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

Highlights of 2011 ISAPP Activities

• ISAPP will be celebrating its 10th 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

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Finland

Industry Advisory Committee, Junior Representative
Ravi Menon, General Mills
USA
**2011 Industry Advisory Committee Member Companies**

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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)


Appendix A. 9th Annual Meeting of ISAPP
The 9th 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