

EFSA Publishes Health
Claims Guidance
for Probiotics

Stickiness:
A Route to Effective
Probiotic Selection?

Probiotics Help
Reduce Respiratory
Infections in Children

Gut Microbiota:
A Path to
Understanding Obesity

Probiotics Show
Potential for
Treating Colitis

Bactalk Newsletter
Winter 2010

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Message from the President



Dear IPA Members,

As I often do while passing weekends on the road, last evening I went to a movie. Up In The Air stars George Clooney as Ryan Bingham, a hired hand brought in to fire people at companies in the downsizing mode. While the movie struck a little close to home,

what with Mr. Bingham spending much of his life in airports and hotels, the probiotic industry should have no need for his type in the foreseeable future.

To the contrary, market reports are rife with positive probiotic forecasts. MarketsandMarkets reports the global probiotic market is expected to record a CAGR of 12.6% from 2009 to 2014. They forecast the market to be worth \$32.6B by 2014 with Europe and Asia accounting for nearly 42% and 30% of the total revenues, respectively. JustFood forecasts the probiotic market will increase in value by almost 38% from 2008 to 2013.

Usually I'm a little skeptical of such rosy forecasts, especially as we have seen a recent slowing of year-on-year probiotic growth rates. However, there remain large untapped populations for the industry to target. And while regulatory pressure to better document probiotic

health benefits may be seen as a short term roadblock, enhanced clinical documentation should serve us well over a longer horizon.

IPA is firmly committed to fostering continued healthy probiotic growth. Ioannis Misopoulos, our Executive Director, has been very active in championing our membership's interests to EFSA, Codex and Health Canada. He and the Executive Committee have recently been busy finalizing plans for IPA's 2nd World Congress to be held in Miami on April 16-17, 2010. If you've not already done so, please register soon for the World Congress. Space is filling fast and we want to make sure our members are able to attend.

In closing, we appreciate the support of our members and remind you to assist us by encouraging industry non-members to consider joining our ranks.

Health regards and I look forward to seeing you soon in sunny Miami, Scott

P.S. Kudos to Jarrow Rogovin and company for the new, creative and very apropos name and logo of your newsletter!!

EFSA PUBLISHES HEALTH CLAIMS GUIDANCE

The European Food Safety Authority (EFSA) has stressed that genetic typing for probiotics and compliance with the International Code of Nomenclature are critical factors for health claim submissions.

The guidance comes in the form of a Q&A document published by the agency in regard to article 13.5 and article 14 health claims.

Issued in the fall, it goes some way to addressing the lack of direction faced so far by the probiotics industry in the health claims process, which has contributed to the large proportion of negative health claim opinions issued to date. The latest of these came at the beginning of October when EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) turned down 171 generic article 13.1 probiotic dossiers.

According to EFSA, the main reason for the unfavourable outcomes was an insufficient characterization of the probiotics in question, which meant its NDA panel could not verify that the scientific evidence provided related to the same substance for which the health benefits were claimed.

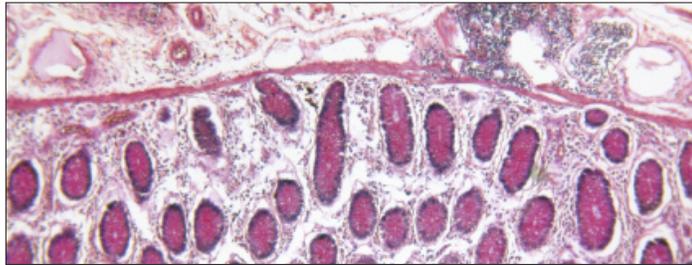
EFSA's Q&A document highlights a number of key issues it addresses while assessing article 13.5 and 14 dossiers:

- Probiotics should be sufficiently characterized (including genetic typing) at strain level by internationally accepted molecular methods.
- Strains should be named according to the International Code of Nomenclature.
- A constituent must be sufficiently characterized to establish that the submitted studies were performed on that specific constituent.
- Characterization must be sufficient to allow appropriate conditions of use to be defined.
- It may be necessary to distinguish between a specific product formulation, a specific constituent or combination of constituents.

- It would be beneficial – but not required for substantiation of a claim – for strains to be deposited in an internationally recognized culture collection with an access number, for control purposes.
- Information must also be provided that shows a consistent effect of the claimed benefit in the final product.
- Claimed effects need to be specific enough to be testable and measurable by generally accepted methods. For example, ‘gut health’ is too general, whereas ‘transit time’ is more specific and can be measured, so is preferable.

The document also clarifies EFSA’s position on proprietary and confidential data: proprietary data must be included in a dossier if it is necessary to substantiate a claimed effect, while the designation of confidential information must be kept to a minimum. Broad descriptions of data and information considered essential for the scientific assessment are released in the opinion. The protection of proprietary data is the responsibility of the European Commission.

The Q&A document can be accessed at the following link:
http://www.efsa.europa.eu/cs/BlobServer/Report/nda_report_ej1339_FAQ_on_Health_Claims_final_EN.pdf?ssbinary=true



STICKINESS: A ROUTE TO EFFECTIVE PROBIOTIC SELECTION?

A protein that can help bacteria stick around for longer in the gut could improve our understanding of which probiotic strains are likely to be most beneficial to health.

UK researchers say they have obtained the first crystal structure of a mucus-binding protein (MUB) from a strain of lactic acid bacteria naturally found in the gastrointestinal tract. This breakthrough, they say, could help explain how probiotic bacteria bind to the mucus layer protecting the gut lining.

Probiotics need to interact with cells lining the gut in order to have a beneficial effect, and by attaching to surfaces in the gut – such as the mucus layer – they have more time to exert their effect, explain the scientists from the Institute of Food Research and the University of East Anglia.

Mucus adhesion has been well studied for pathogenic bacteria, but there is less understanding of what helps commensal bacteria (or gut bacteria) bind to the tract.

The new research, published in November 2009 in the *Journal of Biological Chemistry*, indicates that mucus-binding proteins are more abundant in lactic acid bacteria than other types, and particularly in strains that inhabit the gut. It may be the presence of these proteins that contributes to the ability of lactic acid bacteria to interact with the host, say the scientists.

So how can these findings help probiotic producers? According to the scientists, their findings could result in a more effective probiotic design and selection. This, they say, needs to be based on molecular knowledge since the attachment of bacteria to mucus is molecule specific (via different types of mucus-binding proteins) as well as strain specific.

PROBIOTICS HELP REDUCE RESPIRATORY INFECTIONS IN CHILDREN

Children who attend day care centres are 2-3 times more likely to develop respiratory tract infections than children who stay at home. But a daily dose of probiotics could significantly reduce their risk of developing the majority of this type of infection.

Researchers in Croatia found that probiotics given to children in their milk also helped reduce the duration of infections and the number of days with respiratory symptoms.

Out of the 281 children taking part in the prospective, randomized, double-blind, placebo-controlled trial, 139 were given 100 ml of a fermented milk containing a lactobacillus probiotic at a dose of 10⁹ colony-forming units (CFU). 142 children received the same milk without added probiotics.

The children were given the milk products once per day for three months, with parents reporting on cases of infections or side-effects every 10 days. All infections were diagnosed by local general practitioners, who were responsible for the care of each child and who were asked to record the details of the infections experienced during the period.

According to the researchers, the children taking probiotics had a significantly lower risk of developing upper respiratory tract infections compared to the placebo group. They were also at a lower risk of episodes of infections lasting longer than three days.

These findings prompted the researchers to conclude that probiotics are a valid measure for the prevention of upper respiratory tract infections, and can also help reduce absences from day care centres due to illness.

The researchers noted, however, that the probiotics had no effect on lower respiratory tract infections or on gastrointestinal infections. The study was published in the journal of *Clinical Nutrition*.



GUT MICROBIOTA: A PATH TO UNDERSTANDING OBESITY

A breakthrough in the understanding of how the gut ecosystem contributes to obesity could pave a new way for exploring the actions and efficacy of novel probiotics.

In a paper published in November in *Science Translational Medicine*, US researchers describe how they successfully transferred gut bacteria from humans to ‘germ-free’ mice bred with no microorganisms in their guts.

Their findings go one step further than previous research in the field, showing that this transplanted gut community can then be passed on from mothers to their offspring... and that changes in the diet can have an immediate effect on gut microflora.

The researchers transplanted microbes from human faeces into germ-free mice, which were then fed a high-fat, high-sugar, ‘Western’-style diet. This obesity-

promoting diet caused a rapid change in the population of gut bacteria present, compared to mice fed a low-fat diet.

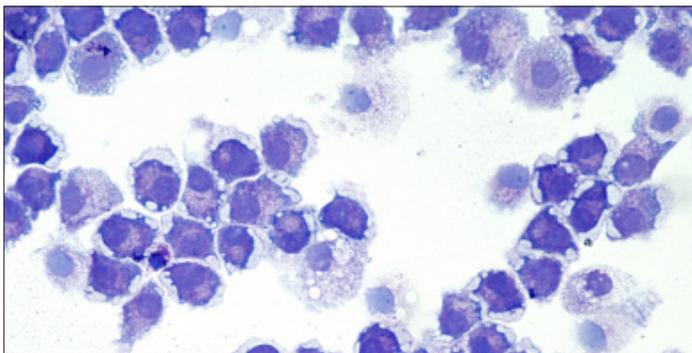
The mice on the Western diet showed an increase in body fat. But the researchers also found that simply transplanting the microbiota from the high-fat fed mice into a set of germ-free mice caused the new mice to get fatter, even though they were fed a low-fat diet.

According to the research team, these findings put the spotlight on human gut microbiota as a new factor to consider in the quest to understand and treat

obesity, estimated by the World Health Organization to affect 300 million people around the world.

The testing model could be used to examine how different factors – including diet – could influence the microbial populations in our gut, and how these, in turn, influence health and disease predispositions.

The researchers suggest that their germ-free mouse system could also provide an original pipeline for the discovery of new classes of probiotics that affect nutrient harvest in a given diet context.



PROBIOTICS SHOW POTENTIAL FOR TREATING COLITIS

Probiotic bacteria may help in the recovery from colitis by promoting new blood vessel growth in intestinal cells, a new study has found.

Colitis, which occurs when the inner tissue of the colon becomes inflamed and damaged, can cause painful sores, bloating, weight loss and bleeding. Ulcerative colitis is one of the major types of Inflammatory Bowel Disease.

According to a study published in the American Journal of Physiology – Gastrointestinal and Liver Physiology, mice treated with probiotics during the non-inflammatory stages of the disease were aided in recovery, showing reduced rectal bleeding and less inflamed tissue than mice not receiving probiotics. Weight gain was also higher in the probiotic group.

The US researchers say their study also suggests that probiotics may help heal intestinal wounds more quickly, by encouraging the growth of new blood vessels. This process – known as angiogenesis – is crucial for wound healing and repair. By promoting angiogenesis in the inner tissue of the colon – the mucosa – during recovery of mice from colitis, probiotics show potential for clinical use to facilitate intestinal wound healing, they say.

Probiotics in the News

Probiotics create a lot of media buzz. To arm yourself with reliable information about probiotics, check out the following links:

The Gut Check: Popularity Of 'Probiotics' Reflects Desire For More Intestinal Fortitude
The Hartford Courant, Dec 27 2009

http://www.courant.com/business/custom/consumer/hc-con-gutbacteria.artdec27_0,1356029.story

Probiotics May Help Treat IBD Symptoms, WeMD, Oct 29 2009

<http://www.webmd.com/ibd-crohns-disease/news/20091029/probiotics-may-help-treat-ibd-symptoms>

Good Germs May Fight Bad Colds & Flu, CBS4, Nov 18 2009

<http://cbs4.com/health/germs.cold.flu.2.1320381.html>

News from the IPA Office

IPA and Codex Alimentarius

IPA attended its first Codex Alimentarius meeting as an observer on Milk and Milk Products in Auckland, New Zealand from January 31st – February 4th 2010. The meeting's objective was for countries to discuss and agree on minimum requirements of Drink Based Fermented Milks and establish a standard. Multi lateral agreement was reached on several levels and the final report was sent to the Codex Commission for adoption.

IPA in association with IFAC submit comments to Health Canada regarding NHPD Recommendations for the Evidence Requirements for Efficacy, Safety, and Quality of Natural Health Products

At the end of January 2010, IPA in association with IFAC, submitted a document to Health Canada pertaining to the new Guidance on Probiotics to be released in the spring by the Natural Health Products Directorate (NHPD). The document addressed questions sent by NHPD to both organizations in order to help them with their mission of providing an objective guidance to the industry.

Stay tuned in the next edition of Bactalk for more exciting news regarding the newly formed IPA marketing committee

DON'T MISS THE SECOND BIENNIAL IPA WORLD CONGRESS SCHEDULED FOR APRIL 16TH – 17TH AT THE HILTON MIAMI.

Registration is now open at www.ipaworldcongress.com

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