

SUBSTANTIAL EQUIVALENCE OPINION

Bovine Lactoferrin

The Food Safety Authority of Ireland (FSAI) received an application in February of 2016 from Warrnambool Cheese & Butter Factory Company Holdings Ltd. (WCB) of Australia for an opinion on the substantial equivalence of its bovine lactoferrin to bovine lactoferrin previously authorised to Morinaga Milk Industry Co. Ltd. and FrieslandCampina through Commission Implementing Decisions 2012/725/EU and 2012/727/EU, respectively. The definition of bovine lactoferrin originally set out in Commission Implementing Decision 2012/725/EU is amended by Commission Implementing Decision (EU) 2015/568.

Bovine lactoferrin is a 77 kDa iron-binding glycoprotein naturally present in cow's milk. The novel ingredient, a single polypeptide chain made up of 689 amino acids, is produced from cow's milk in a process similar to that for the existing comparators, with product specifications generally comparable to those set out in Annex I of Commission Implementing Decisions 2012/725/EU and 2012/727/EU.

Bovine lactoferrin purified from cow's milk does not have a significant history of consumption in the EU prior to 1997 and so is considered novel within the category set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97: "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

The compositional specifications for WCB's bovine lactoferrin are supported by analytical results for 3 non-consecutive batches, and are generally comparable to the EU-authorised bovine lactoferrin (Annex I of Commission Implementing Decisions 2012/725/EU and 2012/727/EU). Protein is the primary component of the novel ingredient ($\geq 95\%$) along with minor levels of moisture, ash, arsenic and iron. HPLC and Western Blot analyses demonstrate that lactoferrin is the predominant protein present in the novel ingredient, with minor levels of other milk proteins. Lactoferrin makes up a slightly lower percentage of the total protein in the novel ingredient ($\geq 90\%$) relative to the authorised comparators ($>95\%$). However, this is balanced by

the fact that the novel ingredient has a higher overall protein content ($\geq 95\%$) compared to the authorised comparators ($>93\%$). This means the final lactoferrin content in the novel ingredient is $\geq 85.5\%$ compared to $>88.4\%$ for the authorised comparators. The applicant provides information to support a stability profile of 12 months at 25°C . However, a shelf life of 36 months at 25°C is proposed, which was determined by a related company to which the applicant licences the lactoferrin manufacturing process.

Nutritional Value and Metabolism

WCB's bovine lactoferrin is derived from cow's milk using a similar process to EU-comparators and possesses a similar compositional profile. Therefore, the nutritional value and metabolism of is not expected to differ.

Intended Uses

The novel bovine lactoferrin is intended as a direct replacement for existing bovine lactoferrin and will be used in the same food products and at the same maximum use levels indicated in Annex II of Commission Implementing Decisions 2012/725/EU and 2012/727/EU.

Level of Undesirable Substances

The applicant provides analytical results for heavy metals (lead, cadmium, arsenic, mercury) which were all below the limit of detection. Mycotoxins (aflatoxin M_1) were not detected, while dioxins and dioxin-like polychlorinated biphenyls were within relevant EU legislative limits. Microbiological analysis for yeasts, moulds, *Staphylococcus*, *Salmonella*, *Listeria*, *E. coli*, *B. cereus* and *E. sakazakii* yielded acceptable results. The applicant provides results for additional contaminants tested on an annual basis including nitrate, nitrite, melamine, cyanuric acid, Ochratoxin A, benzo(a)pyrene and radioactivity, all of which were considered to be within acceptable limits.

Conclusions

The FSAI is satisfied from the information provided by Warrnambool Cheese & Butter Factory Company Holdings Ltd. that their bovine lactoferrin is substantially equivalent to bovine lactoferrin authorised through Commission Implementing Decisions 2012/725/EU and 2012/727/EU. The novel ingredient will be used in the

same food categories and at the maximum use levels set out in Annex II of the Commission Implementing Decisions, without prejudice to the provisions of Regulation (EC) No 1925/2006 and Directive 2009/39. The designation of the novel ingredient in foods containing it will be “Lactoferrin from cow’s milk”.