Frequently asked questions

This list of frequently asked questions (FAQs) is a guidance to assist the food industry to better understand the scope of the amendments to the Food Regulations regarding labelling and advertising for infant formula.

This is a guidance document and is not intended to gather views/comments to the answers for the questions.

Contents

Scope of the amendments to the Food Regulations

1. <u>What are the regulatory amendments regarding the labelling and advertising for infant formula?</u>

The scope of the amendments to the Food Regulations relating to the labelling and advertising of infant formula is summarised below.

- Certain types of claims or representations will **not** be allowed on the label or advertisement of infant formula; these include:

  (i) a claim which states, suggests or implies that the infant formula[1] has, or may have, a health effect[2]*;

  (ii) a claim which compares the infant formula to breast milk;

  (iii) any of the following:

  - a representation of an infant or infants (whether or not accompanied by text);
  - a representation of a pregnant woman or nursing woman (whether or not accompanied by text);
  - a word like “humanised” or “maternalised”, or words of similar import;
  - a claim which idealises the use or effect of the infant formula

  (iv) a claim which states, suggests, or implies the energy, carbohydrate and other nutritive property of any ingredient of the infant formula, other than those listed under Regulation 252(5) and (6) of the Food Regulations; and

  (v) a claim which states, suggests, or implies that the infant formula is enriched or fortified, or is an excellent source of the ingredients listed under Regulation 252(5) and 252(6) of the Food Regulations.

[1] For the purpose of this document, the term “infant formula” also includes any component, ingredient, constituent, or any other feature of the infant formula.

[2] Please refer to question 6 for a more detailed explanation on “health effect”.

- The label on any package for infant formula will be **required** to contain:

  (i) statements, preceded by the words “Important Notice” or words of similar import, to ensure that consumers understand that
    - breastmilk is best for infants; and
    - infant formula should be used on the advice of a doctor or healthcare practitioner; and

  (ii) a warning statement about the health hazards of improper use, preparation or storage of infant formula.

- The label on infant formula sold or to be sold as lactose free, low lactose or words of similar import will be **required** to contain:
  (i) a total lactose content not greater than 10 mg per 100 kcal;
  (ii) the words “lactose free” or “low lactose” or words of similar import;
  (iii) a nutrition information panel on the label, specifying the exact amount of lactose in the infant formula; and
  (iv) the words “Not suitable for infants with galactosaemia”.

- A label on any package of any infant formula, or an advertisement about any infant formula, may contain a claim which states, suggests or implies the presence of hydrolysed milk protein or whey protein in the infant formula.

The draft legal text of the amendments to the Food Regulations regarding labelling and advertising of infant formula is available at www.sfa.gov.sg/legislation.

2. What is an infant formula?

Under Regulation 252 of the Food Regulations, infant formula shall be any food described or sold as an alternative to human milk for the feeding of infants. It shall be a product prepared from milk of cows or other animals or both or from other edible constituents of animals, including fish, or plants and which have been proved suitable for infant feeding. The said Regulations define infants as a person not more than 12 months of age.

Some examples of infant formula include soy formula, hydrolysed milk protein formula, whey protein formula and milk formulas without lactose, that are labelled to be formulated for infants 0 to 12 months of age.

3. Do the regulatory amendments apply to infants’ food?

The new regulatory amendments only apply to infant formula (*as defined under Regulation 252 of the Food Regulations* – refer to question 2). It is not applicable to other infants’ foods intended for feeding infants as a complementary food from over the age of 6 months, such as cereals and fruit puree.

4. Do the regulatory amendments apply to formula for special medical purposes intended for infants?

The regulatory amendments currently do not apply to Formula for Special Medical Purposes intended for Infants[3]. This product refers to a formula in liquid or powdered form intended for use:

(i) as a substitute for human milk or infant formula that complies with Section 2, Description[4], of the Codex Standard for the labelling of and claims for foods for special medical purposes (Codex Stan 180-1991); and

(ii) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

Some examples include formula for infants with metabolic diseases (e.g. maple syrup urine disease) or formula for premature/low birth weight infants.

5. Would companies with existing stocks be allowed to exhaust their products in the market after the grace period?

The regulatory amendments are targeted to be gazetted by September 2019. The industry will be given a 12-month grace period, to comply with the new regulations.

Prohibition on use of claim which states, suggests or implies that the infant formula has, or may have, a health effect

6. Is there a definition for "health effect"?

"Health effect" means an effect on the human body, including an effect on one or more of the following:

(a) growth and development;
(b) physical performance;
(c) mental performance;
(d) a biochemical process or outcome;
(e) a physiological process or outcome;
(f) a functional process or outcome.

[3] Codex Standard on Formula for special medical purposes intended for infants (Codex Stan 72-1981)

[4] ***Foods for special medical purposes*** are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

7. What are some examples of claims regarding health effect which are prohibited under this regulatory amendment?

In principle, claims regarding health effect envisioned under the amended Food Regulations, are intended to correspond to "health claims" as defined under the "Codex Guidelines for Use of Nutrition and Health Claims", established by the international food standards-setting body, the Codex Alimentarius Commission.

Some examples of prohibited claims regarding health effect are:

(i) Nutrient function claims that include:

- "Choline helps support overall mental functioning"
- "Iron supports the child's natural defences"
- "Zinc helps in physical development"
- "Zinc supports the child's natural defences"

(ii) Other function claims which include:

- "DHA and ARA are important building blocks for development of the brain and eyes in infant"
- "Nucleotides support body's natural defences"
- "Nucleotides are essential to normal cell function and replication, which are important for the overall growth and development of infant"
- "Taurine helps to support overall mental and physical development."
- "Oligofructose (fructo-oligosaccharides) stimulates the bifidobacteria, resulting in a significant increase of the beneficial bifidobacteria in the intestinal tract. At the same time, the presence of less desirable bacteria is significantly reduced."
- "Prebiotic promotes the growth of good *Bifidus* bacteria to help maintain a healthy digestive system."
- "Prebiotic blend (galacto-oligosaccharides and long chain fructo-oligosaccharides) support the child's natural defences."
- "Probiotics to help maintain a healthy digestive system"
- "Probiotics helps in digestion."
- "Probiotics helps to maintain a desirable balance of beneficial bacterial in the digestive system."
- "Probiotics helps to suppress/fight against harmful bacteria in the digestive system, thereby helping to maintain a healthy digestive system."
- "Probiotics"/ "Prebiotics"

(iii) Claims implying health effects such as :

- Words in any languages, singly or with affix
  - "proBone", "XtraCare", "HappiTummi", "HealthGuard"
- Acronyms and/or "sounds-like"
  - "e-mune" sounds similar to "immune"
  - "ez" sounds similar to "easy"
  - "dzgest" sounds similar to "digest"

- Words or pictorial representations[5], which includes but not limited to human anatomy and medical equipment, implying the prevention, alleviation or curing of any disease and conditions affecting the body
- "Clinically proven", "Expert Care"
- "Sensitive", "Gentle", "Hypoallergenic", "Comfort"
- "Risk of allergy", "For fussiness, gas"

8. <u>Can approved claims regarding health effect that were applicable to both infants and young children continue to be used on labels and advertisements of food intended for consumers more than 12 months of age?</u>

Yes, claims regarding health effect that are currently approved for use on products intended for consumers more than 12 months of age can continue to be used on the labels and advertisements of these food. However, traders should, in no way, relate these claims to infants.

SFA will be updating the Guide to Food Labelling and Advertisement to reflect the changes once the amendments to the Food Regulations are gazetted.

9. <u>Can the approved claims regarding health effect be used on formula that is labelled for consumers with an age ranging from infant to young children (i.e. more than 12 months of age), with a qualifying statement to indicate that the health claim is only applicable for consumers more than 12 months of age?</u>

No. The prohibition of claims regarding health effect applies to all infant formula (0 – 12 months). As the product in question is claimed to be suitable for consumption by consumers within the age group of 0 to 12 months, it is considered as an infant formula. Therefore, it is required to meet the safety standards and labelling requirements (including the new requirements) for infant formula.

10. <u>Are the claims regarding the presence of "probiotics"/ "prebiotics" in general terms (without identifying the specific identities) considered as claims regarding health effect that are prohibited?</u>

Not all microorganisms and food constituents can be claimed for their probiotics/prebiotics effects. In order to qualify as a "probiotic"/ "prebiotic", these substances have to confer a beneficial health effect. Therefore, the claims regarding the presence of "probiotics"/"prebiotics" in general terms (without specifying the specific identities) would be prohibited (see question 11 below for further explanation).

[5] For the purpose of this document, "pictorial representation" includes a graphic representation and an anthropomorphic or humanlike depiction.

11. Can we claim for the presence of the microorganisms or food substances added, for example, "*Lactobacillus reuteri*"/ "inulin"?

Yes. The claim on the presence of the microorganisms and optional ingredients (refer to question 18) with the declaration of their exact identities are allowed. However, traders should not suggest any health effects of these substances.

12. Are claims like "intelligent", "bright", "clever", "smart" prohibited on infant formula products?

Text claims that relate to intellectual potential such as "intelligent", "bright", "clever", "smart", or pictorial representations such as mortar board, graduation gown etc, would be regarded as claims implying certain health effect, and are therefore prohibited for use on infant formula.

Prohibition on use of other claims

13. What are some examples of claims which directly or indirectly compare infant formula to breast milk?

Examples of claims which directly or indirectly compare infant formula to breast milk include: "moving on from breastfeeding", "closer to/inspired by breastmilk", "{name of ingredient} sourced/obtained from breastmilk", or "{*name of ingredient*} similar to breastmilk".

14. What are some examples of claims which idealise the use or effect of infant formula?

Examples include:

(a) representations which suggest or imply that the use or consumption of the infant milk formula results in exaggerated health or other effect; and

(b) claims, which suggest that the infant formula is the ideal source of food for infants, for example, "the best" or "the ideal method of infant feeding", "complete nutrition", "provides balanced nutrition".

In addition, companies must ensure that information about the appropriate use of the products (i.e. method of preparing the formula) must not discourage breast feeding.

15. Are baby or child related subjects (e.g. cots or young animals) and anthropomorphic characters allowed on labels of infant formula?

Baby related objects like baby cot, pram, bassinet, mittens, socks, rattle, rocking chair, young animals are allowed, provided that they do not suggest any of the claims prohibited by the Regulations.

16. <u>Referring to the regulation (within the text box) below, what nutrients are covered under the prohibition?</u>

Certain types of claims or representations will **not** be allowed on the label or advertisements of infant formula; these include • a claim which states, suggests, or implies the energy, carbohydrate and other nutritive property of any ingredient of the infant formula, other than those listed under Regulation 252(5) and (6) of the Food Regulations

Claims with respect to the nutrients specified under regulation 252(3) of the Food Regulations must not be made. The list of nutrients is as tabulated below.

1. Protein	10. Folic acid	19. Calcium
2. Fat	11. Pantothenic acid	20. Phosphorus
3. Vitamin A	12. Vitamin B12	21. Magnesium
4. Vitamin D	13. Vitamin K1	22. Iron
5. Vitamin C	14. Vitamin H	23. Iodine
6. Vitamin B1	15. Vitamin E	24. Copper
7. Vitamin B2	16. Sodium	25. Zinc
8. Nicotinamide	17. Potassium	26. Manganese
9. Vitamin B6	18. Chloride	27. Selenium

Based on the tabulated list of nutrients, claims regarding <u>specific nutrients</u> such as “Contains vitamin D”, “HiCal”, which is interpreted as high in calcium; as well as <u>generic claims</u> to describe group/blend of these nutrients such as “Contains essential nutrients”, “Added with vitamins”, “Antioxidants”, “Nutriblend”, “System of nutrients”, are not allowed.

In addition to the tabulated list, <u>claims with respect to energy and carbohydrate</u> are also not allowed.

17. <u>Referring to the regulation (within the text box) below, what are the examples of acceptable and non-acceptable claims?</u>

Certain types of claims or representations will **not** be allowed on the label or advertisements of infant formula; these include • a claim which states, suggests, or implies that the infant formula is enriched or fortified, or is an excellent source of the ingredients listed under Regulation 252(5) and 252(6) of the Food Regulations.

Claims with respect to the *<u>presence</u>* of ingredients specified under regulations 252(5) and 252(6) of the Food Regulations are permitted. The list of nutrients is tabulated below.

1. Essential amino acids in natural L forms: • Isoleucine • Leucine • Lysine • Methionine • Phenylalanine • Threonine • Tryptophan • Valine	2. Nucleotides • Cytidine 5'-Monophosphate • Uridine 5'-Monophosphate • Adenosine 5 -Monophosphate • Guanosine 5'-Monophosphate • Inosine 5'-Monophosphate	3. Long chain polyunsaturated fatty acids [including docosahexaenoic acid (DHA) and arachidonic acid (AA)] 4. Galacto-oligosaccharides (GOS) 5. Long chain inulin 6. Oligofructose produced from inulin 7. polydextrose 8. Bovine lactoferrin 9. Beta-palmitin 10. 2'-fucosyllactose (2'-FL) 11. Lacto-N-neotetraose (LNnT)

However, the claims made on the presence of these ingredients should not in any way imply that the infant formula is *<u>enriched, fortified, or is an excellent source</u>* of these ingredients. Companies must also ensure that no references to breast milk should be made.

Some examples are tabulated below:

Acceptable claims	Non-acceptable claims
• "Contains DHA" • "Contains GOS"" • "With inulin" • "Added with GOS" • "Added with *Bifidobacterium lactis* {*must specify the exact species*}"	• "High/Rich in DHA" • "XX% higher in GOS/ More GOS" • "Rich source of inulin" • "Added with prebiotic* (GOS)" • "Added with probiotics*"

* Refer to question 10 *for explanation regarding use of the terms 'prebiotic' and 'probiotics'.*

18. Would the declaration of nutrients under the nutrition information panel and statement of ingredients be prohibited?

No. In general, the declaration of nutrition information panel (NIP) and statement of ingredients would not be prohibited.

It is a requirement for infant formula to be declared with a NIP, stating the amounts of the essential nutrients, and statement of ingredients listing all ingredients and additives use in the product.

19. Referring to the regulation (within the text box) below, does "words of similar import" include claims like "Lower lactose" and "Reduced lactose"?

The label on infant formula sold or to be sold as lactose free, low lactose or words of similar import **will be** required to contain:

(i) a total lactose content not greater than 10 mg per 100 kcal;
(ii) the words "lactose free" or "low lactose" or words of similar import;
(iii) a nutrition information panel on the label, specifying the exact amount of lactose in the infant formula; and
(iv) the words "Not suitable for infants with galactosaemia".

No. Claims like "lower lactose" and "reduced lactose" are nutrient comparative claims that compare the lactose level of two or more foods. The use of such comparative terms, which include "reduced", "less than", "fewer", "increased", "more than", to indicate the lactose content of infant formula, is not acceptable.

If food traders would like to communicate on the lactose content of the infant formula, only claims such as "lactose free" or "low lactose" may be used provided that

(i) the total lactose content in the product is not greater than 10 mg per 100 kcal;
(ii) a nutrition information panel is declared on the label, specifying the exact amount of lactose in the infant formula; and
(iii) a statement indicating the product is not suitable for infants with galactosaemia is declared. This statement must be in the same font size and prominence as the statement on the absence of lactose and in close proximity to it. An example of this statement is "Not suitable for infants with galactosaemia".

20. If the infant formula contains a total lactose content of more than 10mg in per 100kcal, can statements like "Suitable for lactose intolerance" be allowed?

No. Statements to indicate that the infant formula is suitable for infants with lactose intolerance are only allowed if the product contains a total lactose content not greater than 10mg in per 100kcal.

This is to protect consumers so that purchasers do not [self-prescribe] and purchase infant formula based on claims (*e.g. Suitable for lactose intolerance*) made on the labels.

21. Can the product descriptor "Extensively hydrolysed infant formula" be used for infant formula containing hydrolysed milk protein isolate?

Currently, there is no legal and internationally recognised definition for "extensively hydrolysed infant formula". Companies should bear the responsibility to justify and explain to consumers the differences between 'extensively hydrolysed protein' and 'partially hydrolysed protein'.

In addition, claims to suggest that such formulas are suitable for infants with potential to develop allergy or infants with allergy, for example "hypoallergenic", is prohibited (refer to question 7).

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