GUIDELINES TO INDUSTRY AND HEALTH CARE PERSONNEL: THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN,

R. 991 OF 6 DECEMBER 2012 ("REGULATIONS")

These guidelines represent the National Department of Health's (NDOH's) view on how the Regulations should be interpreted. This document has been produced to provide advice on the legal requirements of the Regulations and should be read in conjunction with the legislation itself. The text should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power.

This document provides guidance to industry, namely: **manufacturers, distributors, importers, and retailers** of designated products covered in the Regulations. It also aims to help enforcement officers, health care personnel and other interested parties interpret the provisions of the Regulations.

In a guide such as this, it is impractical to attempt to answer every question on the Regulations that may arise. Consequently, the most frequently asked questions have been addressed using a "question and answer" format.

It remains the responsibility of individual businesses to ensure compliance with the law and to all requirements related to the foodstuffs concerned, such as: labelling, ingredients, sale and promotion, etc., as stipulated in the relevant Regulations published in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) ("the Act").

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1. Background

The Department of Health ("DOH") is responsible for ensuring that foods sold in South Africa are safe. This applies to foods produced domestically, as well as foods imported from foreign countries. The Act and subsequent relevant regulations comprise the national laws governing food products under DoH's jurisdiction.

This guideline document focuses mainly on the sections of the Regulations which relate to labelling, advertising, sale and promotion, and the provision of information and education relating to infant and young child feeding and nutrition.

The DOH receives many questions from manufacturers, distributors, importers and retailers about the proper labelling of their food products. Under DOH's laws and regulations, DOH does not pre-approve labels for food products. To help minimize legal action and delays, it is recommended that manufacturers and importers become fully informed about the applicable laws and regulations before offering foods for distribution in South Africa. Questions concerning the labelling, advertising, or sale and promotion of food products governed by these Regulations, as well as questions regarding the provision of information and education relating to infant and young child nutrition may be directed to Dr N Dlamini: dlamiR@health.gov.za or Ms A Behr: behra@health.gov.za at the Department of Health.

2. Regulatory Framework for Foodstuffs Intended for Infants and Young Children

2.1 Relevant Acts and National Regulations

- Foodstuffs, Cosmetics and Disinfectant Act (No.54 of 1972), and relevant amendments[1]
- National Health Act (Act No 61 of 2003), and relevant amendments
- Health Professions Act (Act No 56 of 1974), and relevant amendments
- Regulations relating to Foodstuffs for Infants and Young Children (R. 991 of 2012)

[1] Both R146 of 2010 and R991 of 2012 will be applicable, depending on the issue at hand:

- Examples:
- Where R991 differs from R146 (e.g. claims), R991 will override R146 because it is more specific; and
- Where R991 does not address a particular issue (e.g. date marking) R146 becomes the default legislation to comply with. This principle shall be complied at all times

- Regulations Relating to the Labelling and Advertising of Foodstuffs (R. 146 of 2010), and relevant amendments
- Regulations Relating to the Prohibition of the Manufacturing, Importation, Exportation and Sale of Polycarbonate Infant Feeding Bottles Containing Bisphenol A (R. 879 of 2011)
- Regulations Relating to Trans-Fat in Foodstuffs (R. 127 of 2011)
- Regulations Governing Microbiological Standards for Foodstuffs and Related Matters (R. 692 of 1997)
- Regulations related to Dairy products and Imitation Dairy Products (R 2581 of 1987), in terms of the Agricultural Product Standards Act, 1990 (Act No. 119 of 1990)

Correction, Amendment and Extension Notices of R991

- **Extension Notice No. R.433, 18 June 2013**
- **Amendment No. R.434, 18 June 2013 (Regulation 9(3) was omitted)**
- **Correction Notice No. R.365, 24 May 2013**

2.2 Relevant Codex Standards

- Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Stan 72-1981; revised 2007 and amended 2011)
- Codex Standard for Follow-up Formula (Codex Stan 156-1987; amended 1989, 2011)
- Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (Codex Stan 74-1981, Rev. 1-2006)
- Codex Standard for Canned Baby Foods (Codex Stan 73-1981)
- Codex guidelines for formulated complementary foods for older infants and young children CAC/GL 8-1991
- Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)
- Codex General Standard for Food Additives (Codex Stan 192-1995, Rev. 2010, 2011)
- Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979, Rev. 2008)
- Codex Standard for the Labelling for Foods for Special Medical Purposes (Codex Stan 180-1991)
- Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997 Rev 1-2004)

2.3 Other relevant guidelines and international standards:

- WHO/FAO Guidelines for the safe preparation, storage and handling of powdered infant formula (http://www.who.int/foodsafety/publications/micro/pif2007/en/)
- WHO International Code of Marketing of Breastmilk Substitutes (http://www.who.int/nutrition/publications/code_english.pdf)

3. General Matters

1. What is the status of the WHO International Code of Marketing of Breastmilk Substitutes in the context of these Regulations?

Answer: The Regulations give effect to the principles and aims of the WHO International Code of Marketing of Breastmilk Substitutes dealing with labelling, marketing, educational information and responsibilities of health authorities. However, the WHO International Code does not have independent legal standing in South Africa. It is the Regulations which have legal force in South Africa and with which industry must comply.

Please note: The International Code of Marketing of Breastmilk Substitutes and its subsequent resolutions should be adhered until the Regulations Relating to Foodstuffs for Infants and Young Children come into force.

4. Definitions

"graphic representation" means illustrations, photographs, drawings or pictures of infants, young children, child characters, cartoons or any other forms that resemble them, human or not, such as humanized fruits, vegetables, animals and/or flowers, among others.

2. What constitutes a humanised figure?

Answer: For the purposes of these regulations, a humanised figure is any inanimate object that is portrayed or endowed with human characteristics or attributes. Examples include: fruits, vegetables, flowers, etc. with arms and legs, an image of the sun with eyes, giving animals human characteristics such as walking on only two legs.

3. Would a non-humanised teddy bear be acceptable?

Answer: No, it will not be acceptable**.**

4. Provide clarity on the current definition of "low cost" by using an example.

Answer: Regulation 9 stipulates that "No manufacturer or distributor shall distribute free, or at "low cost" supplies or samples of designated products to health care personnel or any other person, or to a health establishment..." The term "low cost" has been defined in the Regulation as "a price lower than the whole-sale price or in absence of such a price, lower than 80% of the retail price". In order to limit confusion an example is given in terms of the retail price, namely:

If the usual retail price for product X, was R100 including VAT, then it may not be sold at less than R80 including VAT.

The term "low cost" in the context of the Regulation could also be referring to a "low price".

5. What does "Sale device" in reference to regulation 7 mean?

Answer: Regulation 7(2) specifies prohibited promotional practices or devices include, but are not limited to, "sale devices" such as…. The term "sale devices" in reference to regulation 7 means any method or activity of encouraging any person to purchase or use designated products listed in sub-regulation 7(1). It refers to but are not limited to -

- advertising designated products;
- special displays for designated products;
- additional kickbacks for purchasing designated products; and
- discounts or any incentives or gifts specifically targeting designated products.

However, any standard "sale device" e.g. a customer loyalty programme used by retailers selling products other than the designated products in order to promote their business are permitted. Designated products specified in regulation 7 (1) are only permitted to be awarded basic points in the loyalty programme. Additional points awarded for purchasing a designated product, or incentives or gifts awarded to consumers for purchasing a designated product, shall not be permitted.

6. What does the word "rebate" mean?

Answer: Regulation 7(2) specifies that prohibited promotional practices or devices include, but are not limited to, "sale devices such as rebates…" Guidance relating to the interpretation of "rebates" in the context of the Regulations is that the term "rebates" used in Regulation

7(2) (a) refers to discounts off the retail price and not rebates negotiated between manufacturers and retailers based on overall category growth. The terms “discounts in any form” stipulated in Regulation 7(2)(a) encompasses “rebates” in the context of the Regulation.

Trading terms between manufacturers or distributors and retailers are not prohibited under R991, except where the term/expenditure directly relates to activities that are prohibited in the Regulation such as advertising**.**

7. Are Formulas for Special Medical Purposes ("FSMPs") intended for young children above one year outside the scope of the Regulations R991? If yes, are they subject to other regulations?

Answer: Yes. Formulas for special dietary management intended for young children above one year fall outside the scope of the Regulations R991.
Foods for FSMPs excluding infant and follow-up formula intended for infants until one year will be covered under phase two of the Food Labelling Regulations. For the interim in the absence of current Regulations, the Codex Standard 180-1991 for the Labelling of FSMPs and Regulations Relating to the Labelling and Advertising of Foodstuffs (R. 146 of 2010) should be adhered to.

8. What are FSMPs (excluding infant formula and follow-up formula for special medical purposes intended for infants below one year)?

Answer: The term “FSMP” also refer to as “Foods for the dietary management of persons with specific medical conditions.” Guidance in terms of which products would be classified as FSMPs excluding infant and follow-up formula for special medical purposes is provided below.

The FSMPs **(excluding infant formula and follow-up formula for special medical purposes intended for infants below one year)**, has to comply with the following requirements:

(a) Specially formulated product that can be administered enterally, either by mouth or through an enteral tube that uses the digestive system. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis;
(b) Intended for the exclusive or partial feeding of patients who-

- because of therapeutic or chronic medical needs e.g. patients with renal, liver, gastrointestinal or respiratory disease, is seriously ill and requires the use of the product as a major component of the dietary management of the disease or condition's itself;
- has limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein e.g. patient with short bowel syndrome and cystic fibrosis; and
- has other special distinctive medically-determined nutrient requirements determined by the underlying medical condition, whose dietary management cannot be achieved by modification of the normal diet alone, by other foods for special dietary uses or by a combination of the two;

(c) specifically formulated and processed for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognised scientific principles, are established by medical evaluation (as opposed to naturally occurring food used in a natural state);

Note:

- Any commercial marketing, including advertising of enteral foods for special medical purposes to the general public is prohibited.
- FSMPs exclude foodstuffs formulated and presented in any manner as being for the nutritional support of persons living with HIV and AIDS, tuberculosis, Not Acutely Malnutrition (NAM), moderate acute malnutrition (MAM), obesity or overweight or general nutritional support during convalescence. While a specific individual's diet alone may not supply the full amount of nutrients necessary, generally it can be achieved by the modification of the normal diet alone.

9. Are enteral foods that are used as the sole source of nutrition for children 1 to 10 years considered FSMPs?

Answer: Yes, an enteral food intended to be used as the sole source of nutrition for children 1 to 10 years is classified as a FSMP provided it complies with all the criteria and requirements of a FSMP. For the interim in the absence of current FSMP Regulations, the Codex Standard 180-1991 for the Labelling of FSMPs and Regulations Relating to the Labelling and Advertising of Foodstuffs (R. 146 of 2010) should be adhered to. Any commercial marketing, including advertising of enteral foods for special medical purposes to the general public is prohibited. If the enteral foods intended to be used as the sole

source of nutrition for children 1 to 10 years do not meet the criteria for a FSMP the product needs to comply with R991 and R146.

10. Is malnutrition a condition for which a FSMP could be labelled and marketed?

Answer: Food products specially processed and formulated for the dietary management of patients with severe acute malnutrition will be categorised as a FSMP. Severe Acute Malnutrition is defined by the World Health Organisation as a weight for height under the reference mean by more than 3 standard deviations, or a Mid-upper arm circumference of less than 11.5 cm, or the presence of bilateral nutritional oedema.

Enteral foodstuffs presented in any manner for the dietary management or support of persons, Not Acutely Malnourished (NAM), moderate acutely malnourished (MAM) *and* overweight (overnutrition) are not categorise as FSMP.

Malnutrition has not been defined in the Regulations. The term malnutrition refers to both undernutrition and overnutrition.

Not Acutely Malnutrition (NAM) also known as Undernutrition is defined as:
Low weight-for-age; below minus two standard deviations (SD)/ z-score -2SD below the international reference for weight-for-age; and

Moderate acute malnutrition (MAM) is defined as weight-for-height indicator between minus 3 and minus 2 standard deviations (SD) / z-score between -3 and -2 of the international standard or a mid-upper arm circumference (MUAC) between 11.5 cm and 12.5 cm in children 6-60 months old.

5. Labelling, Composition, Packaging and Other Manufacturing Matters (Regulations 2, 3 and 4)

11. What graphics are allowed on the labels of complementary foods?

Answer: Only images of actual ingredients such as fruits and vegetables or the prepared product in the case of porridge, cereal etc. is allowed. See also: definition of “graphic representation”, Regulation 2(2) (a), Regulation 2(3), and Regulations Relating to the Labelling and Advertising of Foodstuffs, R.146, Regulation 34.

12. The Regulations makes reference to "no person shall import, offer for sale or sell any-..." Many of the designated products are imported and require additional labelling work prior to release to the market. Current practice allows under special condition importation for re-labelling and then inspection and release through Port Health approved processes before being made available for sale. Can this practice continue?

Answer: There is no change in import control of these products. The consignment will be released by Port Health if in compliance with the relevant Regulations.

13. Are manufacturers required to add the statement "do not add salt and/or sugar" to liquid milks, powdered milks, modified powdered milks and powdered drinks?

Answer: According to Regulation 4(1)(g) the products mentioned in regulation 4(1) should include the expression "Do not add salt and/or sugar" in close proximity to the preparation instructions in capital letters at least 2 mm in height. Therefore, the product can either have do not add salt or do not add sugar or do not add salt and sugar depending on the relevance of the type of product. For instance liquid milks, powdered milks, modified powdered milks and powdered drinks it may be relevant only to indicate "Do not add sugar". In cases where no preparation instructions are necessary, the wording "do not add salt and/or sugar" could be indicated anywhere on the label.

14. Do the regulations require that ALL nutritional information is determined by a reputable laboratory through chemical or microbiological analysis and that this is shown on the product label?

Answer: Annexure A & B nutritional information is mandatory for nutritional analysis using a reputable laboratory; this includes vitamins & minerals as per Codex Standards (See section 2.2). Where additional vitamins and minerals are voluntarily added, Regulation 50(13) of R. 146 applies.

15. If claims have been approved under other International authorities and regulations may they continue to be shown on the label?

Answer: No. Regulation 2(4)(a)(i) clearly stipulates "no health, medicinal or nutrition claims shall be permitted in any manner for any designated product.

16. Do the Regulations allow the use of specific logos which symbolise groups of nutrients or benefits to the consumer?

Answer: No. Specific logos which symbolises groups of nutrients or benefits to the consumer amount to claims. According to the Regulations Relating to the Labelling and Advertising of Foodstuffs (R. 146 of 2010) a "claim" in relation to a foodstuff is defined as, "means any written, pictorial, visual, descriptive or verbal statement, communication, representation or reference brought to the attention of the public in any manner including a trade name or brand name and referring to the characteristics of a product, in particular to its nature, identity, nutritional properties, quality, durability, origin or method of manufacture or production.

17. Do the Regulations allow for a logo or trademark which denotes that the designated products has health giving properties?

Answer: No. Regulation 13(d) of the Regulations Relating to the Labelling and Advertising of Foodstuffs (R. 146 of 2010) prohibits the words "health" or "healthy" or other words or symbols implying that the foodstuff in and of itself or a substance of the foodstuff has health-giving properties in any manner including the name or trade name, except in the case of the fortification logo as determined by regulations made under the Act and regulation 51(2).

18. Do the Regulations allow mentioning a nutrient or nutrients on the front of package label of designated products, for example: 'With Iron"?

Answer: No, this will be considered a claim. Mandatory nutritional information should be provided in the Nutritional Information Table. No health, nutrient or medicinal claim may be made outside the table on the label.

The mention of nutrients as a mandatory part of nutrition labelling or the mention of substances in the list of ingredients is not considered to be a nutrient or health claim. However, should certain nutritional information be emphasized or highlighted in any manner in the Nutritional Information Table through colour differences, differences in font types, letter size or in any other manner, it shall be considered to be a claim for that/those particular nutrient(s).

19. May promotional material on complementary foods contain nutrition and health claims?

Answer: No. Regulation 3 of R. 146 stipulates that no person shall advertise a foodstuff in any manner, which contains any information, claim, reference or declaration not permitted on the label in accordance with these regulations. See Regulation 2(4)(a)(i); “no health, medicinal or nutrition claims shall be permitted in any manner for any designated product”

20. Why do the Regulations prohibit health and nutrition claims on complementary foods?

Answer:

Reasons for prohibiting claims:

- Nutrition and health claims are often misleading to caregivers of infants and young children and frequently serve as a marketing tool, rather than to provide valid educational information intended to improve an infant or young child’s nutritional status.
- Claims do not encourage the consumption of a variety of locally available foods.
- Nutrition claims do not guarantee the availability of the nutrients.
- Promoting a single nutrient is not beneficial. Bioavailability of nutrients is interdependent.

Prohibiting nutrition claims on complementary foods does not prohibit access to the nutritional content of designated products. In fact, the Regulations require that the nutritional contents of a designated product be reflected in the Nutritional Information Table following the Codex requirements.

This decision is in line with the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997 Rev 1-2004), section 1.4 which clearly states that, “Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.”

21. Do the Regulations allow for the use of "line marketing" (digits 1, 2, 3) on the labels of designated products?

Answer: Yes. Although the use of "line marketing" digits such as 1, 2, 3 etc. is not explicitly prohibited by the regulations, it is important to note that the age range must be provided on all designated products (See Regulation 3(1)(a)(i) and 4(1)(a)).

22. Can a trademark be construed as to imply a claim?

Answer: No. A trademark that implies a claim is not permitted. The definition of Health claim "means any representation that states, suggests or implies..." and Nutrition claim "means any representation that refers to a specific nutrient or food constituent content..." In addition Regulation 13(c) of R146 stipulates the use of a logo, mark, symbol, written or verbal statement or any other manner of communication cannot be used as a means to make claims about food that would otherwise not be allowed.

23. Do the requirements to sell designated products only in containers which are re-sealable apply to products sold in quantities intended to be consumed as a single serving?

Answer: No. Regulation 2(1)(c) requires that containers be re-sealable during subsequent *appropriate* storage. It is the Department's view that if a product is sold in quantities intended to be consumed as a single serving, subsequent storage would not be appropriate and therefore these containers need not be re-sealable.

24. Can endorsements/certification logos such as organic, free range, recyclable packaging, etc. be used on the labels of designated products?

Answer: Yes. According to Regulation 47 of the Regulations Relating to the Labelling and Advertising of Foodstuffs (R.146), words such as "free range", etc. when linked to specific protocols registered with the Department of Agriculture in terms of the Agricultural Products Standard Act, 1990 or the National Regulator for Compulsory Specifications Act, 2008, or regulations under these Acts exist and permits such wording on the pre-packed labeling of the relevant products.

The endorsement/certification logo for organic will be allowed if the product has been produced, processed, and handled in compliance with organic production standards and certified by a recognised accredited certification body or authority.

Please note: *The Regulations relating to the Labelling and Advertising of Foodstuffs require that all information related to requirements shall be kept on record by the manufacturer, importer, or seller and failure to produce the relevant documentation within 2 (two) working days upon request by an inspector, or employee of the Department shall constitute an offence.*

25. Which sweeteners are prohibited in foodstuffs intended for infants and young children?

Answer: According to Regulation 2(17), the sweeteners listed in Table 1 of the General Standard for Food Additives (GSFA) of the Codex Alimentarius Commission are prohibited in foodstuffs intended for infants and young children.
The intention of this provision is to allow sweeteners as permitted in Codex Standards. Note: sucrose, fructose, glucose, glucose syrup, honey, lactose are allowed in accordance with relevant Codex Standards.

26. What are the legibility requirements for the labels of designated products?

Answer: The Regulations prescribe the letter size (size of font) for information provided on labels of designated products. Regulation 3(1) and 3(2) set forth requirements that certain statements on the container or label of any infant or follow-up formula be 3mm in height for the smallest letters for a 400g tin of the product and at least 2mm in vertical height for other defined statements.

Where letter size requirements are not specified in the Regulations Relating to Foodstuffs for Infants and Young Children, R.991, it is important to note that Regulation 8 in the Regulations Relating to the Labelling and Advertising of Foodstuffs, R.146, will apply.

27. Can the font size and /or certain statements be removed from single serving liquid infant and follow-up formula? (Single serving products (200ml or 100ml per serving) do not have enough space for all the languages including the other requirements).

Answer: An amendment to the Regulation is under consideration to allow the label of a single serving liquid infant and follow-up formula to include the required information and/or statements in the English language in the font size specified and where possible, at least one other official language of the Republic of South Africa.

28. What are the language requirements for labels of designated products?

Answer: The Regulations stipulate that the information on the container or label of infant or follow-up formula should in the English language and that certain information referred to in Regulation 3(6)(a) should be included on a self-adhesive label or information leaflet in five other official languages. Regulation 6(2)(b) also stipulates that the instructions for proper cleaning of feeding bottles be in the English language; provided that the information be repeated in at least five other official languages on a self-adhesive label or package insert.

In instances where the language requirements are not defined in the Regulations, as in the case of complementary foods and liquid milks, powdered milks, etc., it is important to note that Regulation 7 of the Regulations Relating to the Labelling and Advertising of Foodstuffs will apply.

29. What are infant or follow-up formulas for special dietary management intended for infants with specific medical conditions"?

Answer: Products that comply with the criteria lay down in the provisions of Section B of the Codex Standard 72-1981 and Regulations 991 would be accepted for marketing as formula for special medical purposes intended for infants.

The criteria are as follows:

(a) Specially formulated product intended for infants that substitute human milk or standard infant formula to meeting the special nutritional requirements arising from the medical condition such as metabolic conditions as determined by medical evaluation.

(b) Intended for the exclusive or partial feeding of infants-

- With limited or impaired capacity to take, digest, absorb or metabolise human milk or infant/follow-up formula or certain nutrients contained therein; or
- Who have other special distinctive medical-determined nutrient requirements determined by the underlying medical condition, whose dietary management cannot be achieved by human milk or infant/follow-up formula; and

(c) are administered orally or through a naso-gastric tube or other route that uses the digestive system

(d) specifically formulated and processed for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

Infant or follow-up formulas for special dietary management intended for infants with specific medical conditions has been defined in the Regulations, means a formulated product that complies with the latest adopted version of the Codex Standard 72- 1981 titled “Standard for infant formula and formulas for special medical purposes intended for infants”.

This definition should be read in conjunction with the definitions of infant formula (suitable for infants during the first months of life up to the introduction of appropriate complementary feeding), follow-up formula (suitable for an infant from six month on or a young child) and the definition of an infant (means a person not more than 12 months of age). The definitions in the Regulation apply for the purpose of the Regulations.

The Codex Standard 72-1981 is divided in two sections. Section A refers to Infant Formula, and Section B deals with Formulas for Special Medical Purposes Intended for Infants. Part B cross-reference back to Part A (Standard for Infant Formula) for most of its requirements.

The provisions set out by Codex for formulas for special medical purposes draw considerably on both the provisions of the Codex Standard for the Labelling of Foods for Special Medical Purposes (Codex Stan 180-1991) and those of the Codex Standard for Infant Formula.

The Codex definition for formula for special medical purposes intended for infants applies for infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding but for the purpose of this Regulations it applies for infants (a person not more than 12 months of age).

30. Do the Regulations allow the indication for use of infant and follow-up formula for the special dietary management intended for infants with specific medical conditions?

Answer: Yes. The indication for use should be provided on infant or follow-up formula for special dietary management intended for infants with specific medical conditions. The indication for use is not considered to be a health, medicinal or nutrition claim. For example a Lactose Free Infant formula should indicate it is for the dietary management of infants with lactose intolerance.

It should be noted that the appropriate indication for use should be supported by scientific data.

31. Do the Regulations allow symptoms of a condition to be used as an indication for use on the container or label of infant or follow-up formula for special dietary management intended for infants with specific medical conditions?

Answer: The Codex Standard 72-1981 and Regulation 991 make no reference to the use of symptoms as indication of use. The indication for use should be indicated as follows "For the dietary management of ....." with the blank filled in with the specific disease(s), disorder(s), or medical condition(s) for which the product is intended, and for which it has been shown to be effective".

32. What mandatory statements are required to be on the container or label of infant or follow-up formula for special dietary management intended for infants with specific medical conditions?

Name of the product	**Indication for use** **The condition, disease or disorder for which the food has been specially formulated; See 3(2)(a)(i)** **Examples of acceptable wording**	**Mandatory Statements required by R991 and Codex Stan 72 -1981**
Lactose free formula	For the dietary management of infants with lactose intolerance	3(2)(a)(ii) "Breast milk is the best food for babies" unless contraindicated based on medical grounds". 3(2)(a)(iii) Age Range 3(2)(a)(iv) sterility statement 3(2)(a)(v) "**USE UNDER MEDICAL SUPERVISION**" 3(2)(c)The nutritional modifications which have been made to the formula indicated in the nutritional information Table. *CODEX STAN 72 – 1981* A statement that the product is not to be used for parenteral administration shall appear on the label. 9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition
Preterm infant formula	For the dietary management of infants born prematurely or of low birth weight	
Hypoallergenic formula*	For the dietary management of infants with cow's milk allergy	
Anti-reflux formula	For the dietary management of infants suffering from severe regurgitation	
Free amino acid based formula Hypoallergenic formula*	For the dietary management of infants with cow milk allergy, multiple food protein allergies.	
Galactose free formula	For the dietary management of infants with galactosemia	

***Hypoallergenic formula must comply with the criteria in R146 46(2) in terms of the claim hypoallergenic for each batch.**

6. Specific Labelling and Other Requirements of Sweetened Condensed Milk, Imitation Dairy and Goat's Milk (Regulation 5)

33. Which products would be considered to be imitation dairy products?

Answer: The definitions section of the Regulations defines "imitation dairy" to mean: any product other than a dairy product, that is of animal or plant origin and in general appearance, presentation and intended use corresponds to a dairy product.

The following would constitute "imitation dairy" products for the purposes of the Regulations such as:

a. Coffee creamers
b. Tea creamers
c. Imitation milk blends
d. Imitation condensed milk
e. Any formulated imitation milk or milk powder

34. Follow-up formula made from goat's milk, should it carry a warning: "Not for infant feeding"?

Answer: No, on condition the Follow-up formula made from goat's milk is in compliance with R991, Regulations Relating to the Labelling and Advertising of Foodstuffs in terms of the Act and Regulations Related to Dairy products in terms of the Agriculture Standard Act, 1999 it would not need to carry the warning: "Not for infant feeding".

7. Specific Labelling and other Requirements of Feeding Bottles, Feeding Cups and Teats (Regulation 6)

35. What graphics are allowed on the label, package or container of a feeding bottle, teat or feeding cup?

Answer: Only graphics illustrating cleaning and sterilisation and the logo of the manufacturer or distributor.

36. Can the feeding bottle or cup itself have graphic representation?

Answer: Yes. Regulation 6(3) prohibits any graphic representation other than for illustrating cleaning and sterilisation and the logo of the manufacturer or distributor to be on the label, package or container of a feeding bottle, teat or feeding cup. The intention of this provision is to ensure the carer can see if the bottle and/or feeding cup are thoroughly cleaned (milk residue increases the risk of bacterial growth), to ensure gradings are clearly visible and not to encourage the use of a bottle or a feeding cup.

8. Sale and Promotion (Regulation 7)

37. Does the DOH intend to prohibit all advertisements and promotional practices related to designated products?

Answer: Yes. This Regulation prohibits all advertisements and promotional practices for designated products, with the exception of complementary foods. Complementary foods can still be advertised and promoted to the general public, but not through health care personnel or health establishments.

38. Can the following trade practices for complementary foods continue at retail level in terms of the Regulations?

Answer: Complementary foods are exempted from the promotional practices in terms of Regulation 7(2). However, numerous restrictions do apply to the promotion and advertising of complementary foods (e.g. prohibition of claims, no toys or incentives, etc.) and according to Regulation 9 any promotional practice that result in providing free or low cost complementary food is prohibited.

Please see below examples of practices that are not prohibited and practices that are prohibited for complementary foods.

The following practices <u>are not prohibited</u> for complementary foods:

- Can be promoted and sold at baby expo
- Competitions with prizes. The prizes may not include any designated product including complementary foods.
- Tie-in-sales e.g. R1 airtime on the purchase of a jar. Tie-in-sales may not include any designated products.
- Special displays in retail outlets
- Advertisements about the availability of the product and the price of the product.

The following practices <u>are prohibited</u> for complementary foods:

- Giving of discount vouchers that a consumer can use to purchase a complementary food.
- Buy two and get one free is prohibited.
- No samples including tasters can be given to mothers at a baby expo / retail outlets. Sample is defined as "any quantity of a designated product provided at no cost".
- No free samples can be given to a 'baby box' service.
- No health, nutrition or medicinal claims can be made on the label or educational material.
- Enticing consumers to subscribe to a baby club and offer complementary foods at a discounted price is a promotional practice. Therefore no manufacturer, distributor or retailer of designated products referred to in sub-regulation 7(1) or a person on behalf of the aforementioned may offer/host baby clubs. See Regulation 7(2)(b).

39. If a company produces products with the same brand name as designated products, can promotional products be given at events, for example T-shirts, caps, feeding sets, etc., if they only carry the brand name? Does this exclusion only cover products listed in 7 (1)?

Answer: No. Any event for the general public must not feature a brand name of a product associated with products listed in sub-regulation 7(1).

40. Is the promotion of breast pumps that carry the same brand name as a designated product permitted?

Answer: Breast pumps do not fall under the scope of the Regulations. Promotion of breast pumps should not be promoted in conjunction or contain references to designated products refers to in sub-regulation 7(1). It should be noted that a breast pump advertisement which refer to the use of a bottle to feed expressed breast milk is promoting products within the scope of the Regulations.

41. Offering price discounts on a designated product, even if not advertised, seen as promoting it?

Answer: Price discounts, even if not advertised, is a promotional method and therefore prohibited for products listed in Regulation 7(1).

42. Do the Regulations determine product placement of designated products in Retail outlets?

Answer: Although the Regulations do not prescribed product placement in terms of choice of shelf e.g. .eye-level-shelves Regulation 7(2)(a) prohibit any **special displays** to promote sales. As a result a retailer should not use, point-of-sale displays, product pyramids, shelf talkers, gondola ends and window displays which relate to products listed in Regulation 7(1)(a).

43. Can a manufacturer and/or retailer sell designated products at a Baby Expo?

Answer: Manufacturers and/or retailers may exhibit and sell non-designated products and complementary foods at a Baby Expo. A Baby Expo is a promotional practice and therefore setting up a store within an exhibition to sell designated products refer in Regulation 7(1) to consumers would be seen as a promotional practice and therefore it would not be permitted.

44. Are tenders exempted from the Regulations?

Answer: All tenders (Government and Private) are not exempted from the Regulations. Regulation 2 of the Regulations Governing the Labelling and Advertising of Foodstuffs, R 146 of 2010 clearly stipulates that “No person shall manufacture, import, sell or any pre-packaged foodstuff for sale unless the foodstuff container, or the bulk stock from which it is taken is labelled in accordance with these regulations. Non-compliance with the above condition will invalidate the bid for such item/s offered.” In other words, all foodstuffs offered for sale in any manner within South Africa (for human consumption) shall comply with these stipulations. All bidders should ensure to be full incompliance with R 991 by 6 December 2014 (as per extension granted by Department of Health’s Minister) and resubmit new labels.

Tender committees adjudicating designated products prior to 6 December 2014 should ensure the labels of designated products are compliant with requirements of existing relevant Regulations under the Foodstuffs, Cosmetics and Disinfectant Act (N0.54 of 1972), the International Code of Marketing of Breastmilk Substitutes and the relevant Codex Standards.

Regulation 9 of R991 does not limit the tender process and prohibit the submission of samples for tender purposes. The samples are not distributed at free will it is a tender requirement to submit two samples per application.

45. Should a consumer call the company telephone number (provided for quality complaint purposes) and request where to purchase a particular brand designated product or have queries around stock availability, may a member of the company answer the question?

Answer: Yes, a member of the company may indicate the product is available at retail outlets.

Refer to the table in Annexure 1: Sponsorship of Professional meetings/congresses, seminars targeting health care personnel for questions 46 to 53.

46. Can industry still provide financial contributions to professional associations (e.g., South African Nursing Council, The Association for Dietetics in South Africa, The South African Paediatric Association, etc.)?

Answer: Under the Regulations there is no specific ban on industry providing financial contributions to professional associations. However, these financial contributions/sponsorships:

- Should not be specific to a meeting addressing Infant and Young Child Nutrition
- Should not be used to promote any designated product through health care personnel and health establishments.
- Are prohibited for health care personnel working in infant and young child nutrition. In addition, Regulation 7(5) stipulates that industry or anyone on their behalf may not produce, distribute or present educational information relating to infant and young child nutrition. See also: Health Professions Council of South Africa (HPCSA) Guidelines on Over-servicing, Perverse Incentives and Related Matters.

47. Can financial contributions and sponsorships be made to health care providers who works with adults e.g. to attend an event that focuses on adult renal disease?

Answer: Yes. The Regulations do not prohibit sponsorships to health care providers to attend an event that addresses adult nutrition e.g. nephrologist to attend an event that focuses on adult renal disease.

48. Can health care personnel not working in IYCN receive sponsorship/financial contributions from a manufacturer, distributor retailer and their representative of designated products?

Answer: Under the Regulations there is no specific ban on industry providing financial contributions or sponsorship to health care personnel not working in IYCN to attend conference unrelated to designated products or infant and young child nutrition.

It is important to note that Health Care Personnel employed within the Public Sector should adhere to the Public Service Regulations, 2001 and all subsequent amendments. With respect to gifts and donations refer to Chapter 2 (Code of Conduct) and Chapter 3 (Financial Disclosure).

49. Can health care personnel be invited to product launches?

Answer: No. According to Regulation 7(3) no person shall sell, promote, or advertised any designated product, including complementary foods, through health care personnel and health establishments. Product launches are a promotional practice and therefore prohibited. Technical scientific material that relates to the product may be provided to health care providers e.g. professional journals, Departmental meetings (not sponsored), professional association meetings (not sponsored).

50. Do sponsorships for conferences need to be anonymous or can conference organisers state which companies provide the sponsorship?

Answer: Conference organizers may state which companies provide sponsorship of the conference itself. What the Regulations intend to avoid is creating any conflicts of interest or perverse incentives for individual health care personnel. Consequently, pooled resources are mandated for industry sponsorship of health care personnel. The main rationale underpinning Regulation 7(2)(j) is that companies should not be allowed to use sponsorship

of health care personnel working in infant and young child nutrition as a means of creating brand loyalty or as a marketing tactic. It is important to note that conferences should not be used as platforms to promote and advertise designated products.

51. Can manufacturers have an exhibition stand at healthcare professional conferences to impart information of a technical & scientific nature relating to designated products?

Answer: Yes. Manufacturers of designated products may have an exhibition stand at conferences and are allowed to provide technical and scientific material that relates to their designated products but not information on infant and young child nutrition in general. Promotional practices such as competitions with prizes, or any other incentives and gifts (including samples) and displays of designated products refer to in Regulation 7(1) are prohibited. Display samples are seen as a promotional practice and therefore it would not be permitted.

52. Can registered health care providers employed by industry promote and advertise designated products?

Answer: No. Direct or indirect contact between company personnel and the general public for the purpose of promoting products referred to in Regulation 7(1) is prohibited. It is important to note that complementary foods are exempt from this prohibition. However, according to regulation 7(3) no person, including health care personnel, shall sell, promote or advertise any designated product, including complementary foods, through health care personnel or health establishments. This means that registered health care providers employed by companies may still liaise with relevant procurement staff at health establishments, but may only provide technical, scientific material to health care providers.

53. May manufacturers or distributors still continue establishing educational meetings relating to infant and young child nutrition from which healthcare professionals may gain CPD points? These meetings involve the company requesting an independent Health Care Professional to educate others. A small honorarium would be given to the speaker to compensate for the time taken.

Answer: No. According to Regulation 7 (5) no manufacturer, distributor, retailer, importer or person on behalf of the aforementioned shall produce, distribute and present educational information relating to infant and young child nutrition. However, they may establish

education meetings for CPD points if it is unrelated to infant and young child nutrition e.g. adult nutrition

54. Can health establishments sell designated products to the general public?

Answer: Yes. Health establishments may sell designated products to the general public in limited circumstances. Institutional pharmacies in private health establishments may sell designated products but may not advertise or promote any designated product. However, health care personnel may not sell, promote or advertise designated products.

55. Is a pharmacy a health establishment and therefore not permitted to sell any designated products except an institutional pharmacy as indicated in Regulation 7(3)?

Answer: The Regulations define a pharmacy as a "retail outlet" and not as a "health establishment". Regulation 7 (3) prohibits health establishments from selling designated products. However, there is an exemption for institutional pharmacies, which may sell designated products.

56. Is a pharmacy that has an in-house clinic, considered to be a retail outlet?

Answer: Retail outlets, including a retail pharmacy, do not constitute a healthcare establishment and as such are able to sell designated products. An in-house clinic room is considered to be a healthcare establishment and therefore would not be permitted to sell, promote or display designated products (as per regulation 7, 9 and 10).

57. Can health care personnel still demonstrate the appropriate use of designated products?

Answer: Yes. Although designated products may no longer be displayed in health establishments it is the responsibility of the health care personnel to demonstrate the preparation of powdered infant formula safely and correctly to those mothers who need to use it. It is important to note, that this may only be done on an individual basis and should not be done in group settings.

58. Can health care providers give product specific recommendations?

Answer: Health care providers should communicate a range of available products to the client and not only one specific brand because this would be considered promotional. Specific product recommendations can be made if the infant or young child has been diagnosed by medical evaluation with a specific medical condition that requires a specific formula and only one FSMP is available on the market for the condition.

59. Is industry allowed to provide meals and refreshments at meetings where infant and young child nutrition is the sole or partial topic of discussion?

Answer: No. As stipulated in Regulation 7(3), industry is not allowed to provide "gifts" to health care personnel whether in cash or kind. Furthermore, meals and refreshments are specifically included in the definition of gift provided in the Regulations.

60. Regulation 7(4) says that companies cannot provide educational material that promotes products referred to in Regulation 7(1). Are companies still allowed to give guidance on the appropriate use of products for infants and young children?

Answer: Yes. It is also important to note that Regulation 7(4) does not apply to complementary foods, but numerous restrictions do apply to the promotion and advertising of complementary foods (e.g., prohibition of claims, limits on graphic representation, no toys or incentives, etc.).

61. Does Regulation 7(5) create a blanket ban where no manufacturers, distributors retailers, or importers of any commercial product, whether infant and young child products or not, may produce/distribute/present information on infant and young child nutrition?

Answer: Yes. In terms of Regulation 7(5), it does create a blanket ban where no manufacturers, distributors, retailers, or importers may produce/distribute/present information on infant and young child nutrition. This is not limited to companies that produce designated products. The intent of this provision is to ensure that educational information that is not product related, but rather information that intends to impart knowledge on infant and young child nutrition is not company sponsored or promotional in any way. It is important to note that health care personnel may not sell, promote or advertise designated products

62. May health care providers and professional associations write generic educational information, including articles, on infant and young child nutrition provided these are not done on behalf of a manufacturer?

Answer: Yes. Health care providers and professional associations may write generic education information relating to infant and young child nutrition but it should not be on behalf of a manufacturer, distributor, retailer or importer. A statement should be included to stipulate it was not written on behalf of a manufacturer, distributor, retailer, or importer.

63. May health care providers and professional associations write generic educational materials, provided these are not linked to any brand or product?

Answer: Yes. Health care providers and associations may write generic educational materials, including articles, on infant nutrition provided these are not linked to any brand or product.

Educational material is defined in the Regulations as any material intended for the public that purports to give guidance on the appropriate use of products for infants and young children.

Regulation 7 (4) stipulates that no manufacturer, distributor, retailer, importer or person on behalf of the aforementioned shall produce or distribute any educational material on infant and young child feeding that promotes any products referred to in sub-regulation 7 (1).

9. Prohibition of the Distribution of Free or Low-Cost Designated Products or Samples (Regulation 9)

64. With regard to Regulation 9, is the intention to prohibit the distribution of free samples of complementary foods to healthcare workers and health establishments only, or does this restriction apply to the general public as well?

Answer: The term “sample’ has been defined in the Regulations meaning “any quantity of a designated product provided at no cost”. It is the intention of the Regulations to prohibit the distribution of free or low cost supplies or samples of all designated products to health care personnel or any other person, except in limited circumstances as outlined in Regulation 9(2) and 9(3). Therefore, no manufacturer or distributor shall distribute free samples of complementary foods to the general public. Taste testing is also considered a sample and

therefore prohibited. Samples are promotional by nature and has been included in the definition of promote.

65. Do the Regulations prohibit the provision of samples for tender purposes?

Answer: No. Regulation 9 of R991 does not prohibit the submission of samples of each product in the following circumstances:

- for tender purposes. It is a tender requirement to submit e.g. two samples per application for evaluation purposes.
- for laboratory analysis

66. Can samples of designated products be provided for listing of products where retailers need to see the product physically to make sure the shelves are big or high enough and plan the shelves so that all the products fit in the isle?

Answer: Samples of designated products can be provided to retailers for the listing of designated products provided these products should be collected once listing is finalised.

67. Are donations of designated products to emergency relief operations allowed?

Answer: Regulation 9 prohibits the donations of designated products except to hospices, orphanages or places of safety. An amendment to the Regulation is under consideration to allow donations of complementary food to other social welfare institutions and emergency situations.

10. Display of a designated product or educational material (Regulation 10)

The purpose of Regulation 10 is to remove any association which a mother may perceive between the health establishment and manufacturers and distributors.

68. Who is responsible for ensuring that designated products, educational material and the name or logo of manufacturing or distributing companies are not displayed in health establishments?

Answer: This provision entered into force on 6 June 2013. The primary obligation for ensuring that these items are not displayed in health establishments lies with industry. This means that industry has a legally binding obligation not to supply any materials or designated

products for display in a health facility units taking care of infants, young children, pregnant women or mothers of infants and young children from 6 June 2013 onwards.

However, the Department recognizes that there are items that were displayed in health establishments prior to 6 June 2013. Consequently, the Department will be sending a directive to provincial departments of health notifying them that all said products and items should be removed from public and private health establishments with immediate effect.

It should be noted that it is a joint responsibility of the industry, healthcare establishment and the health care providers to ensure that designated products are not displayed.

69. May health care personnel in private health establishments display designated products in their offices or counselling rooms?

Answer: No. Regulation 10 prohibits designated products, educational material which bears brand names or descriptions of designated products, or the name and/or logo of a manufacturing or distributing company of designated products from being displayed in any health establishment, whether public or private.

70. May a manufacturer or distributor of designated products display information relating to their non-designated product portfolio be acceptable with both the non-designated product brand and company logo?

Answer: The Regulations do not prohibit a manufacturer or distributor of designated products to provide information related to their non-designated product portfolio with both the designated product brand and company logo.

Technical scientific material on designated products may be provided to health care providers provided it meets the conditions stipulated in Regulation 11. It should be noted that Regulation 10 stipulates that “No persons within any health establishment may display in a unit taking care of infants, young children, pregnant mothers or mothers of infants and young children designated products, any educational material which bears the brand name or any description of a designated product, or the name and or logo or both of the manufacturing or distributing company of designated products, when the material includes any message about infant and young child nutrition or feeding practices”.

11. Material directed at Health Care Providers (Regulation 11)

71. What does "technical aspects" in reference to Regulation 11(3) mean?

Answer: Regulation 11 stipulates a person, manufacturer or distributor may provide "technical scientific material" to a health care provider, and set down conditions which the material need to be complied with.
The term "technical scientific material" has been defined in the Regulations. "It means any material containing proven technical and/or scientific data about designated products or related to knowledge of nutrition, intended for health care personnel".

The technical scientific material should meet the following conditions:

- Is restricted to current scientific and factual matters, and is in accordance with the relevant regulations under the Act; It refers to the clinical trials on the end product itself; and it doesn't include theoretical information extracted from scientific research studies.
- For Infant or follow-up formula for special dietary management intended for infants with specific medical conditions, a statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification based on recognized scientific principles should be included in the nutritional information table on the label and may be provided separately from the package to health care providers. This does not constitute a claim.
- No health, medicinal or nutrition claims, whether in text or picture format;
- It relates to the technical aspects and methods for use of the designated product; and
- It excludes any promotion of the designated product in any manner.

The term "technical aspects" is not defined in the regulation. This relates to the scientific and factual matters regarding the compositional issues (nutritional information table and list of ingredients), indication of use, suggested feeding schedules, directions for the preparation and method of use, storage instructions and shelf life of the designated product.

It should be noted the Regulations define "health care provider" as "any person providing health services and/or social services in terms of any law..." Therefore, persons who are not

connected such as community health workers do not qualify to receive any scientific and factual information.

72. May industry place advertisements of designated products in medical journals or other similar publications which are intended for use by health care providers?

Answer: No. Please refer to Regulation 7(1)(f), which defines advertisements in written publications to be a promotional practice. There is no exemption made to professional health journals. Industry may provide technical scientific material about their designated products in the journal but it should comply with the conditions specified in Regulation 11. It should be noted that it exclude any promotion of designated products.

73. Is the inclusion of a picture of the designated product beside the technical and scientific information for the Health Care Provider considered promotional?

Answer: No. A picture or pack-shot of the designated product can be used which would identify the product only if the picture or pack-shot meets the labelling requirements as stipulated in the relevant regulations published in terms of the Act. It should be noted that pack-shots of designated products used on articles such as carrier bags are considered promotional.

12. COMMENCEMENT (Regulation 16)

74. When do the Regulations commenced?

An Extension Notice was published in the Government Gazette No. R.433, 18 June 2013 stipulating revised dates when the Regulations come into effect. The dates are as follows:

- **6 June 2013:**
  - Prohibition of the distribution of **free or low-cost designated products or samples (Regulation 9)**
  - Prohibition of the **display** of a designated product or educational material **(Regulation 10)**
- **6 December 2013**:
  - Sale and promotion **(Regulation 7)**
  - Gift packs **(Regulation 8)**

  - Material directed at health care providers (**Regulation 11**)
- **6 December 2014:**
  - Labelling, composition, packaging and other manufacturing matters of designated products **(Regulations 2,3,4,5 and 6)**

13. TRANSITIONAL MEASURES (Regulation 17)

75. Should manufacturers, distributors and retailers remove all non-compliant designated products from the market, after 6 December 2015, regardless of the date of manufacture thereof?

Answer: Yes. According to Regulation 17 all non-compliant designated products should be removed from the market after 6 December 2015. However, an amendment to the Regulation is under consideration to use the date of manufacture as the date from which full compliance to the provisions of these regulations are applicable.

ANNEXURE A AND B

76. Are the listing of nutritional information as per Annexure A and B in terms of font sizes, bold, capitalization mandatory?

Answer: According to Regulation 8 (d) in the Regulations Relating to the Labelling and Advertising of Foodstuffs, R.146, the listing of ingredients and proportions of ingredients shall be in a letter type of uniform size, colour, font and prominence throughout and the first letter may be a capital letter.

The Nutritional information shall always be presented in the tabular format as per Annexure A and B. Regulation 13 (c) in R 146 stipulates that where the size of the label is restricted by the physical size of the product and less than 900 mm^2 remains after the requirements in terms of these regulations have been met, the nutritional information may be indicated in a linear format. The listing of the nutritional information shall be in a letter type of uniform size, colour, font and prominence throughout and the first letter may be a capital letter.

77. The nutritional information table in Annexure A and B notes Total dietary fibre and Sodium, whereas R 146 notes Dietary fibre and Total sodium. Is this the intention to have different nomenclature?

Answer: It was not the intention to have different nomenclature. Therefore the nomenclature dietary fibre and total sodium as indicated in R146 can be used.

78. Annexure B, # after dietary fibre indicates need to method of analysis is not required as we are unable to make dietary fibre claims and therefore should be removed from the Annexure.

Answer: Although no claim can be made, the Regulations as per Annexure B require that the dietary fibre content and the method of analysis to be indicated beneath the table.

79. Why is there a disconnect in terms of the declaration of nutritional information between R146 and R991? Annexure A requires a quantified single serving size expressed in g or ml but it is not applicable to infant formulas, follow up formulas and FSMP for infants as there will be a feeding table indicating the volumes required by different age ranges.

Answer: The declaration of nutritional information as per Annexure A is in line with 9.3 in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)

The declaration of nutrition information shall contain the following information:

a. The amount of energy, expressed in KJ, and the number of grammes of protein, carbohydrate and fat per 100g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instruction on the label.
b. The total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2 of the standard per 100g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instruction on the label.
c. In addition, the declaration of nutrients in a) and b) per 100 KJ is permitted.

80. Why is there a disconnect between the NRV unit of measure and the Codex standard? For example a nutrient may round to zero mg from 2 mcg and would be required to be included on the label as zero mg, although present in the product at the Codex level. Please advise which unit of measure takes precedence.

Answer: The declaration of nutritional information as per Annexure A (for infant formula, follow-up formula, or infant formula or follow-up formula for special dietary management for infants with specific medical conditions) does not require that the NRV be stated. The table also stipulates for vitamins and minerals the appropriate unit of measure can be used. Since, these values are so small it should be stated as per laboratory report. For example, According to the Codex standard for Infant Formula, Biotin needs to be present at a minimum amount of 0.4 µg/100kJ; this should not be rounded off.

The declaration of nutritional information as per Annexure B (for complementary foods and liquid milks, powdered milks, modified powdered milks and powdered drinks) does require % NRV per serving. The table also stipulates for vitamins and minerals the appropriate unit of measure can be used although some vitamins e.g. Vit B1, B2, B6 etc. are declared as mg in Annexure C of R991. Since, these values are so small it should be stated as per laboratory report. Rounding off should only be done in cases of more than 2 decimal places.

81. Do all complementary foods, liquid milk, powdered milk, modified powdered milk and powdered drinks need to include all possible vitamins and minerals in the required nutritional information table?

Answer: No. Please refer to the Regulations Relating to the Labelling and Advertising of Foodstuffs (R.146), (Annexure 2) which details the minimum nutritional information that must be included in the nutritional information table (e.g., energy, protein, carbohydrate, fat, dietary fibre and sodium).

However, the general principal is that where a Codex Alimentarius Standard requires the declaration of vitamins and minerals for a particular foodstuff, the information required by Codex should be listed in the nutritional information table. For example, the Codex Standard for Processed Cereal-Based Foods for Infants and Young Children requires that calcium, vitamin B1, vitamin A and vitamin D be included.

Manufacturers may include other vitamins and minerals in the nutritional information table on a voluntary basis. Vitamins and/or minerals added to a particular food should be selected from the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Young Children (CAC.GL 10-1979).

Please note: The listing of vitamins and nutrients in the nutritional information table is allowed in the nutritional information table only. This does not constitute a nutrition claim for the purpose of the regulations.

82. How do you calculate age appropriate NRV's? Do you need to include both of the tables included in the Regulations if the product is marketed to infants 6 to 12 months and 13 to 36 months?

Answer: It is ideal to include both tables if label space permits. If space does not allow, an average could be used between 6 to 12 months and 13 months to 36 months. It would be important to indicate on the label that the average was used.

To calculate body mass, use the WHO median weight ranges for girls and boys to come to an average weight for 6 to 12 months of **8.5 Kg**. Please indicate on the label beneath the table as a footnote the source of data (e.g. WHO average weight for 6 to 12 months).

If a product is labelled for "8 months and older", you would then only use the weight ranges on WHO for the 8 month category upwards. As the younger ages would bring down the average weight and then push up the % NRV. The average weight for 6- 12 months is 8.5 kg and for 8 to 12 months is 8.8 kg.

Annexure 1

Sponsorship of Professional meetings/congresses, seminars targeting health care personnel

Members include health care personnel working in infant and young child nutrition

	Meeting/event agenda unrelated to Infant and Young Child Nutrition and/or refer to no designated products e.g. focus on adult health/nutrition (1)	**Meeting/event Agenda include Infant and Young Child Nutrition and/or refer to designated products (only one company involved) (2)**	**Congresses/seminars/workshop Agenda: include infant and young child nutrition is <u>the sole or partial topic</u> of discussion. (more than one company involved, e.g. Nutrition Congress, Paediatric Conference) (3)**	**Educational meetings that addresses infant and young child nutrition from which health care providers gain CPD points <u>No reference to any designated products</u> (4)**
Presentation of educational information relating to infant and young child nutrition. R 7(5)	No presentation is made on IYCN	No. No manufacturer, distributer, retailer, importer or person on behalf aforementioned…R 7(5)	No. No manufacturer, distributer, retailer, importer or person on behalf aforementioned…R 7(5)	No. No manufacturer, distributer, retailer, importer or person on behalf aforementioned… R 7(5)
Promotion and sponsorships	No promotion of designated products at the event	Sponsorships, donations, gifts are seen as promotional methods.	Contribution or sponsorship is made into a pool of funds for congress organisers Sponsored delegates should have no obligations to the company involved. IYCN Workshop within a congress can't be sponsored by individual company or on behalf of the company	Sponsorships, donations, gifts are seen as promotional methods
Sponsorship by Industry of Designated Products	**Yes, if company produce products related to adult nutrition**	**No,** see definition promote (include sponsorship)	**Yes, into a pool of funds R 7(2)(j)**	**No**
Sponsorship by Industry of Non-Designated Products	**Yes**	**No,** no person may promote R 7(3)	Yes, can sponsor specific sessions unrelated to infant and young child feeding	**No**

Financial contributions or sponsorships to health care professionals to attend a meeting/event	**Yes, can be made to health care professionals who works with adults**	**No**	**Yes into a pool of funds**	**No**
Can a designated product be displayed at professional congresses or meetings	**No**	No displays. May provide technical scientific material that relates to the designated product(s). It excludes any promotion e.g. no gifts, prizes	No displays. May provide technical scientific material that relates to the designated product(s). It excludes any promotion e.g. no gifts, displays	No displays. May provide technical scientific material that relates to the designated product(s). It excludes any promotion e.g. no gifts, prizes
Can samples of designated products be given	**No, R 9**	**No**	**No**	**No**
Can conference organisers state which companies provide the sponsorship?	**Yes**	**No unless meeting unrelated to IYCN**	**Yes**	**NA**
Is industry allowed to provide meals and refreshments	**Yes**	**No**	**No, Pool of funds for sponsors – conference organisers will acknowledge**	**No**

Relevant Regulations

7 (2) (c) the distribution of any information or educational material on the nutrition or feeding of infants and young children, except in accordance with sub-regulation 7 (4); (**Considered promotion)**

7(3) **No person shall sell, promote, or advertise any designated product**, including complementary foods, **through health care personnel or health establishments**. Prohibited promotional practices include, but are not limited to:

(a) provision or offer, direct or indirect, of any gift in cash or in kind, contribution, or benefit to health care personnel whether intended for such worker's personal use or not; and

7(1) (i) financial contributions or sponsorship to health care personnel working in infant and young child nutrition;

7(1)(j) sponsorship of meetings targeting health care personnel where infant and young child nutrition is the **sole or partial topic of discussion**, unless contribution or sponsorship is made into a pool of funds for congress organisers with the proviso that a fair and transparent process be followed in the election and sponsoring of delegates to attend such events. Sponsored delegates should have no obligations to the company involved

7(5) No manufacturer, distributor, retailer, importer or person on behalf of the aforementioned shall present educational information relating to infant and young child nutrition.

Definitions

"promote" means to employ any method scheme or design, of encouraging or enticing a person or group of persons, in whatever form, to purchase or use a designated product, and includes but is not limited to, advertising, point-of-sale advertising, the giving of samples, special sales, free supplies, donations, sponsorships, **gifts, whether related or unrelated to purchases of designated products**, free utensils or other articles, prizes, carrier bags with pack-shots or product logos, prizes or special displays at retail outlets, discount coupons, premiums, loss-leaders, tie-in sales, rebates and other give-aways;

"gift" means something given free of charge, and in this context, includes, but is not limited to, free samples of designated products, meals and refreshments, diaries, stationery, calendars, cot tags, stickers, growth charts, prescription pads, tongue depressors or any item of whatever value **by manufacturers, distributors, retailers and their representatives, of the designated products;**

"educational information" means any written or audio-visual material or information disseminated by an individual that seeks to impart knowledge, such as presentations, brochures or articles;