



Annual Report International Scientific Association for Probiotics and Prebiotics

January 1-December 31, 2015

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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 strives to have all activities 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 Chief Science Officer, Mary Ellen Sanders, PhD. A non-voting position of IAC representative on the board is filled by Dr. Saskia van Hemert.

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

MESSAGE FROM THE PRESIDENT, DR. KAREN SCOTT

It has been another busy year, both for ISAPP and the probiotic and prebiotic industry generally. Despite the continued publication of peer-reviewed research articles illustrating the health benefits of probiotics and prebiotics to different consumers, regulatory bodies in Europe resist change to their negative views about probiotic claims for foods. Encouragingly, the prebiotic inulin was allowed a bowel health claim. In the United States, through much engagement with ISAPP, the FDA has eased its opinion that all human research on probiotics

should be considered drug research. This opens a path long closed in the United States so that research on probiotic foods and supplements in human subjects can proceed. Meanwhile probiotics and prebiotics are being developed as targeted drug therapies, expanding the range of the types of products that will be available in the near future. ISAPP continues to back the sound science in this area, facilitating publication of reviews and comments, and supporting eminent scientists attending scientific meetings, or sponsoring sessions within the meetings themselves. We have also continued to make representations on behalf of the science to various regulatory bodies including EFSA, FDA and FTC.

Since 2002, ISAPP has worked to promote the science of probiotics and prebiotics to other scientists and regulators. This year, ISAPP expanded that objective to inform the general public. An excellent new initiative is the development of three consumer infographics, specifically designed to let consumers know facts about [probiotics](#), [prebiotics](#) and [fermented foods](#). We are grateful to Dr. Chris Cifelli, who previously represented the Industry Advisory Committee on the ISAPP board, for driving this effort as chair of the newly created Science Translation Committee. These infographics are highly visible on the new ISAPP website, www.isappscience.org, (another initiative of this committee) which has updated the whole look of ISAPP on the Internet interface. This new website URL reflects the non-profit nature of ISAPP than the former URL.



Finally I would like to recognise the continual contribution made by so many to the success of ISAPP. The ISAPP board members are regularly asked for comments and feedback on current topical issues, and we are also grateful to previous members of the board who are frequently requested to provide additional expertise and assistance. Our industry colleagues from the IAC make important contributions to workshop discussions, suggesting topics and identifying new issues where a response from ISAPP would be helpful, in addition to importantly persuading their parent companies to continue supporting ISAPP. We are grateful to all our supporters.

HIGHLIGHTS OF 2015 ISAPP ACTIVITIES

ISAPP convened its 13th **Annual Meeting** May 19-21, 2015 at the Georgetown University Hotel and Conference Center, Washington DC, USA. Dr. Dan Merenstein served as local host for this meeting. Outcomes from this meeting include publications by Hutkins et al ([2015](#)), Sanders et al. ([2016](#)), Quigley ([2016](#)) and Reid et al ([2016](#)), listed in the next section. [A full meeting report is available.](#)



For several years, ISAPP has fought to improve the situation regarding **FDA's position of requiring Investigational New Drug Applications for human research on probiotics**, and more recently on most food and dietary supplement research. Requiring INDs has discouraged human research on probiotics in the US. Our ongoing efforts included a private meeting with Center for Biologics Evaluation and Research (CBER) ([summary](#)), a meeting with Center for Food Safety and Applied Nutrition ([summary](#)), filing comments on several FDA guidances or proposals on the topic ([here](#) and [here](#)), and most recently by focusing on this issue in a discussion group at our 2015 ISAPP meeting in Washington DC ([report](#) and [publication](#)). We are happy to report that on October 30, 2015, the FDA has stayed sections of this guidance. We believe ISAPP's actions played an important role in the FDA decision.

ISAPP provided public comment on September 8, 2014 to the European Food Safety Authority regarding EFSA's intent to revise the guidance on scientific requirements for health claims on foods related to gut and immune function. [ISAPP comments](#).

ISAPP reacted to a publication in the European Journal of Gastroenterology and Hepatology by [Han et al. 2016](#). This paper uses nomenclature for 'probiotic' strains that is decades old. In a commentary published in Gut Microbes ([Hill et al., 2016](#)), members of the ISAPP board of directors calls on researchers and journal editors to **recognize the importance of proper strain identification and conformation to systematic nomenclature** for the microbes used as probiotics.

ISAPP sponsored four speakers to the **Asian Society for Lactic Acid Bacteria** meeting in Bangkok, Thailand, July 2015. Talks on the updated definition of probiotics and clinical use of probiotics were delivered.

ISAPP sponsored **a symposium titled *Microbes and Women*** May 8, 2015, the Netherlands. Jessica A. Younes, Ph.D. Department of Biomedical Engineering and the Kolff Institute organized the symposium with ISAPP input.

ISAPP provided input on microbiome research priorities to the White House Office of Science and Technology Policy (June 2015). [ISAPP Comments](#).

Drs. Michael Cabana and Daniel Tancredi led a team of medical and statistics experts in preparing an individual patient data meta-analysis for use of *L. reuteri* to alleviate symptoms of colic. They published the [protocol](#) and submitted an abstract to present results at the 2016 Pediatric Academic Societies meeting on this topic. This team will convene at the 2016 ISAPP meeting in Turku to finalize this analysis.

ISAPP provided travel support for Prof. Bruno Pot to speak September 4-5, 2014 at the NIH National Institute of Allergy and Infectious Diseases meeting, *Gastrointestinal Microbiota in Allergy and Advances in Probiotics Workshop*. Dr. Pot provided important insights on probiotic



strain selection strategies for allergy endpoints. ISAPP board members, Mary Ellen Sanders and Michael Cabana, also delivered lectures at this meeting.

ISAPP filed comments with the FDA regarding impact of [Proposed Rule](#) on labeling prebiotics on foods. An important outcome of this FDA rule would be changing the definition of fiber, which would impact the ability of food manufacturers to list prebiotics as fiber on food labels. [ISAPP Comment](#).

The 2016 ISAPP Annual Meeting will be held June 7-9, 2016 in Turku Finland. The [program](#) covers an array of hot topics in the field of probiotics, prebiotics and the microbiome.

2015 ISAPP PUBLICATIONS

This list includes summaries of some group discussions at annual meetings as well as other ISAPP-related activities. [Full list of ISAPP publications](#).

- Reid G, Kumar H, Khan AI, Rautava S, Tobin J, Salminen S. [The case in favour of probiotics before, during and after pregnancy: insights from the first 1500 days](#). Beneficial Microbes, Submitted.
- Hill C, Scott K, Klaenhammer TR, Quigley E, Sanders ME. [Commentary: Probiotic nomenclature matters](#). Gut Microbes. Feb 3:1-10.
- Quigley EMM. 2016. [Leaky gut – concept or clinical entity?](#) Curr Opin Gastroenterol 32:74-79.
- Sanders ME, Shane AL, Merenstein DJ. [Advancing human probiotic research in the United States: challenges and strategies](#). 2016. Gut Microbes. Mar 10:1-4.
- Hutkins RW, Krumbeck JA, Bindels LB, Cani PD, Fahey G, Goh YH, Hamaker B, Martens EC, Mills DA, Rastal RA, Vaughan E, Sanders ME. [Prebiotics: why definitions matter](#). Curr Opinion Biotechnol. 37:1-7.
- Sung V, Cabana MD, D’Amico F, Deshpande G, Dupont C, Indrio F, Mentula S, Partty A, Savino F, Szajewska H, Tancredi D. 2014. [Lactobacillus reuteri DSM 17938 for managing infant colic: protocol for an individual participant data meta-analysis](#). BMJ Open:e006475. doi:10.1136/bmjopen-2014-006475.
- Kumar H, Salminen S, Verhagen H, Rowland I, Heimbach J, Banares S, Young T, Nomoto K, Lalonde M. 2015. [Novel probiotics and prebiotics: road to the market](#). Current Opinion in Biotechnology 32:99–103.



BOARD OF DIRECTORS OCTOBER 1, 2014 – SEPTEMBER 30, 2015

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Sensus
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UAS Laboratories
Valio
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Yakult
Zespri



APPENDIX. SUMMARY OF 13th MEETING OF ISAPP – WASHINGTON DC

[Link to full 2015 meeting report.](#)

The 2015 ISAPP meeting was held on the Georgetown University campus in Washington DC. The venue was the Georgetown University Hotel and Conference Center. The popular Late Breaking News session featured 11 short, volunteered presentations on an array of topics including the correct pronunciation of “ISAPP” and use of probiotics from the perspective of economic benefit to society. The SFA poster session followed, which facilitated exchanges among the students and professional participants. The professional participants comprised 111 total delegates representing 19 countries (Australia, Bangladesh, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Singapore, Sweden, Switzerland, United Kingdom and United States). Sixty-one of the meeting participants were invited experts (including the eleven ISAPP Board members), 47 were industry members and 3 young scientists served as rapporteurs. Taking advantage of the program being in Washington DC, which facilitated regulatory and legal participation in the event, the first plenary session focused on regulatory restrictions in the United States on conducting human research on probiotics. The session featured presentations by an attorney, an FDA director and three clinicians. The second plenary session targeted two evolving areas of clinical intervention for probiotics and prebiotics: brain function and liver function. The final plenary was microbiome-oriented, exploring microbiome and evidence for causal role in health and disease. As usual for the ISAPP meetings, six discussion groups were held, on a range of topics. Some hot topics such as the need to update the prebiotic definition were hotly debated. Follow-up from the meeting is expected to result in several publications from the 6 discussion groups. A spectacular conference dinner was held at the National Academy of Sciences in their historic DC building, where Colin Hill was thanked for his past 3 years of service as ISAPP president, and Karen Scott was welcomed as the incoming president. Other events at the meeting included the Learning Forum – an educational session designed for ISAPP’s Industry Advisory Committee members to go into depth on topics of emerging importance, and the wrap up session, in which chairs from each discussion group are allowed 20 min to recap highlights of their respective groups. The details of the 3-day program are found in the full meeting report. 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.