SUBSTANTIAL EQUIVALENCE OPINION

Lactoferrin

The Food Safety Authority of Ireland (FSAI) received an application in November of 2015 from Tatura Milk Industries Ltd. in Australia for an opinion on the substantial equivalence of its lactoferrin to bovine lactoferrin previously authorised to Morinaga Milk Industry Co. Ltd by Commission Implementing Decision 2012/725/EU. The definition of bovine lactoferrin originally set out in Commission Implementing Decision 2012/725/EU is amended by Commission Implementing Decision (EU) 2015/568.

Naturally present in cow's milk, lactoferrin is a 77 kDa iron-binding glycoprotein consisting of 689 amino acids. The source for the novel ingredient is cows' milk and the production process is similar to that for bovine lactoferrin already authorised in the EU. Raw milk is skimmed, pasteurised and filtered before being passed through an ion-exchange column. The bound lactoferrin is subsequently eluted from the column, micro filtered and freeze dried prior to packing. The specifications of the novel lactoferrin are comparable to those set out in Annex I of Commission Implementing Decision 2012/725/EU and it is intended for use in the same food groups and maximum use levels as detailed in Annex II of the same Commission Implementing Decision.

Lactoferrin is considered a novel ingredient and is categorised in accordance with *Article 1.2(e)* of the novel food Regulation EC No. 258/97 as "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".

Composition

Results from batch analysis of the applicant's lactoferrin demonstrate their product has comparable specifications to those described in Annex I of Commission Implementing Decision 2012/725/EU in relation to moisture, ash, arsenic, iron, protein, pH and solubility. The packaged novel ingredient has a shelf life of at least 2 years when stored in a cool, dry environment.

Nutritional Value and Metabolism

The source of the novel ingredient, the production process and product specifications are comparable with the EU authorised bovine lactoferrin. Therefore, the nutritional value and metabolism of Tatura Milk Industries Ltd lactoferrin is not expected to differ from the authorised bovine lactoferrin. The risk of allergenicity is also expected to be no different to other bovine lactoferrin ingredients available in the EU.

Intended Uses

Tatura Milk Industries Ltd intends placing lactoferrin on the EU market for use only in the food products and at the maximum use levels listed in Annex II of Commission Implementing Decision 2012/725/EU.

Level of Undesirable Substances

The applicant provides results of analyses for heavy metals (i.e. lead, arsenic) and microorganisms including aerobic plate count, coliforms, *Escherichia coli*, *Bacillus cereus*, coagulase positive *Staphylococcus aureus*, *Salmonella*, *Shigella*, yeasts and moulds, *Listeria* and *Enterobacter sakazakii*. Batch analysis indicates the applicant's lactoferrin is within specification for all parameters tested.

Conclusions

The FSAI is satisfied from the information provided by Tatura Milk Industries Ltd that their lactoferrin is substantially equivalent to bovine lactoferrin authorised by Commission Implementing Decision 2012/725/EU. In accordance with *Article 2* of the aforementioned Decision, Tatura Milk Industries Ltd lactoferrin will be designated as "Lactoferrin from cow's milk" in foods that contain it. The use and maximum use levels of the novel ingredient will be those set out in Annex II of Commission Implementing Decision 2012/725/EU and without prejudice to the provisions of Regulation (EC) No 1925/2006 and Directive 2009/39/EC.