



# **Annual Report**

## **International Scientific Association for Probiotics and Prebiotics**

January 1 – December 31, 2011

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### **Introduction**

ISAPP is an international non-profit collaboration of scientists dedicated to advancing the science of probiotics and prebiotics. The mission statement of ISAPP is: To engender and disseminate information on high quality, multidisciplinary, scientific investigation in the fields of probiotics and prebiotics, and to advance the development of scientifically substantiated, health-promoting probiotic and prebiotic products worldwide. 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.

For additional details, see website [www.isapp.net](http://www.isapp.net)

### **Highlights of 2011 ISAPP Activities**

- ISAPP will be celebrating its 10<sup>th</sup> anniversary in 2012. The Board will review ISAPP objectives, activities and priorities for our next 10 years. This discussion will be initiated with a meeting January 15-16, 2011 of the BOD met in Toronto. Included will be an effort to update the ISAPP website and mission statement.
- The board considered creating a council composed of scientists with a history with ISAPP, to advise the board and take on special projects.
- The board continued to respond in a considered and science-based manner to the challenges of different regulatory frameworks involving health benefit claim substantiation.
- The board continued to build on a case-by-case basis working relationships with collaborative organizations, such as AGA, ILSI Europe, ILSI North America, World



Gastroenterology Organisation and other potential partner organizations interested in advancing the science and communication for probiotics and prebiotics.

- The board worked with Food Chemical Codex (part of the United States Pharmacopeia) and a team of specialists in lactic acid bacteria to develop a monograph for live microbial cultures. The hope is that this will be a first step toward establishing standards for the use of live microbes in foods.
- The Board of Directors prepared a letter to the editor of British Journal of Nutrition expressing concerns about the situation with EFSA review of probiotic and prebiotic claims in Europe. This letter was published in 2011, [Probiotic and prebiotic claims in Europe: seeking a clear roadmap.](#)
- On behalf of ISAPP, Mary Ellen Sanders attended a meeting of the European Food Safety Authority (EFSA) NDA committee with stakeholders to discuss guidance on the scientific requirements for health claims related to gut and immune function, held in Amsterdam, Dec 2, 2010. A meeting report was filed.
- Probiotics and Prebiotics Webinar Lecture Series. ISAPP partnered with the American Gastroenterological Association and the International Life Sciences Institute-North America to offer four lectures:
  - Human Gut Microbiota and Health - Robert Rastall, Ph.D./Glenn Gibson, PhD.
  - Interventions to Influence Health and Disease with Probiotics - Karen Madsen, PhD.
  - Clinical Endpoints Using Probiotics and Prebiotics for IBD, IBS, and Infectious Diarrhea - Fergus Shanahan, MD.
  - Practical Guidelines on Probiotics and Prebiotics Use - Michael Cabana, MD, MPH.These [lectures are archived and available free of charge.](#) In addition, a written summary of these presentations is submitted for publication: Wallace TC, Guarner F, Madsen K, Cabana M, Gibson G, Hentges E, Sanders ME. [Human gut microbiota and its relationship to health and disease.](#) 2011. Nutrition Reviews. 69:392-403.
- ISAPP submitted comments to the FDA regarding their draft guidance document “Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND.” US regulatory consultant and long time ISAPP associate, James Heimbach, took the lead in preparing a response, which was embellished after circulating among the board and outside US and European legal counsel. ISAPP’s primary concern with the guidance document is that it proposes to address all human research, but the document does not adequately or appropriately address the lawful conduct of human research on foods in the US *without the need for an IND*. If this guidance is issued, it may have a chilling effect on the willingness of institutional review boards in the US to approve conduct human research without an IND out of fear of FDA reprisal. [ISAPP’s comments](#); [FDA guidance document](#).
- ISAPP Board members Mary Ellen Sanders and Gregor Reid are participating in a University of MD NIH-funded project on Federal Regulation of Probiotics. [Further information](#).



## Board of Directors October 1, 2010 – September 30, 2011

### *President*

Glenn Gibson, PhD  
School of Food Biosciences  
The University of Reading  
UK

### *Vice President*

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North Carolina State University  
USA

### *Past President*

Gregor Reid, BS. Hons PhD MBA  
Lawson Health Research Institute  
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Division of General Pediatrics  
University of California, San Francisco (UCSF)  
USA

### *Treasurer*

Karen Scott PhD  
Rowett Research Institute  
Scotland

### *Program Chair*

Francisco Guarner, MD PhD  
Digestive System Research Unit

University Hospital Vall d'Hebron  
Spain

### *Members at Large*

Nathalie M. Delzenne, PhD  
Université Catholique de Louvain  
Belgium

Colin Hill BSc MSc PhD DSc MRIA  
Alimentary Pharmabiotic Centre  
University College Cork  
Ireland

George Fahey  
Department of Animal Science  
University of Illinois  
USA

### *Executive Director*

Mary Ellen Sanders, PhD  
Dairy and Food Culture Technologies  
USA

### *Industry Advisory Committee Senior Representative*

Arthur Ouwehand, Danisco  
Finland

### *Industry Advisory Committee, Junior Representative*

Ravi Menon, General Mills  
USA



## 2011 Industry Advisory Committee Member Companies

Abbott Laboratories	General Mills
Agropur	Gnosis BioResearch
Beneo-Orafti	Institut Rosell
Biocodex	Kellogg USA
BioGaia	Kraft
Boehringer-Ingelheim	Mead Johnson Nutrition
Cargill	Merck
California Dairy Research Foundation	Nestle
Chr. Hansen	NIZO
Clasado Ltd.	Nutricia Research
The Coca-Cola Company	Pfizer
Dairy Management Inc.	Probi
Danisco	Procter & Gamble
Danone	Protexin
Dow Chemical	Valio
DSM Food Specialties	Winclove
FrieslandCampina Domo	Yakult
Fonterra	



## **2011 ISAPP Publications**

This list includes summaries of some group discussions at annual meetings as well as other ISAPP-related activities. (For full list of publications see <http://isapp.net/activities.asp#publications>)

Champagne CP, Ross RP, Saarela M, Hansen KF, Charalampopoulos D. [Recommendations for the viability assessment of probiotics as concentrated cultures and in food matrices](#). Appl Environ Microbiol. Int J Food Microbiol. 2011 Oct 3;149(3):185-93.

Guarner F, Sanders ME, Gibson G, Klaenhammer T, Cabana M, Scott K, Reid G, Delzenne N, Fahey G, Hill C. 2011. [Probiotic and prebiotic claims in Europe: seeking a clear roadmap](#). Br J Nutr. 2011 Dec;106(11):1765-7.

Wallace TC, Guarner F, Madsen K, Cabana M, Gibson G, Hentges E, Sanders ME. 2011. [Human Gut Microbiota and Their Relationship to Health and Disease](#). Nutrition Reviews 69:392-403.

Sanders ME, Salminen S, Heimbach JT, Pot B, Tancredi D, Lenoir-Wijnkoop I, Bañares S, Lähteenmäki-Uutela A, Gueimonde M. 2011. [Health claims substantiation for probiotic and prebiotic products](#). Gut Microbes 2:1-7.

Monachese M, Cunningham-Rundles S, Diaz MA, Ermond E, Guerrant R, Hummelen R, Kemperman R, Kerac M, Kort R, Merenstein D, Panigrahi P, Ramakrishna B, Safdar N, Shane A, Trois L, Reid G. 2011. [Probiotics and prebiotics to combat enteric diarrheal diseases and HIV in the developing world: a consensus report](#). Gut Microbes 2:198-207.

## **Appendix A. 9th Annual Meeting of ISAPP**

The 9<sup>th</sup> annual meeting of ISAPP was held October 23-25, 2011 in Berkeley, California, USA. The meeting is summarized at the following link locations:

[Meeting Report](#)

[Summaries of Discussion Groups](#)

[Participants List](#)