

FDA Declares Probiotics Produced by DuPont to be Generally Recognized As Safe (GRAS)

PROBIOTICS (from *pro* and *biota*, meaning “for life”) are health-enhancing bacteria. Probiotics are more formally defined by the Food and Agriculture Organization of the United Nations as: “live microorganisms which, when administered in adequate amount, confer a health benefit on the host.” A growing body of scientific evidence suggests that consumption of probiotic bacteria with certain foods or as diet supplements can treat, and even prevent, some illnesses. Northern Europeans typically consume large quantities of these beneficial microorganisms because of their tradition of eating foods fermented with bacteria, such as yogurt. Probiotic-laced beverages are also big business in Japan.



In contrast, consumer interest in United States for probiotics is only a recent phenomenon. However, that may change as a result of recent recognition that probiotics are safe for integration into a wide range of food products.

DuPont Nutrition & Health, a division of international conglomerate E.I. DuPont de Nemours, has received confirmation from the **U.S. Food & Drug Administration (FDA)** that the probiotic strains in its *Bifidobacterium lactis* range are "**generally recognized as safe**" (**GRAS**) and suitable for use in all food products

and dietary supplements. GRAS affirmation by FDA confirms that the science behind these strains is sufficient to guarantee their safety in foods and supplements.

Many health professionals believe that probiotic microorganisms help with digestion and offer protection from harmful bacteria, just as the existing "good" bacteria naturally found in the human body already do. According to experts at the Mayo Clinic, for example, probiotics can raise the nutritional profile of consumers and their diets when taken as a dietary supplement or integrated into certain food production processes.

Prebiotics are nondigestible carbohydrates that act as food for probiotics. When probiotics and prebiotics are combined, they form a “**synbiotic**.” Fermented dairy products, such as yogurt and kefir, are considered synbiotic because they contain live bacteria and the fuel they need to thrive. Probiotics are found in foods such as yogurt, while prebiotics are found in whole grains, and foods such as bananas, onions, garlic, honey and artichokes. Because these natural sources often are unavailable to significant consumer populations, the food industry has recognized the

value of adding probiotics and prebiotics to some food products, as well as making the microorganisms available as dietary supplements.

One of the most clinically studied probiotic strains available today, the *B. lactis* range, includes *Bifidobacterium lactis* HN019, marketed as "HOWARU Bifido." *Bifidobacterium lactis* Bi-07 and *Bifidobacterium lactis* Bl-04 are part of the FloraFIT custom probiotics range which offers food manufacturers flexibility with a wide selection of strains for the formulation of dietary supplements and nutritionals.

The results of human clinical trials conducted for DuPont's probiotic range document the immune and digestive health benefits of probiotics in infants, children and healthy adults. Dupont recently published a study published in the peer-review journal *Clinical Nutrition*, and additional studies by DuPont are in progress. These findings are part of a larger network of scientific analyses focused on probiotics. Among the most recent is the *Human Microbiome Project*, initiated by the U.S. National Institutes of Health. Analyses to date support the conclusion that the strains in HOWARU and FloraFit probiotics are natural, beneficial components of the gastrointestinal tract.