboratory study





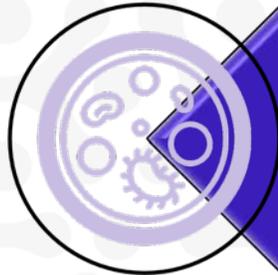
# IPA GEOGRAPHICAL EXPANSION



# IPA EU Mission



Develop better information for the use of the term probiotic,  
Assess the regulatory context in a broader way and  
Provide legal interpretation and advise



Participate in consultations and EFSA panels on relevant topics  
such as:  
Novel food guidelines, QPS status and guidance (new), taxonomy  
changes, roadmap microbiome



Join forces, align and continually network with scientific and  
regulatory bodies and key stakeholders such as:  
EDA, IDF, EHPM, EFFCA, EUFIC, ILSI, FIL/IDF and more...

# Use of the Term 'Probiotic' in Europe for Foods, Beverages, and Dietary Supplements: Key Achievements

(the legal references and assessments are available)

## THE COUNTRIES IN GREEN ALLOW THE TERM PROBIOTIC ON LABELS

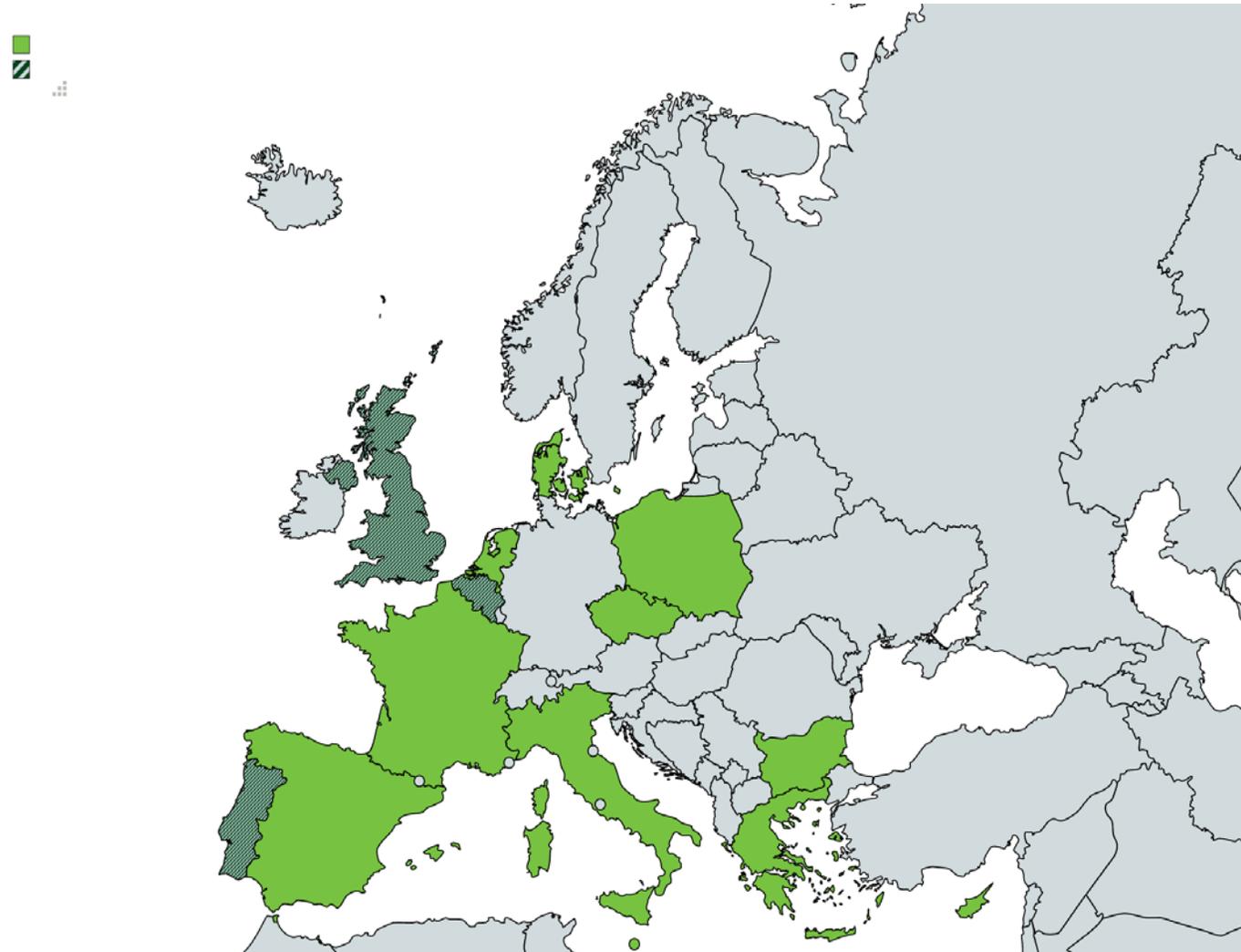
- WITH REFERENCE TO NUTRITIONAL /PHYSIOLOGICAL EFFECTS AND/OR
- AS THE NAME OF THE CATEGORY

Bulgaria, Czech Republic, Cyprus, Denmark, France, Greece, Italy, Malta, The Netherlands, Poland, Portugal (MRP for the imported product) and Spain.

- ALLOWING THE USE OF THE TERM ONLY WITH THE AUTHORISED HEALTH CLAIM ON 'LACTOSE DIGESTION'

Portugal, Belgium and the United Kingdom.

**Update June 2024:** IRL recently issued a paper with focus on Assessment of the safety of "probiotics" in food supplements/ no changes about the status



# Probiotics & EU Policies: A Nutritious Breakfast

*Come join us to discuss the opportunities of probiotics in Europe for consumers and Europe's competitiveness*



MEP Pietro Fiocchi



30  
JANUARY



**ipa**   
EUROPE  
INTERNATIONAL  
PROBIOTICS ASSOCIATION



# Biotic Trends & Challenges

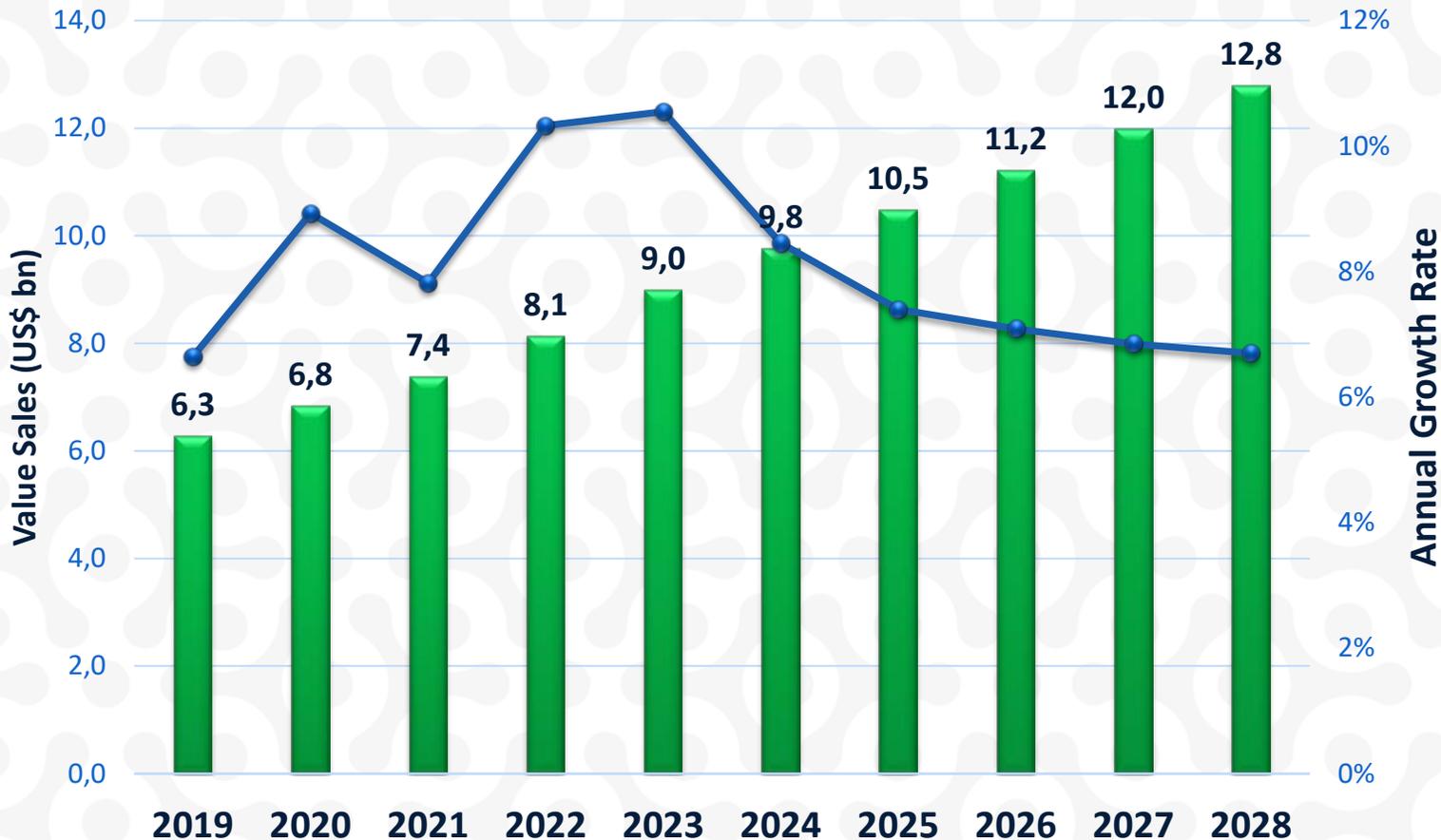
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Some Facts



# Global Probiotic Market 2023 & Beyond

World Probiotic Supplements Value Sales (US\$ bn),  
2019-2028



**US\$ 9.0 bn**

Probiotic Supplements Market Size, 2023

**9.4%**

Historic CAGR (2019-2023)

**7.0%**

Forecast CAGR (2024-2028)

**US\$ 3.0 bn**

Absolute Growth (2024-2028)

# Some Regional References

## AMERICAS

Market Size (2023): US\$ 3.0 bn  
Historic CAGR (2019-23): 5.8%  
Forecast CAGR (2023-28): 4.4%

## EUROPE

Market Size (2023): US\$ 2.0 bn  
Historic CAGR (2019-23): 5.7%  
Forecast CAGR (2023-28): 6.2%

## ASIA-PACIFIC

Market Size (2023): US\$ 3.7 bn  
Historic CAGR (2019-23): 15.8%  
Forecast CAGR (2023-28): 9.2%

## MIDDLE EAST & AFRICA

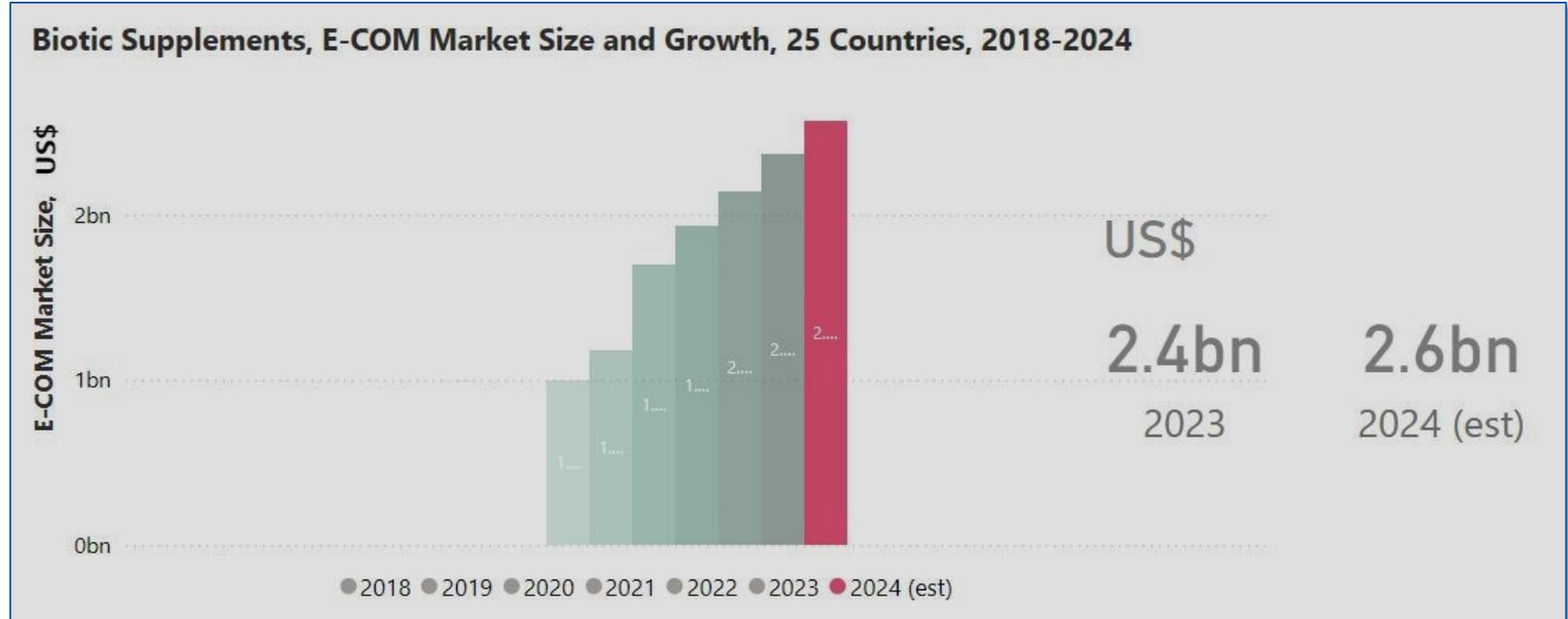
Market Size (2023): US\$ 0.1 bn  
Historic CAGR (2019-23): 11.6%  
Forecast CAGR (2023-28): 8.0%



# Absolute Growth Next 4 Years

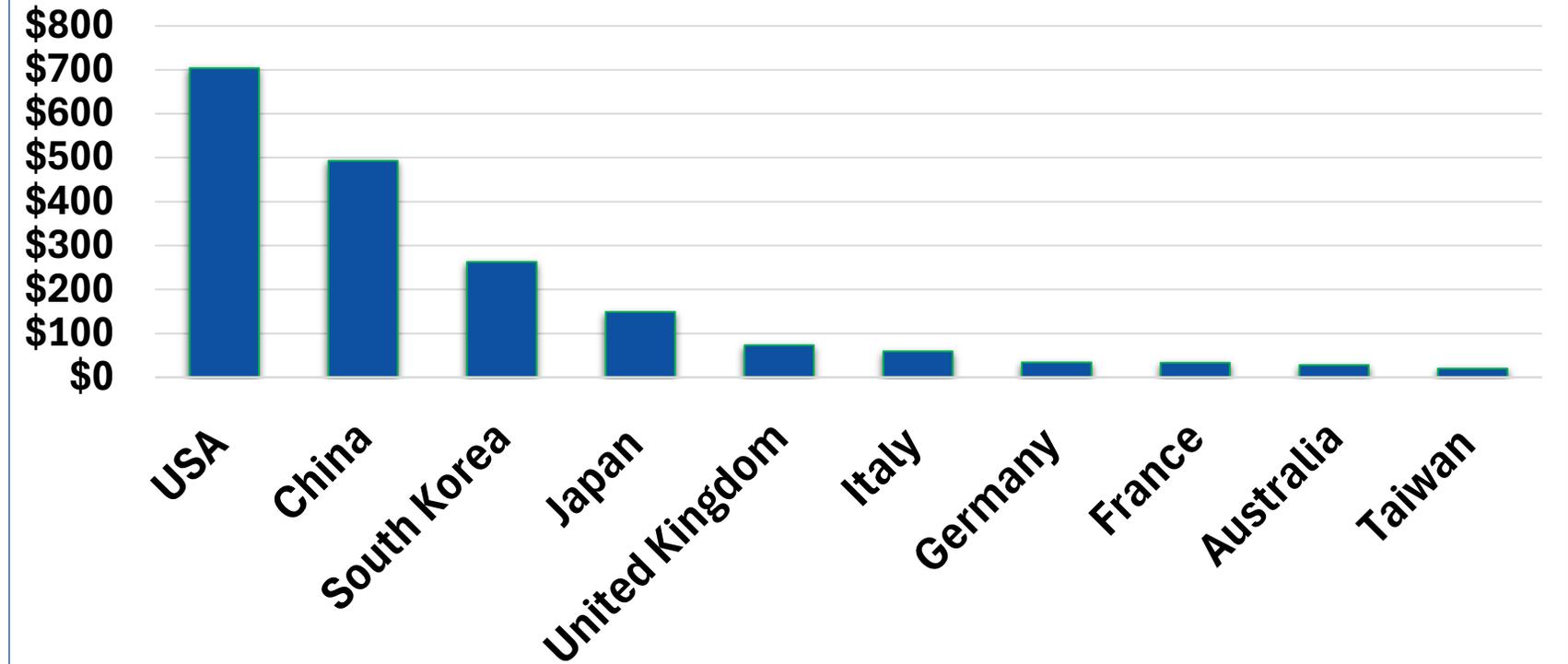


# E-Comm Probiotic Highlights



# E-Comm Probiotic Highlights

## Top 10 Country Ranking



Represents 77% of Global E-comm



# Confused Categories

*"Η αρχή της σοφίας είναι ο καθορισμός των όρων"*

*"The beginning of wisdom is the definition of terms"*

- Socrates

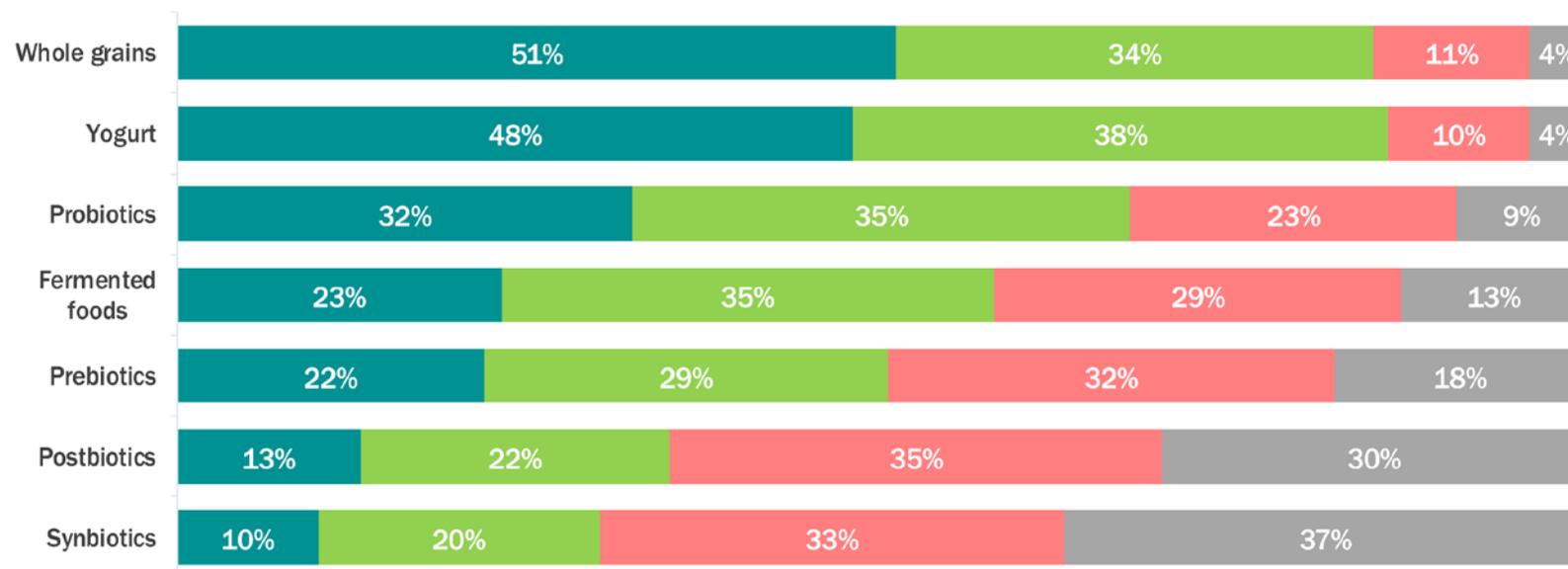
*"The beginning of wisdom is to call things by their proper name."*

- Confucius



# Biotic Consumer Awareness

High for Pro-, lower for pre- and post-biotics



- I consider myself familiar, and I actively try to consume them
- I consider myself familiar, but I do not actively try to consume them
- I do not consider myself familiar
- I have never heard of this before



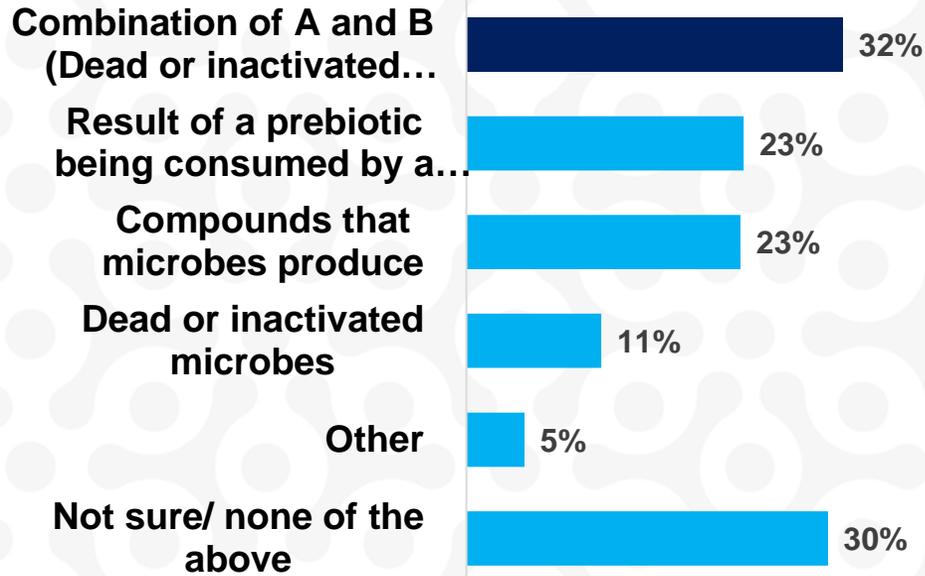
1000 people phone survey US adults 18+

<https://foodinsight.org/wp-content/uploads/2022/04/IFIC-Gut-Health-and-Probiotics-Survey.pdf>

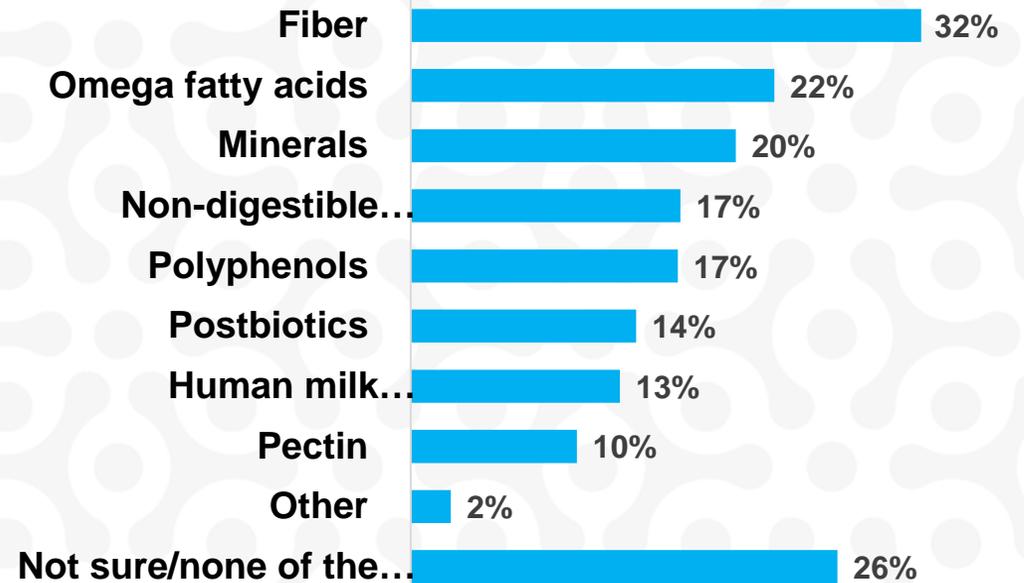
Consumers are not overly familiar with the specifics of what a prebiotic or postbiotic is

Consumers confusion reigns - even when asked to understand ingredients within a category

What do you consider as a postbiotic?  
Please select all that apply.  
Global

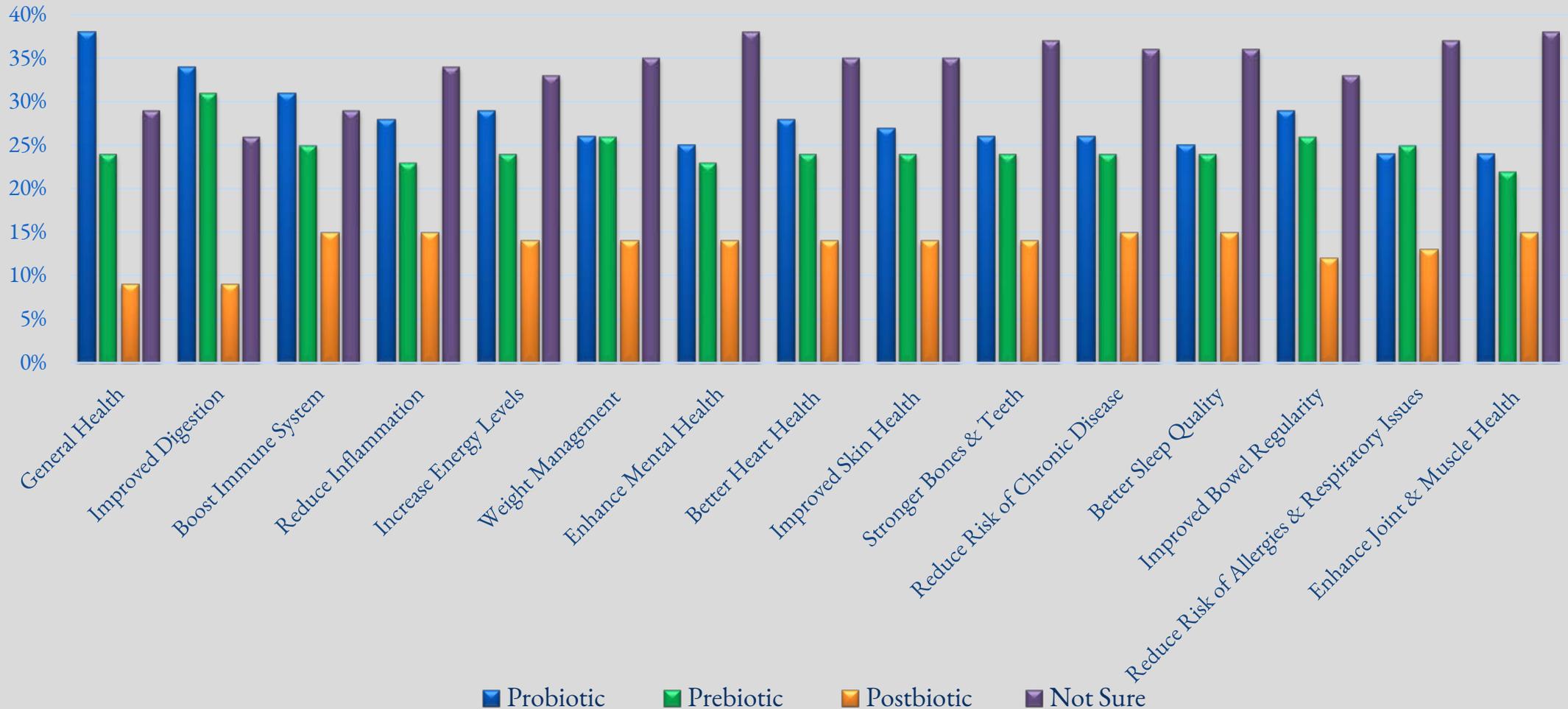


What do you consider as a prebiotic?  
Please select all that apply.  
Global



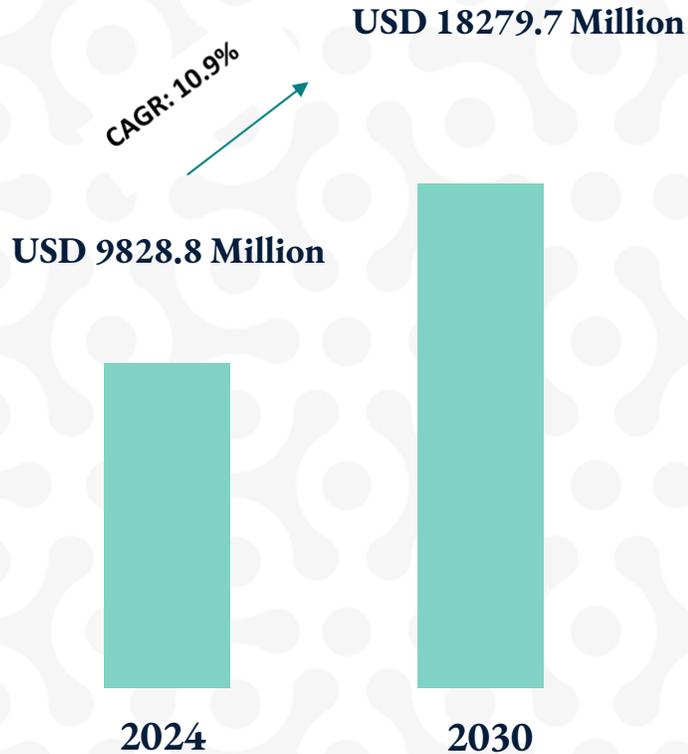
# Biotic Preferences Per Condition Management

Which Biotic do you prefer most for the following health reasons - Pro, Pre, Post, Biotics





# Prebiotic ingredients market

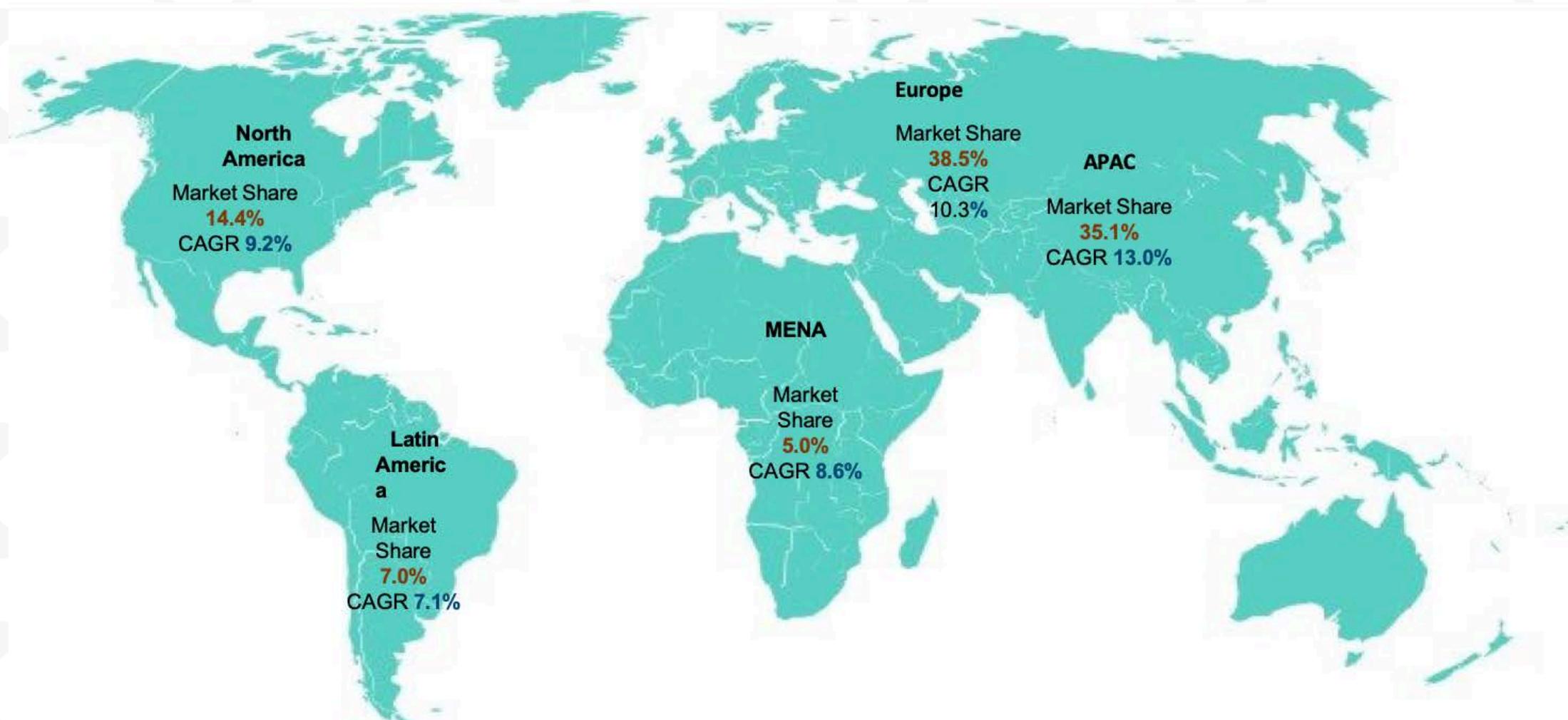


## KEY HIGHLIGHTS

- Global prebiotic ingredients market is estimated to close at USD \$9828.8 Million in 2024
- Inulin dominated global market in 2024
- Europe dominated global market in 2024
- Asia Pacific projected to grow at fastest CAGR during forecast period.

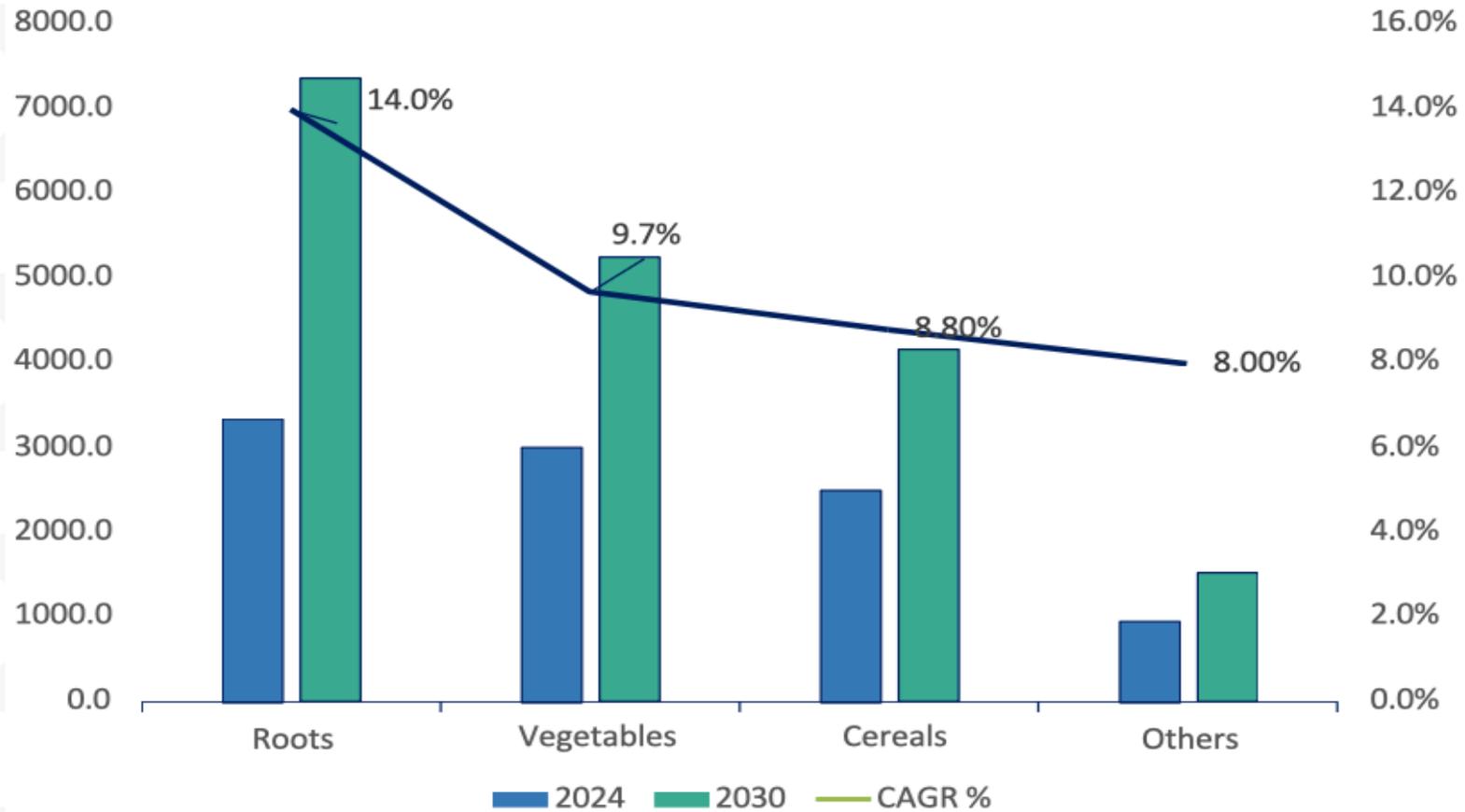


# Share by region global prebiotic ingredient market 2023





# Global Prebiotic Market, By Source







# “Prebiotic” Definitions

## **Academic**

+5 definitions  
since 1995

## **Regulatory**

No established  
regulatory  
definition for  
prebiotics to  
date

## **Industry**

Multiple  
iterations  
depending on  
company and  
region



# Prebiotic Manuscript Published



**Download here:**

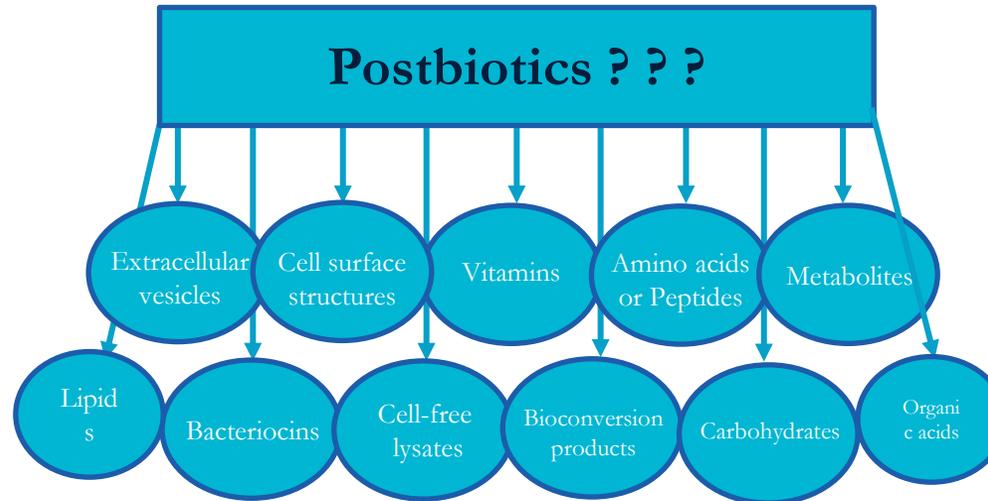


# Postbiotic Highlights

There is no consensus on a definition for what a postbiotic is. Up to 2023, over **10 different** definitions have been proposed.

To date there are **no regulations** on postbiotics in any country that IPA is aware of.

(Sept. 2023)



Some postbiotics have been found to have **immune-modulating effects**, helping to regulate the immune system and reduce inflammation.

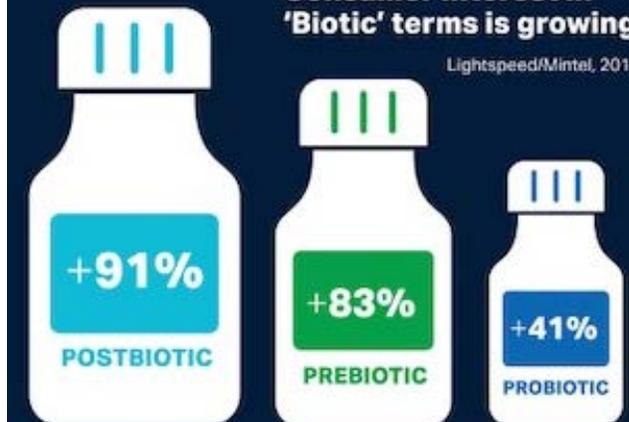
Ref.: Shokryazdan, P. et al. J. Am. C. Nutr. 2017.

Certain postbiotics have **antioxidant abilities** that protect cells from oxidative damage and support health.

Ref.: Ditu, L.M. et al. Anaerobe. 2014.

Consumer interest in 'Biotic' terms is growing!

Lightspeed/Mintel, 2019.





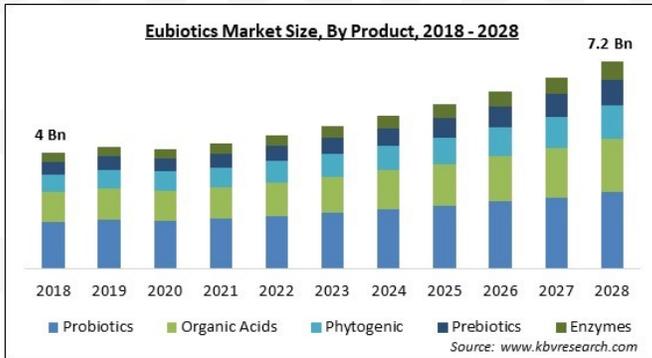
# Postbiotic, or... Market?



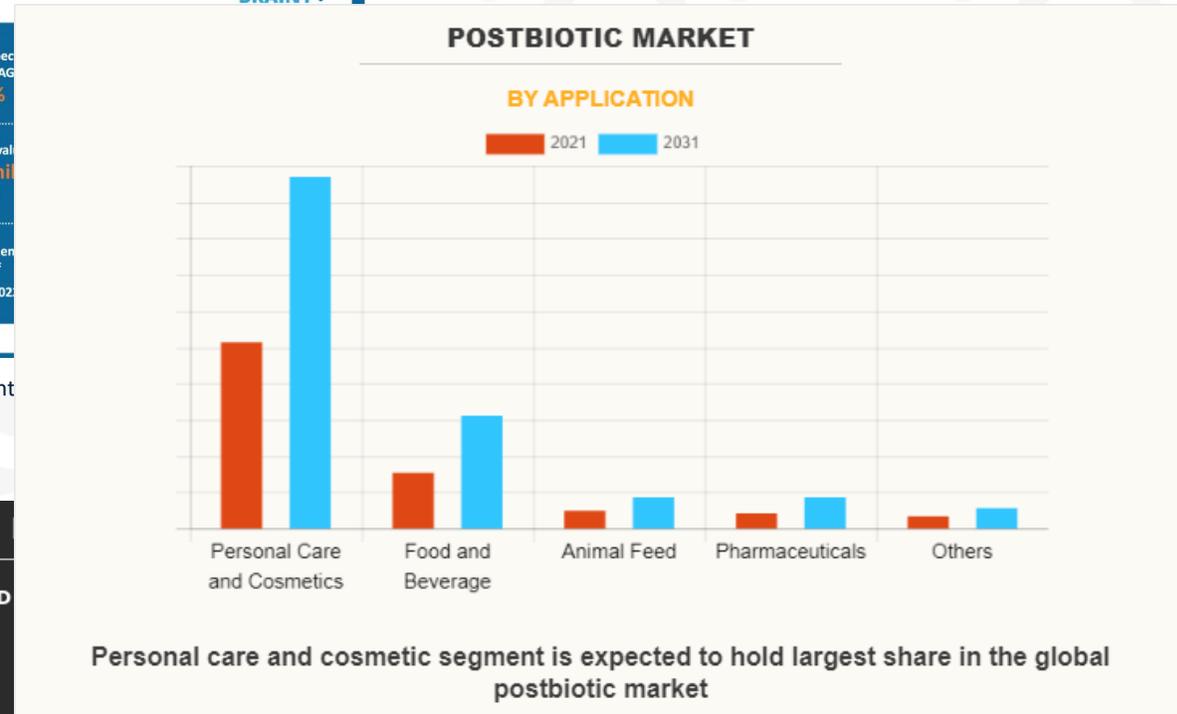
Postbiotic Supplements Market Size, Growth Outlook 2024-2032



www.thebrainyinsight



kbvresearch.com



www.alliedmarketreserach.com

**POSTBIOTIC OPPORTUNITIES AND - 2031**

Postbiotic market is expected to reach **\$3 Billion** in 2031

Growing at a **CAGR of 6.8%** (2022-2031)

Postbiotic Market Size, Share, Outlook, Trends | Forecast, 2031





# “Postbiotics” – consensus or confusion?

## Published Definitions since 2009 and Names Used to Describe the Category

1. **Jonannsen** 2009 <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1365-2222.2009.03368.x>
2. **Howarth** 2010 <https://pubmed.ncbi.nlm.nih.gov/20018806/>
3. **Taverniti and Guglielmetti** 2011 <https://pubmed.ncbi.nlm.nih.gov/21499799/>
4. **Tsilingiri and Rescigno** 2013 <https://pubmed.ncbi.nlm.nih.gov/23271068/>
5. **Shenderov** 2013 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3747726/>
6. **Patel and Denning** 2013 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3575601/>
7. **Aguilar-Toalá et al** 2018 <https://doi.org/10.1016/j.tifs.2018.03.009>
8. **Langella and Martin** 2019 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6536656/>
9. **Wegh** 2019 <https://www.mdpi.com/1422-0067/20/19/4673>
10. **Collado** 2019 <https://pubmed.ncbi.nlm.nih.gov/31965850/>
11. **Johnson** 2019 <https://pubmed.ncbi.nlm.nih.gov/31426502/>
12. **Foo** 2019 <https://www.sciencedirect.com/science/article/abs/pii/B978012815249200021X?via%3Dihub>
13. **Kiewicz et al** 2020 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7468815/>
14. **Chugh and Kamal-Eldin** 2020 <https://www.sciencedirect.com/science/article/abs/pii/S221479932030014X>
15. **Zendeboodi et al** 2020 <https://www.sciencedirect.com/science/article/abs/pii/S221479932030028X#bib0115>
16. **Nataraj et al** 2020 <https://pubmed.ncbi.nlm.nih.gov/32819443/>
17. **Salimen et al** 2021 <https://www.nature.com/articles/s41575-021-00440-6>
18. **do Carmo** 2021 <https://www.sciencedirect.com/science/article/abs/pii/S0924224420307172>
19. **Rafique** 2023 <https://www.sciencedirect.com/science/article/pii/S2666154323002156>

# How Do You Categorize and Identify Non-viable Microbial 'Biotics

*Simone Guglielmetti*



[simone.guglielmetti@unimib.it](mailto:simone.guglielmetti@unimib.it)

# Schematic of **postbiotic ingredient** production process



Culture medium containing microbial cells and/or cell fractions

*Killing method*



*Separation technique*

Intact dead microbes

*Fragmentation/lysis method*

Note: combinations of these products are also possible

*Separation technique*

Culture medium

Culture medium & cell fractions

Cell fragments & cytoplasmic content



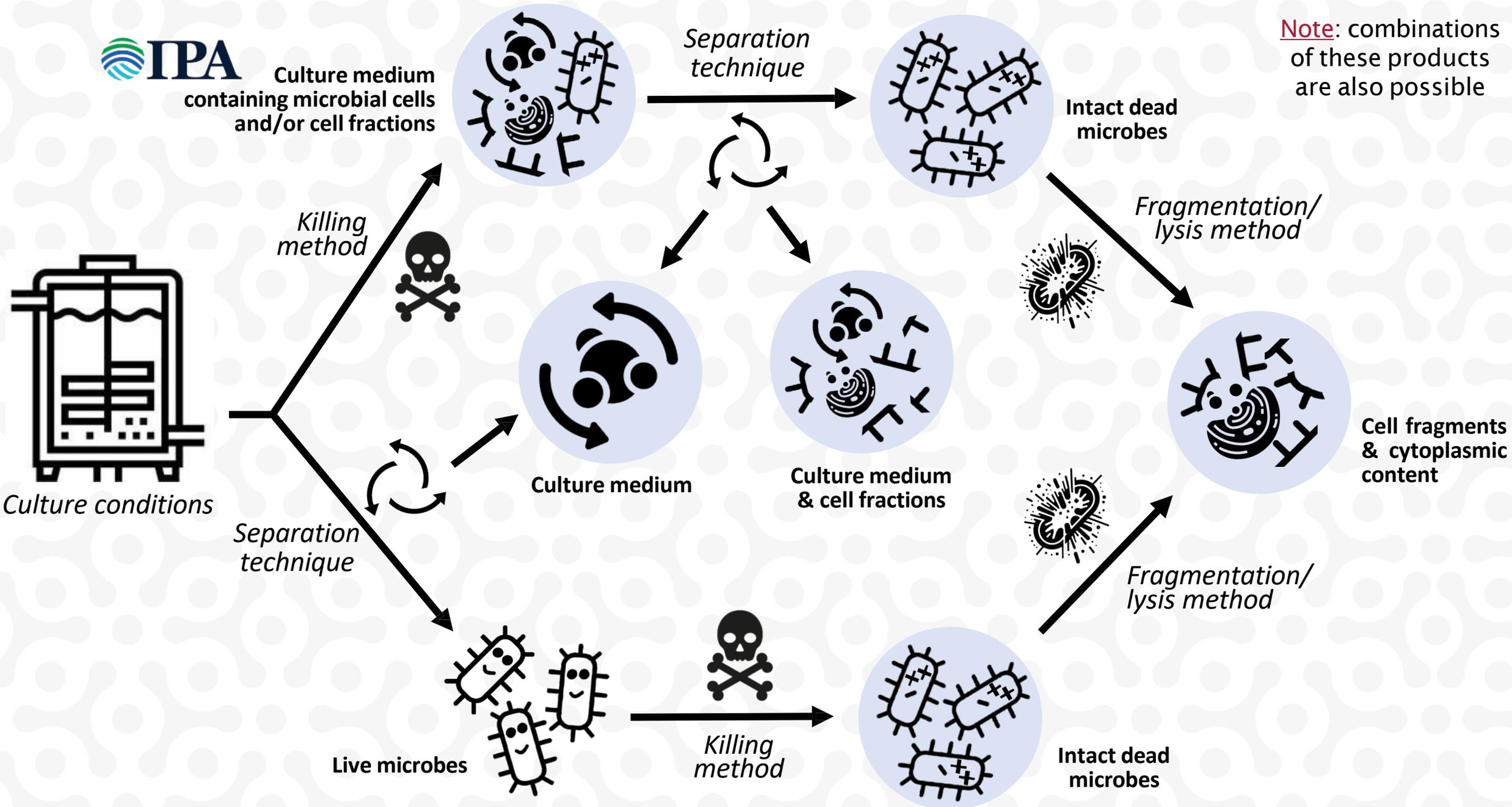
*Culture conditions*

Live microbes

*Killing method*

Intact dead microbes

*Fragmentation/lysis method*

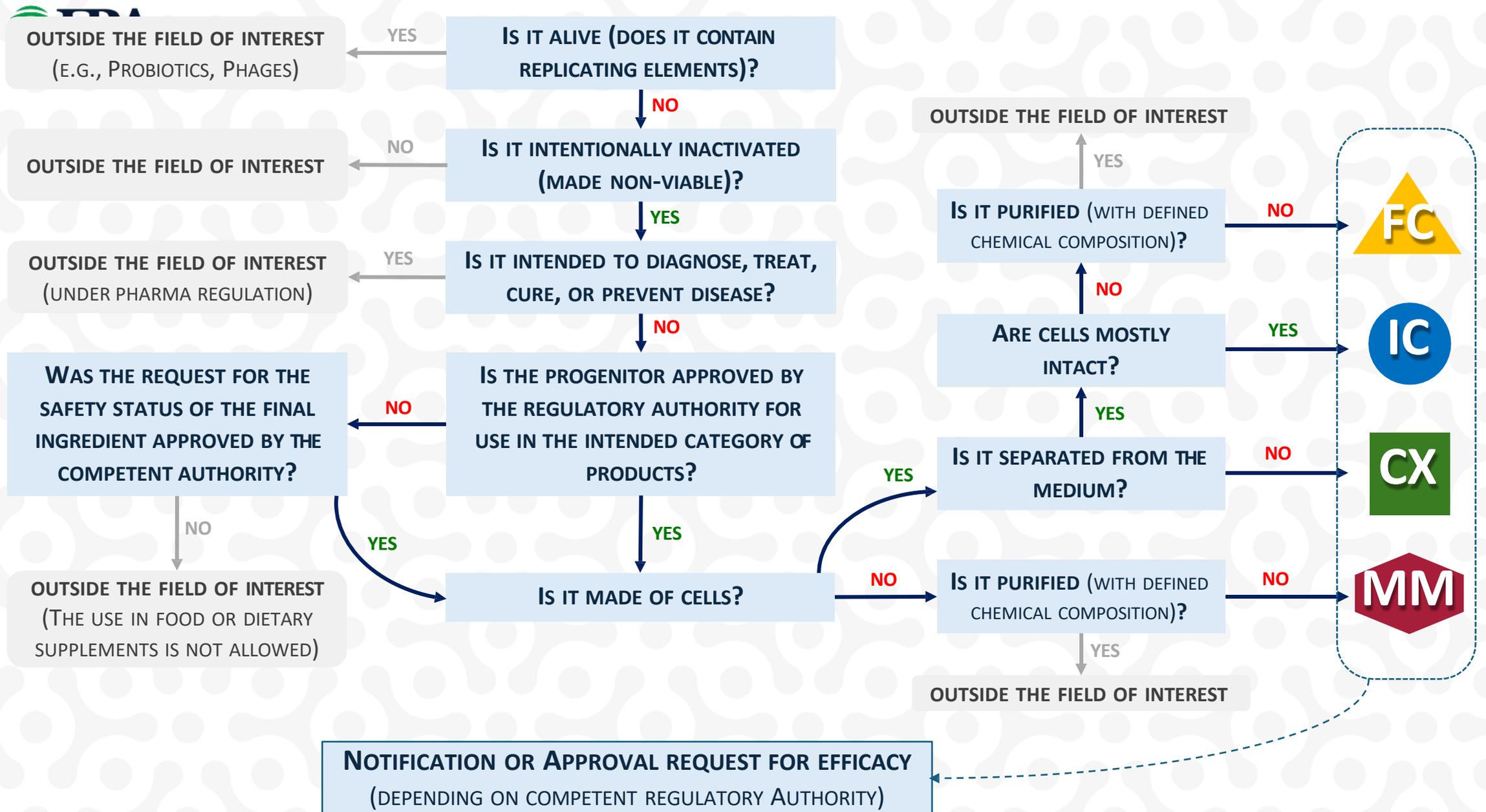




Category	Description	
	Fragmented microbial cells	Bioactive ingredients made of intentionally fragmented microbial cells (lysates or cell extracts), separated from the culture medium.
	Intact non-viable microbial cells	Bioactive ingredients made of intentionally inactivated (non-viable) whole microbial cells (i.e., mostly intact), separated from the culture medium.
	Complex non-viable microbial preparations	Bioactive ingredients consisting of unpurified culture medium containing intentionally inactivated (non-viable) microbial cells and/or cell fractions.
	Microbial metabolic products	Bioactive ingredients consisting of metabolic products of microbial cells within their unpurified or partially purified culture medium (e.g., spent culture medium). These compounds may be the result of microbial metabolic activities or the microbial biotransformation of exogenous molecules.



# Decision tree for the **classification** of postbiotics (foods and dietary supplements)



# Ultimate Objective for this manuscript



- **HARMONIZING STANDARDS AND REGULATIONS** → to ensure safety, quality, efficacy, and foster innovation in the NMB industry.
- **FIXING CLEAR DEFINITIONS AND CRITERIA** → to avoid the whole category being perceived as a **marketing gimmick** and to facilitate effective **communication among stakeholders**.

*The roadmap paper is ready for publication...*

## OUTLINE

1. Introduction
2. The field (scope) of application
3. Regulatory considerations
4. The classification of NMB agents
5. Manufacturing of NMB agents
  - 5.1. General considerations
  - 5.2. Starting material
  - 5.3. Inactivation
  - 5.4. Qualification: enumeration and quantification techniques
  - 5.5. Shelf Life and Stability
6. A word on efficacy
7. Addressing approval of each category
8. Nomenclature
9. Labelling
10. Final remarks and conclusions



INTERNAL

©IPA 2024

- 1 **Commercial and regulatory frameworks for postbiotics: non-viable agents of microbial origin conferring a beneficial physiological effect**

3 Simone Guglielmetti<sup>1</sup>, Marie-Eve Boyte<sup>2</sup>, Cathy L. Smith<sup>3</sup>, Arthur C. Ouwehand<sup>4</sup>, George

4 Paraskevagos<sup>5</sup>, Jessica A. Younes<sup>5</sup>



# Scientific Committee

## SC Members

- ~ 40 SC members
- Five (5) different time zones
- 1300 publications
- 400+ yrs. experience

## SC Task Forces

- Critical Response Team
- Blog and scientific content review
- Strategic
- IPA EU
- Ad hoc projects

## Manuscripts –Planned for 2024

1. Probiotic clinical studies and their outcomes
2. Agents for probiotic stimulation
3. Biotics MoA
4. Characterization / reporting of Biotics Research
5. Predictability & Translation of Biotic Preclinical Research
6. Beyond Classical Probiotics
7. Probiotic Colonization
8. Probiotic foods/fs vs pharma – published

# Education and Communication



## Websites Developments

- New IPA-Biotics site
- HCP's website
- Consumer outreach

## Looking ahead in 2025:

>> Continue the Work

>> Aligning with IPA Global Goals, creating tools/contents, and attending various events to provide support:

## Creation of engaging content :

- infographics
- social media posts
- insightful blogs
- contributions to media articles
- podcasts

Published in various channels :

Website / Social Media / Spotify / During Shows & Events

Targeting Various Audience :

Industries, Academics, Consumers, HCP's, Regulators

Expand geographical and category representation

Support the Expanded Scope

Educate Health Care Practitioners

Drive Global Regulations

Advance technology and quality best practices

Promoting IPA as “The Global Voice of Pre, Pro, and Post-biotics™”.



# Educating the Different Stakeholders



Consumer



HCP's



Regulators



Academics



Media



**IPA Education and Communication**



# University Education & Outreach

## Educating the educators

- IPA first ever Probiotic University course
- Within a Master of Science in Nutrition Business Leadership Degree
  - ✓ One of a kind program
  - ✓ Evidence - based
  - ✓ Targeting the nutrition industry and beyond
- 24 hours of Probiotic Education (2 credits)
- Completed end January 2023
- Some quotes from our students
  - ✓ "Education about probiotics needs to happen at the institutional education level."
  - ✓ "I was pushed outside of my box about what probiotics are and about."
  - ✓ "This should be a required course, and Naturopaths should be required to understand about probiotics."





# University Education & Outreach

## Educating the educators

- Second University course Shanghai China Sept 2024
- School of Medicine Shanghai Jiao Tong University
- Over 100 graduates





## The Key Essentials

- Education and Communication is Key
- Simple Messaging and Understandable Benefits
- Respect The Science
- Do not Forget the Regulatory Environment
- Do Not Overlook E-commerce Platform
- Asia will surpass America Biggest Market
- Quality (standards & Best Practices) & Justified Benefits
  - Attractive to Consumers
  - Forges Credibility
- Talk with us at [www.internationalprobiotics.org](http://www.internationalprobiotics.org)





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**We bring Clarity to a complex world.**

*The IPA is a global non-profit organization bringing together through its membership, the Pre-, Pro- and Post- biotic sector's stakeholders including but not limited to academia, scientists, health care professionals, consumers, industry, and regulators.*

# END OF YEAR REPORT

**Discover Our Key Achievements of 2024**

*Advancing the Probiotics, Prebiotics, and Postbiotics Industry Worldwide*

- 122 Member Companies Worldwide
- 9 Committees
- Global Outreach in 67 Countries

 [WWW.IPA-BIOTICS.ORG](http://WWW.IPA-BIOTICS.ORG)

 [info@internationalprobiotics.org](mailto:info@internationalprobiotics.org)

To find out more...



# End of Year Report 2024



**Download here:**



# Thank You!

GEORGE PARASKEVAKOS, *MBA*

*IPA, Executive Director*



[www.ipa-biotics.org](http://www.ipa-biotics.org)



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