Guidance on the Addition of Nutritive Substances Derived from Milk in Infant Formula Products

Interpretative Advice: Australia New Zealand Food Standards Code Standard 2.9.1
Issued: July 2012

Regulatory Requirements

The Australia New Zealand Food Standards Code regulates the use of nutritive substances in food, including in infant formula products. Generally, nutritive substances are not permitted to be added to food unless expressly permitted in the Food Standards Code (clause 9 of Standard 1.1.1).

Standard 2.9.1 – Infant formula products reaffirms this general prohibition in clause 6(1) but it has an additional phrase not present in Standard 1.1.1, the entire clause 6(1) is quoted below:

6 Restrictions and prohibitions
(1) A vitamin, mineral, food additive or nutritive substance must not be added to infant formula product unless –
(a) expressly permitted by this Code; or
(b) it is naturally present in an ingredient of the infant formula product.

Discussion
Addition of lactoferrin to infant formula products has been brought to the Ministry for Primary Industries' attention as an issue which needs to be clarified. The context of the issue is wider than lactoferrin and applies to any nutritive substance which is naturally present in milk (or any other ingredient for that matter that might be used to make infant formula products, such as soy products or vegetable oils). This advice will however focus on dairy ingredients. There are 2 points of view that have been identified regarding the interpretation of 6(1)(b) in Standard 2.9.1.

One point of view is that if a nutritive substance is already naturally present in an ingredient of the infant formula product (e.g. in the base milk powder) then its extracted from can be added to increase the amount of that substance beyond what is naturally present. "Naturally present" would mean that the source of the extracted nutritive substance being added to the infant formula product needs to be the same as the food ingredient in which it is naturally present. For instance lactoferrin can be found in a number of tissues and body fluids and can be produced transgenically, but any lactoferrin added to infant formula product would have to be derived from milk.

The second point of view is that if a non-approved nutritive substance is naturally present in an ingredient in infant formula product then no action is required on the part of the manufacturer to remove it, but the manufacturer cannot add more of that substance. Under this view, whatever lactoferrin is present in the base milk powder of a product is acceptable, but the manufacturer cannot add extracted lactoferrin to increase the level beyond what is naturally present in the base milk powder, even if the level in the base milk powder is less than is normally found in bovine milk.

If clause 6(1)(b) is considered in isolation both views could reasonably be arrived at.

The first point of view opens the infant formula standard to uncontrolled and potentially excessive addition of nutritive substances. Well-meaning, but not well informed, manufacturers could add a nutritive substance that, on the face of it, appears to be harmless and/or providing a potential benefit, but in fact the substance itself, or the levels at which it is added, presents a risk to infant health. Arguably the general requirements of the Infant Formula Standard, the Food Act, and principles of GMP around additives (only use that which is necessary to achieve the effect) would require the infant formula product to be safe and suitable, so any products found to be unsafe could be withdrawn and compliance action taken. However this is a food type that represents a sole or predominant source of nutrition for many infants; and infants are considered a vulnerable population group. Therefore, globally, there is a general consensus that a (fairly generous) measure of precaution is appropriate when considering changes to infant formula composition and there is a preference for safety and suitability to be demonstrated using a robust risk assessment process prior to placing the product on the market. Therefore the more liberal view runs

counter to the generally risk averse approach of many international standards and the Australia and New Zealand Food Regulation Ministerial Council Policy Guideline for Regulation of Infant Formula Products[1].

The second point of view would prevent standardisation of an infant formula within the range of what can be naturally present in the base food ingredient being used for Infant Formula, thus introducing the potential for compositional inconsistency between batches. At different times of the milking season the natural level of various milk constituents, including lactoferrin can vary quite substantially. It is reasonable for an infant formula manufacturer to want to achieve a consistent level of lactoferrin (and other natural milk constituents) across all batches of infant formula. Therefore addition of lactoferrin, when undertaken to achieve consistent levels across batches of a product line could be seen as a reasonable and sensible proposition. But the second point of view regarding the meaning of clause 6(1)(b) would prevent this.

In examining the ANZFA public consultation documents policy discussion and drafting notes around this particular clause of the infant formula standard it appears the more restrictive understanding of clause 6(1)(b) was intended. Some of these documents are available on the FSANZ website, and further documents can be requested from FSANZ. Manufacturers should however be familiar with the general purpose behind the infant formula standard, which is to have robust controls around infant formula composition. It may also be noted that Standard 2.9.1 provides specific permissions for the addition of several other 'milk' components. Examples include calcium, choline and vitamins and minerals. It could be argued that these express permissions would not be required if the more liberal view of clause 6(1)(b) was the intended interpretation.

It could be argued that, cow's milk is deficient in lactoferrin when compared to human breast milk (which contains approximately ten times the amount of cow's milk), and there may be some benefits to inclusion of lactoferrin in infant formula products. On the other hand overseas risk assessments related to categorisation of lactoferrin note bovine lactoferrin is not the same as human lactoferrin These risk assessments, and information from industry sources also suggest extracted lactoferrin may not have the same form, or ratio of forms, of lactoferrin that is found in unprocessed cow's milk, or in milk powder. These factors have lead to questions about the safety and suitability of bovine lactoferrin addition to infant formula products, and if safe to add – should there be limits applied? A formal risk assessment would allow a measured consideration of benefits versus risk of adverse health effects that may arise due to such factors as safety, bioavailability, any differences in form or function of the substance (compared to both the equivalent human breast milk component and unextracted component in the source ingredient), interactions with other ingredients and product stability factors. This is beyond the scope of this guidance.

Ministry for Primary Industries Current Position and Guidance

MPI acknowledges the ambiguity of clause 6(1)(b) when read without the background policy and drafting context, i.e. that both the liberal and restrictive interpretations are plausible. MPI also takes the view that the more restrictive interpretation of this clause is the one most consistent with the general purpose of the Food Standards Code, and the infant formula standard in particular, and is the one most consistent with the drafting and policy documents behind this standard. MPI will be seeking to have this clause clarified to make this intent clearer in the text of the infant formula standard thus no longer leaving room for disparate interpretation.

FSANZ is proposing to conduct a comprehensive review of Standard 2.9.1 in the near future. As part of the infant formula standard review MPI encourages infant formula manufacturers to identify those milk derived nutritive substances, like lactoferrin, which are seen as important for improving the nutritional quality of infant formula products. Manufacturers should then submit, with appropriate scientific justifications, applications to FSANZ for express permissions for these nutritive substances to be included in the updated infant formula standard (although it should also be noted that such applications can be made at any time, and manufacturers may choose to seek amendment of the current standard rather than wait for completion of the review).

Until the infant formula standard is revised, MPI advises that infant formula manufacturers may be producing outside the intent of the food standards code if they add milk derived nutritive substances as separate ingredients to infant formula products. Their products may also be in breach of the explicit text of the code when it is revised, unless the nutritive substances they are adding have been given express permission in the infant formula standard.

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[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/00E8A0712A1A5C3BCA2578A7007FBE77/$File/Policy%20Guideline%20on%20the%20Regulation%20of%20Infant%20Formula%20Products.pdf