



Annual Report

International Scientific Association for Probiotics and Prebiotics

January 1 – December 31, 2013

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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 only scientific organization dedicated specifically to probiotics and prebiotics, bringing together scientists from all pertinent disciplines, including food science, microbiology, immunology, biochemistry, nutrition, molecular biology and medicine. As a scientific society, ISAPP strives to have all activities focused on science, not the promotion of any specific commercial products. The activities of ISAPP are determined by an academic board of directors, and facilitated by the organizations Chief Science Executive.

For additional details, see website www.isapp.net

MESSAGE FROM THE PRESIDENT, DR. COLIN HILL

2013 proved to be a very active year for ISAPP, shaped by the ongoing paradox of excellent science battling against a somewhat negative public and regulatory perception of probiotics and prebiotics. As an organization which exists to advance scientific excellence it would be easy to simply focus on the positives, and pat ourselves on the back for being involved in an area of scientific research which is regularly published in prestigious journals, and continues to unearth new and fascinating insights into the important interactions between diet, microbes and host. However, we cannot ignore the wider picture, in which our partner industries struggle to convince regulators of the quality of probiotic and prebiotic science, and perhaps also to convince shareholders of the value of investing in further research. To that end we have tried to ‘fight the good fight’ and bring the science and the scientists into direct contact with the regulatory authorities and participate in the conversation surrounding this important field. We recognize of course that there are no ‘bad guys’ in this debate, and that we all strive for the



same goal; good science-based products delivered by responsible companies to an informed consumer. Details of some of our activities and publications in 2013 are provided below, but I particularly welcome the meeting with the FTC to gain clarity on substantiation of probiotic claims in the USA, the issuing of a response to FDA Guidance on Investigational New Drug requirements, and the convening of an Expert Panel to discuss the definition of “probiotic” (the outcome of which will be published later this year as an open access paper in Nature Reviews Gastroenterology and Hepatology).

Once again this year I have struck by the professionalism, zeal and willingness to ‘pitch in’ displayed by the Board members and by other scientists who have willingly and voluntarily given of their time, energy and intellect. This is truly appreciated.

I also want to thank Dr Mary Ellen Sanders, our Executive Science Officer, for her boundless energy and inexhaustible good humour in the face of the trials and tribulations of dealing with the Board, the IAC and the Regulatory Community (a task which must be like minding mice at a crossroads).

HIGHLIGHTS OF 2013 ISAPP ACTIVITIES

ISAPP convened its 2013 meeting in collaboration with the New York Academy of Sciences and the Sackler Institute for Nutrition Sciences June 12-14 in New York City. The first day of the meeting was a sold-out, open registration conference, titled [Probiotics, Prebiotics and the Host Microbiome: the Science of Translation](#), followed by a 2-day ISAPP-only event. See the [full meeting report](#) for details.

ISAPP simplified its mission statement. It now reads: To advance scientific excellence in probiotics and prebiotics.

ISAPP completely revamped its website, www.isapp.net. It now provides easier access to important information on the site, such as ISAPP highlights, annual meeting information, a link to the SFA and latest news posts.

ISAPP met with the FTC to gain clarity on substantiation of probiotic claims in the USA. On February 11, 2013, ISAPP, represented by Mary Ellen Sanders (executive director), Daniel Merenstein, Greg Leyer (Sr. ISAPP-IAC representative) and Chris Cifelli (Jr. ISAPP-IAC representative), met with Mr. Richard Cleland, Assistant Director, Division of Advertising Practices with the Federal Trade Commission to gain a better understanding of FTCs perspective on conducting research intended to substantiate structure/function or health claims for foods in the United States. Mr. Cleland’s forthright approach in his responses was much appreciated. This [report](#) itemizes the questions posed by ISAPP and the responses provided by Mr. Cleland.



ISAPP Responded to FDA Guidance on Investigational New Drug requirements. ISAPP was a signatory, along with other professional societies, on a letter requesting that the FDA retract its final [guidance \(issued September 2013\)](#) on when food and dietary supplement research must be conducted under and Investigational New Drug Application. A face-to-face meeting with the FDA was also requested. [Letter](#).

ISAPP filed comments with the 2015 US Dietary Guidelines Committee to consider probiotics or prebiotics as part of dietary guidelines. [Probiotic comment](#) (#61). [Prebiotic comment](#) (#58).

ISAPP convened a panel of experts to discuss the definition of “probiotic” – 12 years after it was first proposed by the FAO/WHO working group. An expert panel addressing proper use of the term “probiotic” was convened by ISAPP October 24, 2013 in London UK. The panel, chaired by Prof. Glenn Gibson, comprised 10 academic experts and ISAPP’s executive director. A manuscript summarizing conclusions from the discussion is In Press with Nature Reviews in Gastroenterology and Hepatology. Although the panel agreed to continue endorsement of the [FAO/WHO 2001 definition of probiotics](#), the manuscript discusses how research and developments over the past 12 years since the definition was proposed impact current implementation of the word ‘probiotic’ by all stakeholders. [The Panel](#). (October 25, 2013)

ISAPP is working with the World Gastroenterology Organisation to develop educational materials for 2014 [2014 World Digestive Health Day](#). The theme of the 2014 WDHD is “Gut Microbes - Importance in Health & Nutrition.” ISAPP updated its consumer guidelines for probiotics and prebiotics ([Choosing a Probiotic Product](#); [Choosing a Prebiotic Product](#)). Furthermore, short video clips on prebiotics, probiotics and the host microbiome are in preparation by Glenn Gibson, Gregor Reid and Mary Ellen Sanders.

ISAPP publication highlights. ISAPP worked closely with the editor for the Annals of the New York Academy of Sciences to publish 2 papers from the 2013 ISAPP meeting and one paper from the 2012 ISAPP meeting. (See below under 2013 ISAPP Publications.)



2013 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.](#)

Sanders ME, Lenoir-Wijnkoop I, Salminen S, Merenstein D, Pot B, Petschow BW, Nieuwdorp M, Tancredi D, Cifelli D, Jacques P, Gibson G. 2014. [Probiotics and Prebiotics: Prospects for Public Health and Nutritional Recommendations.](#) Annals NY Acad Sci 1309:19-29.

Sanders ME, Klaenhammer TR, Ouwehand AC, Pot B, Johansen E, Heimbach JT, Marco ML, Tennilä J, Ross RP, Franz C, Pagé N, Pridmore RD, Leyer G, Salminen S, Charbonneau D, Call E, Lenoir-Wijnkoop I. 2014. [Effects of genetic, processing, or product formulation changes on efficacy and safety of probiotics.](#) Annals of the New York Academy of Sciences 1309:1-18.

Sheridan PO, Bindels L, Saulnier DM, Reid G, Nova E, Holmgren K, O'Toole PW, Bunn J, Delzenne N, Scott KP. 2013. [Can prebiotics and probiotics improve therapeutic outcomes for undernourished individuals?](#) Gut Microbes 5(1).

Petschow B, Doré J, Hibberd P, Dinan T, Reid G, Blaser M, Cani P, Degnan F, Foster J, Gibson G, Hutton J, Klaenhammer TR, Ley R, Nieuwdorp M, Pot B, Relman D, Serazin A and Sanders ME. 2013. [Probiotics, prebiotics, and the host microbiome: the science of translation.](#) Annals of the New York Academy of Sciences 1306:1-17.

Shane AL, Deshpande GC, Merenstein D. [Improved neonatal outcomes with probiotics.](#) JAMA Pediatr. 2013; 167:885-6.

Saulnier DM, Ringel Y, Heyman MB, Foster JA, Bercik P, Shulman RJ, Versalovic J, Verdu E, Dinan TG, Hecht G, Guarner F. 2013. [The Intestinal Microbiome, Probiotics, and Prebiotics in Neurogastroenterology.](#) Gut Microbes 4:17-27.

Blatchford P, Ansell J, Godoy, MRC, Fahey G, Garcia-Mazcorro JF, Gibson GR, Goh YJ, Hotchkiss AT, Hutkins R, LaCroix C, Rastall RA, Reimer R, Schoterman M, Van Sinderen D, Venema K, Whelan K. Probiotic mechanisms, functions and applications. Inter J Probiotics Prebiotics 8: 109-132.



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2013 INDUSTRY ADIVOSRY COMMITTEE MEMBER COMPANIES

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Fonterra	UAS Laboratories
Friesland Campina	Valio
Ganeden	Winclove
General Mills	Yakult
Glycom	



APPENDIX. 11TH ANNUAL MEETING OF ISAPP

See [full 2013 meeting report](#).