

*IV Congreso Iberoamericano de Ingeniería de los Alimentos
Montevideo, 4-6 setiembre 2024*

El microbioma como actor principal en la alimentación del futuro

Fermentados, probióticos y postbióticos

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Declaración de **CONFLICTOS DE INTERÉS**

Actividades de vinculación tecnológica (capacitaciones, asesoramientos, desarrollo de productos, controles de calidad, disertante) con empresas productoras de alimentos fermentados, sucedáneos de leche materna, fórmulas infantiles, probióticos y postbióticos.

Miembro de la junta directiva de la Asociación Científica Internacional de Probióticos y Prebióticos (ISAPP) www.isappscience.org

Cesárea

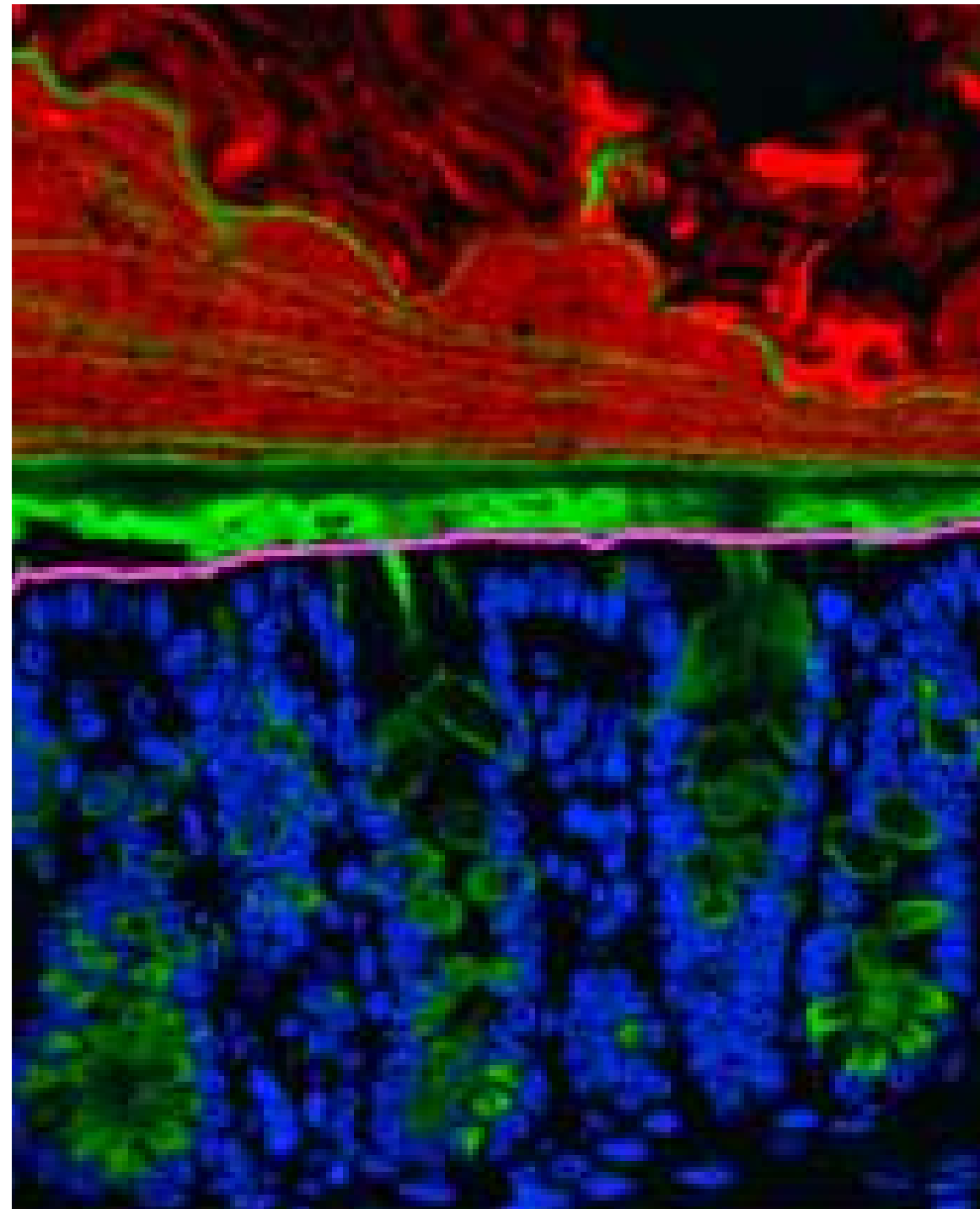
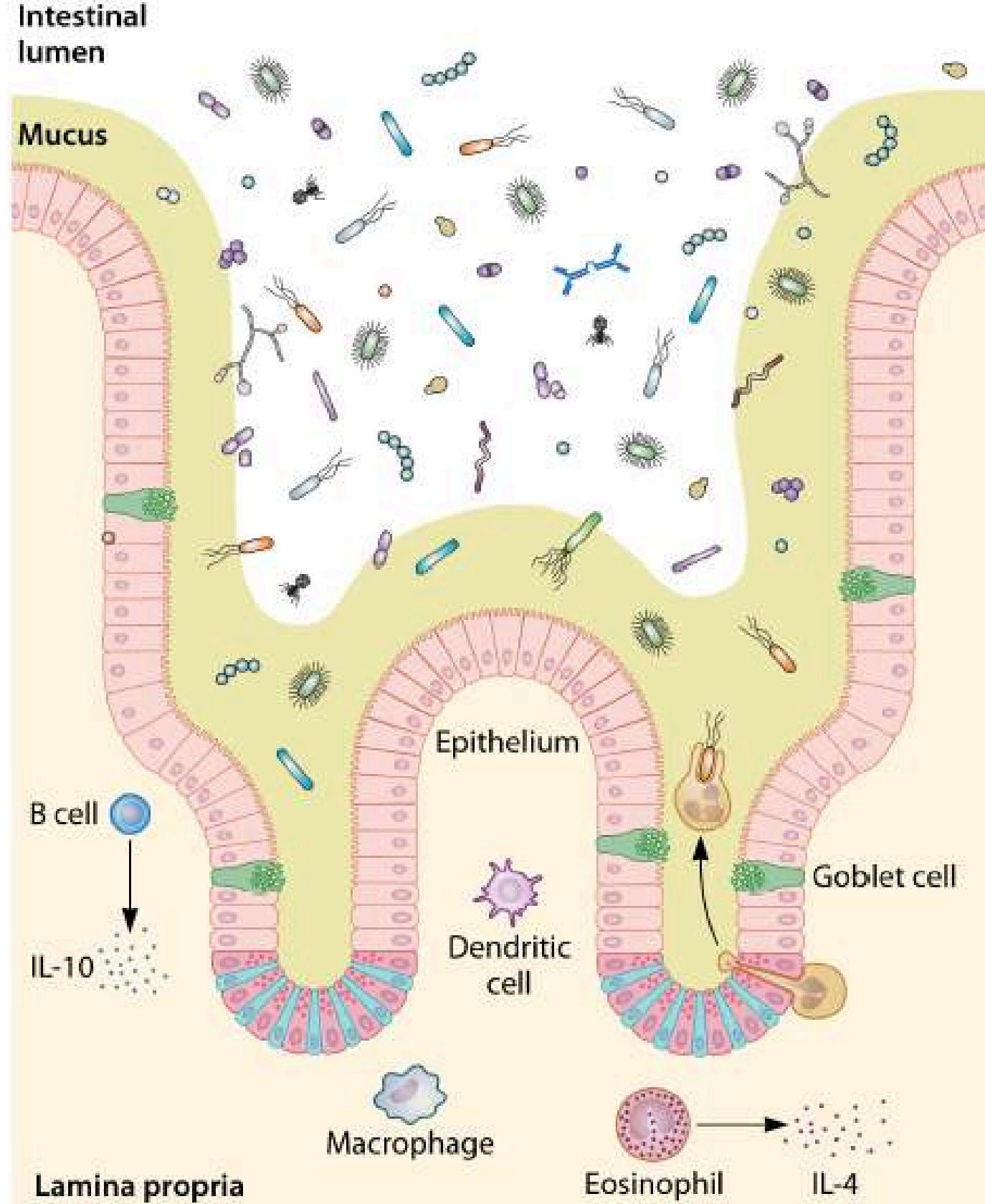
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Antibióticos

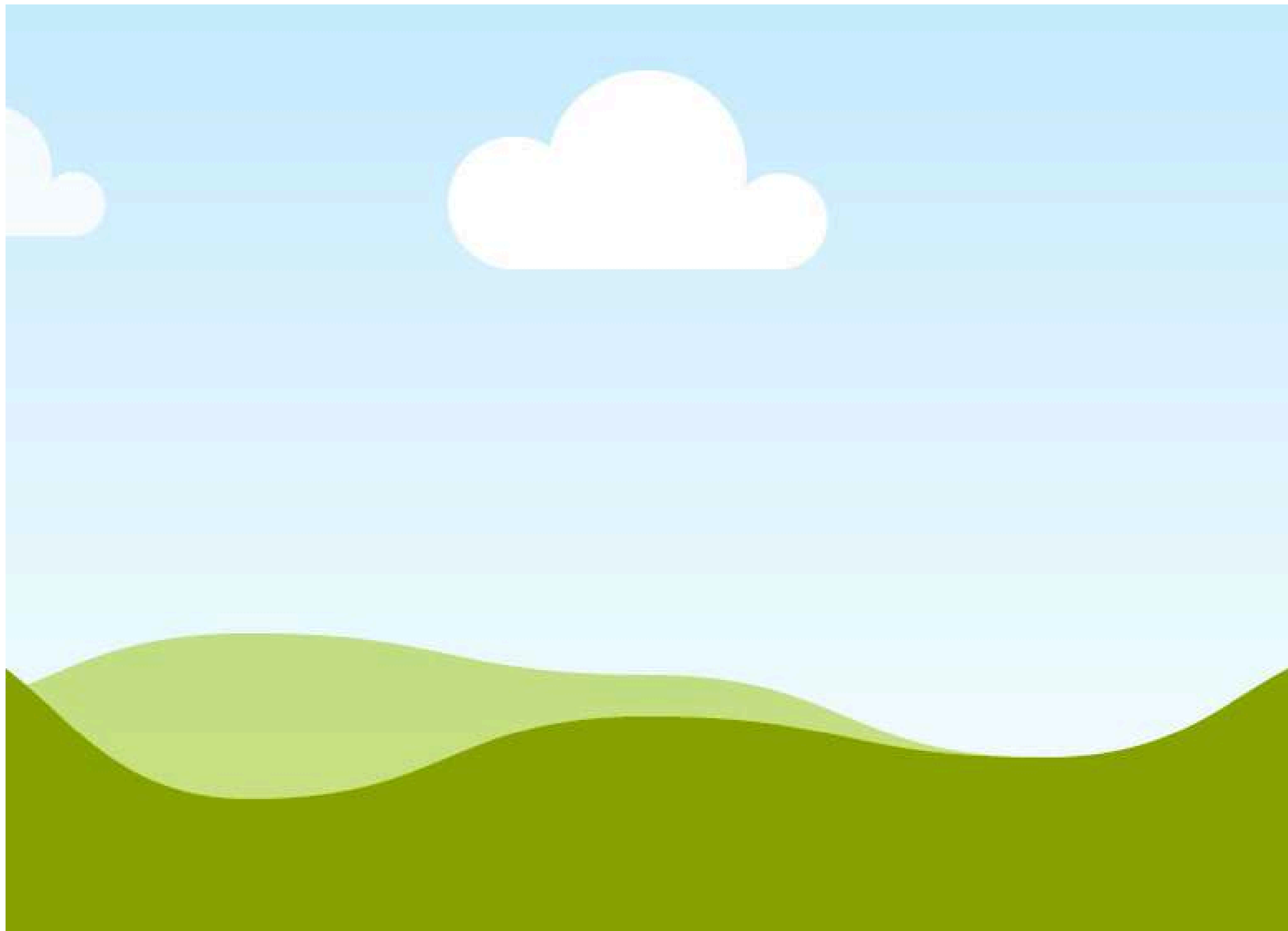


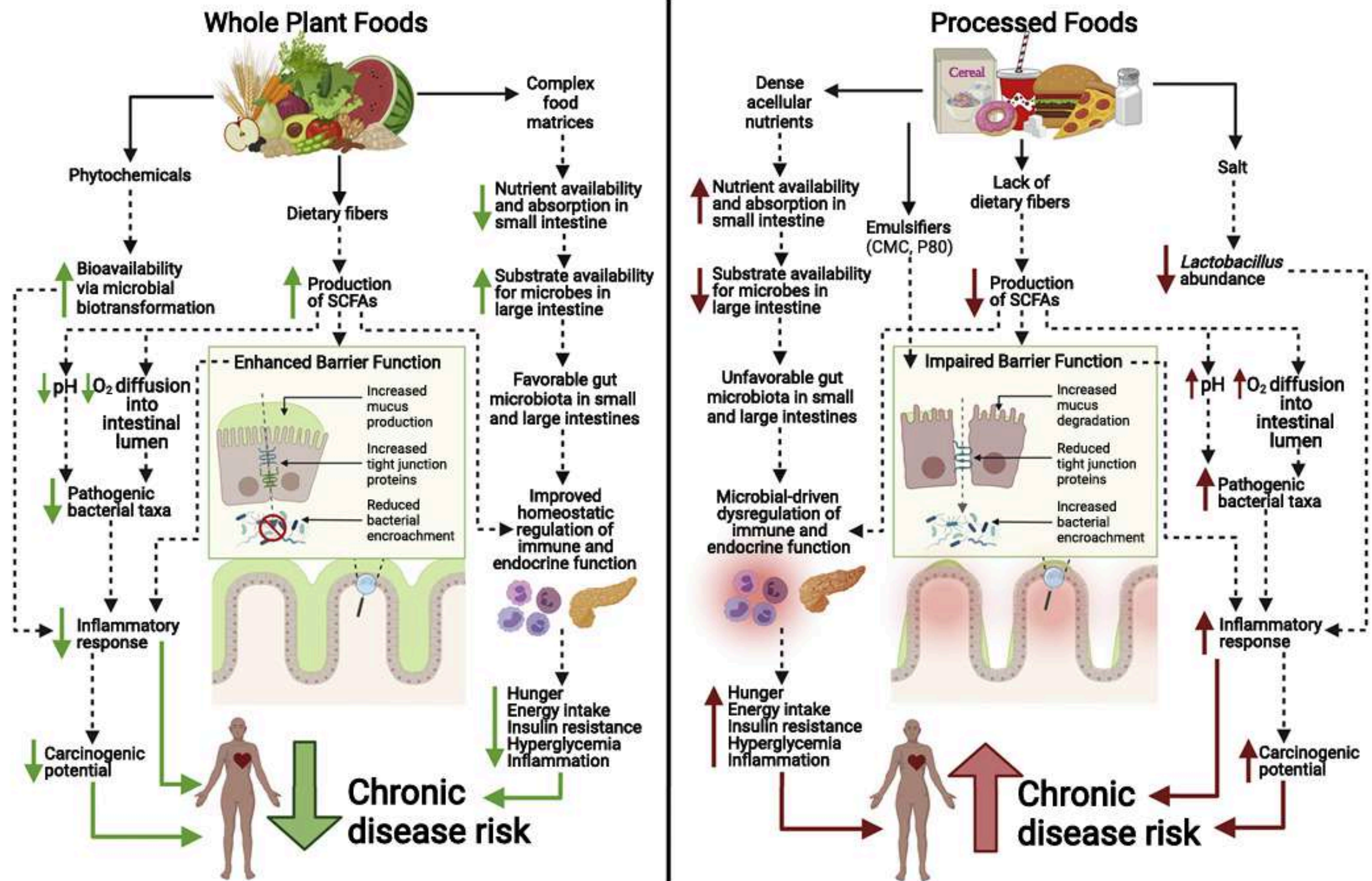


Fibras en la AC

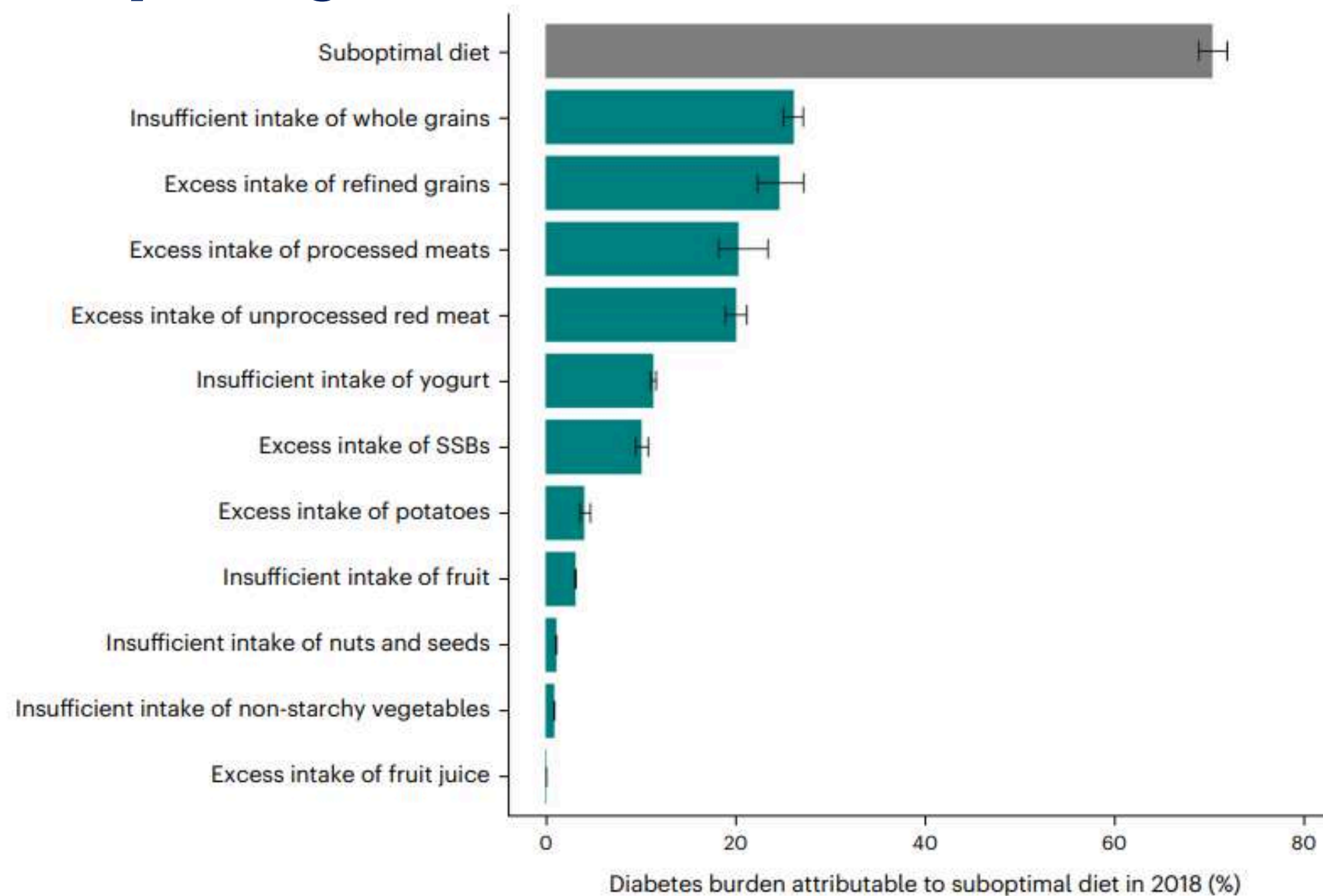


Tropini C, Earle KA, Huang KC, Sonnenburg JL. The Gut Microbiome: Connecting Spatial Organization to Function. *Cell Host Microbe*. 2017 Apr 12;21(4):433-442.



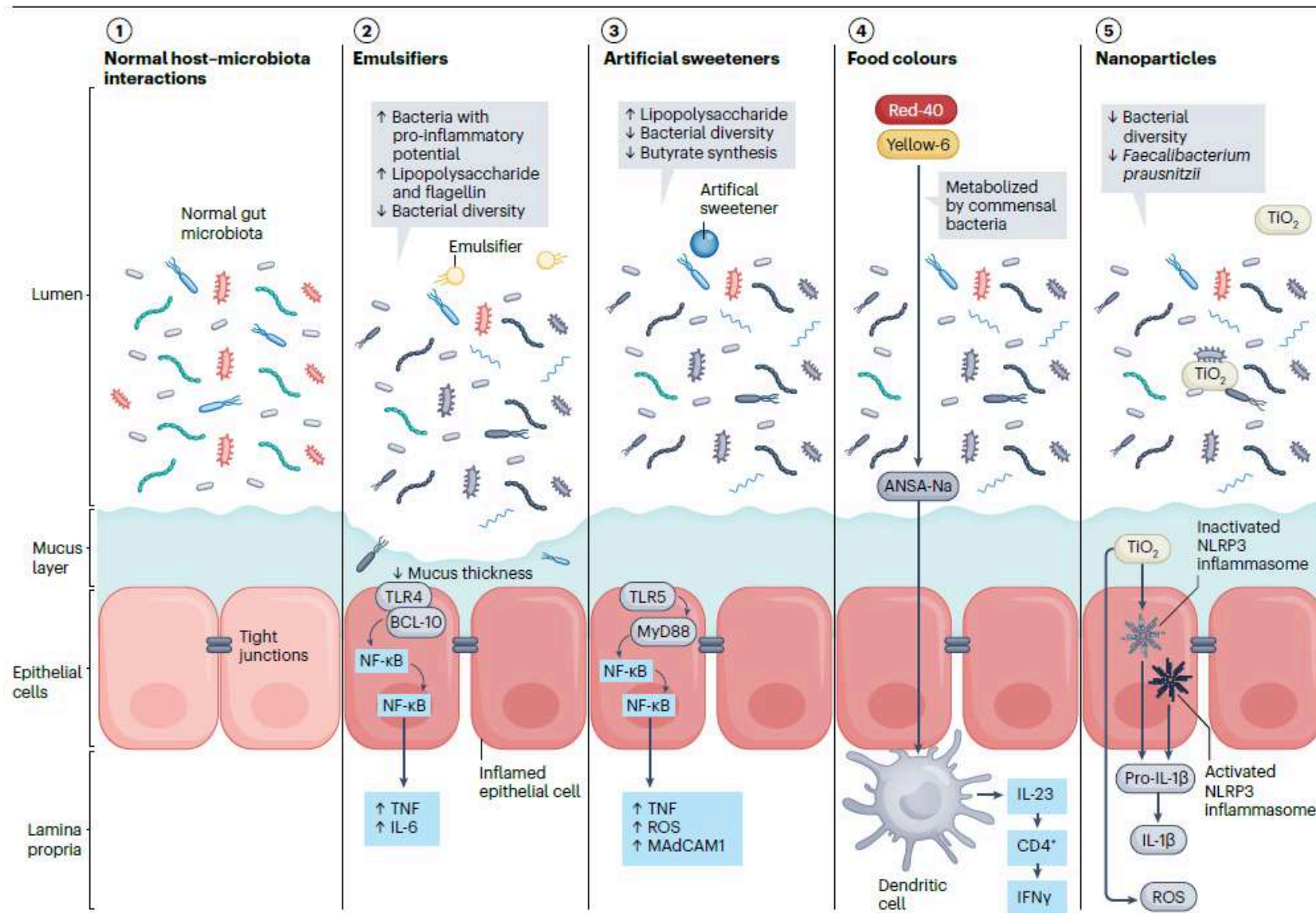


Alimentación y riesgo de diabetes



O'Hearn, M., Lara-Castor, L., Cudhea, F. *et al.* Incident type 2 diabetes attributable to suboptimal diet in 184 countries. *Nat Med* **29**, 982–995 (2023).

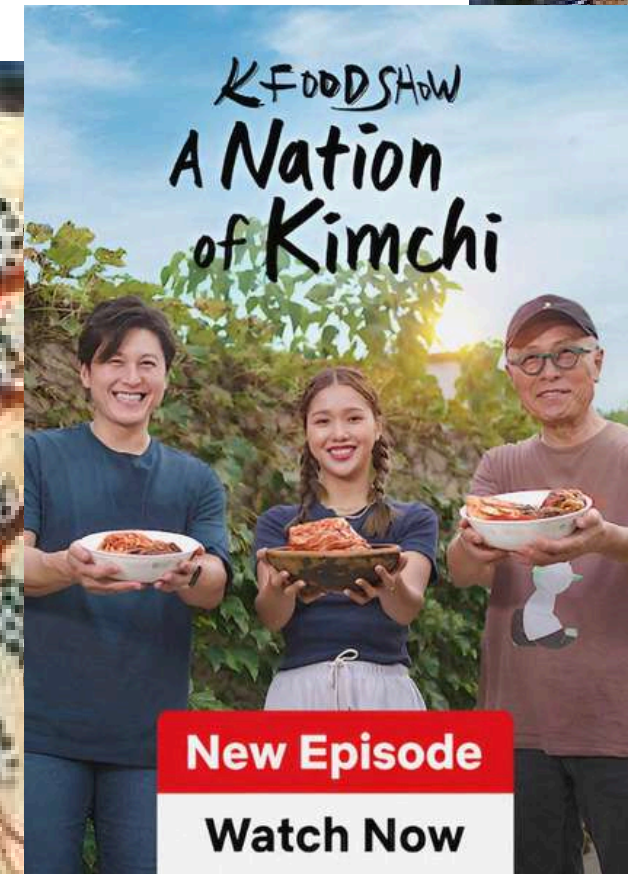
La alimentación del futuro: ¿debería ser la alimentación del pasado con la inocuidad de hoy?



Lección aprendida por la pandemia de COVID19



Fermentación y civilización



Fermented Food in Egypt: A Sustainable Bio-preservation to Improve the Safety of Food

[Samir A. Mahgoub](#) 

Chapter | [First Online: 27 April 2018](#)

Microbiology and Technology of Fermented Foods

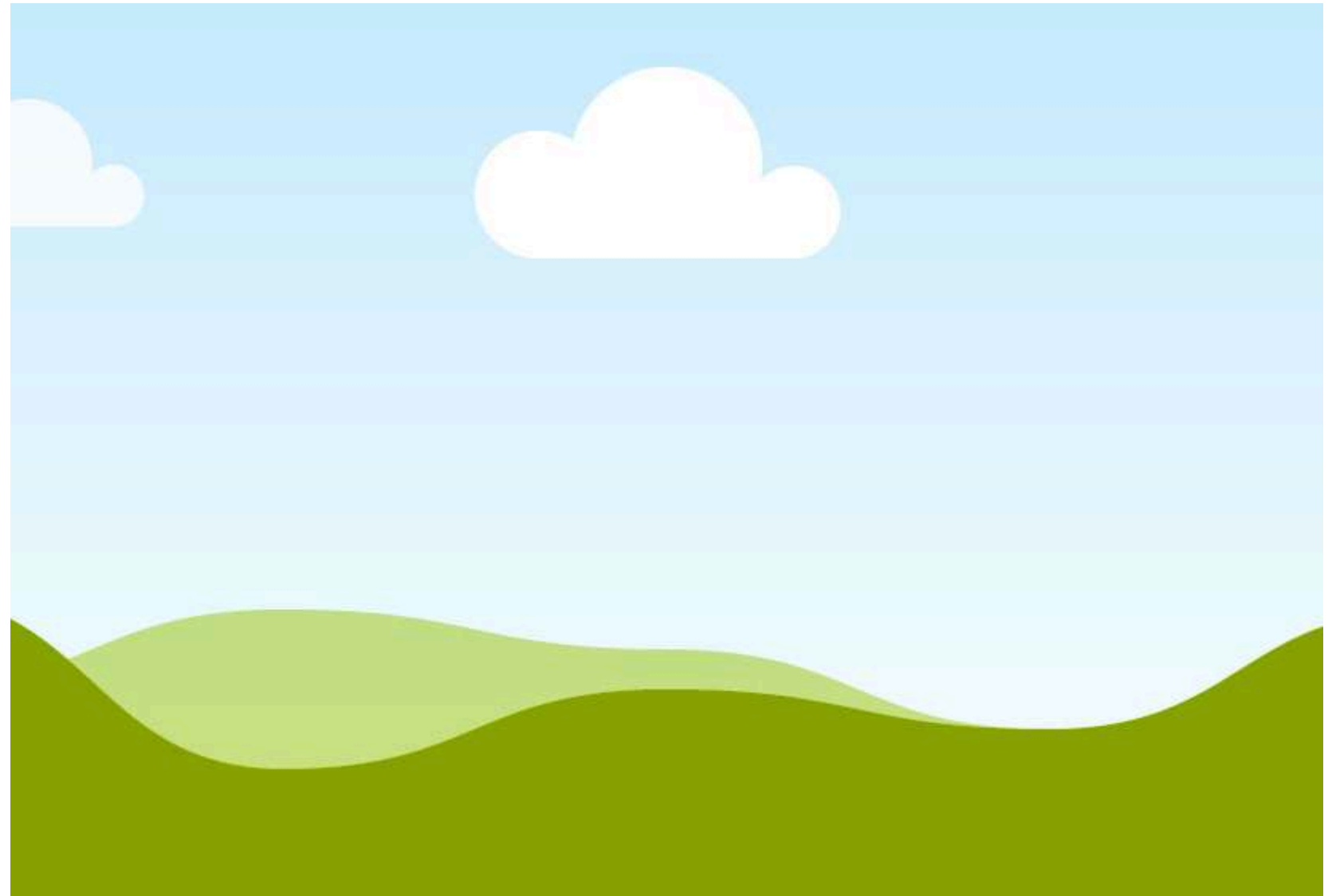
Second Edition

Robert W. Hutkins

IFT | Press



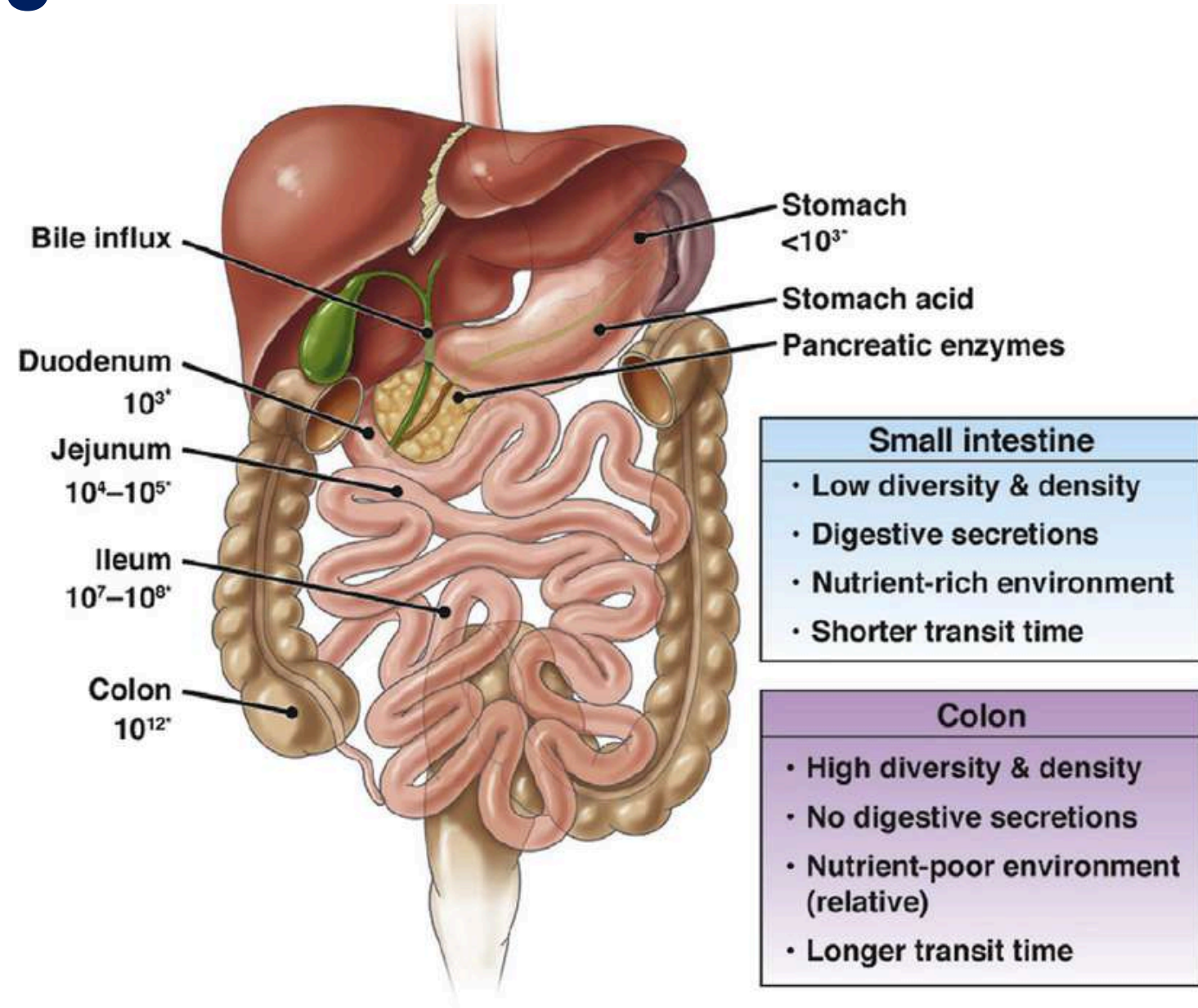
WILEY Blackwell



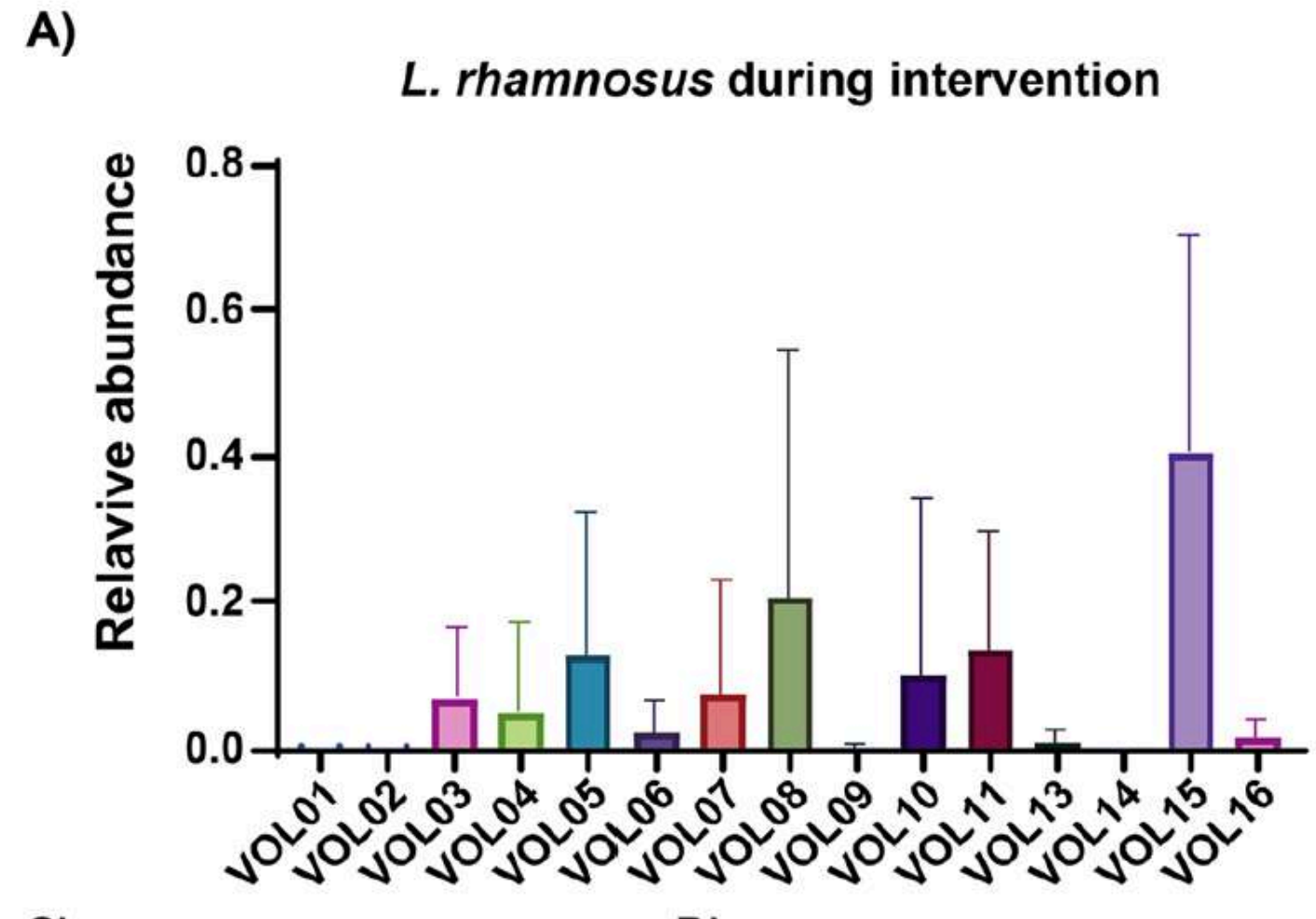
“Alimentos elaborados mediante el crecimiento microbiano deseado y las conversiones enzimáticas de sus componentes”



¿Cuán influenciable es la microbiota del intestino?



Kastl et al, (2020). The Structure and Function of the Human Small Intestinal Microbiota: Current Understanding and Future Directions. Cell. Mol. Gastroenterol. Hepatol., 9(1), 33–45.



Zaccaria et al (2023). Endogenous small intestinal microbiome determinants of transient colonisation efficiency by bacteria from **fermented dairy products**: a randomised controlled trial. Microbiome, 11(1), 43

¿A qué se deben los efectos benéficos?

nature reviews gastroenterology & hepatology

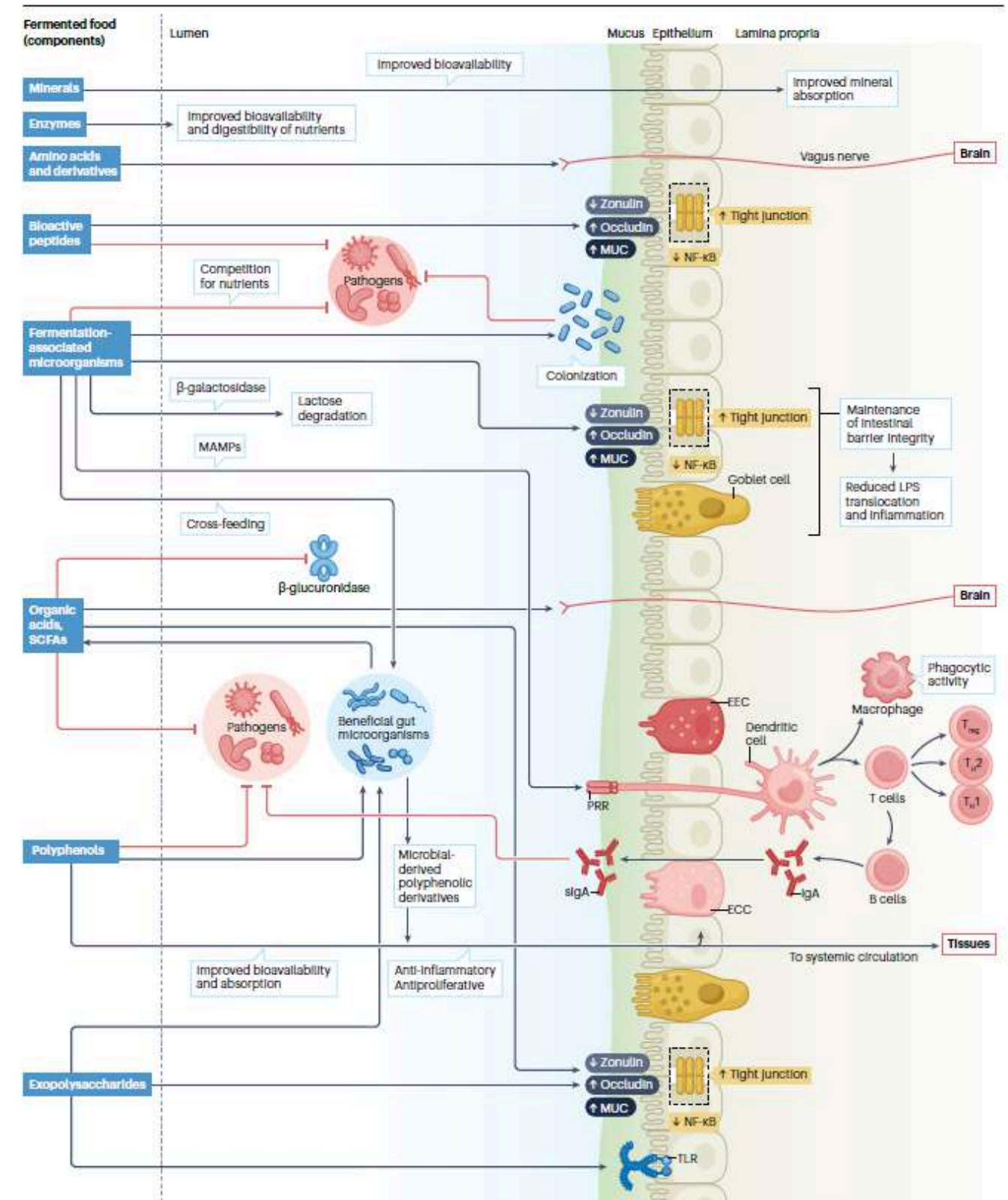
<https://doi.org/10.1038/s41575-023-00869-x>

Review article

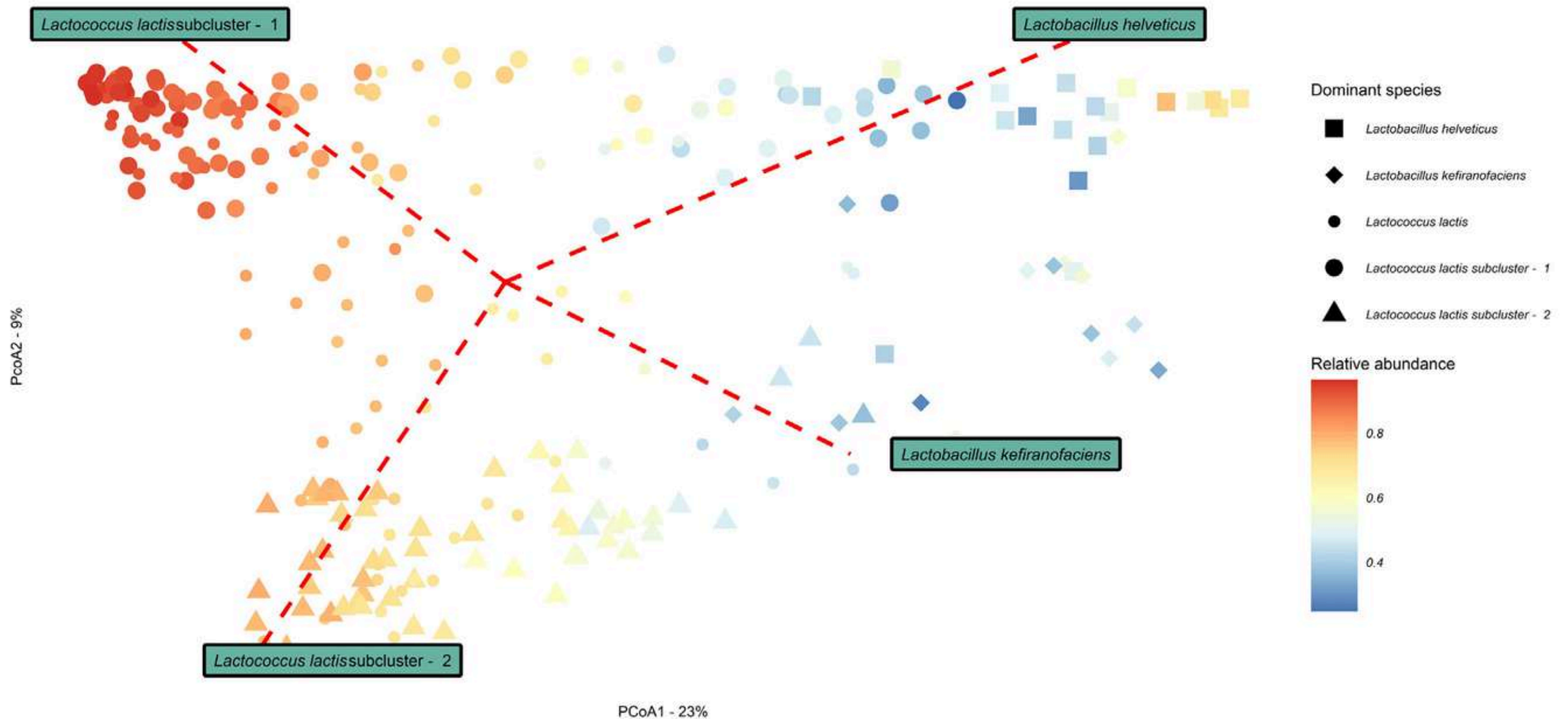
Check for updates

Fermented foods and gastrointestinal health: underlying mechanisms

Arghya Mukherjee^{1,6}, Samuel Bressler^{1,2,6}, Elrini Dimidi³, Maria L. Marco⁴ & Paul D. Cotter^{1,2,5}✉



¿Son todos los kefires iguales?



El kéfir de agua en el Código Alimentario Argentino

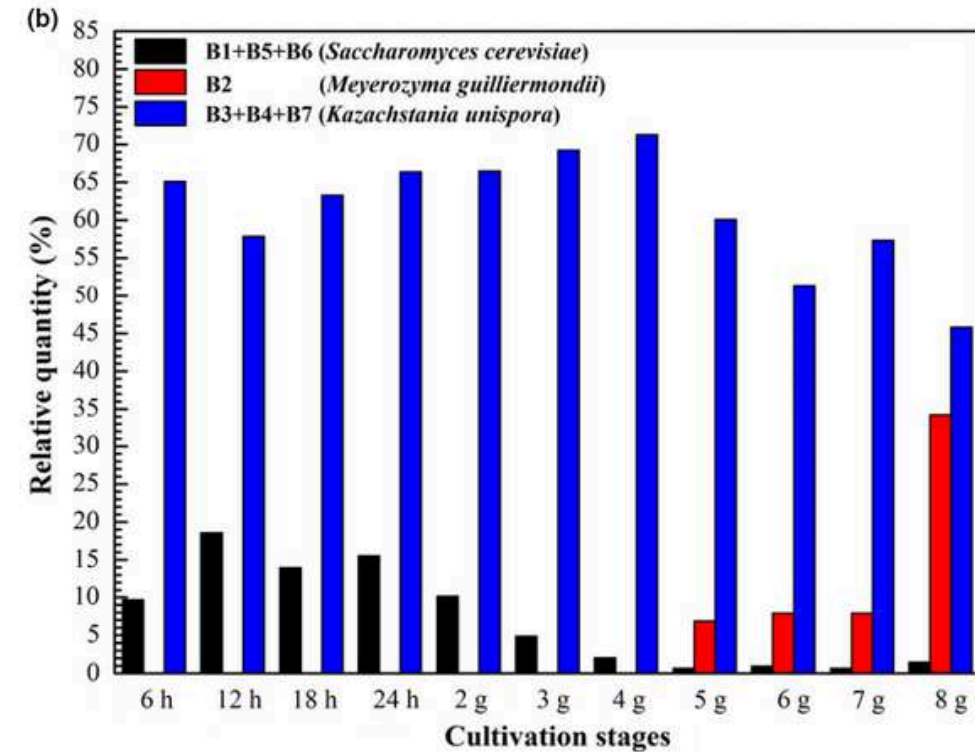
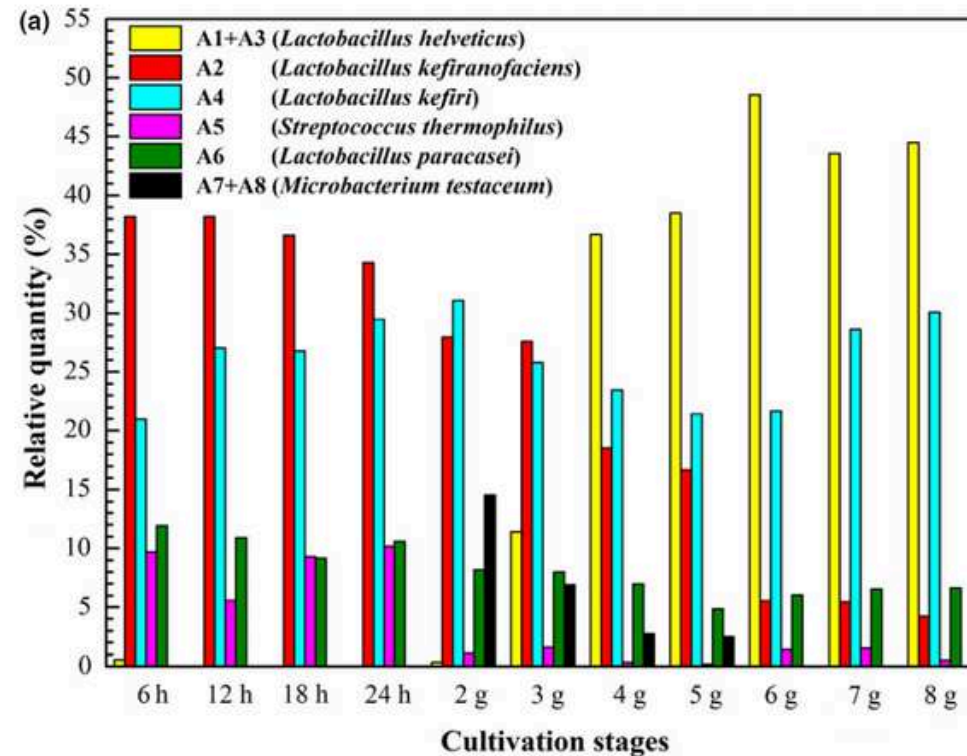
SECRETARÍA DE CALIDAD EN SALUD Y
SECRETARÍA DE BIOECONOMÍA

Resolución Conjunta 7/2024

RESFC-2024-7-APN-SCS#MS

ARTÍCULO 1º.- Incorpórase el Artículo 1.084 tris al Capítulo XIII: "Bebidas Fermentadas" del Código Alimentario Argentino, el que quedará redactado de la siguiente manera: "Artículo 1.084 tris: Se entiende como Kéfir de agua (Water kefir o Sugary kefir) a la bebida obtenida a partir de la fermentación de gránulos de kéfir de agua en agua azucarada de la cual se han retirado los nódulos (cultivo iniciador). La bebida podrá ser adicionada con jugos o pulpas de fruta, extractos vegetales, especias, frutas secas, miel u otros ingredientes permitidos en el presente Código.

La composición microbiológica del kéfir cambia a lo largo de los subcultivos de los gránulos



Microbial diversity and stability during primary cultivation and subcultivation processes of Tibetan kefir

International Journal of Food Science and Technology 2015, 50, 1468–1476

Wei Gao,¹ Lanwei Zhang,^{1*} Zhen Feng,² Hui Liu,¹ Nditange Shigwedha,¹ Xue Han,¹ Huaxi Yi,¹ Wenli Liu¹ & Shuang Zhang¹

¹ School of Food Science and Engineering, Harbin Institute of Technology, 73 Huanghe Road, Harbin 150090, Heilongjiang, China

² College of Food Science, Northeast Agricultural University, 59 Mucai Road, Harbin 150030, Heilongjiang, China

No todos los kefires tienen las mismas propiedades

B.C.T. Bourrie et al.

Journal of Functional Foods 46 (2018) 29–37

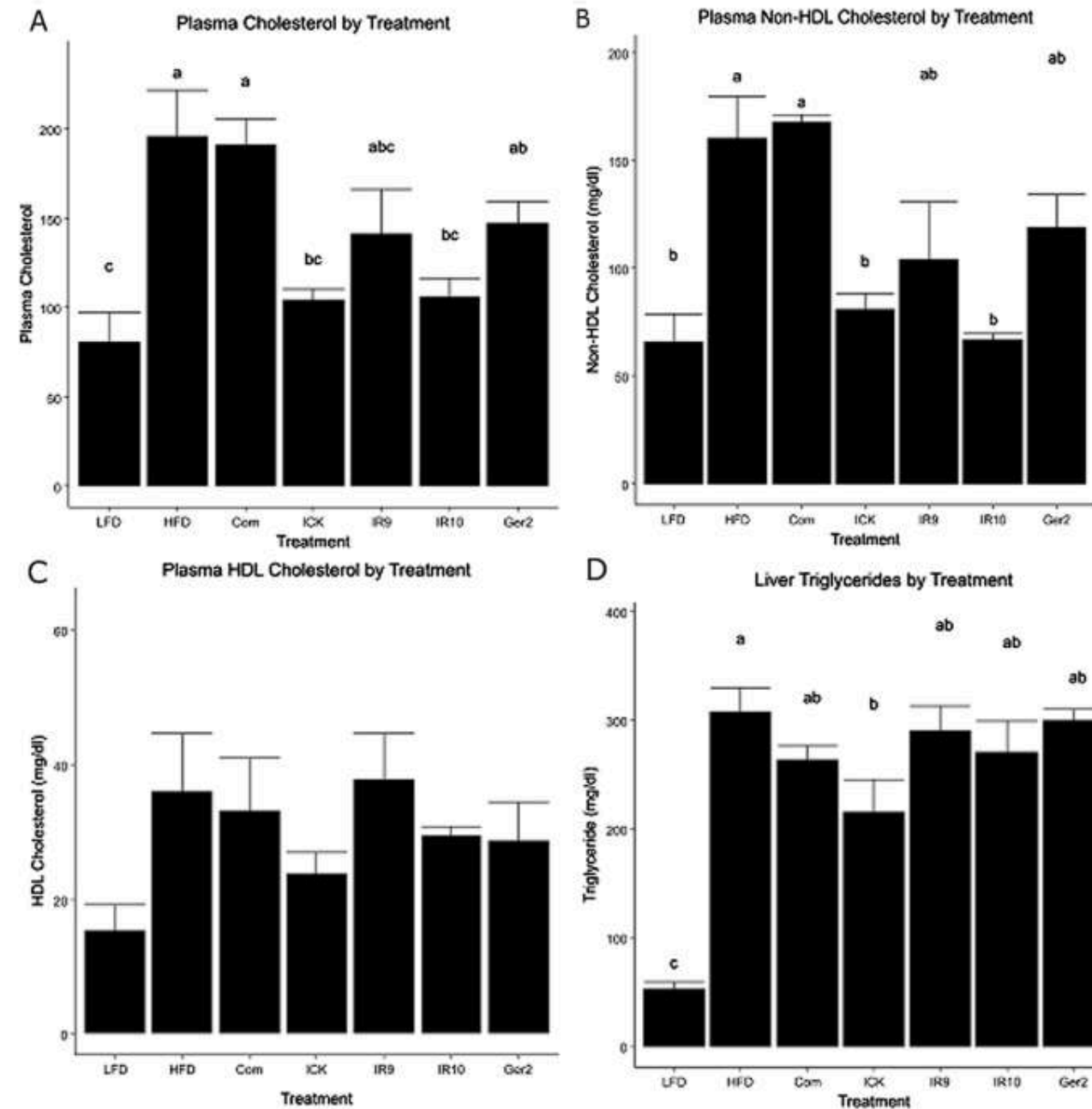
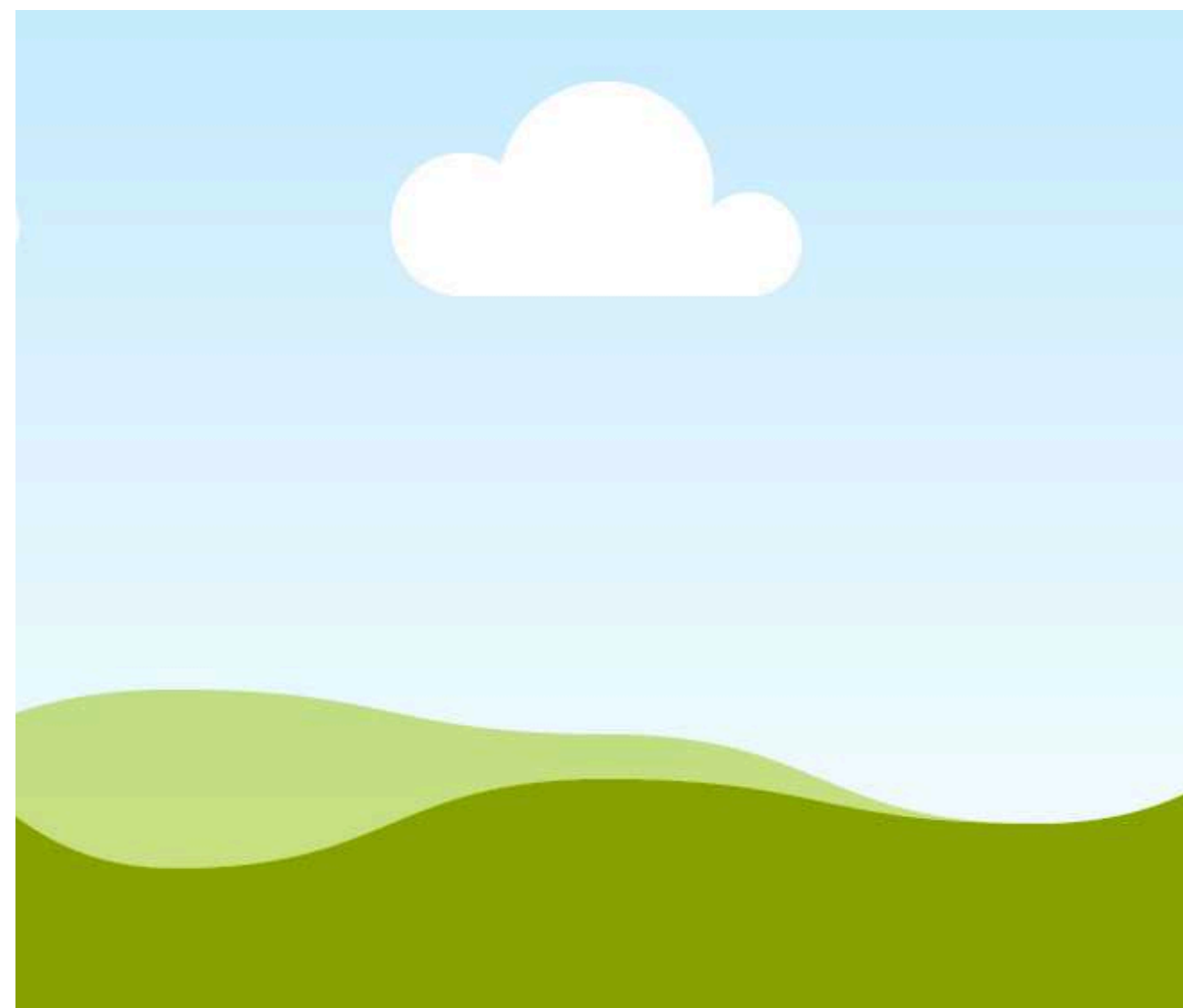


Fig. 3. Plasma total cholesterol (A), non-HDL cholesterol (B), HDL cholesterol (C) and liver triglyceride levels (D) in mice fed different kefir. Levels are expressed in mg/dl for both cholesterol and triglycerides. Means that do not share a letter are significantly different ($P < 0.05$). $N = 7-8$.

De la evidencia a las recomendaciones nutricionales

Table 3. Health benefits of milk *kefir* in human studies

Volunteers	Research purpose	Dose	Duration	Effects	Reference
Diabetic patients (<i>n</i> 60)	To determine the effect of <i>kefir</i> on glucose and lipid profile control in patients with type 2 diabetes mellitus	600 ml/d	8 weeks	The <i>kefir</i> decreased the fasting blood glucose and HbA1C levels and can be useful as a complementary or adjuvant therapy for the prevention of diabetes. <i>Kefir</i> consumption did not result in lowered plasma lipid concentrations	Osdrahimi <i>et al.</i> (2015) ⁽⁷³⁾
Healthy overweight or obese premenopausal women (<i>n</i> 75)	To compare the potential weight-reducing effects of <i>kefir</i> and milk in a dairy-rich non-energy-restricted diet in overweight or obese premenopausal women	Two servings/d of milk or <i>kefir</i>	8 weeks	The <i>kefir</i> drink led to a similar weight loss compared with low-fat milk	Fathi <i>et al.</i> (2015) ⁽¹³⁶⁾
Patients with functional constipation (<i>n</i> 20)	To evaluate the effects of <i>kefir</i> on the symptoms, colonic transit and bowel satisfaction scores of patients with chronic constipation	500 ml/d	4 weeks	<i>Kefir</i> had positive effects on the constipation symptoms	Turan <i>et al.</i> (2014) ⁽¹³⁷⁾
Healthy volunteers (<i>n</i> 22)	To evaluate if <i>kefir</i> can be considered an alternative to fluoride rinse	100 ml/d	2 weeks	The <i>kefir</i> drink could inhibit salivary mutans streptococci as well as the sodium fluoride rinse. <i>Kefir</i> may be used in caries control strategies adjunctively	Ghasempour <i>et al.</i> (2014) ⁽¹³⁸⁾
Healthy volunteers (<i>n</i> 18)	To evaluate the influence of <i>kefir</i> consumption on inflammatory markers in healthy adults	200 ml/d	6 weeks	<i>Kefir</i> was able to control the inflammatory response	Adiloğlu <i>et al.</i> (2013) ⁽⁸⁰⁾
Patients with dyspepsia (<i>n</i> 82)	To evaluate the effect of <i>kefir</i> conjugated triple therapy for <i>Helicobacter pylori</i> eradication	250 ml of <i>kefir</i> twice daily	2 weeks	<i>Kefir</i> improved the efficacy and tolerability of triple therapy in eradicating <i>Helicobacter pylori</i>	Bekar <i>et al.</i> (2011) ⁽¹³⁹⁾
Healthy children (<i>n</i> 125)	To examine the role of <i>kefir</i> in preventing antibiotic-associated diarrhoea	150 ml/d	2 weeks	<i>Kefir</i> did not prevent antibiotic-associated diarrhoea	Merenstein <i>et al.</i> (2009) ⁽¹⁴⁰⁾
Patients with colorectal cancer (<i>n</i> 40)	To investigate the effect of <i>kefir</i> consumption on mucositis induced by fluorouracil-based chemotherapy	250 ml twice per d	On the first 5 d of each chemotherapy cycle	<i>Kefir</i> consumption had no effect on serum proinflammatory cytokine levels and on the incidence of mucositis development in cancer patients	Topuz <i>et al.</i> (2008) ⁽¹⁴¹⁾
Healthy mildly hypercholesterolaemic male subjects (<i>n</i> 13)	To determine whether <i>kefir</i> supplementation would alter plasma lipids in mildly hypercholesterolaemic men		4 weeks	<i>Kefir</i> consumption did not result in lowered plasma lipid concentrations	St-Onge <i>et al.</i> (2002) ⁽⁷²⁾

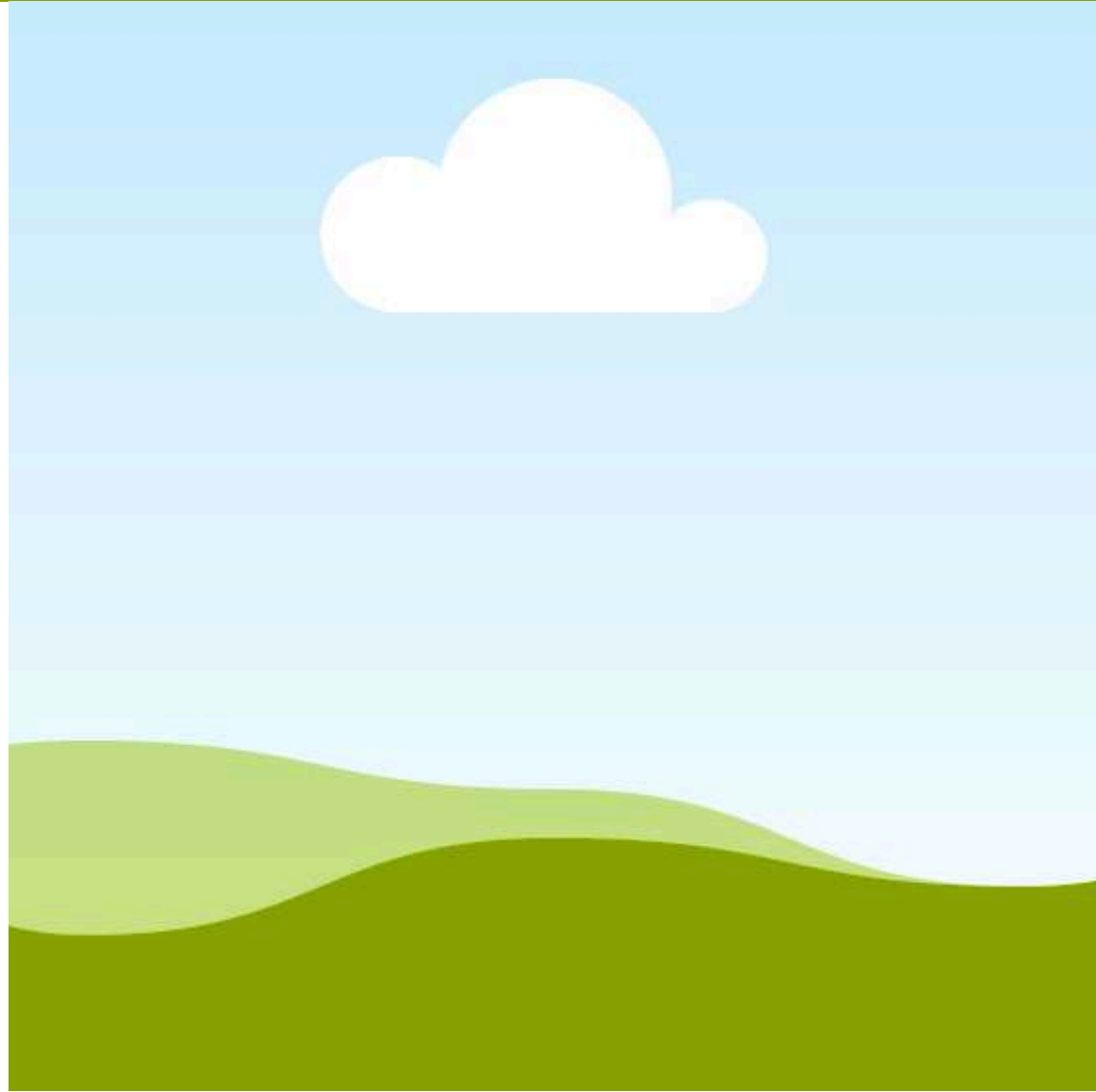
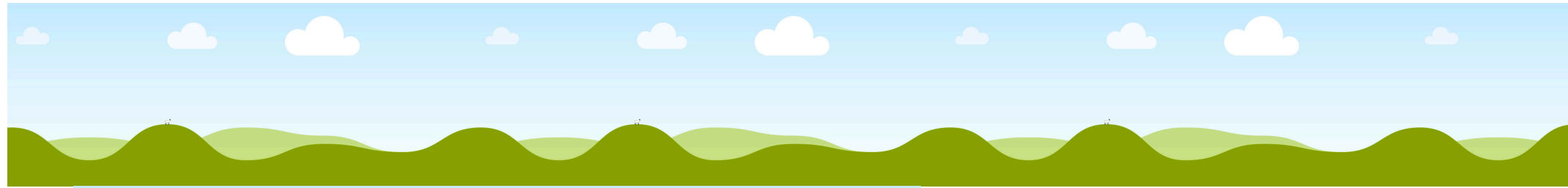


Daily

Regularly: 3 to 5 times/week

Occasionally: 1 to 2 times/week

Briefly, the major fermented foods consumed were beer, kimchi, kombucha, pickled vegetables, sauerkraut, and yogurt.



1 porción
yogurt, kefir, buttermilk, kvass = 170 g
kimchi, sauerkraut, other fermented veggies = 1/4 taza

Para utilizar microorganismos como vectores de salud se necesita:

Identidad de/los microorganismo/s

Seguridad de/los microorganismo/s

Inocuidad del producto

Estudios de **eficacia** (RCT)

Dosis conocida y verificable en el producto

Reproducibilidad de lote a lote

Probióticos

Postbióticos



Córdoba
1 - 4 de Octubre 2001

Microorganismos vivos que, cuando son administrados en cantidades adecuadas, otorgan un beneficio a la salud del consumidor (FAO/WHO, 2002).

Alimentos fermentados y probióticos en niños. La importancia de conocer sus diferencias microbiológicas

Fermented foods and probiotics for children. The importance of knowing their microbiological differences

Dr. Gabriel Vinderola^a y Dr. Gonzalo Pérez-Marc^b

Artículo especial

Arch Argent Pediatr 2023;e202310168

Postbióticos: un nuevo miembro en la familia de los bióticos

María del C. Toca^a, Fernando Burgos^b, Omar Tabacco^c, Gabriel Vinderola^d

Abordaje de los probióticos en pediatría: el rol de *Lactobacillus rhamnosus* GG

Approach to probiotics in pediatrics: the role of Lactobacillus rhamnosus GG

Christian Boggio Marzet^a, Fernando Burgos^b, Mónica Del Compare^c, Ingrid Gerold^d, Omar Tabacco^e, Gabriel Vinderola^f

Immunomodulation properties of biotics and food allergy in pediatrics

Fernando Burgos^a, Tomás Herrero^b, Jorge Martínez^c, Omar Tabacco^d, Gabriel Vinderola^e

Creciente disponibilidad de cepas en Argentina

Diarrea atb: *L. rhamnosus* GG, *S. boulardii*, *B. clausii*

Acné: *L. rhamnosus* SP1

Dermatitis atópica en niños: *L. bulgaricus* PXN 39, *L. acidophilus* PXN 35,

B. breve PXN 25, *B. infantis* PXN 27, *L. rhamnosus* PXN 54,
S. thermophilus PXN 66, *L. casei* PXN 37

Embarazada con antecedentes de alergia: *L. rhamnosus* GG

Cólicos del lactante: *L. reuteri* DSM17938

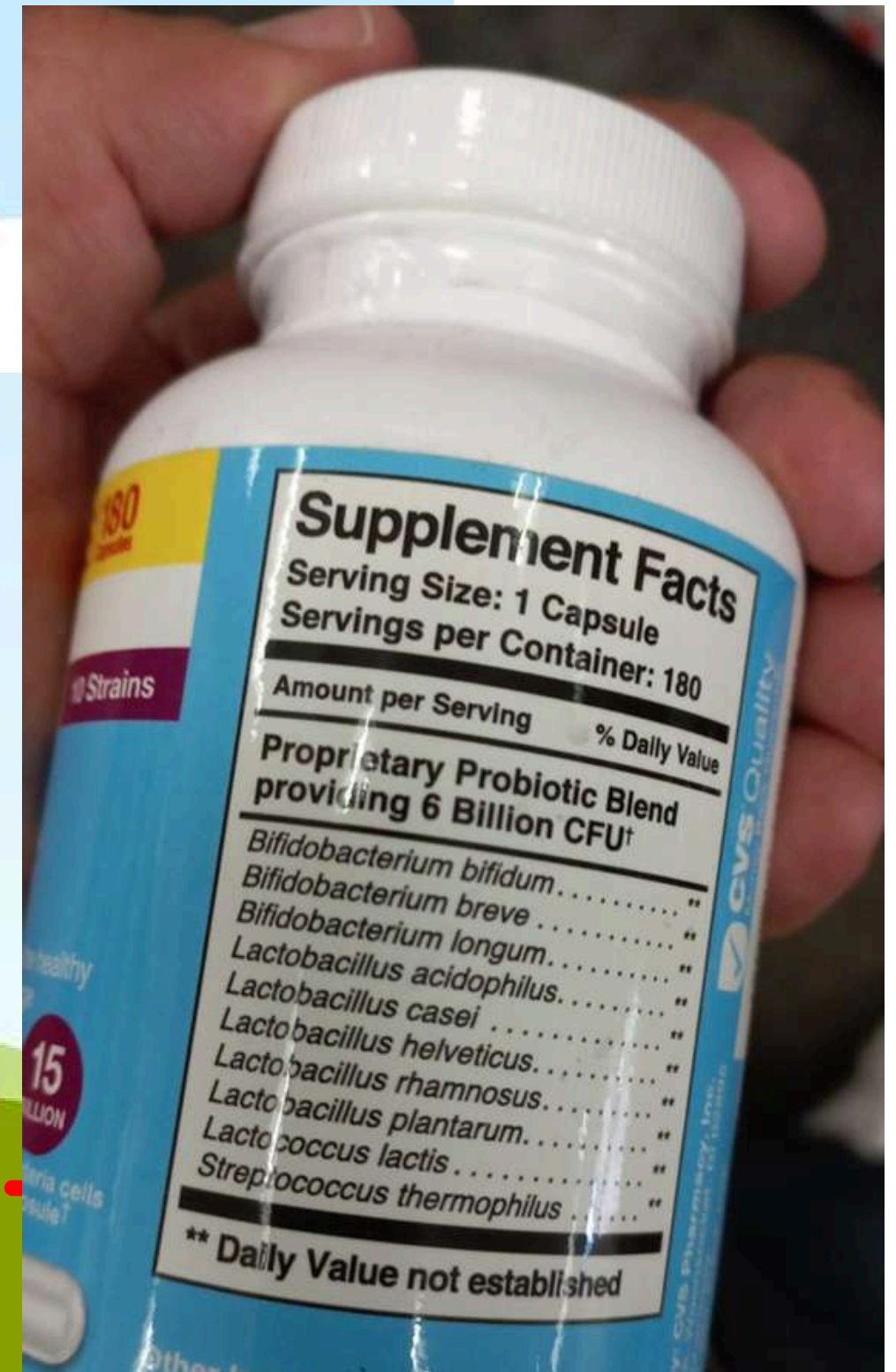
Diarrea del viajero: *L. rhamnosus* GG, *S. boulardii*

Herradicación *H. pylori* junto a atb: *S. boulardii*

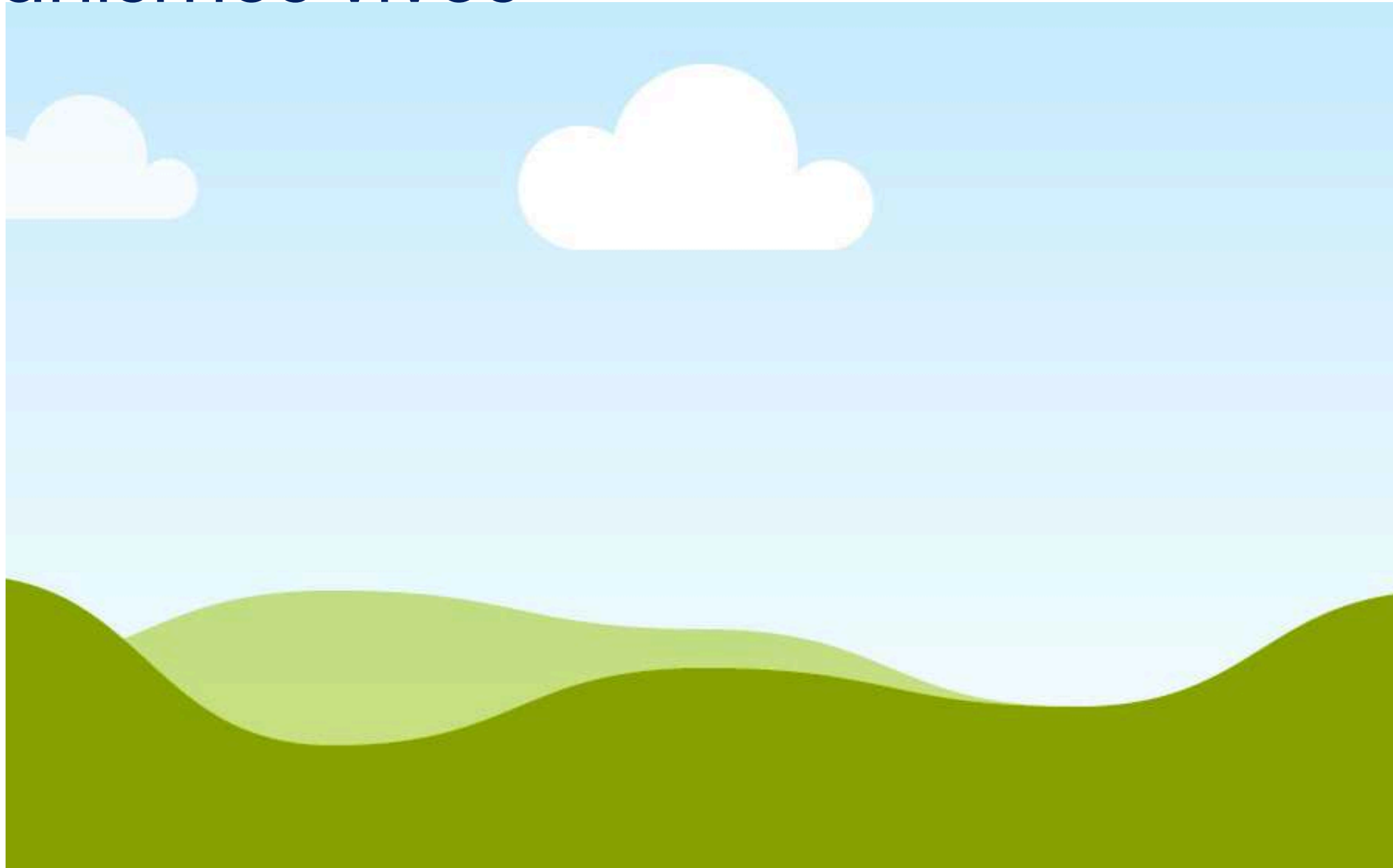
Intestino irritable: *L. rhamnosus* GG

Infecciones vaginales: *Lactobacillus crispatus*

El largo camino del desarrollo de un probiótico



Cambios en el estilo de vida: progresiva menor ingesta de microorganismos vivos



Recommended daily allowance (RDA) for microbes?

August 19, 2018 / in Consumer Blog, featured, ISAPP Science Blog /

By Prof. Colin Hill, Alimentary Pharmabiotic Centre, Food for Health Ireland, University College Cork



Dietary recommendation on adequate intake of live microbes: a path forward

Marco ML, Hill C, Hutkins R, Slavin J, Tancredi DJ, Merenstein D, Sanders ME. Dietary recommendation on adequate intake of live microbes: a path forward. Submitted, Curr Dev Nutr.

Concepto de Microorganismos Dietarios Vivos

The Journal of Nutrition 153 (2023) 1143–1149



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journal homepage: www.journals.elsevier.com/the-journal-of-nutrition

Nutritional Epidemiology

Positive Health Outcomes Associated with Live Microbe Intake from Foods, Including Fermented Foods, Assessed using the NHANES Database

Colin Hill^{1,†}, Daniel J. Tancredi^{2,†}, Christopher J. Cifelli³, Joanne L. Slavin⁴, Jaime Gahche⁵, Maria L. Marco⁶, Robert Hutkins⁷, Victor L. Fulgoni III⁸, Daniel Merenstein⁹, Mary Ellen Sanders^{10,*}

Efectos benéficos del consumo de microbios vivos

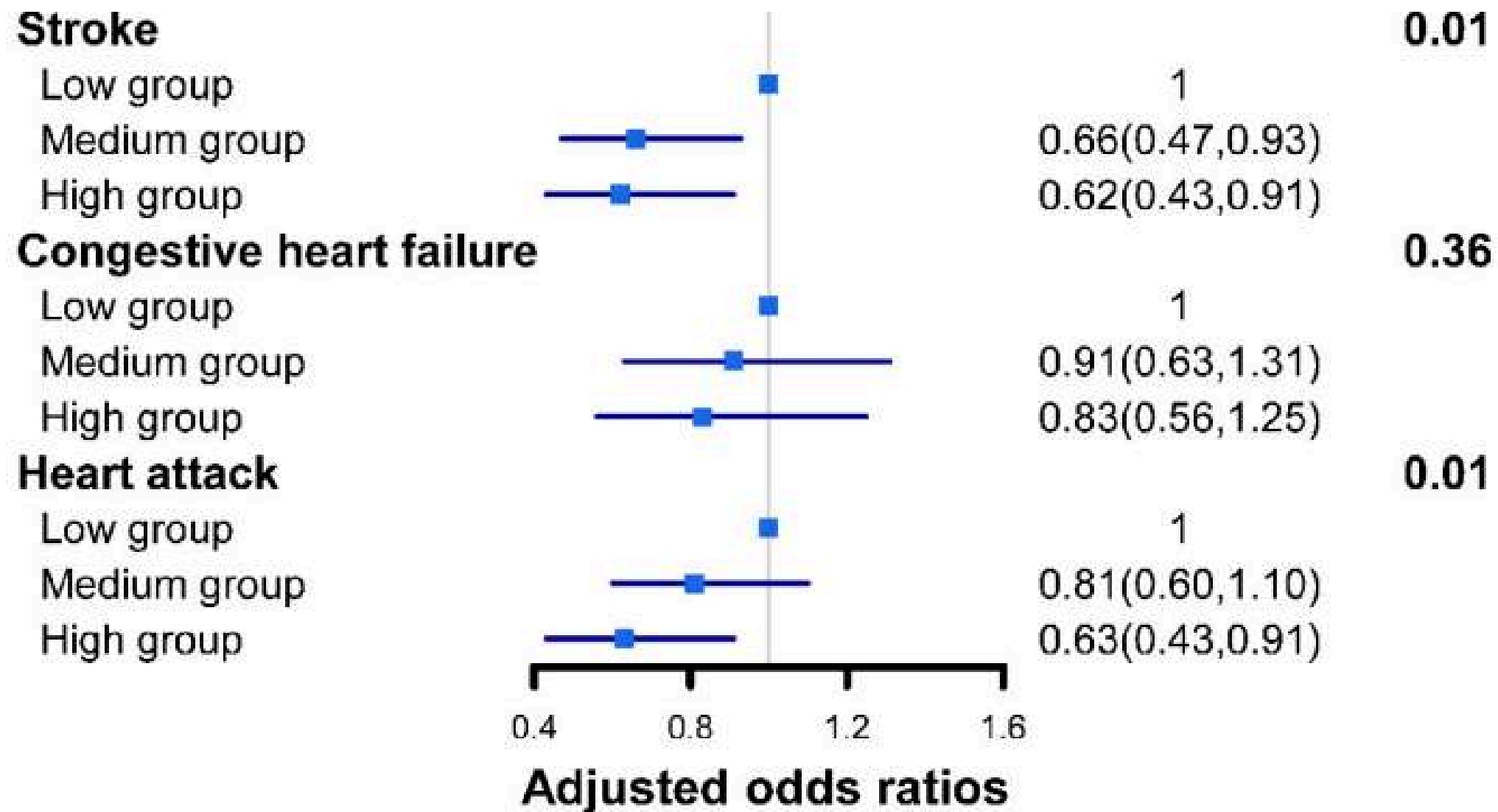
El consume diario de 100 g de alimentos con una carga alta de microorganismos vivos, se asocia con menor presión sistólica, proteína C reactiva, glucosa e insulina en ayunas, triglicéridos, circunferencia de cintura, IMC y mayor nivel de lipoproteínas de alta densidad (HDL).

Alta carga de microorganismos vivos: $> 10^7$ UFC/g o mL (10^9 UFC totales)

Alimentos fermentados: yogur, quesos frescos, kefir de agua, kefir de leche, kombucha, chucrut, kimchi, hummus fermentado...

Suplementos microbianos, suplementos probióticos

Efectos benéficos del consumo de microbios vivos



> *J Affect Disord.* 2024 Jan 1;344:198-206. doi: 10.1016/j.jad.2023.10.015. Epub 2023 Oct 10.

"High dietary live microbe intake is correlated with reduced risk of depressive symptoms: A cross-sectional study of NHANES 2007–2016"

Xuefei Wang¹, Huaicheng Wang², Qianwen Yu³, Shibo Fu², Zeqiang Yang², Qinyong Ye⁴, Fabian Lin⁵, Guoen Cai⁶

> *Clin Nutr.* 2024 Jul;43(7):1675-1682. doi: 10.1016/j.clnu.2024.05.030. Epub 2024 May 23.

Higher dietary live microbe intake is associated with a lower risk of sarcopenia

Kemin Yan¹, Xiaoyi Ma¹, Chen Li¹, Xiang Zhang², Manxuan Shen¹, Sai Chen¹, Jia Zhao², Wen He¹, Hua Hong¹, Yingying Gong³, Gang Yuan⁴

> *J Gerontol A Biol Sci Med Sci.* 2024 Aug 19;glae202. doi: 10.1093/gerona/glae202. Online ahead of print.

Dietary Live Microbes Intake Associated with Biological Aging and Mortality

Xu Zhu^{1 2}, Wenhong Chen¹, Jing Xue³, Wenjie Dai⁴, Rehanguli Maimaituerxun⁴, Yamin Liu⁴, Hui Xu¹, Qiaoling Zhou¹, Quan Zhou⁵, Chunyuan Chen^{6 7}, Zhenxing Wang^{6 7}, Hui Xie^{6 7}

> *Oral Dis.* 2024 Jan 23. doi: 10.1111/odi.14869. Online ahead of print.

Live dietary microbes and reduced prevalence of periodontitis: A cross-sectional study

Jie Lin¹, Hui Yang¹, Zhengshen Lin¹, Lingqiao Xu¹

Affiliations + expand

PMID: 38263606 DOI: 10.1111/odi.14869

> *J Nutr.* 2024 Feb;154(2):526-534. doi: 10.1016/j.tjnut.2023.11.032. Epub 2023 Dec 9.

Association between Dietary Intake of Live Microbes and Chronic Constipation in Adults

Shuanli Yang¹, Qin Hong², Teng Wu³, Yunhe Fan³, Xiaobing Shen⁴, Xiushan Dong⁵

> *Arch Osteoporos.* 2024 Aug 3;19(1):69. doi: 10.1007/s11657-024-01429-9.

Association of dietary live microbe intake with prevalence of osteoporosis in US postmenopausal women: a cross-sectional study

Feng Yuan¹



Postbióticos

“el poder de los muertos”

Postbióticos: 3 conceptualizaciones

Metabolitos
producidos por
probióticos que
confieren un
beneficio



**Microorganismos
no viables que
confieren un
beneficio a la
salud**



Metabolitos
producidos por la
microbiota
intestinal

Aclarando el concepto y la definición



Review

The Concept of Postbiotics

Gabriel Vinderola ^{1,*}, Mary Ellen Sanders ² and Seppo Salminen ³

- ¹ Instituto de Lactología Industrial (INLAIN, UNL-CONICET), Facultad de Ingeniería Química, Universidad Nacional del Litoral, Santa Fe 3000, Argentina
 - ² International Scientific Association for Probiotics and Prebiotics, Centennial, CO 80122, USA; maryellen@isappscience.org
 - ³ Functional Foods Forum, Faculty of Medicine, University of Turku, 20014 Turku, Finland; sepsal@utu.fi
- * Correspondence: gvinde@fiq.unl.edu.ar; Tel.: +54-9-3426-31-1943

Abstract: The scientific community has proposed terms such as non-viable probiotics, paraprobiotics, ghostbiotics, heat-inactivated probiotics or, most commonly, postbiotics, to refer to inanimate microorganisms and/or their components that confer health benefits. This article addresses the various characteristics of different definitions of ‘postbiotics’ that have emerged over past years. In 2021, the International Scientific Association for Probiotics and Prebiotics (ISAPP) defined a postbiotic as “a preparation of inanimate microorganisms and/or their components that confers a health benefit on the host”. This definition of postbiotic requires that the whole or components of inactivated microbes be present, with or without metabolic end products. The definition proposed by ISAPP is comprehensive enough to allow the development of postbiotics from different microorganisms, to be applied in different body sites, encouraging innovation in a promising area for any regulatory category and for companion or production animals, and plant or human health. From a technological perspective, probiotic products may contain inanimate microorganisms, which have the potential to impart a health benefit. However, their contribution to health in most cases has not been established, even if at least one probiotic has been shown to confer the same health benefit by live or inanimate cells.

Keywords: postbiotics; inanimate; probiotics; International Scientific Association for Probiotics and Prebiotics; ISAPP; non-viable probiotics; heat-inactivated probiotics; microorganisms



Citation: Vinderola, G.;

frontiers | Frontiers in Microbiology

TYPE Perspective
PUBLISHED 10 January 2024
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Frequently asked questions about the ISAPP postbiotic definition

Gabriel Vinderola^{1*}, Mary Ellen Sanders², Marla Cunningham³ and Colin Hill⁴

¹Instituto de Lactología Industrial (CONICET-UNL), Faculty of Chemical Engineering, National University of Litoral, Santa Fe, Argentina, ²International Scientific Association for Probiotics and Prebiotics, Centennial, CO, United States, ³International Scientific Association for Probiotics and Prebiotics, Brisbane, QLD, Australia, ⁴APC Microbiome Ireland, University College Cork, Cork, Ireland

The term postbiotic was defined by the International Scientific Association of Probiotics and Prebiotics (ISAPP) as “a preparation of inanimate microorganisms and/or their components that confers a health benefit on the host.” Although the ISAPP definition is widely cited, some concerns were aired after publication, and alternative definitions of postbiotic, as well as different terms for inactivated microbes, have been previously suggested. This paper addresses questions about the ISAPP definition that have been raised in different forums, including scientific meetings, social media commentary and personal communications. We focus on the rationale, scope, wording, composition and commercial implementation, as well as what is expected of postbiotics regarding safety, efficacy, quantification and mechanisms of action. We hope that exploring these questions will further clarify the definition and its scope and support a common understanding of the concept of postbiotics.

KEYWORDS

postbiotics, International Scientific Association for Probiotics and Prebiotics, ISAPP, biotic, inanimate microorganism

Demasiados términos en uso para microorganismos No viables



Review

Postbiotics and Their Potential Applications in Early Life Nutrition and Beyond

Carrie A. M. Wegh¹, Sharon Y. Geerlings¹, Jan Knol^{1,2}, Guus Roeselers² and Clara Belzer^{1,*}

Review

Health Benefits of Heat-Killed (Tyndallized) Probiotics: An Overview

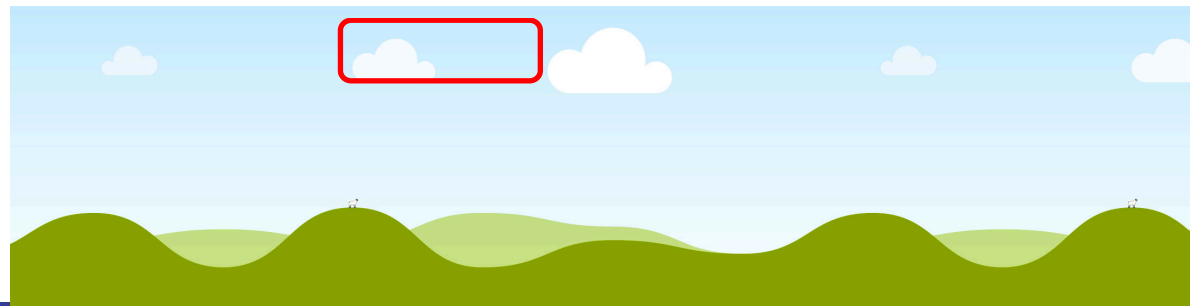
Núria Piqué^{1,2,*}, Mercedes Berlanga¹ and David Miñana-Galbis¹



Commentary

Para-probiotics for Preterm Neonates—The Next Frontier

Girish Deshpande^{1,2}, Gayatri Athalye-Jape³ and Sanjay Patole^{3,*}



Ghost probiotics with a combined regimen: a novel therapeutic approach against the Zika virus, an emerging world threat

Vivek K. Bajpai, Vishal Chandra, Na-Hyung Kim, Rajni Rai, Pradeep Kumar, Kangmin Kim, Abhinav Aeron, Sun Chul Kang, D. K. Maheshwari, MinKyun Na, Irfan A. Rather & Yong-Ha Park

> *Int Immunopharmacol.* 2015 Apr;25(2):474-84. doi: 10.1016/j.intimp.2015.02.006. Epub 2015 Mar 2.

Non-viable Immunobiotic Lactobacillus Rhamnosus CRL1505 and Its Peptidoglycan Improve Systemic and Respiratory Innate Immune Response During Recovery of Immunocompromised-Malnourished Mice

Yanina Kolling¹, Susana Salva¹, Julio Villena¹, Gabriela Marranzino¹, Susana Alvarez²

Journal of Applied Microbiology

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REVIEW ARTICLE

Bioactives from probiotics for dermal health: functions and benefits

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Cell fragments

> *Probiotics Antimicrob Proteins.* 2021 Dec;13(6):1539-1545. doi: 10.1007/s12602-021-09785-5. Epub 2021 Apr 11.

Comparison of Cytokine Expression in Human PBMCs Stimulated with Normal and Heat-Shocked Lactobacillus plantarum Cell Lysate

Marzieh Sanaei^{1,2}, Mehdi Mahdavi³, Neda Setayesh², Ahmad Reza Shahverdi^{1,2}, Zargham Sepehrizadeh^{1,2}, Mohammad Hossein Yazdi^{4,5}

Objetivos de Isapp

Unificar los diferentes términos utilizados para referirse a microorganismos no viables: *non-viable probiotics, heat-inactivated probiotics, inactivated probiotics, heat-treated probiotics, heat-killed probiotics, tyndallized probiotics, postbiotics, paraprobiotics, ghost probiotics, cell lyzates, cell fragments*

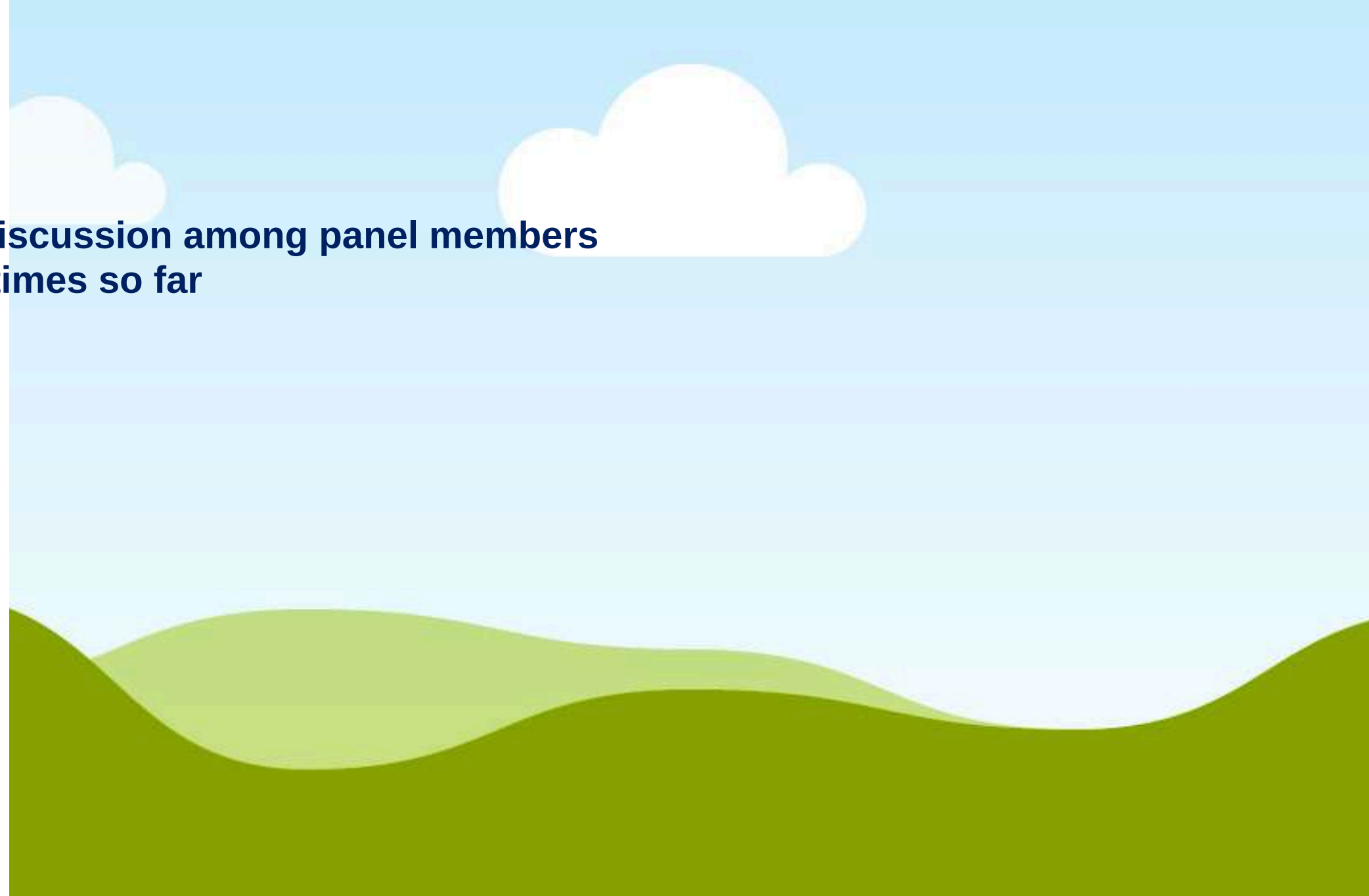
Proponer una definición consenso para el término

May 4th, 2021

- 110,000 accesses

More than 1 year of discussion among panel members

Cited more than 800 times so far



A preparation of inanimate microorganisms and/or their components that confers a health benefit on the host.

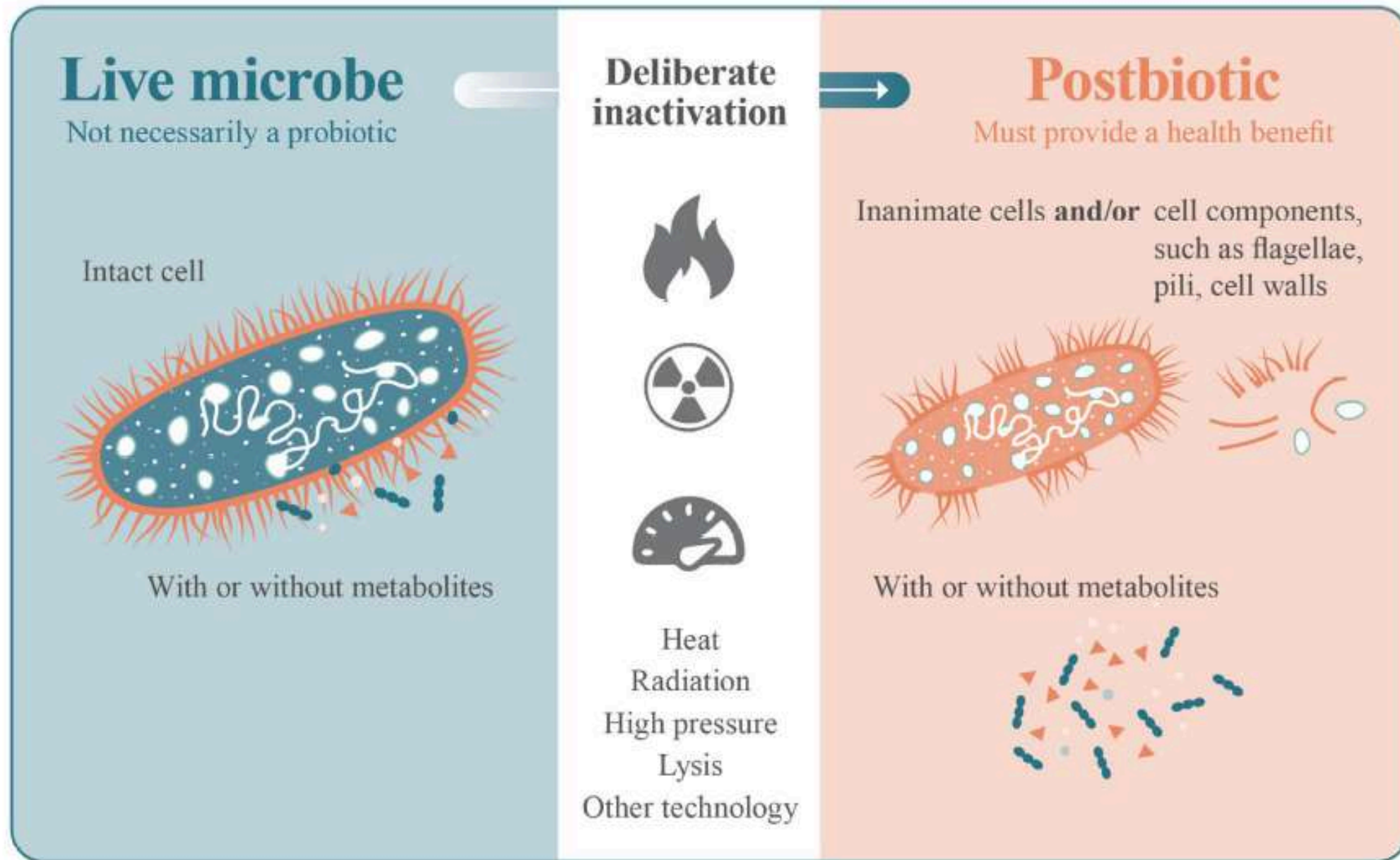
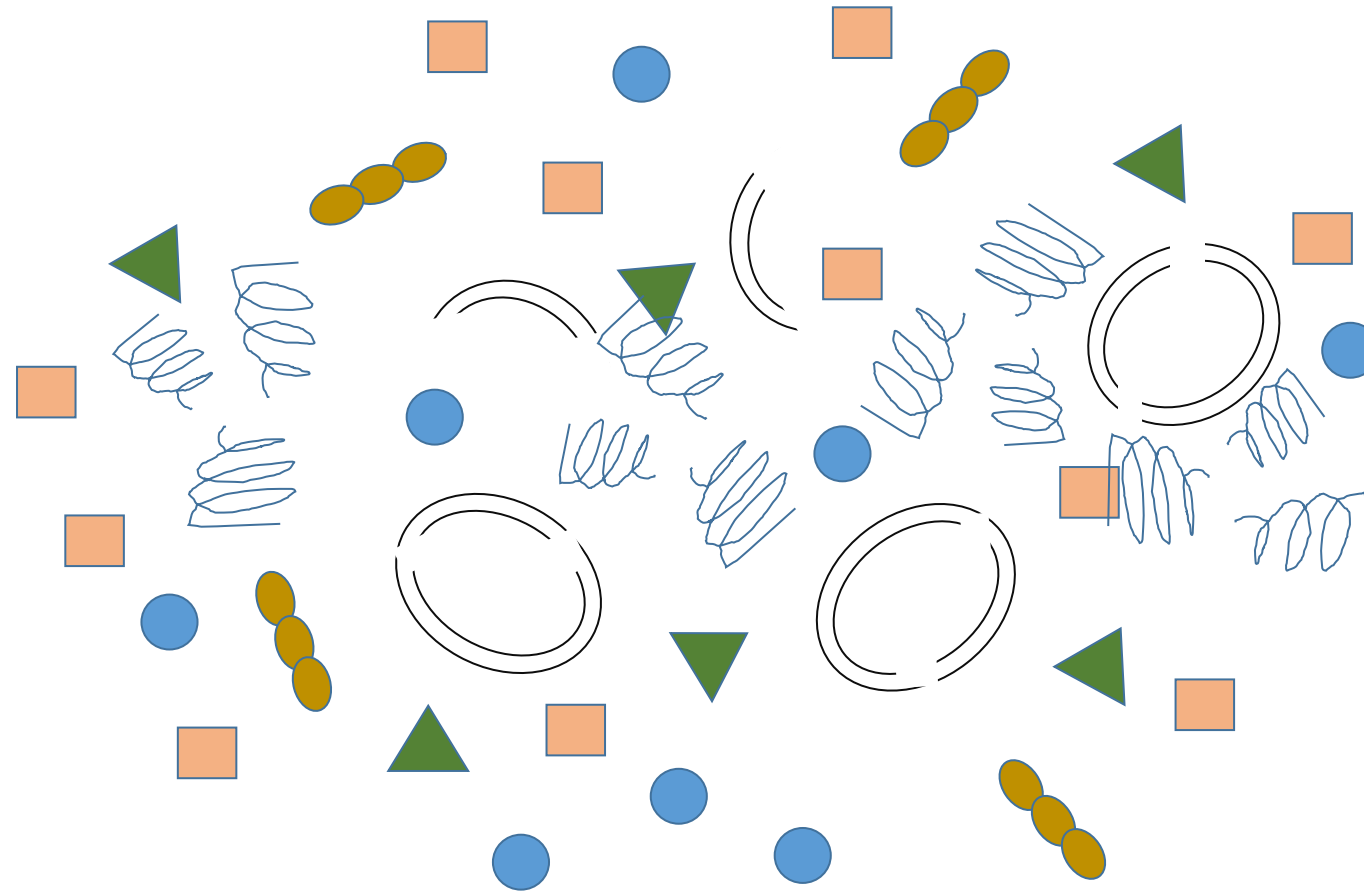


FIGURE 1

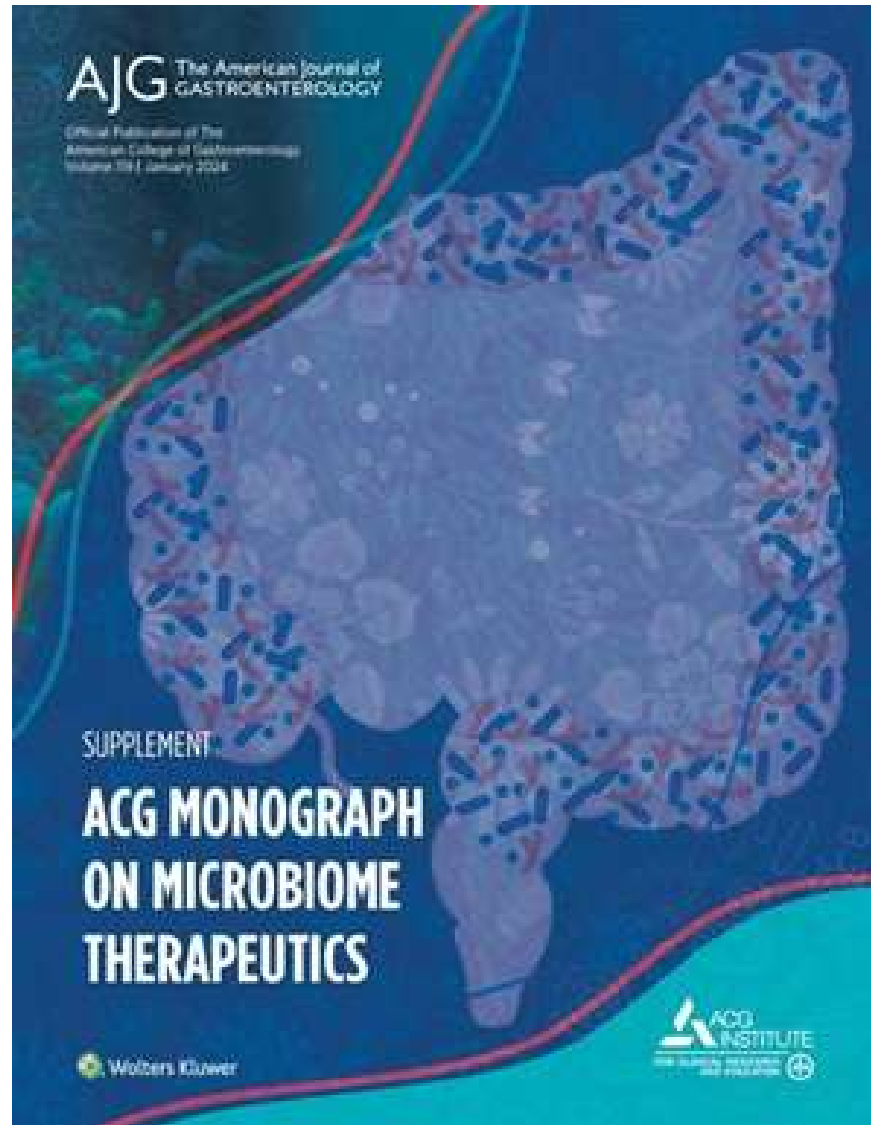
A deliberate process of viability termination (such as heat, radiation, high pressure or lysis) is applied to a live microbe as part of the manufacturing process of a postbiotic. The inactivation step may leave intact inanimate cells, cell components or a mixture of intact inanimate cells and cell components. The progenitor microbe does not necessarily have to be a probiotic.

De una preparación de microorganismos inanimados..



...a una molécula definida y con nombre propio: butirato (no es un postbiótico)

American College of Gastroenterology



January 2024 - Volume 119 - 1S

Synbiotics are a mixture comprising “live microorganisms and substrate(s) selectively utilized by host microorganisms that confers a health benefit on the host (2).” Postbiotics are defined as a “preparation of inanimate microorganisms and/or their components that confers a health benefit on the host (3).” This definition is intended to include inactivated or killed organisms, but does not include purified microbial metabolites. Furthermore,

Health Canada está considerando el término

Postbiotics

- ISAPP “preparation of inanimate microorganisms and/or their components that confers a health benefit on the host” definition published 2021
- Still debate regarding the definition
- Public understanding of the term still lacking
 - CBC news article 2022 – Health Canada has not approved any NHP with postbiotics as the “recommended use or purpose”
 - American survey found many did not properly understand the term and the health benefits.

NNHPD requirements for postbiotics (in development)

- Some probiotic specifications may apply (i.e. strain identification, contact with priority allergen, antibiotic resistance, etc.)
- Information regarding to how cells were inactivated /confirm cell are inactivated
- Quantification using “mg”. CFUs are not acceptable
- Clinical trial demonstrating health benefit (product specific)

HEALTH CANADA

Brian McNeill, officer Health Canada

The China Institute of Food and Drug Control

Postbiotics quantification: China health foods association rallies firms to draft industry standards

By Tingmin Koe

24-Jan-2024 - Last updated on 24-Jan-2024 at 01:44 GMT



Notice on the establishment of a group standard drafting working group for the "Guidelines for Counting and Detection of Postbiotic Inactivated Cells"

Release date: 2024-01-18

Australia, Reino Unido, Singapur, Suiza



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Requirements for microorganism characterisation in Listed Medicines and Registered Complementary Medicines

Guidance for applicants

Version 1.0, February 2023

Overview

This guidance provides information for applications relating to microorganisms as active ingredients for use as new substances in listed medicines, or as active ingredients in registered complementary medicines (RCM). Listed medicines and RCM containing microorganisms as active ingredients are generally referred to as probiotics or **postbiotics**.

This document provides tailored guidance that is not covered in the [Australian Regulatory Guidelines for listed medicines and RCM](#) and ensures that microorganisms, when identified and characterised, are safe for their intended use in keeping with modern best practice.

Scope

For the purpose of this guidance, microorganisms are whole and intact cells of bacteria and fungi (including yeasts) that are live or non-viable. This guidance is intended for the pre-market assessment of new live and whole/intact non-viable microorganisms potentially used as probiotics and **postbiotics** and should be considered in conjunction with the [Mandatory](#)

antes



Probiotics Center

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LAC-Shield (heat-killed *L. paracasei* MCC1849)

Application

Paraprobiotics

LAC-Shield (heat-killed *L. paracasei* MCC1849)

Application | Clinical Efficacy

ahora



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¿Cómo cuantificarlos?

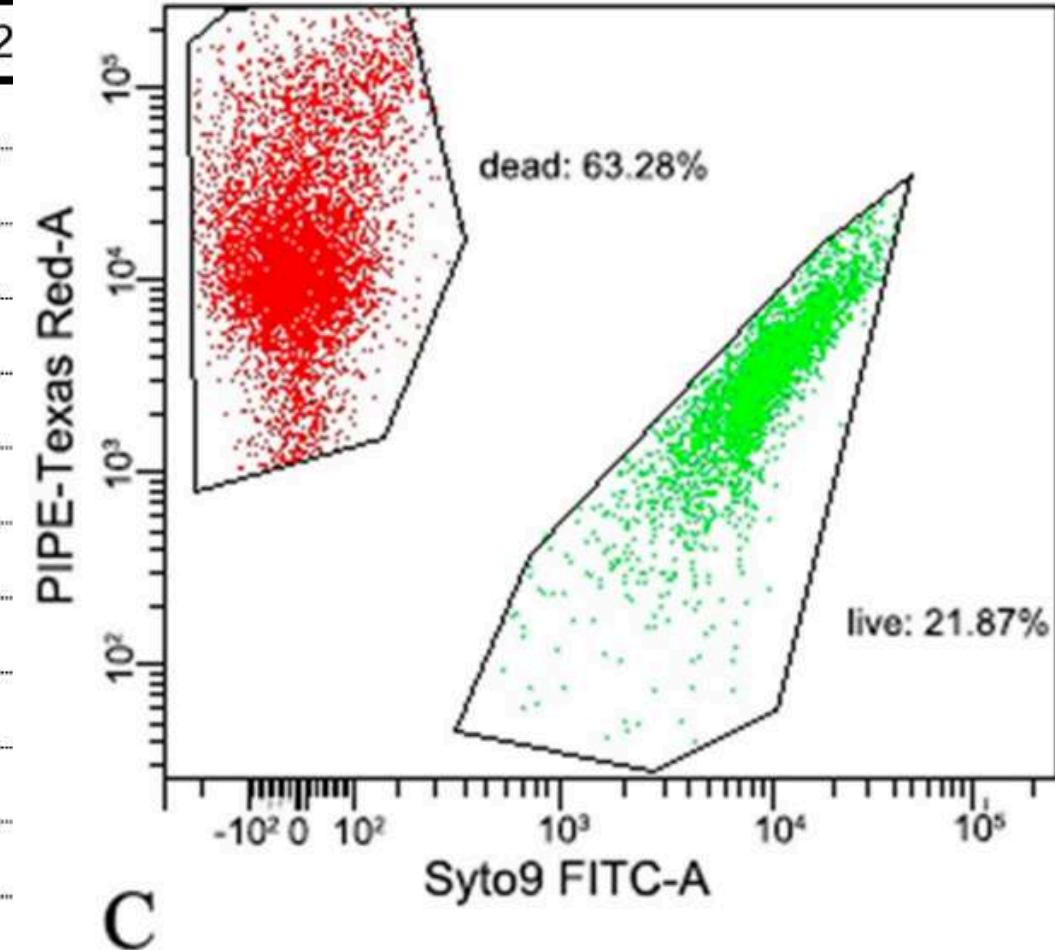
DISCUSSION GROUP, ISAPP MEETING 2024, CORK, IRELAND: industry scientists and academics



SPECIFICATION

PRODUCT NAME	Probiotics powder	PROBIOTICS TYPE	<i>Akkermansia muciniphila</i> AH39
PRODUCT FORM	Freeze dried powder	PACKAGE SIZE	1/5kg
INNER PACKING	Aluminum Foil & PE Bag	OUTER PACKING	Foam Box & Carton

TEST ITEMS	SPECIFICATIONS	TEST METHODS
Cell count (cells (TFU)/g)	$\geq 1.0 \times 10^{11}$ (100B)	ISO 19344 IDF232
Physical & Chemical Properties		
Color	Off-white to beige	GB/T 29602
Aspect	Powder	GB/T 29602
Odor	No abnormal odor	GB/T 29602
Moisture %	≤ 5.0	GB 5009.3
Water activity	≤ 0.2	GB 5009.238
Heavy Metals		
*Lead (Pb) ppm	≤ 0.05	GB 5009.12
*Arsenic (As) ppm	≤ 0.5	GB 5009.11
*Cadmium (Cd) ppm	≤ 0.05	GB 5009.15
*Mercury (Hg) ppm	≤ 0.02	GB 5009.17
Microbiology		
Aerobic mesophilic total count (CFU/g)	≤ 500	ISO 4833-1



Postbiotics: a perspective on their quantification

Gabriel Vinderola^{1*}, Andrzej Benkowski², Marion Bernardeau³, Maria Empar Chenoll

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Algunos productos en el mercado

Yili launches first ambient drinking yogurt with large pieces of fruit using Tetra Pak technology

By Jim Cernak of

21 Jun 2014 | Last updated on 22 Jun 2016 at 08:24 AMPT



Aspergillus oryzae: A Toolbox for Animal Health

Posted September 28th, 2021

Aspergillus oryzae is a multi-cellular, filamentous fungi that has deep roots in Chinese and Japanese culture, where it has been used for centuries to make sake, soy sauce and other fermented foods. Now, A. oryzae is making its mark on animal agriculture, too. It all started back in the 1940s when H.E. Kistner discovered, and subsequently patented, a direct-fed microbial produced from a select strain of A. oryzae, which would come to be known as Amaferm®, now a registered trademark of BioZyme®, Incorporated.



LAC-SHIELD™ & POSTBIOTICS



Immuno-modulation by heat-killed *Lactiseibacillus paracasei* MCC1849 and its application to food products



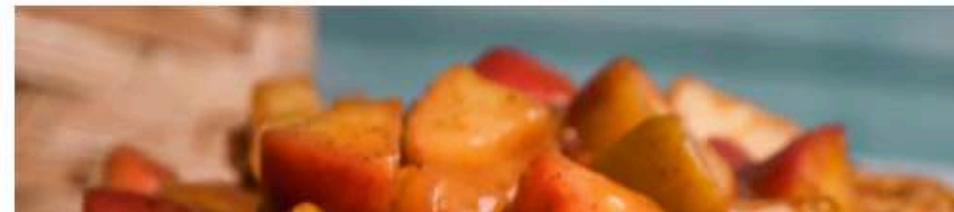
AIR FRYER VEGAN TOFU "FISH"



VEGAN MAPO TOFU RECIPE



TOFU CAULIFLOWER MASH



Aplicaciones no adecuadas para m.o. vivos

Immunity coffee: Australian firm creates postbiotic blend in Nespresso-compatible capsules and instant powder

By Tingmin Koe

16-Nov-2022 - Last updated on 16-Nov-2022 at 03:17 GMT



Postbiotics, being heat-killed, can be incorporated into functional beverages such as hot coffee.



OPEN ACCESS

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Postbiotics in the medical field under the perspective of the ISAPP definition: scientific, regulatory, and marketing considerations

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Postbióticos como productos farmacéuticos

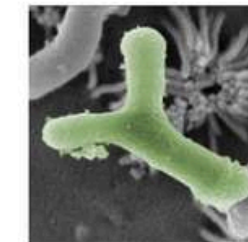


Kijimea® Colon Irritable PRO - una innovación para las molestias intestinales



Principio activo

Kijimea® Colon Irritable PRO contiene un ingrediente activo único en el mundo: la cepa bacteriana inactivada térmicamente *B. bifidum* HI-MIMBb75. Esta cepa de bifidobacterias es el desarrollo del acreditado y probado principio activo de Kijimea® Colon Irritable.



Representación de la cepa de bifidobacterias patentada *B. bifidum* HI-MIMBb75

Microbios y salud pública

Chapter

Nutrition Economics

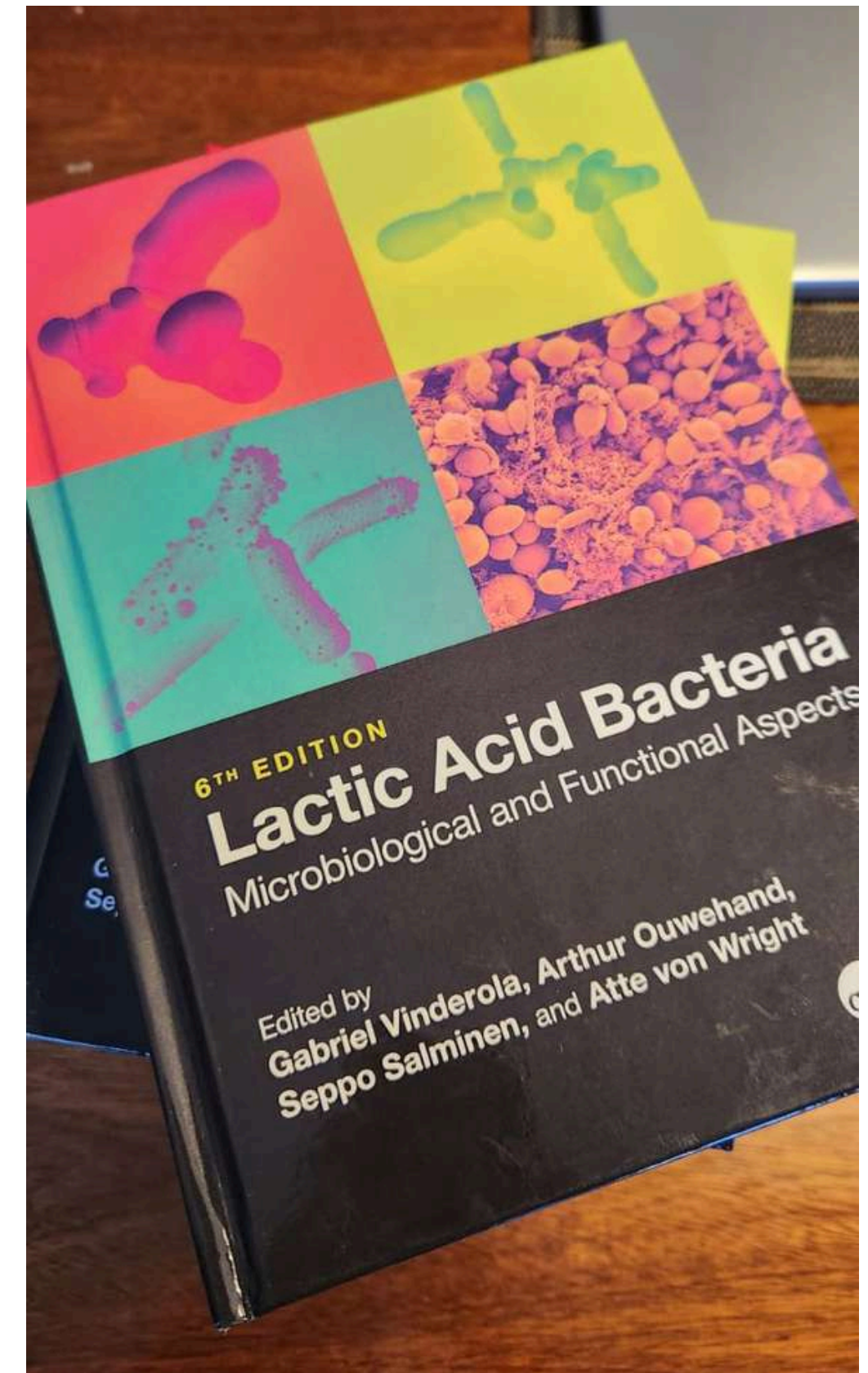
Adding Value to Fermented Foods and Biotics

By Irene Lenoir-Wijnkoop, Aki Koponen, Seppo Salminen

Book [Lactic Acid Bacteria](#)

Edition 6th Edition

First Published 2024



Algunos mensajes

La **microbiota** se está instalando como un objetivo de acción pero también como un centinela que podría vigilar la funcionalidad e inocuidad de los alimentos del futuro: aprobación por la microbiota antes que por un ente regulatorio?

Los **alimentos fermentados** pueden contribuir a diversidad a la microbiota, pueden ejercer efectos antiinflamatorios a nivel intestinal (acción preventiva). Desafío tecnológico: variabilidad y escalado.

Los **probióticos** están cada vez más presentes en la práctica médica. Hay una creciente cantidad de cepas sin RCT que se podrían utilizar bajo el concepto de “**Dosis Diaria de Microorganismos Vivos**”, si el camino a probióticos se dificulta.

El concepto emergente de los **postbióticos** puede contribuir a incluir microorganismos funcionales a alimentos no aptos para probióticos por sus características fisicoquímicas, proceso productivo o condiciones de conservación: oportunidad de innovar.

*IV Congreso Iberoamericano de Ingeniería de los Alimentos
Montevideo, 4-6 setiembre 2024*

Gracias !!!



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I N L A I N