

SUBSTANTIAL EQUIVALENCE OPINION

Bovine Lactoferrin (Vitalarmor® LACTOFERRIN)

The Food Safety Authority of Ireland (FSAI) received an application in November of 2015 from Armor Protéines S.A.S in France for an opinion on the substantial equivalence of its bovine lactoferrin (Vitalarmor® LACTOFERRIN) to bovine lactoferrin previously authorised to Morinaga Milk Industry Co. Ltd. and Friesland Campania through Commission Implementing Decisions 2012/725/EU and 2012/727/EU, respectively. Commission Implementing Decision (EU) 2015/568 amends the definition of bovine lactoferrin originally set out in Commission Implementing Decision and 2012/725/EU.

Bovine lactoferrin is a naturally occurring iron-binding glycoprotein found in cow's milk. The source of the novel bovine lactoferrin is skimmed cows' milk that has been pasteurised. The novel ingredient is produced in a similar process to that for the EU-authorized comparators, with specifications comparable to those set out in Annex I of the relevant Commission Implementing Decisions. Vitalarmor® LACTOFERRIN will be used in the same foods and at the same maximum use levels as the authorised comparators (Annex II of the Commission Implementing Decisions) and will be designated on those foods as "lactoferrin from cow's milk".

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

Vitalarmor® LACTOFERRIN appears as a light pink powder and is produced from cow's milk to cGMP standards and in accordance with HACCP principles. HPLC analysis of the novel ingredient confirms the identity of the major protein fraction as lactoferrin, with a purity of approximately 97%. The compositional specifications of the novel ingredient are similar to those for the authorised comparators in terms of protein, moisture, ash, arsenic and iron. Lactoferrin content is at >95% of total protein, and the slight differences observed in the mineral content are insignificant as

minerals represent only a minor fraction ($\leq 1\%$) of the overall ingredient and so have little nutritional impact. A shelf-life of 24 months is proposed for Vitalarmor® LACTOFERRIN when stored dry (humidity $< 70\%$) at room temperature (20°C) in the original unopened container, and at 41 months when stored at 4°C .

Nutritional Value and Metabolism

As the composition of the novel and authorised lactoferrin is very similar, the nutritional value and metabolism is not expected to differ significantly.

Intended Uses

Armor Protéines intends placing Vitalarmor® LACTOFERRIN on the EU market as a direct replacement for existing EU-authorised bovine lactoferrin. Food uses and maximum use-levels will not deviate from those specified in Annex II of Commission Implementing Decisions 2012/727/EU and 2012/725/EU which include infant formulae and follow-on formulae, foods for special medical purposes and foods for the general population.

Level of Undesirable Substances

The applicant provides analytical results for contaminants including heavy metals (lead, cadmium, arsenic and mercury), mycotoxins, dioxins and dioxin-like polychlorinated biphenyls (PCBs), and microorganisms, all of which are within relevant EU legislative limits where they exist.

Conclusions

The FSAI is satisfied from the information provided that Vitalarmor® LACTOFERRIN is substantially equivalent to bovine lactoferrin authorised to Morinaga Milk Industry Co. Ltd. and Friesland Campania through Commission Implementing Decisions 2012/725/EU and 2012/727/EU, respectively. Vitalarmor® LACTOFERRIN produced by Armor Protéines S.A.S in France will be used in the food categories and at the maximum use levels set out in Annex II of the relevant Commission Implementing Decisions, without prejudice to the provisions of Regulation (EC) No 1925/2006 and Directive 2009/39. The designation of Vitalarmor® LACTOFERRIN in foodstuffs containing it will be “Lactoferrin from cow’s milk”.