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By email to: [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au)

Subject: Submission on Application A1253---Bovine-lactoferrin-in-infant-formula

Please find attached my submission in response to the call for public comment on Application A1253---Bovine-lactoferrin-in-infant-formula.

This submission is made in my capacity as a former NFA/ANZFA staff member (1991-2000) and an independent food regulatory affairs consultant (2001 to the present). It is not made on behalf of, or in partnership with, any food business, food industry organisation or other 3rd parties.

Yours sincerely

[REDACTED]

## Submission on A1253 Bovine-lactoferrin-in-infant-formula

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The proposal by FSANZ, in draft variations contained in Call for submissions – Application A1253, to list bovine lactoferrin as substance *used as a nutritive substance* is:

- inconsistent with the original intent of the nutritive substances classification;
  - unnecessary for the claims identified in the application; and
  - potentially very difficult to comply with and enforce; and
  - likely to cause commercial damage to food businesses with products in development or already in the market.
- 
- [used as a nutritive substance](#)

A definition of nutritive substance was included in Standard 1.1.1 from the first adopted version of the ANZ Food Standard Code. There was no similar category in the previous Australian Food Standards Code, nor the NZ Food regulations. In the original definition a nutritive substance was defined as:

***nutritive substance*** means a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides.

In the superseded Australian Food Standards Code, the substances named in the new nutritive substance definition, namely vitamins, minerals, amino acids, electrolytes and nucleotides, were all regulated as food additives. The decision to align the food additives standard (1.3.1) in the new ANZ Food Standards Code with the principles applied in the recently established Codex General Standard for Food Additives meant that, going forward, only substances performing a technological function would be regulated as food additives.

The naming of the substances in the definition and the absence of a broader definition for “a nutritional purpose”, indicates that the intent for the new classification was that it would only apply to the named substance types, previously regulated as food additives, and similar chemically defined substances. It was not intended to be applied more broadly to any ingredient that had a functional property in food. Whilst the current definition exempts “a substance normally consumed as a food”, it is unclear whether this applies to “a food” that is highly refined and normally only consumed as an ingredient in other foods, or only to whole foods consumed as is. Indeed if taken literally, without regard to the original intent quite ridiculous interpretations are possible that could apply to almost any refined and chemically defined ingredient with macronutrient properties, that is not normally consumed as a food on its own. For example, any of the following could be defined as nutritive substances if the standard is interpreted without regard to its original intent:

- a highly refined disaccharide added to foods to provide energy, since these are chemically defined substances that are not normally consumed on their own as foods but are generally mixed with other foods for a non-nutritional, organoleptic purpose (i.e. sweetness);

- highly refined polyunsaturated vegetable oils, such as MCT oils, from coconut oil added to ultra low carb foods to support ketosis; or
- resistant starches added to food to increase the dietary fibre content of a food.

Clearly, such ridiculous interpretations were not the intended purpose of *Used as a nutritive substance*.

The definition of Used as a Nutritive Substance, specifies *..a substance..... added to “the food”*. When read in conjunction with the meaning of **food** in the various enforcement jurisdictions’ food laws, for example the Victoria Food Act 1984 and NZ Food Act 2014 (extracts below), the intended limitations of the definition are clear. Logic dictates that an ingredient which comprises **“the food”** cannot also be a “substance added to the food”. The food acts’ definitions indicate that any ingredient that contributes to the structural, textural, organoleptic or macro-nutritional properties of **the food**, or is added to perform a technological function is **a food**. It is an integral component of **“the food”** in which it is present in. Consequently, it cannot, at the same time, be a “substance added to **the food**”.

For example:

Victoria Food Act 1984 - "food" includes—

- (a) *any substance or thing of a kind used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared);*
- (b) *any substance or thing of a kind used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a);*

NZ Food Act 2014 *food*—

- (a) *means anything that is used, capable of being used, or represented as being for use, for human consumption (whether raw, prepared, or partly prepared); and*
- (iv) *any ingredient or other constituent of any food or drink, whether that ingredient or other constituent is consumed or represented for consumption on its own by humans, or is used in the preparation of, or mixed with or added to, any food or drink; and*

It is reasonable to conclude that the definition of used as a nutritive substance, is only intended to apply to an ingredient that does not contribute to the defining structural, textural or other organoleptic properties nor the macronutrient profile of **“the food”**, nor performs a technological function in **“the food”**. Consequently, a concentrated or refined ingredient comprising one or more of the major macronutrients (i.e. fats, proteins, available carbohydrates or dietary fibre) is not a substance *Used as a Nutritive Substance*.

Formulated Supplementary Sports Food (Standard 2.9.4 & Schedule 29) provide an excellent illustration of the correct use of “nutritive substance” in this regard. The core food is not specified or defined in Std 2.9.4 other than to establish maximum limits for sodium & potassium and for vitamins, minerals and amino acids specified in Schedule 29. Examples of such food might include a protein shake, a cola flavoured electrolyte drink, a snack bar or a ready to eat meal. The ingredients contributing to the macro nutrient profile of these foods are not specified and may include any safe and suitable pre-approved ingredients from categories listed under Std 1.1.1—10(5) or un-standardised ingredients. These ingredients, when assembled, comprise **“the food”**. The substances permitted as nutritive substances are listed in S29-19, whilst amino acids and vitamins & minerals are listed separately in S29-18 and S29—16, respectively. The inclusion of the amino acids and

vitamins & minerals in separate tables may suggest recognition that they may also be added for alternative purposes to a nutritional purpose.

It should also be noted that the definition does not provide an option for the “nutritional purpose” to be limited to specific groups of consumers, nor limit its use in the same food for other, non-nutritional, purposes. Thus a substance cannot be classified as “Used as a nutritive substance” when added to infant formula but not when added to a food for adults for exactly the same purpose. In addition, Vitamin C, Vitamin E and nucleotides may all also be used as food additives, antioxidants ascorbic acid and tocopherols, respectively, and flavour enhancers, regulated under Standard 1.3.1. Consequently, whilst designation of a substance as used as a nutritive substance applies to all foods to which it is added for the stated nutritional purpose, it does not prevent the same substance being added to the same foods or to other foods for an alternative purpose to the identified nutritional purpose.

- **Addition of lactoferrin the milk products**

Standard 2.5.1 – Milk subclause 2.5.1-4(ii) permits “milk components” to be added to “cows milk” provided that it “has the same whey protein to casein ratio as the original milk”. As a normal components of milk, this clause permits bovine lactoferrin to be added back to cows milk to replace that denatured by heat treatment or other processing.

Also the ACNF has provided that opinion that bovine lactoferrin is a “Normal constituent of bovine milk at 20-200 µg/mL (2-20 mg/100 mL)”. When added to bovine milk at 10-100 mg/100mL or 100 g it is a Traditional Food and is not a Novel Food.

In its Call for submissions – Application A1253 and Supporting document 1 (Risk, benefit and technical assessment – Application A1253), FSANZ identifies the health effects under consideration as:

- (i) a reduced the risk of bacterial and viral infection, and
- (ii) reduction in the severity and duration of infection in relevant animal infection models.

Clearly effect (i) is a “health effect” (i.e. immune support) rather than a nutritional effect. It is significant that FSANZ website indicates that 3 food business have already notified the same food-health effect relationship for lactoferrin.

Effect (ii) is a therapeutic effect, alleviation of a disease, not a health effect, and would not be suitable for a health claim on food. One again, it is not a nutritional purpose.

The conclusion drawn from this is that lactoferrin is being added as a normal component ingredient of cows milk, and, as such, it is a part of the milk product, i.e.” **the food**”, and is not a substance **used as nutritive substance** added to “**the food**”.

Since lactoferrin is already permitted to be added back to cows milk and no permission is required to add it in the context of the current application. It must be concluded that approval for it to be used as nutritive substance, for an undefined “nutritional purpose”, is not established by the application.

- **Compliance and enforcement**

The absence of a clear definition of “nutritional purpose” as used in the definition of Used as nutritive substance, as discussed above, exposes the standard to almost unlimited interpretation

and over reach, unless it is read along side the relevant overarching food act. Perhaps the most extreme, publicly acknowledged case of this overreach to date related to the determination, in 2007, that FOS and GOS were nutritive substances when added to infant formula but not, with no apparent justification, when added to foods for adults for the same purposes. In the subsequent court case, *New South Wales Food Authority vs Nutricia*, the judge identified this overreach in interpretation and commented that there was a ‘serious issue to be tried’ in relation to whether or not inulin was in fact to be considered a ‘nutritive substance’ or a ‘food’ for the purposes of the Australia New Zealand Food Standards Code.

The Office of Legislative Drafting and Publishing (OLDP) Food Standards Code audit report, prepared in response to proposals to expressly exclude FOS & GOS from the definition of used as nutritive substance (proposal P1025), identifies, in relation to “Issues arising from Nutricia judgement” & in response to the drafting instructions received from FSANZ, that “nutritional purpose” should be defined and also observed that the dictionary definition of nutrition: *‘the act or process of nourishing or being nourished...food; nutriment’* includes the word ‘food’ creating circularity that needs to be avoided in the definition. The OLDP audit report also noted that: *“It is sometimes not clear how fundamental concepts (such as substance, biologically active substance, nutritive substance, vitamins and minerals, component) relate to each other”*. Nonetheless, a definition of “nutritional purpose” is not included in the Code.

From a compliance and enforcement perspective, given that as discussed above, bovine lactoferrin:

- (i) may already be added to cows milk at up to 100mg/100ml or 100g, and
- (ii) when added to achieve a health effect, such as immune support, it is achieving a health purpose (immune support) not a nutritional purpose.

If bovine lactoferrin is identified as a substance **used as a nutritive substance** in the Code, it would be necessary to ensure that there is no ambiguity around the “nutritional purpose” for its addition. It would be important for FSANZ to ensure that this purpose was consistent with the original intent of the standard and did not conflict with or contradict other provisions of the Code, such as those relating to food compositional standards or other, non-nutritional, health effects, such as general level health claims about immune support.

- [Food businesses with products in development or already in the market](#)

The FSANZ website identifies that three business have already notified food-health effect relationship regarding bovine lactoferrin and immune support. There are also a number of bovine milk based food products already in the market containing added bovine lactoferrin and others under development. Unless it were very specific and clearly exempted health effects involving immune support, any approval of lactoferrin as a substances used as nutritive substance, could adversely affect these, and other, food businesses who are already selling or are developing Food Standard Code compliant safe and suitable milk products containing added bovine lactoferrin.

The FSANZ Act 1991 section 18 *Objectives of the Authority in developing or reviewing food regulatory measures and variations* does not provide any justification for the development of a food standard that removes competitors’, otherwise complaint safe and suitable, food products that meet existing standards, from the market for the sole commercial benefit of a paying applicant.

If FSANZ proceeds to approve bovine lactoferrin to be used as a nutritive substance the amendments to the Code should also make it clear that this does not overrule or conflict with the additional of it

to cows milk products permitted in Standard 2.5.1-4(ii), nor with addition of lactoferrin to foods to achieve a notified health effect.