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March 16<sup>th</sup>, 2011

**Re: Application for the Approval of Bovine Lactoferrin for use as a Novel Food Ingredient under the novel food Regulation (EC No. 258/97)**

Dear Dr. Lewis,

A novel food application submitted by Morinaga Milk Industry Co. was formally accepted by the Food Safety Authority of Ireland (FSAI) on February 28th, 2011. The application is for the approval of Bovine Lactoferrin as a novel food ingredient under Regulation (EC) No. 258/97. This ingredient is intended to be used as a food ingredient in foods for the general population, and for Particular Nutritional Uses (PARNUTS - Directive 89/398/EEC), including infant and follow-on formulae.

Under normal circumstances, and in line with the novel food Regulation, the Food Safety Authority of Ireland (FSAI) would carry out a safety assessment of the ingredient and report back to the Commission within 90 days. However, since an earlier proposal on Bovine Lactoferrin (DMV International) is currently under assessment by EFSA, the Food Safety Authority of Ireland would recommend that the application summary and dossier is sent to EFSA to review in conjunction with the previous application.

The potential intake of Bovine Lactoferrin from food and PARNUTS as proposed by the applicant needs to be addressed in the context of overall intake of this ingredient from all possible sources. As this matter is currently being addressed at EU level, the FSAI is of the opinion that an additional assessment, as set out in *Article 6.3* is required in order to determine whether this product meets the criteria for acceptance as a novel food ingredient as set out in *Article 3.1* of the novel food Regulation.

If you have any questions please do not hesitate to contact me.

Regards,

Dr. Patrick O'Mahony  
*Chief Specialist, Biotechnology*