

## SUBSTANTIAL EQUIVALENCE OPINION

### **Bovine Lactoferrin (Bioferrin®)**

The Food Safety Authority of Ireland (FSAI) received an application in June of 2013 from Glanbia in Ireland for an opinion on the substantial equivalence of its bovine lactoferrin (Bioferrin®) to bovine lactoferrin previously authorised to Morinaga Milk Industry Co. Ltd. through Commission Implementing Decision 2012/725/EU. The source of Glanbia's lactoferrin is cow's milk whey, a by-product of the cheese manufacturing industry and also a source of the authorised lactoferrin. The production process for Bioferrin® is very similar to that for the authorised lactoferrin, yielding products with very similar specifications. Bioferrin® will be designated as "Lactoferrin from cow's milk" in line with Commission Implementing Decision 2012/725/EU, while it will be used only in the food groups set out in Annex II of that Implementing Decision. The applicant considers the ingredient to be novel and fall within the category of "food and food ingredients consisting of, or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use" as set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97.

#### **Composition**

Bioferrin® and the authorised lactoferrin are derived from cow's milk or its derivatives using very similar production and purification processes. A compositional comparison demonstrates the close similarity between Bioferrin® and the authorised bovine lactoferrin in terms of the level of protein, moisture, arsenic, ash etc, as specified in Annex I of the Implementing Decision. The applicant demonstrates batch consistency with respect to the composition of Bioferrin® along with a product stability of greater than 30 months.

#### **Nutritional Value and Metabolism**

Bioferrin® and the authorised lactoferrin are derived from cow's milk using very similar processes with the result that the composition of both products is practically

identical. Therefore the nutritional value and metabolism of Bioferrin® is not expected to be any different to the authorised lactoferrin.

### **Intended Uses**

The applicant intends placing the Bioferrin® on the EU market in general foods and foods for particular nutritional (PARNUTS), including foods for special medical purposes (FSMPs) as well as infant and follow-on formulae. The permitted uses and maximum use levels set out in Annex II of Commission Implementing Decision 2012/725/EU that pertains to the authorised bovine lactoferrin will also apply to Bioferrin®.

### **Level of Undesirable Substances**

Bioferrin® and the authorised lactoferrin are produced from the same raw material using a largely similar process and therefore it can be assumed that there will not be any significant differences in the levels of undesirable substances. The applicant demonstrates satisfactory results for lead and arsenic analysis in Bioferrin® along with a microbiological profile similar to that for the authorised lactoferrin.

### **Conclusions**

The FSAI is satisfied from the information provided by the applicant that Glanbia's Bioferrin® is substantially equivalent to bovine lactoferrin authorised to Morinaga Milk Industry Co. Ltd. through Commission Implementing Decision 2012/725/EU. Bioferrin® will be designated as "Lactoferrin from cow's milk" in line with Commission Implementing Decision 2012/725/EU. Bioferrin® will only be used in the food categories and to the maximum use levels set out in Annex II of that Implementing Decision and without prejudice to the provisions of Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Directive 2009/39 of the Parliament and the Council.