Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Letter to Industry: Requirements Related to Nutrition Information and Nutrition and Health Claims for Infant Formula

January 8, 2007

Purpose

The Canadian Food Inspection Agency (CFIA) and Health Canada (HC) would like to clarify the requirements related to nutrition information and nutrition and health claims for infant formula (human milk substitutes).

The amendments to the *Food and Drug Regulations* (FDR) pertaining to Nutrition Labelling, Nutrient Content Claims and Diet Related Health Claims came into force on December 12, 2005. The new nutrition labelling provisions (i.e. the Nutrition Facts table) do not apply to infant formula since there are specific labelling requirements set out in the FDR for these products. However, the requirements and restrictions under the *Food and Drugs Act and Regulations* with respect to nutrient content claims and health claims do apply, with additional specific provisions and restrictions indicated in the FDR. This letter outlines the provisions for nutrition information and nutrient content and health related statements and claims for infant formula.

Compliance with Canadian Legislation

It is the responsibility of all manufacturers, importers and distributors of infant formula to ensure that their products comply with Canadian legislation and other relevant guidelines and policies. The CFIA and Health Canada also strongly urge the infant formula industry to support and implement the principles of The *International Code of Marketing of Breastmilk Substitutes*.

The distribution of this letter is intended to assist manufacturers and distributors of infant formula to understand the FDR and to make any necessary changes and corrections to the labelling and advertising of their products. Product labels and advertisements for infant formula are expected to be in compliance by April 10, 2007, after which date the CFIA will be conducting a nationwide inspection initiative to verify compliance with the *Food and Drugs Act and Regulations.*

Nutrition Labelling

The labelling requirements for infant formula are set out in Division 25 of the *Food and Drug Regulations* [B.25.057]. These requirements are different from those of the Nutrition Facts table appearing on other food products. The titles "Nutrition Facts", "Valeur nutritive" or "Valeurs nutritives" cannot be used on the labels of infant formula. [B.01.401 (4) & (5), FDR]. In addition, the nutrition information for infant formulas cannot include the percentage of the daily value of fat; saturated fat and trans fat; sodium; potassium; carbohydrate; fibre or cholesterol; or the number of Calories from fat or saturated and trans fat. [B.25.059]

The label of an infant formula must declare per 100 grams or 100 millilitres as sold and per stated quantity when ready to serve: the content of protein, fat, available carbohydrate, ash, and when present, crude fibre, in grams; the energy value in Calories; the amount of vitamins and mineral nutrients listed in table II to Division 25 in International Units or milligrams; and the content of choline and any added nutritive substance normally contained in human milk (e.g., nucleotides, DHA and ARA) in grams or milligrams. [B.25.057]

Nutrient Content Claims and Statements

All infant formula is subject to specific mandatory nutrient requirements set out in the FDR [Division 25]. It is therefore considered inappropriate and misleading to use nutrient content claims as these imply that the product for which the claim is made is superior to another infant formula. This includes those claims that compare the content of a particular nutrient in one formula to that of another formula, e.g., claims that an infant formula is the “highest” in a particular nutrient may not be made.

Health Canada’s policy is that nutrient content claims are only acceptable for formulas represented solely for infants 6 months of age or older (i.e. follow-up formulas). The reason for this is that follow-up formulas contain higher levels of some nutrients, such as calcium, to meet the needs of the older infant and nutrient content claims serve to differentiate between starter and follow-up formulas. Statements are allowed with regard to the iron content of an infant formula, if the formula contains at least 1 mg of iron per 100 Calories. These statements are allowed because traditionally there were infant formulas with low and high amounts of iron.

It is Health Canada’s intention to formalize this policy with regard to nutrient content claims by setting out new requirements in the proposed regulatory amendments for the addition of vitamins and mineral nutrients to foods.

If a permitted nutrient content claim is made on the label of an infant formula it must appear in both English and French.

Representations Pertaining to Presence of Specific Fatty Acids

Prior to the promulgation of the December 2002 amendments pertaining to Nutrition Labelling, Nutrient Content Claims and Health Claims, the FDR allowed statements or claims to be made regarding the presence of specific fatty acids in infant formula. It is intended to continue to allow statements regarding the presence of specific fatty acids in infant formula particularly to differentiate products with and without added sources of the long chain fatty acids, docosahexaenoic (DHA) and arachidonic (ARA), whose addition to formulas is not mandatory. For example, the statement “with added DHA (an omega-3 fatty acid) and ARA (an omega-6 fatty acid)” would be acceptable. However, since all infant formulas are required to contain linoleic acid, an omega-6 fatty acid, and alpha-linolenic acid, an omega-3 fatty acid, it is important that statements regarding the content of “omega-3" and “omega-6" fatty acids do not in any way imply that DHA and ARA are the only omega-3 and omega-6 fatty acids in an infant formula.

References to Breast Milk

The *International Code of Marketing of Breastmilk Substitutes*, to which Canada is a signatory, outlines labelling principles that promote clear labelling regarding the appropriate use of an infant formula while promoting breastfeeding. Comparing infant formula to breast milk, including comparisons of the levels of a nutrient in infant formula to the levels of the same nutrient in breast milk, is contrary to the message embodied in the *Code*. While the *Code* has not been incorporated into Canadian domestic legislation, the infant formula industry is encouraged not to make a reference to breast milk on a label or advertising of infant formula, other than a statement regarding the superiority of breastfeeding or that breast milk is the optimal method of feeding infants.

Also, highlighting an ingredient in infant formula as a key component of breast milk is considered misleading and is contrary to section 5(1) of the *Food and Drugs Act* as many components in breast milk are equally important.

Biological Role Claims

Biological role claims are claims that refer to the generally recognized nutritional function of energy or nutrients as an aid in maintaining the normal functions of the body for the maintenance of good health, or for normal growth and development. Provisions for biological role claims are found in section B.01.311 of the *Food and Drug Regulations*.

Biological role claims are not allowed for a food or for an ingredient in a food; they can only be made regarding the energy value or nutrients in a food. An acceptable biological role claim would be:

“DHA and ARA support normal brain and eye development”

It is important to note that biological role claims relate to the **normal** function of the body.

Claims to the effect that a relationship exists between a nutrient in a food and an aspect of health beyond normal function (i.e., beyond the normal function of the body necessary for the maintenance of good health and development), would be considered to be health claims rather than biological role claims. Consequently, the inclusion of the word “normal” in the above example is essential to ensure the integrity of this biological role claim.

A biological role claim **cannot** refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or symptoms of same, **nor can it** refer directly or indirectly to correcting, restoring or modifying organic functions. In addition, the claim cannot refer directly or indirectly to the treatment, prevention or cure of diseases listed in Schedule A of the **Food and Drugs Act**, [subsection 3(1)].

A list of acceptable biological role claims may be found in section 8.5 of the 2003 Guide to Food Labelling and Advertising.

Health Claims

The use of health claims on food labels and in advertising of foods including infant formulas is limited by the **Food and Drugs Act**. Although the **Food and Drug Regulations** currently allow five diet-related health claims on food labels, these are not permitted on foods for children under two years of age, including infant formulas. The dietary recommendations that lay the foundation for these claims are for adults and are not appropriate for infants and young children.

While health claims are not allowed for infant formula, indications for the use of formulas which, for example, identify products for the dietary management of medical conditions such as aminoacidurias and disorders of mineral metabolism, would be considered acceptable. However, it should be noted that any new appropriate indication for use without a long history of documented use would need to be supported by data from clinical studies performed with the specific infant formula. The data that would be required to support an indication for the use of an infant formula would be subject to the same standards of evidence required for health claims. In this regard, please consult the Interim Guidance Document - Preparing a Submission for Foods with Health Claims: Incorporating Standards of Evidence for Evaluating Foods with Health Claims.

Manufacturers of infant formula are required to submit to Health Canada the written text of all labels and package inserts as part of the mandatory pre-market notification of new and changed infant formulas. While subsequent label revisions of infant formula by the manufacturer do not now require government notification, it is the intention of Health Canada to consider an amendment to the **Food and Drug Regulations** to also require pre-market notification when there are changes made to an existing indication for the use of an infant formula or to any statements or claims, or when a new indication, statement or claim is proposed in labelling or advertising.

Other Claims

Claims or statements that help to distinguish between formulas or to identify a specialized infant formula by describing its ingredient composition, e.g., "protein hydrolysate", "lactose-free", "soy", are generally considered acceptable.

Pictorials

The *International Code of Marketing of Breastmilk Substitutes* also recommends that labels do not carry pictures of infants on the container or label of infant formula. The infant formula industry is encouraged to support the *Code* and refrain from displaying pictures of infants or young children on labels or advertisements for infant formula. All other pictorial representations should meet the guidelines set out in the *2003 Guide to Food Labelling and Advertising*.

Advertising

All advertising for infant formula should comply with all the above provisions. This includes advertisements in magazines, websites, advertising flyers, shelf talkers, and advertisements and pamphlets displayed in physicians' offices and hospitals. All manufacturers, importers and distributors of infant formula must employ due diligence to ensure that retail stores and outlets producing advertising for their products respect these provisions.

More information on labelling and advertising is available in the 2003 Guide to Food Labelling and Advertising.

Thank you for your continued cooperation.

Sincerely,

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