Researcher calls for new approach to regulating probiotics

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In today's *Nature* scientific journal Dr. Gregor Reid, Director of the Canadian R&D Centre for Probiotics at Lawson Health Research Institute and a scientist at Western University, calls for a Category Tree system to be implemented in the United States and Europe to better inform consumers about probiotics.

Globally, the market for probiotics (beneficial microorganisms) exceeds $30 billion; however, consumers have little way of knowing which products have been tested in humans and what they do for health. Furthermore, the regulatory system in the US maintains that any product that claims to impact disease must be categorized as a drug. Therefore, scientists can't test if a probiotic yogurt relieves patients with inflammatory bowel disease without first registering the yogurt as a drug. According to Dr. Reid, this regulation has halted a lot of great research on probiotics in North America and has ramifications for probiotic research and development in Europe. "In Europe, bureaucrats have set up a system that has so far refused to acknowledge results of excellent clinical studies," states Dr. Reid. "The net result is an impasse, reduced R&D, and consumers left in limbo."

Dr. Reid's proposal, as discussed in *Nature*, is to set up a system in which probiotics must all pass a set of minimum requirements before they can be called a probiotic. According to Dr. Reid, this would force many companies to conduct research studies on their products, or call them something other than probiotic. To receive a product stamp, a set of well-defined experiments would have to be performed. Once completed, the

product could then receive a Category 1 or 2 stamp.

"Thus, regulators could quickly and easily determine whether or not the product met the standard and approve the stamp, and consumers would be able to understand the extent to which the product had been tested," states Dr. Reid. "With collective discussion amongst probiotic experts and regulatory agencies, this could be a universal stamp across the globe."

For food and supplement products that are more complicated, or targeted for vulnerable populations like children and the elderly, Dr. Reid proposes that documentation requirements would be higher and an expert panel or process might be needed to determine if this Category 3 level was reached.

"This is long overdue given the intransigence of European Food Safety Authority and US Food & Drug Association at present," states international expert in probiotics, Professor Glenn Gibson of the University of Reading, United Kingdom. "The idea clearly has merit given the current confusing situation for consumers, but will regulators have the courage to even consider implementing something so sensible? Sadly I doubt it, although given the high profile of the publication in *Nature*, and sincerity of the idea, I can only live in hope."

More information: Dr. Reid's commentary, "Categorize probiotics to speed research", can be found in the current issue of *Nature* at www.nature.com/nature/index.html

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