

INTERNATIONAL SCIENTIFIC ASSOCIATION FOR PROBIOTICS AND PREBIOTICS

WWW.ISAPPSCIENCE.ORG



STEWARDSHIP

Individually and collectively, we endorse the proper use of the terms 'Probiotics' and 'Prebiotics'

ADVANCING THE SCIENCE

We encourage research by facilitating interactions among scientists in the field, helping regulators understand the science, and publishing evidence-based summaries that highlight research gaps and promote needed research



EDUCATION



We endeavor to disseminate scientifically accurate information on probiotic, prebiotic and microbiota science to enhance understanding of the science among researchers, students, and regulators

2016 ANNUAL REPORT





January 1-December 31, 2016

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Turku, Finland – Meeting Site for 2016 ISAPP Conference



INTRODUCTION

ISAPP is an international, non-profit collaboration of scientists, which exists to advance scientific excellence in probiotics and prebiotics. ISAPP is the leading scientific organization dedicated specifically to probiotics and prebiotics, bringing together scientists from all pertinent disciplines, including microbiology, immunology, biochemistry, nutrition, molecular biology, food science and medicine.

As a scientific society, ISAPP activities are focused on science, not the promotion of any specific commercial products. Currently under the leadership of ISAPP President, Dr. Karen Scott, the activities of ISAPP are dictated by an academic Board of 10 directors, and facilitated by the ISAPP's Executive Science Officer, Mary Ellen Sanders, PhD. Each year, the Industry Advisory Committee elects a representative to serve in a non-voting, advisory role to the Board of Directors, as a mechanism to ensure industry ideas and concerns are communicated to the Board.

This report features highlights of ISAPP accomplishments from 2016. ISAPP's many accomplishments for 2016 include: our Annual Meeting in Turku Finland, hosted by Board member Prof. Seppo Salminen; peer-reviewed publications on key issues for probiotic and prebiotic science; and outreach activities, such as consumer-friendly infographics and monthly blog postings, championed by ISAPP's Science Translation Committee, chaired by Dr. Christopher Cifelli.

For additional details, see the newly updated ISAPP website www.isappscience.org







2016 MESSAGE FROM THE PRESIDENT – DR. KAREN SCOTT

Once again it has been a busy year, for ISAPP and for the entire probiotic and prebiotic industry. Peer-reviewed research articles illustrating the health benefits of probiotics and prebiotics continue to be published, even though regulatory bodies remain slow in approving specific health claims. ISAPP has stimulated meticulous scientific research, facilitating the publication of review articles and comments, and supporting eminent scientists attending scientific meetings, or sponsoring sessions within the meetings themselves. We continue to make representations on behalf of the science to regulatory bodies around the world, including EFSA, FDA and FTC.

ISAPP, through the hard work of the Science Translation Committee, has worked diligently in 2016 to translate the science of probiotics and prebiotics to the general public. Several infographics were designed to communicate facts about probiotics, prebiotics and fermented foods to consumers. Monthly blogs, started in 2016, are written by individual BOD members and other scientists on topics of particular interest to them related to probiotic/prebiotic fields. The next initiative of this committee is the production of short



informational videos on specific topics, funded by educational grants from sponsor companies.

As ever, I would like to finish by recognising the remarkable contributions made by so many to the success of ISAPP. The wisdom and insight of the current ISAPP Board members guides all ISAPP activities and their hard work is the engine that drives ISAPP's accomplishments. We are also grateful to previous members of the Board who provide ongoing expertise and assistance. Our industry colleagues from the Industry Advisory Committee make important contributions in challenging ways ISAPP can extend its influence and enhancing the scientific discussions during the meeting. I would like to extend a special thank you to Saskia van Hemert and Margariet Schoterman who served as senior and junior (respectively) IAC representatives to the Board. Lastly, none of our activities would be possible without the generous sponsorship of the industry members of ISAPP, for which we are immensely grateful.

Sincerely,
Dr. Karen Scott
ISAPP Board President



HIGHLIGHTS OF 2016 ISAPP ACTIVITIES

The mission of ISAPP is to advance scientific excellence in probiotics and prebiotics. ISAPP is an independent, science-based voice for the probiotic and prebiotic fields. During a long-term planning meeting held after the 2016 annual meeting, the ISAPP Board of Directors reiterated the need to focus on ISAPP's core values:

Stewardship. Individually and collectively, we endorse the proper use of the terms 'Probiotics' and 'Prebiotics'.

Advancing the science. We strive to encourage research by facilitating interactions among scientists in the field, helping regulators understand the science, and publishing evidence-based summaries that highlight research gaps and promote needed research. We encourage funding of independent researchers by industry, foundations and government in order to advance the science of probiotics and prebiotics.

Education. We endeavor to disseminate scientifically accurate information on probiotic, prebiotic and microbiota science to enhance understanding of the science among researchers, students, and regulators. We promote communication of evidence-based recommendations on the use of probiotics and prebiotics by consumers and healthcare providers.

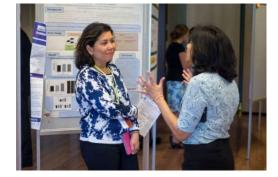
The board considered at great length the many excellent suggestions regarding ISAPP priorities that emerged from the IAC-Board of Directors joint meeting on June 7. Among these were (1) convening an annual meeting in Asia; (2) opening the annual meeting poster session to submissions from industry scientists; (3) increasing visibility of ISAPP; and (4) doing a better job of communicating the science of probiotics and prebiotics to consumers and healthcare providers. All of these suggestions were accepted by the board and are currently in the process of implementation.

Stewardship

- In response to a published paper that used outdated nomenclature, ISAPP Board members responded with a published commentary: Commentary: Probiotic nomenclature matters.
- On December 9, 2016, ISAPP convened a consensus panel of academic experts in London to discuss the current concept of prebiotics. The panel – chaired by Glenn Gibson - discussed

definition, selectivity, specificity, functionality, health effects, and more. The panel has prepared and submitted a paper to summarize conclusions.

- The FDA <u>published an approach</u> to requirements for Investigational New Drugs for human research on foods that ISAPP considered inadequate. ISAPP responded with a comment published <u>here</u>.
- An organization, <u>Labdoor</u>, evaluates dietary supplements, including probiotics. ISAPP has been in



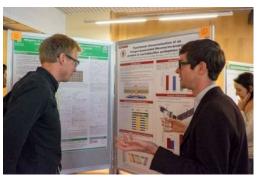


discussions with them urging them to adopt evaluation criteria based on the FAO/WHO 2002 guidelines.

- ISAPP supports the concept of third-party verification of probiotic and prebiotic product quality. Towards this end, ISAPP has met with both Underwriters Laboratories and USP to discuss progress in their probiotic verification programs, has reviewed recent USP monographs for several probiotic strains and participated in a Roundtable discussion on establishing prebiotic standards.
- ISAPP supports use of probiotics and prebiotics in healthcare when research substantiates efficacy and safety for the use. Unfortunately, the probiotics carried by hospital pharmacies often are not products with the best substantiated efficacy. ISAPP conferred with the <u>American Society of Hospital Pharmacists</u> during a phone call, to discuss the process of how probiotics are chosen for formularies and to encourage pharmacists to develop evidence-based approaches to probiotic selection.
- On behalf of ISAPP, Dan Merenstein submitted a proposal to the <u>United States Preventive</u> <u>Services Task Force</u> asking them to consider making a recommendation on probiotics for antibiotic associated diarrhea. Unfortunately, they responded saying that this health issue was outside their scope and they would not investigate.
- During the strategic planning meeting convened after the annual meeting in Turku, the ISAPP Board of Directors decided to develop priorities for the years ahead. Top priorities included targeting Asia for our 2018 meeting and expanded efforts to communicate the science of probiotics and prebiotics to consumers and healthcare providers through improved website, infographics and development of short informational videos.

Advancing the Science

- In March 2016, ISAPP participated in an ILSI-North America Microbiome Committee meeting to discuss paths forward for linking microbiota changes to health in humans.
- ISAPP convened its 14th annual meeting June 7-9, 2016 in Turku, Finland. Meeting report. A
 post-meeting survey showed that 95% felt the meeting met their expectations. Specific
 information on the meeting is found in the subsequent section of this report.



- What is the best dietary source of live microbes? To help answer this question, ISAPP has coordinated a review paper to be authored by Board member Robert Hutkins (University of Nebraska) on 'Live Microbes in Fermented Foods'. The objective is to compile what is known about levels of live microbes in fermented foods. Submission goal is June of 2017.
- ISAPP is sponsoring a systematic review on probiotics and antibiotic use. The protocol, "Does probiotic consumption reduce antibiotic utilization for common

acute infections? A systematic review", was registered with PROSPERO, registration number CRD42016052694. This review is important to determine if probiotics might have a role to play in public health efforts on antibiotic stewardship.

- I S A P P
- The individual patient data meta-analysis on the impact of Lactobacillus reuteri on colic in infants will be submitted for publication shortly. This ISAPP-sponsored collaboration of nine academic experts will provide the best assessment of current evidence on this topic.
- One December 9, ISAPP responded to the FDA draft guidance, "<u>Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry</u>." ISAPP expressed concerns about several aspects of the FDA's stated approach to new dietary ingredients for dietary supplements, including the lack of direct pathway for newly isolated microbes to become supplements. Comments were submitted electronically Comment Tracking Number: 1k0-8thx-lv15.

Education

- ISAPP's Science Translation Committee developed materials targeting communication of the science of probiotics and prebiotics to the lay public. Toward this end, four infographics have been published: Probiotics. Prebiotics. Fermented Foods, Deciphering a Probiotic Label: US Version. Furthermore, blogs authored by Board members and invited guest authors are now a monthly feature on the ISAPP website. This committee also oversaw a huge overhaul of the ISAPP website, now at www.ISAPPScience.org.
- Collaborating with IPA, ISAPP Board members and industry members worked with IPA's executive director to publish (open access) a paper titled, 'Probiotic Use in At-Risk Populations'.
 This paper is a response to the death, which may have resulted from a contaminated probiotic supplement, of a premature infant.
- ISAPP provided a stipend to facilitate the 2016 update of the World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics. This guideline, which has the most downloads of all practice guidelines produced by WGO, is available in six languages. The previous update was in 2011. These updated guidelines will be available in 2017.
- At the 2016 conference, we had significantly elevated engagement with our future scientists through the <u>Students and Fellows</u>

 <u>Association</u>, including a dedicated poster session, a presentation during the workshop summary session and two talks. SFA poster abstracts and conference summary is <u>available</u>.



- Recognizing the value of industrysponsored research, the industry members of ISAPP were invited to submit research topics to be presented in two dedicated speaking slots at our 2016 annual meeting.
- The 2014 ISAPP consensus paper published in Nature Reviews in Gastroenterology and Hepatology paper continues as a highly sought perspective paper on proper use of the term 'Probiotic'. This paper has been downloaded over 27,000 times and achieved Highly Cited Paper on Web of Science Core Collection status. It also had an Altmetric score of 143 which showed it was: Picked up by 5 news outlets; Blogged by 4; Referenced in 2 Wikipedia pages; and Mentioned in 1 Google+ posts.



2016 ISAPP PUBLICATIONS



- Sanders ME, Merenstein DJ, Ouwehand AC, Reid G, Salminen S, Cabana MD, Paraskevakos G, Leyer G. 2016. <u>Probiotic Use in At-Risk</u> <u>Populations</u>. J Amer Pharmacy Assoc. 56:680-686.
- Reid G, Kumar H, Khan AI, Rautava S, Tobin J, Salminen S. <u>The case in favour of probiotics</u> <u>before, during and after pregnancy: insights from</u> <u>the first 1500 days</u>. Benef Microbes. 2016. 7(3):353-62.
- Hill C, Scott K, Klaenhammer TR, Quigley E,
 Sanders ME. 2016. <u>Commentary: Probiotic</u>
 nomenclature matters. Gut Microbes. Feb 3:1-10.

LOOKING AHEAD FOR ISAPP

The 2017 meeting will be held in Chicago, June 27-29.

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■ The 2018 meeting is planned for Singapore. This is ISAPP's first annual meeting to be convened in Asia. We look forward to engaging Asian scientists from academics and industry to better achieve a global outreach.

HELPFUL LINKS

Full list of ISAPP Publications

14 years of annual meeting reports
Industry involvement in ISAPP



BOARD OF DIRECTORS OCTOBER 1, 2015 – SEPTEMBER 30, 2016

Karen Scott, PhD President University of Aberdeen, Scotland

Seppo Salminen, PhD Vice-President University of Turku, Finland

Colin Hill, PhD. DSC Past President University College Cork, Ireland

Robert Hutkins, PhD Secretary University of Nebraska, Lincoln, USA

Daniel Merenstein, MD Treasurer Georgetown University Medical Center Washington DC, USA

Gregor Reid, PhD, MBA Liaison to Student and Fellows Association London, Ontario, Canada Glenn Gibson, PhD Member-At-Large University of Reading, UK

Eamonn Quigley, MD Member-At-Large Methodist Hospital and Weill Cornell School of Medicine Huston, TX, USA

Michael Cabana, MD, PhD Member-At-Large University of California, San Francisco, USA

Sarah Lebeer, PhD Member-At-Large University of Antwerp, Antwerp, Belgium

Mary Ellen Sanders, PhD Executive Science Officer Centennial, CO USA



June 2016. Board of Directors Bob Hutkins, Eamonn Quigley, Dan Merenstein, Colin Hill, Glenn Gibson, Seppo Salminen, Mary Ellen Sanders, Karen Scott and Gregor Reid (inset). Also shown are Industry Advisory Committee Senior (Saskia van Hemert, bottom row, second from left) and Junior (Margriet Schoterman, bottom row, far left) representatives to the board. Sarah Lebeer joined the board in September 2016.



2016 INDUSTRY ADIVSORY COMMITTEE MEMBER COMPANIES

Prenexus Health **Abbott Nutrition** Ganeden

Bayer **General Mills** Probi

Procter & Gamble Benero/Suedzucker Ingredion

Lallemand Health Biocodex Protexin BioGaia Solutions Sensus Bio-K+ International Mead Johnson Tate & Lyle

CDRF Mondelez **UAS Laboratories**

National Dairy Council Clasado NIZO Winclove Bio Industries

Nutricia Research

Danisco Yakult Danone Research Pepsico Zespri DSM/i-Health Pfizer

Friesland Campina **Pharmavite**

Chr. Hansens

Quotes from Industry Advisory Committee Members

"ISAPP membership expands and strengthens our scientific and regulatory network on prebiotics, which can help us in future collaborations."

"ISAPP provides an independent voice for scientific excellence, and publishing scientific (positions) papers on particular topics in the field of prebiotics."

"The annual meeting is very valuable to be informed of the latest developments in science in the field of pro- and prebiotics with excellent speakers."



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APPENDIX. SUMMARY OF 14th MEETING OF ISAPP – TURKU FINLAND

Link to full 2016 meeting report.

Prof. Seppo Salminen, Vice President of ISAPP hosted the 14th annual ISAPP meeting in Turku, Finland. Main meeting participants comprised 114 professionals (44 industry scientists and 70 invited experts and Board members), from 20 countries (Australia, Belgium, Canada, Denmark, Germany, Finland, France, Ireland, Israel, Italy, Japan, Mexico, the Netherlands, New Zealand, Poland, Spain, Sweden, United Kingdom, Ukraine, and the United States).



ISAPP Annual Meeting Participants: red – Board of Directors, blue – Invited Experts, Purple – Industry Advisory Committee

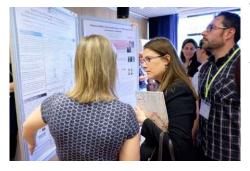
The meeting featured the newest probiotic, prebiotic and microbiome science presented in various session formats, including plenary lectures, an industry-led learning forum, breakout discussion groups with group summaries, a Students and Fellows Association parallel program and rapid fire Late Breaking News talks. For the first time this year, the meeting included featured presentations by industry members targeting their sponsored research.

The meeting began with the ever-popular Learning Forum, addressing topics chosen by ISAPP industry members to cover topics they would like to see addressed either in more depth or with a range of experts. The 2016 Learning Forum focused on the development path for probiotic or prebiotic food products.

The 2016 Keynote Lecture featured ISAPP Board Member Colin Hill discussing "The microbiome – It's more than just the 'bacteriome'."

The Student Fellowship Association presented their posters, facilitating exchange among the students and professional participants. As part of the Poster Session, the Late Breaking News Session featured 11 five minute presentations on topics ranging from off-the-bench news to important issues facing the science, politics, funding, business or humorous aspects of the field.





The second day began with the first plenary session chaired by ISAPP Board Member Bob Hutkins. The discussion featured: Dr. Bruce Hamaker speaking on natural fibers from food and their influence on gut microbiota and human health, Dr. Andy Benson discussing core genome, conservation of SCFA pathways among lactobacilli and bifidobacterial and implications for strain-specificity of probiotic effects, and Dr. Francisco Guarner speaking on low FODMAP diet versus prebiotic supplement for alleviating IBS symptoms.

For 2016 ISAPP expanded the number of breakout discussion groups from six to seven, including the following topics:

- Colic Update: IPDMA and Mechanisms
- Evidence-Based Expectations for Probiotics
- Next Generation Probiotics
- Regulatory Developments for Probiotics and Prebiotics in European Union: Do They Change the Road to the Market?
- Prebiotics, Probiotics and Common GI Symptoms in the General Population (Not Diseases)
- How Do Probiotics and Prebiotics Work at Distant Sites?
- The Culture of Fermented Foods, Including Prebiotic and Probiotic Aspects



The second plenary session chaired by ISAPP Board Member Glenn Gibson featured Dr. Samuli Rautava, Dr. Mike Surette, and Dr. Ali Keshavarzian discussing probiotics in the gut, lungs, and intestines.

The gala dinner was held at the Turku Castle with distinguished hosts, Duke John and his spouse, Princess Catherine of Poland. Built in the late 13th century, the castle is a favorite attraction for modern visitors to Turku. At the gala, Prof. Seppo Salminen accepted thanks for his

tremendous efforts as local host for the meeting. After the meeting, the ISAPP Board of Directors met to consider long range plans for ISAPP. Ideas from board members, industry representatives and external experts were collated, providing focus to ISAPP's future activities. Many ideas generated from the IAC-Board of Directors meeting convened June 7 were adopted as priorities for ISAPP in the coming year. Foremost among these were convening an ISAPP annual meeting in Asia, expanding scientific outreach to consumers and healthcare providers and improving visibility of ISAPP.



The details of the 3-day program are found in the <u>full meeting report</u>. The Student and Fellow Association conducted a concomitant meeting. This meeting would not be possible without the generous support of the many IAC companies and the hard work of the ISAPP's prestigious Board of Directors.