

## AMENDMENTS TO THE FOOD REGULATIONS REGARDING LABELLING AND ADVERTISING FOR INFANT FORMULA: *Frequently asked questions*

This list of frequently asked questions (FAQs) is a guidance to assist the food industry to better understand the public consultation paper on the proposed amendments to the Food Regulations regarding labelling and advertising for infant formula, which is currently posted on the REACH portal and on AVA's website.

This set of FAQs addresses common questions about the regulatory amendments and considerations regarding infant formula.

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

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## 1. 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 Regulations define infants as a person not more than 12 months of age.

## 2. Do the regulatory amendments apply to infant foods?

No. The amendments only apply to infant formula (*as defined under regulation 252 of the Food Regulations – refer to question 1*). They are not applicable to other infant foods such as cereals and fruit puree.

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

The target gazettal date of the proposed amendments is January 2018. The industry will be given a 12-month grace period, up to January 2019, to comply with the new regulations.

Companies are encouraged to start planning and preparing new stocks that may be sold after the 12 months' grace period, that is Jan 2019, so as to be in compliance with the new requirements.

## Prohibition of use of health claims

## 4. What is a health claim?

AVA adopted the definition for health claim endorsed by the Codex Alimentarius Commission, the international food standards-setting body. Under the "Codex Guidelines for Use of Nutrition and Health Claims", "health claims" means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims commonly found on infant formula include:

- (i) Nutrient function claim - refers to nutrition claims that describe the physiological role of the nutrient in growth, development and normal functions of the body.
- (ii) Other function claim - refers to claims concerning specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body, and relating to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

## 5. What are examples of prohibited (health) claims?

Health claims that will not be allowed to be used on labels and advertisements of infant formula are broadly grouped into the following three types:

### (i) Nutrient Function Claims

Examples:

- "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"

### (iii) Other Function Claims

Examples:

- “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) Implied Health Claims (you may refer to [Guidelines on use of signs with implied claims on food labels and advertisements](#)):

Examples:

- 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 illustrations, 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”

**6. Can approved health claims that were applicable to both infants and young children continue to be used for milk formula for consumers more than 12 months of age?**

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

AVA will be updating the Guide to Food Labelling and Advertisement to reflect that accordingly.

**7. If the formula is specified for consumers from 6 months to 2 years old, can approved health claims be used? If not, can statements to indicate that the health claim is applicable for consumers more than 12 months of age be used?**

No. The prohibition of health claims applies to all infant formula (0 – 12 months). As the product in question is claimed to be suitable for consumption by consumers from 6 months onwards, it is considered as an infant formula and is required to meet the requirements (including the new requirements) for infant formula.

**8. Why are the terms “probiotics”/ “prebiotics” considered as health claims, and cannot be used?**

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 effects. Therefore, these terms are regarded as health claims.

**9. Instead of claiming for presence of “probiotics”/ “prebiotics”, 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 16) with the declaration of their exact identities are allowed. However, traders should not make any reference to the health effects of these substances.

**10. What if the brand name of infant formula implies a health claim? Must the brand name be removed?**

Companies should not be using brand names that imply any claims that are prohibited by the Food Regulations.

**Prohibition on idealisation of infant formula**

**11. What are examples of prohibited claims that compare infant formula to breast milk?**

The claim must not make reference to:

- (i) “breastmilk”, “breastfeeding”, “moving on from breastfeeding”, “closer to/inspired by breastmilk”, “{name of ingredient} sourced/obtained from breastmilk” or “{name of ingredient} similar to breastmilk”.
- (ii) terms such as “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.

**12. Does the prohibition of pictorial or graphic representation of pregnant women, nursing women, infants, young children or carers include cartoon illustrations?**

Yes. The following are examples of representations which are considered to ‘idealise’ the use of infant formula when used on labels and advertisements of infant formula:

- Pictorial or graphic representation of nursing mothers, pregnant women, infants, young children or carers (e.g. mothers or fathers).
- Pictorial or graphic representation or text which implies that infant health, happiness, well-being or enhanced abilities (e.g. intellect); or the health, happiness and wellbeing of carers, is associated with infant formula.

**13. What are types of examples that imply infant health, happiness, well-being or enhanced abilities (e.g. intellect) is associated with infant formula?**

Description	Examples
Infant's health	Words like, 'healthy' and 'strong'. Pictures or illustrations depicting 'defence against germs'
Infant's happiness	Words like, 'happy', 'pleased' and 'glad'.
Infant's well-being	Words like, 'comfort', 'relieved' and 'relief'.
Infant's enhanced abilities	Words like, 'smart', 'bright' and 'clever', and letter 'A'. Pictures like 'mortar board' and 'graduation gown' that suggest intelligence potential.

**14. 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 are allowed.

Companies must be mindful to ensure that graphic representations including anthropomorphic characters do not refer or allude to any of the following representations:

- Pictorial or graphic representation of nursing mothers, pregnant women, infants, young children or carers (e.g. mothers or fathers).
- Pictorial or graphic representation or text which implies that infant health, happiness, well-being or enhanced abilities (e.g. intellect); or the health, happiness and wellbeing of carers, is associated with infant formula.

**Prohibition and restriction on use of nutrition claims**

**15. What is the list of nutrients that cannot be claimed on the labels and advertisements of infant formula?**

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 on specific nutrients such as "Contains vitamin D", "HiCal", which is interpreted as high in calcium; as well as generic claims 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, claims with respect to energy and carbohydrate are also not allowed.

For clarity in explaining the rationale of this set of regulatory amendment for infant formula, this group of nutrients will be termed as "essential nutrients" (refer to question 17).

**16. What is the list of nutrients that can be claimed on the labels and advertisements of infant formula?**

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

<p>1. Essential amino acids in natural L forms:</p> <ul style="list-style-type: none"> <li>• Isoleucine</li> <li>• Leucine</li> <li>• Lysine</li> <li>• Methionine</li> <li>• Phenylalanine</li> <li>• Threonine</li> <li>• Tryptophan</li> <li>• Valine</li> </ul>	<p>2. Nucleotides</p> <p>3. Long chain polyunsaturated fatty acids [including docosahexaenoic acid (DHA) and arachidonic acid (AA)]</p> <p>4. Galacto-oligosaccharides (GOS)</p> <p>5. Long chain inulin</p> <p>6. Oligofructose</p> <p>7. Bovine lactoferrin</p> <p>8. Beta-palmitin</p>
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It is paramount to note that claims for these ingredients should not in any way imply that the infant formula is enriched, fortified, or is an excellent source of these ingredients. Companies must also ensure that no references should be made against breastmilk.

Some examples are tabulated below:

Acceptable claims	Not acceptable to be used
<ul style="list-style-type: none"> <li>• “Contains DHA”</li> <li>• “Contains GOS”</li> <li>• “With inulin”</li> <li>• “Added with GOS”</li> <li>• “Added with <i>Bifidobacterium lactis</i> {must specify the exact species}”</li> </ul>	<ul style="list-style-type: none"> <li>• “High/Rich in DHA”</li> <li>• “XX% higher in GOS/ More GOS”</li> <li>• “Rich source of inulin”</li> <li>• “Added with prebiotic* (GOS)”</li> <li>• “Added with probiotics”</li> </ul>
<p>* Refer to question 8 for explanation regarding use of the terms ‘prebiotic’ and ‘probiotics’.</p>	

For clarity in explaining the rationale of this set of regulatory amendment for infant formula, this group of nutrients will be termed as “optional ingredients” (refer to question 17).

**17. Why are claims on “essential nutrients” prohibited, while claims on the presence of “optional ingredients” allowed?**

All infant formula sold in Singapore must contain all the basic nutrients at the levels stipulated under the Food Regulations (i.e. “essential nutrients”). Thus claims made with respect to these nutrients are of little value to consumers and are not necessary.

Other ingredients (i.e. “optional ingredients”) may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies. Companies must ensure that no references should be made against breastmilk.

Claims on the presence of these optional ingredients are allowed to help consumers make informed choices.

This approach strikes a balance between providing information to help consumers make informed choices and excluding information that could be redundant to consumers.

**18. Are “Low lactose” and “Reduced lactose” claims allowed?**

These claims are not allowed as there is no international or national standard on the criteria for the use of these claims. Currently, only claims on the absence of lactose like “Lactose free”/ “Zero lactose” may be used if the following requirements are fully complied with:

- The total lactose content is not greater than 10mg in per 100kcal;
- The exact amount of lactose in the product is declared under the nutrition information panel on the label; and
- A statement indicating the product is not suitable for general use and should be used under medical supervision.

An example of this statement is as below:

Not suitable for general use and should be used under medical supervision

This statement is not prescriptive and other words with the same intent may be used.

**19. Can statements like “Suitable for lactose intolerance” be allowed if the infant formula does not meet the requirements for use of the claim “lactose free” (i.e. contains a total lactose content of more than 10mg in per 100kcal)?**

Claims on special suitability of the infant formula like “suitable for lactose intolerance” are not encouraged.

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

**20. Can the product descriptor “Extensively hydrolysed infant formula” be used for infant formula containing hydrolysed milk protein isolate?**

Currently, there is no legal and international definition for “extensively hydrolysed infant formula”. Companies are responsible for justifying and explaining to consumers the differences between ‘extensively hydrolysed protein’ and ‘partially hydrolysed protein’. All infant formula containing hydrolysed milk protein isolate (*whether it is partially or extensively hydrolysed*) must include the following labelling information on the label. This is to ensure that parents do not self-diagnose.

- A statement indicating that the product is not suitable for general use and should be used under medical supervision; and
- the following statements or other words of similar meaning are included on the label.

Infant formulas containing partially/extensively hydrolysed protein **should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms.** If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby’s care and feeding choices should be under a doctor’s supervision.

This statement is not prescriptive and other words with the same intent may be used.

In addition, claim of "hypoallergenic" would not be allowed to be used on a milk formula added with partially/extensively hydrolysed protein ([refer to question 5](#)).

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