

From the Corners of the World: Probiotic Paradox

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There continues to be sustained growth in antibacterial soaps and detergents used around the home, as well as rapid growth in the new personal care category of hand sanitizers. Interest in antibacterial products has increased dramatically over the past few decades, driven by consumers' obsessions with maintaining a germ-free environment. But the contradiction now comes from the growing consumer demand for probiotics, which is currently one of the hottest categories in the food and nutrition market.

Dr. Jeremy Burton, a microbiologist from New Zealand who spent many years in the development of probiotics at the University of Western Ontario and the University of Otago, recently suggested that “the whole concept of deliberately ingesting or seeding our tissues with microbes is anathema to many humans. After all, the only good germ is a dead germ—at least that’s the message imprinted upon us by the media from an early age. We are urged to rid our homes of all germs and to douse every accessible body crevice with antibiotics, antiseptics and assorted anti-microbials in a heroic attempt to achieve a germ-free environment. This then, is the antimicrobial gospel and let’s face it, microbes have overwhelmingly had bad press.”

Perhaps this viewpoint that all things are either “good” or “bad” stems from our need to be able to narrowly define and label something, so as to better understand it. But biology, and therefore nutrition, is not that simple.

For a similar example of our innate need to label things, one only has to look back to the late 1990s when dietary carbohydrates were “in” and fats were definitely “out.” Then, around 2002, the roles reversed thanks largely to the advent of the Atkins’ diet. This was when fats were considered “good” or at least acceptable, and carbs were definitely “out.” Look also at the incredible surge in positive press over omega 3’s and the equally negative press over trans-fats.

The beauty of all this for a marketer is in the simplicity of the message. There are no confusing or contradictory messages here to impede consumers’ spending, as opposed to the real story, which is “some fats are bad ... and some fats are good”—which poses a marketing conundrum. Instead, the “good vs. bad” message is far easier to communicate and deliver.

But as easy as these simple messages are to deliver, achieving the corresponding consumer benefit has proven to be a lot more difficult. This is largely because in our attempts to render things down to the most fundamental message or concept for the consumer, the complexity of biological systems has been largely overlooked.

The Probiotics Story

Probiotics, it would seem, now appear to be facing a similar challenge—a challenge where not all probiotics are created equal.

So what are probiotics? Probiotics have been defined by the World Health Organization as “live microorganisms which, when administered in adequate amounts confer a health benefit on the host.”

World-reknowned microbiologist, professor John Tagg, stated in a medical publication in October last year that, “Ever since probiotics were kick-started into prominence by the Nobel Prize winner, Eli Metchnikoff, the practice of regular ingestion of intestinal commensal bacterium (especially lactobacilli) to confer health-promoting benefits has been in common use by humans.”

Professor Tagg went on to suggest: “The basis of replacement [probiotic] therapy is the implantation of relatively innocuous ‘effector’ bacteria that are somehow able to competitively exclude or prevent the outgrowth of potentially disease-causing bacteria. Individual bacterial members of our indigenous microbiota are actively engaged in an on-going battle to prevent colonization and overgrowth of their terrain by competing microbes, some of which may have heightened pathogenic potential for the host. Humans have long attempted to intervene in these bacterial interactions.

“Probiotic bacteria, particularly lactobacilli and bifidobacteria, are commonly taken orally to promote a well-balanced intestinal microflora,” professor Tagg continued. “Whilst current intestinal probiotics have been shown to reduce the severity of various inflammatory intestinal diseases and other ailments, they also have other more common uses such as reducing the severity of, or preventing diarrhea caused by infectious microbes or more commonly following the taking of antibiotics.”

Critics Raise Doubts

There are those, however, that would argue with leading luminaries like professor Tagg, suggesting the concept of a probiotic, and their related health benefits, are simply deceptive attempts to promote a substantially undifferentiated product to a health conscious consumer, at inflated prices. According to some leading microbiologists, as recently as 2006, there is no conclusive evidence of probiotics providing health benefits for consumers.

It is true that probiotics do deserve more study, especially as consumer interest in this market continues to increase. In fact, this was the specific recommendation of a 2006 report from the American Academy of Microbiology. Some of the recommendations called for more research surrounding the understanding of host-specific interactions with a standard probiotic, cell-to-cell signaling, and genetic identification and characterization of probiotic strains.

Probiotic Guidelines

There is practical guidance available from an earlier whitepaper on probiotics - “Guidelines for the Evaluation of Probiotics in Food”—which was written by a Joint Working Group Report from Food and Agriculture Organization of the United Nations and the World Health Organization.

In addition to defining a probiotic, this working group also devised a systematic approach to the evaluation of probiotics in food, leading to the substantiation of health claims. The Working Group identified and outlined the minimum requirements needed for probiotic status for food applications.

The Working Group Report states the following standard methods for clinical evaluations. These are comprised of:

- Phase 1 (safety)
- Phase 2 (efficacy)
- Phase 3 (effectiveness)
- Phase 4 (surveillance)

Phase 1 studies focus on the safety of probiotic strains. The Working Group indicates the onus is on the producer to prove that any given probiotic strain is not a significant risk with regard to transferable antibiotic resistance or other opportunistic virulence properties.

Phase 2 studies, generally in the form of randomized, double blind, placebo-controlled (DBPC) design, measure efficacy compared with placebo. In addition, phase 2 studies measure adverse effects. A general recommendation for the testing of probiotic foods is that the placebo be comprised of the food carrier devoid of the test probiotic. Sample size needs to be calculated for specific endpoints. Statistically significant differences must apply to biologically relevant outcomes.

The Working Group stated that probiotics delivered in food are generally not required to be tested in Phase 3 studies, which would provide the “conclusive evidence.” The point of Phase 3 studies is to compare the probiotics with a standard therapy. The Working Group guidelines clearly show in its published process flow diagram that while a Phase 3 study (and by definition, the “conclusive evidence”) is indeed a possible next step after successful completion of a phase 2 study, it is a lateral step and not a prerequisite step in the process of producing a probiotic food.

Given the adherence of many reputable companies to the FAO/WHO guidelines for the manufacture of probiotic foods, which have been in effect since 2002, it is not surprising that there has been little “conclusive evidence” that would otherwise come from the Phase 3 clinical trials. After all, complying with these guidelines only mandates the evidence for safety and efficacy, not effectiveness nor surveillance (which are considered functions of phase 3 and 4 studies, respectively).

Consumer Beware?

When consumer demand increases, sectors like probiotics are sometimes vulnerable to abuse by some manufacturers, who are trying to exploit the good work and reputation of others for their own personal gain. Traditionally, these companies tend to operate on the fringes and largely remain below the radar ... until something goes wrong!

As recently pointed out by professor Tagg, “If bacterial strains are to be classified as probiotics, they should have a sound scientific basis and supportive clinical studies behind them. Unfortunately, a number of strains on the market have little science behind them and some even have erroneous health claims. Additionally, there have been a number of products that are of dubious quality with regards to the viability and correct identification of the organisms they contain. However, from a brief personal survey of probiotic preparations on various retail shelves of health food shops and pharmacies, it appears that there are various high quality preparations available. There are also probiotics available in other food-related stores and in certain dairy products.”

Professor Tagg insists consumers check the packaging to: (1) see if the scientific name of the organism is listed; and (2) check the numbers of viable bacteria anticipated being present in the product up to the date of expiry, and not just at time of manufacture.

Strong Science

It is clear and unequivocal that probiotics offer an array of potential health benefits, but research still remains the key to further understanding their mechanisms of action. Nutrigenomics New Zealand, a government funded research consortium in the area of novel foods for the management of inflammatory bowel disease (IBD) is investigating the role that specific strains of probiotics can play in the treatment and prevention of this type of condition.

Research over the past few years has contributed to the understanding that an oral dose of a probiotic doesn't actually have to colonize or persist in the gut to have a potential health benefit; even the movement of a probiotic through the gut can have a positive effect, giving further support to the notion of consuming probiotics on a daily basis.

More recently, a growing body of scientific data appear to support the use of probiotics in the oral cavity for the prevention of gum disease, tooth decay, bad breath, and even upper respiratory tract infections. A major global pharmaceutical company announced in 2007 that it would take a traditional Eastern medicine approach to its drug discovery program by examining the specific microflora of the gut, as well as the manipulation of the overall gut microflora to positively influence the health of the host.NW



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