



October 2012

HOWARU® Bifido

Introduction

HOWARU® Bifido is the commercial name for the DuPont Nutrition & Health's probiotic single strain *Bifidobacterium lactis* HN019. It is available as a freeze-dried powder or frozen pellet, suitable for direct inclusion in a wide range of food products.

In order to document traditionally used microorganisms as safe food ingredients, the International Dairy Federation (IDF) in collaboration with the European Food & Feed Cultures Association (EFFCA) has compiled a non-exhaustive inventory of microorganisms with documented history of safe use in food. The inventory includes a list of scientific literature documenting the use of microorganisms in food prior to 1997, when the EU Novel Food Regulation was put into force. *Bifidobacterium lactis* is reported in this inventory with documented use dating back to 1980.

Likewise the qualified Presumption of Safety (QPS) risk assessment is a generic harmonized tool developed by European Food Safety Authority (EFSA) to assess the safety of microorganisms. *Bifidobacterium lactis* is on that list too.

Health Claims within EU

Health claim dossiers for **HOWARU® Bifido** were previously submitted for review by EFSA under Article 13.1 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. These dossiers on Immune Health (application 862) and Gut Health (application 865) were subsequently withdrawn by Danisco in April and July 2010 respectively.

Effective June 14, 2012, health claims that were withdrawn will not be legally authorised on product labels or other marketing material.

Submission of Article 13.5 Health Claim Dossiers

DuPont Nutrition & Health is presently undertaking new clinical studies and strengthening the scientific evidence on **HOWARU® Bifido** with the view to submit new Immune Health and Gut Health claim dossiers for review by EFSA under Article 13.5 of Regulation (EC) No 1924/2006. This is being done in accordance with the "Guidance on the scientific requirements for health claims related to gut and immune function" provided by EFSA in April 2011.

Gut Transit Health

A recently published clinical study performed with **HOWARU® Bifido** have shown that consumption of this probiotic strain reduces gut transit time in mildly-constipated adults (Waller et al. 2011) *

The excellent results from this first transit study on **HOWARU® Bifido** gave us a good position in digestive health. EFSA requires reproducibility from multiple studies so a second clinical trial is underway. Provided this study shows good results, DuPont Nutrition & Health will submit a new Article 13.5 health claim dossier for **HOWARU® Bifido** in relation to the maintenance of normal bowel function.

**Dose-response effect of Bifidobacterium lactis HN019 on whole gut, transit time and functional gastrointestinal symptoms in adults. Scandinavian Journal of Gastroenterology; Vol. 46, No. 9, Pages 1057-1064.*



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Immune Health

Several clinical studies performed with **HOWARU® Bifido** have already shown that consumption of this probiotic strain has an impact on important markers of immune function in adults and the elderly. Provided the studies currently underway shows positive results, DuPont will submit a new Article 13.5 health claim dossier for **HOWARU® Bifido** in relation to the maintenance of normal immune function.

Marketing Recommendations

Manufacturers are recommended to move to nutrition claim language while DuPont addresses the current dossier with additional clinical studies to support immune and digestive health claims. Food products can continue to contain **HOWARU® Bifido**, although health claims are not legally authorised on product labels or other marketing material and thus nutrition claim language should be used as an alternative tool to communicate premium products.

As illustrated above, DuPont Nutrition & Health intends to submit new Article 13.5 health claim dossiers to allow manufacturers to actively promote future health claims of **HOWARU® Bifido**. Until this time, DuPont Nutrition & Health recommends that manufacturers observe all relevant European and local Member State legislation regarding the labelling of food and dietary supplement products. DuPont Nutrition & Health will continue to work with manufacturers to identify opportunities for marketing products containing **HOWARU® Bifido** together with other ingredients offering health and nutrition claims.

The position presented in this document reflects DuPont's understanding and interpretation of the current EU legal environment. The decision on the use of DuPont products and on the labelling of the final product remains the sole responsibility of the food manufacturer. The present information is given without any liability on the part of DuPont.