International Scientific Association for Probiotics and Prebiotics www.isapp.net



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Summary of ISAPP Activities 2015

The mission of ISAPP is to advance scientific excellence in probiotics and prebiotics. ISAPP is an important and impartial player in providing a voice for scientific excellence in the field, without acting as a promoter of any individual product. Our annual meeting provides an opportunity for scientists from industry and academia to engage in one-on-one networking and in group discussions on topics selected in combination with our industry partners. These meetings have fostered many productive industry-academia relationships, led to research collaborations and have provided a nucleus of expertise to address important issues in the probiotic and prebiotic fields. We also arrange meetings with regulators, write position papers and convene consensus panels as needed. We are viewed as a strong and independent voice that is true to the science within probiotic and prebiotic fields and we work toward a bright future for probiotic and prebiotic research and translation into products that will promote the health of people globally.

2014-2015 ISAPP Accomplishments and Activities

- Convened the 2015 ISAPP Annual Meeting May 19-21, 2015 at the Georgetown University Hotel and Conference Center, Washington DC, USA. <u>Meeting report</u>. Outcomes from this meeting include publications by Hutkins et al (2015), Sanders et al. (2016), Quigley (2016) and Reid et al (2016).
- 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 CBER (report), a meeting with Center for Food Safety and Applied Nutrition (report), 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). 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.
- European regulatory situation was also addressed by ISAPP, with comments filed September 8, 2014
 regarding EFSA's intent to revise the guidance on scientific requirements for health claims on foods related
 to gut and immune function. ISAPP comments.
- Submitted commentary for publication to address continued disregard by some journal editors and reviewers of the need for proper nomenclature for probiotic strains. (Hill et al. 2016.)
- 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.
- Sponsored *Microbes and Women* symposium May 8, 2015, the Netherlands, Jessica A. Younes, Ph.D. Department of Biomedical Engineering and the Kolff Institute.
- Provided input on microbiome research priorities to the White House Office of Science and Technology Policy (June 2015). <u>ISAPP comments</u>.
- <u>Published protocol</u> and submitted an abstract to present results at the 2016 Pediatric Academic Societies meeting for individual patient data meta-analysis for use of *L. reuteri* to alleviate symptoms of colic. This is an ongoing project, to be completed in 2016.

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- 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.
- Filed comments with the FDA regarding impact of <u>Proposed Rule</u> on labeling prebiotics on foods. <u>ISAPP</u>
 Comment.
- Published <u>consensus statement on the scope and appropriate use of the term probiotic</u> in Nature Reviews in Gastroenterology and Hepatology.
- 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. Report.

Looking Ahead for ISAPP:

• The 2016 ISAPP Annual Meeting will be held June 7-9, 2016 in Turku Finland. See our <u>meeting information</u> page for details on 2016 Program, registration and booking accommodations at the conference hotel.

Recent papers from ISAPP events (ISAPP publications)

- Reid G, Kumar H, Khan AI, Rautava S, Tobin J, Salminen S. <u>The case in favour of probiotics before, during and after pregnancy: insights from the first 1500 days</u>. Beneficial Microbes, Submitted.
- Hill C, Scott K, Klaenhammer TR, Quigley E, Sanders ME. <u>Commentary: Probiotic nomenclature matters</u>. Gut Microbes. Feb 3:1-10.
- Quigley EMM. 2016. <u>Leaky gut concept or clinical entity?</u> Curr Opin Gastroenterol 32:74-79.
- Sanders ME, Shane AL, Merenstein DJ. <u>Advancing human probiotic research in the United States: challenges and strategies</u>. 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. <u>Prebiotics: why definitions matter</u>. 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. <u>Lactobacillus reuteri DSM 17938 for managing infant colic: protocol for an individual participant data meta-analysis</u>. 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. <u>Novel probiotics and prebiotics: road to the market</u>. Current Opinion in Biotechnology 32:99–103.
- Reid G, Brigidi P, Burton JP, Contractor N, Duncan S, Fargier E, Hill C, Lebeer S, Martín R, McBain AJ, Mor G, O'Neill C, Rodríguez JM, Swann J, van Hemert S, Ansell J. <u>Microbes Central to Human Reproduction</u>. Am J Reprod Immunol. 2014 Sep 24. doi: 10.1111/aji.12319. <u>Open Access</u>.
- Hill C, Guarner F, Reid G, Gibson GR, Merenstein DJ, Pot B, Morelli L, Canani RB, Flint HJ, Salminen S, Calder PC, Sanders ME. 2014. The International Scientific Association for Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nature Rev Gastroenterol Hepatol. 11, 506–514. Open Access.
- Sanders ME, Lenoir-Wijnkoop I, Salminen S, Merenstein D, Pot B, Petschow BW, Nieuwdorp M, Tancredi D, Cifelli D,
 Jacques P, Gibson G. 2014. <u>Probiotics and Prebiotics: Prospects for Public Health and Nutritional Recommendations.</u>
 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.