

## **CHAPTER 4**

**Food and Health Bureau  
Food and Environmental Hygiene Department  
Department of Health**

**Nutrition labelling of infant and special dietary foods**

**Audit Commission  
Hong Kong  
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*This audit review was carried out under a set of guidelines tabled in the Provisional Legislative Council by the Chairman of the Public Accounts Committee on 11 February 1998. The guidelines were agreed between the Public Accounts Committee and the Director of Audit and accepted by the Government of the Hong Kong Special Administrative Region.*

Report No. 57 of the Director of Audit contains 12 Chapters which are available on our website at <http://www.aud.gov.hk>.

Audit Commission  
26th floor, Immigration Tower  
7 Gloucester Road  
Wan Chai  
Hong Kong

Tel : (852) 2829 4210  
Fax : (852) 2824 2087  
E-mail : [enquiry@aud.gov.hk](mailto:enquiry@aud.gov.hk)

# **NUTRITION LABELLING OF INFANT AND SPECIAL DIETARY FOODS**

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## PART 1: INTRODUCTION

1.1 This PART describes the background to the audit and outlines the audit objectives and scope.

### Background

1.2 Food labelling provides an important channel of communication between manufacturers and consumers on information about individual food products, such as ingredients, expiry dates, etc. It serves as a tool for food traders to inform and attract potential buyers on the one hand and assists consumers to make informed choices on the other.

1.3 Food labelling is governed by the **Food and Drugs (Composition and Labelling) Regulations (the Regulations — Cap. 132W)** made under the Public Health and Municipal Services Ordinance (PHMSO — Cap. 132). In accordance with Schedule 3 of the Regulations, all prepackaged foods (Note 1) should be legibly marked or labelled (in either English or Chinese, or in both languages) with information including:

- (a) name of the food;
- (b) list of ingredients (including food additives);
- (c) indication of durability;
- (d) special conditions for storage or instructions for use;
- (e) count, weight or volume; and
- (f) name and address of manufacturer or packer.

1.4 ***The 2004 Amendment Regulation.*** In 2004, the Regulations were amended to require the declaration of the presence of any of eight types of allergenic substances (such as cereals containing gluten, eggs, peanuts, soyabeans and tree nuts) and that the food labels should specifically indicate the name or code of the food additive used. The 2004 Amendment Regulation was enacted in July 2004 and came into operation in July 2007.

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**Note 1:** *Schedule 4 of the Regulations exempts certain types of prepackaged foods from the marking or labelling requirements under the Regulations. Examples include prepackaged foods sold at a catering establishment for immediate consumption, fresh fruit, fresh vegetables, and any food consisting of a single ingredient.*

1.5 Figure 1 shows the food labelling requirements for prepackaged foods (including infant and special dietary foods) after the implementation of the 2004 Amendment Regulation.

Figure 1

### Food labelling requirements for prepackaged foods



Source: Food and Environmental Hygiene Department (FEHD) records

1.6 **The 2008 Amendment Regulation.** Before the 2008 Amendment Regulation was implemented, there was no specific law or regulation in Hong Kong governing nutrition information on food labels. The Administration then relied on the general provisions of the PHMSO to regulate food labels (e.g. to prosecute food traders under section 61 of the PHMSO for use of improper labels or advertisements to mislead as to the nutritional or dietary value of any food). The 2008 Amendment Regulation, enacted in May 2008 and came into operation in July 2010, introduced a mandatory **nutrition labelling scheme** for prepackaged foods. The scheme aims to:

- (a) assist consumers in making informed food choices;
- (b) encourage food manufacturers to apply sound nutrition principles in the formulation of foods; and
- (c) regulate misleading or deceptive labels and claims.

## The nutrition labelling scheme

1.7 Nutrients are vital for growth, repair and maintenance of good health. Good nutrition is very important in every stage of life. People of all ages require different nutrients in balanced amount to maintain good health and prevent diseases.

1.8 Provision of nutrition information on food labels is an important tool to promote a balanced diet, hence enhancing public health. According to the Administration, based on overseas experience, labelling of nutrition information has positive impact on food consumption behaviour, and helps save healthcare costs and human lives. While under-nutrition is generally not a public health problem in Hong Kong, an imbalanced diet contributes to obesity and many chronic degenerative diseases such as coronary heart disease, diabetes and certain types of cancer. These nutrition-related diseases are important public health problems in many parts of the world, including Hong Kong.

1.9 The nutrition labelling scheme applicable to Hong Kong was developed with reference to the principles adopted by the Codex Alimentarius Commission (Codex — see Appendix A), local health conditions and international practices. The nutrition labelling scheme covers **nutrition labelling** and **nutrition claims**.

1.10 Nutrition labelling refers to the listing of the nutrient content of a food in a standardised manner. The information is often presented in a tabular format. When nutrition labelling is applied, the value/content of energy plus seven core nutrients (namely protein, carbohydrates, total fat, saturated fat, trans fat, sodium and sugars), or commonly known as “1+7”, are required to be affixed on the nutrition label (in either English or Chinese, or in both languages). Figure 2 shows the nutrition label of a prepackaged food.

**Figure 2**  
**Nutrition label of a prepackaged food**



Source: FEHD records

1.11 Nutrition claims are claims which suggest that a food has particular nutritional properties. Nutrition claims include nutrient content claims (Note 2), nutrient comparative claims (Note 3) and nutrient function claims (Note 4). In regulating these claims, the Administration follows generally the standards and conditions stipulated in the Codex standards and guidelines. Figure 3 shows examples of nutrition claims on prepackaged foods.

**Note 2:** *Nutrient content claims are claims that describe the level of a nutrient contained in a food (e.g. “High calcium”, “Low fat” and “Sugar-free”). Nutrient content claims can only be made for energy and nutrients specified in Schedule 8 of the 2008 Amendment Regulation.*

**Note 3:** *Nutrient comparative claims are claims that compare the nutrient levels of two or more similar foods (e.g. “Reduced fat — 25% less than the regular product of the same brand”). In general, to make a nutrient comparative claim, there must be at least 25% difference (except for vitamins and minerals) in the levels of the nutrient contents between the products being compared.*

**Note 4:** *Nutrient function claims are claims that describe the physiological role of a nutrient in growth, development and normal functions of the body (e.g. “Calcium aids in the development of strong bones and teeth”).*



**Figure 3**  
**Nutrition claims on prepackaged foods**



Legend:  Nutrition claims

Source: FEHD records

1.12 Based on a study commissioned by the Administration in 2005, the introduction of the nutrition labelling scheme would likely impose costs on importers, manufacturers and retailers mainly because of the need to undertake testing and to re-label the prepackaged foods. The initial compliance costs on the trade could be very significant.

### Applicability of the Regulations to infant and special dietary foods

1.13 The Regulations, including the 2004 Amendment Regulation, apply to all prepackaged foods (see paras. 1.3 to 1.5). The 2008 Amendment Regulation (see para. 1.6) introduced a mandatory nutrition labelling scheme for prepackaged foods. **However, the nutrition labelling scheme does not apply to infant and special dietary foods, namely:**

- (a) **formula intended to be consumed by children under the age of 36 months;**
- (b) **food intended to be consumed principally by children under the age of 36 months; and**
- (c) **other food for special dietary uses.**

As early as 2005, the Administration undertook that it would review the need for introducing nutrition labelling requirements covering these foods in the future.

## **Centre for Food Safety**

1.14 **The Centre for Food Safety (CFS), under the Food and Environmental Hygiene Department (FEHD), is the food safety authority in Hong Kong.** It is responsible for implementing territory-wide food safety control policies and enforcing food-related legislations, including overseeing the implementation of the food-labelling-related law and regulations. An organisation chart of the CFS is at Appendix B.

## **Audit review**

1.15 The Audit Commission (Audit) has recently conducted a review of the CFS's work in the regulatory control of food labelling, with focus on the implementation of the nutrition labelling scheme under the 2008 Amendment Regulation, which has been operational for more than one year (see para. 1.6). The audit review has also examined the adequacy of the nutrition labelling of infant and special dietary foods. The objective is to provide input to the Administration on whether there is a need to introduce nutrition labelling requirements covering such foods (see para. 1.13). In conducting the audit review, Audit has commissioned a consultant (a local university) to conduct laboratory tests to verify the information on nutrition labels and to conduct a public opinion survey on food labelling. The audit findings are contained in two separate reports, as follows:

- (a) **nutrition labelling of infant and special dietary foods (the subject matter of this Report); and**
- (b) food labelling (see Chapter 3 of the Director of Audit's Report No. 57).

1.16 Audit's review of the nutrition labelling of infant and special dietary foods focused on the following areas:

- (a) infant and special dietary foods not covered by the 2008 Amendment Regulation (PART 2);
- (b) regulation of nutrition information (PART 3);
- (c) development of a Hong Kong Code of Marketing of Breast-milk Substitutes (PART 4); and
- (d) the way forward and audit recommendations (PART 5).

To support the audit work in (a) and (b) above, Audit has examined various types of infant and special dietary foods. The results of 12 case studies are reported (Cases 1 to 3 in PART 2 and Cases 4 to 12 in PART 3 are relevant).

1.17 Audit has found areas which call for early attention/improvement and has made a number of recommendations to address the issues.

### **General response from the Administration**

1.18 The **Secretary for Food and Health**, the **Director of Food and Environmental Hygiene** and the **Director of Health** appreciate the efforts of the Audit team in auditing the CFS's work in the regulatory control of food labelling and are grateful for the hard work of the team.

### **Acknowledgement**

1.19 Audit would like to acknowledge with gratitude the full cooperation of the staff of the Food and Health Bureau, the CFS, and the Department of Health (DH) during the course of the audit review.

## **PART 2: INFANT AND SPECIAL DIETARY FOODS NOT COVERED BY THE 2008 AMENDMENT REGULATION**

2.1 This PART examines the nutrition labelling of infant and special dietary foods with reference to the Codex standards and guidelines. Three case studies are reported in this PART, as summarised below.

| <b>Case</b> | <b>Audit observations</b>   |
|-------------|---|
| 1           | A few popular foreign infant formulae marketed in Hong Kong deviated from the Codex standards and guidelines in their nutritional composition and labelling (see para. 2.16(a)).                                  |
| 2           | Nutrition and health claims, and other claims were commonly used by formula traders to promote infant and follow-up formulae, which were not in line with the Codex standards and guidelines (see para. 2.16(b)). |
| 3           | Some claims in special dietary foods were not in line with the Codex standards and guidelines (see para. 2.21).   |

### **Background**

2.2 As mentioned in paragraph 1.13, the nutrition labelling scheme under the 2008 Amendment Regulation does not apply to infant and special dietary foods. As early as **November 2003** during the consultation stage, the Administration indicated that the proposed nutrition labelling scheme would not be applicable to infant and special dietary foods as they were targeted at subgroups of the population with special dietary needs. In January 2004, the Consumer Council, the Hong Kong Academy of Medicine and the Hong Kong Nutrition Association Limited suggested to the Legislative Council (LegCo) Panel on Food Safety and Environmental Hygiene (Panel) that infant and special dietary foods should also be included in the scheme.

2.3 In **June 2005**, the Administration informed the LegCo Panel that the proposed nutrition labelling scheme would not cover infant and special dietary foods as a matter of priority and Codex had developed different labelling standards and guidelines for such foods. Nonetheless, the Administration undertook to review the need for introducing nutrition labelling requirements covering these foods in the future. The Panel was however not informed of the timetable for the review.

2.4 In **December 2007**, the Administration again informed the LegCo Panel that the proposed nutrition labelling scheme would not apply to infant and special dietary foods since these foods were regulated under different Codex standards.

2.5 In the event, the **2008 Amendment Regulation** was enacted in **May 2008** and came into operation in **July 2010**, but did not apply to infant and special dietary foods. In **June 2009**, the Hong Kong Medical Association wrote to the LegCo Panel expressing its concern that many infant and toddler food marketed in Hong Kong were imported or sold via Internet and had labels written in foreign languages (neither English nor Chinese), but they fell outside the nutrition labelling scheme and were not regulated by the Government. The Association urged the Administration to safeguard the health of the young generation by including these food products in the nutrition labelling scheme (Note 5).

#### *Coverage of infant and special dietary foods*

2.6 As mentioned in paragraph 1.13, infant and special dietary foods cover the following types of foods:

- (a) ***Formula intended to be consumed by children under the age of 36 months.*** These cover infant formulae and follow-up formulae. According to Codex (Note 6), infant formulae are breast-milk substitutes (Note 7) specially manufactured to satisfy the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding, whereas follow-up formulae are foods intended for use as a liquid part of the weaning diet for infants from the 6th month on and for young children (up to the age of 36 months);

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**Note 5:** *At the LegCo Panel meeting of 22 June 2009, the Administration pointed out that although the 2008 Amendment Regulation did not cover infant formula, all information provided on food labels should be true and not misleading, and the food name and the list of ingredients as well as the instructions for use must be in English, Chinese or both languages.*

**Note 6:** *In the absence of legal definitions, and given that the nutrition labelling scheme was developed with reference to the principles adopted by Codex, the principles/definitions adopted by the CFS or by Codex are used.*

**Note 7:** *According to the World Health Organization, a breast-milk substitute refers to any food being marketed or otherwise represented as a partial or total replacement for breast-milk, whether or not suitable for that purpose.*

- (b) ***Food intended to be consumed principally by children under the age of 36 months.*** These cover foods for infants and young children. According to Codex, infants refer to persons of not more than 12 months of age, whereas young children refer to persons from the age of more than 12 months up to the age of 36 months; and
- (c) ***Other food for special dietary uses.*** The Regulations have not provided any definition of “food for special dietary uses”. However, the CFS has adopted the following principles, which are similar to those used by Codex:

- (i) foods for special dietary uses are those specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific disease and disorders and which are presented as such; and
- (ii) the composition of these food stuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

Source: CFS website

***The 2008 Amendment Regulation does not apply to infant and special dietary foods***

2.7 The nutrition labelling scheme in Hong Kong was developed with reference to the principles adopted by Codex (Codex standards and guidelines — Note 8), local health conditions and international practices (see para. 1.9). According to the Administration, infant and special dietary foods were not included in the scheme because the consumers of these products had different nutritional requirements and concerns vis-a-vis the general population, and these foods were regulated by different Codex standards and guidelines. Nonetheless, the Administration undertook to review the need for introducing nutrition labelling requirements covering these foods in the future (see para. 2.3).

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**Note 8:** *Examples of such Codex standards and guidelines that apply to all prepackaged foods include the Guidelines on Nutrition Labelling (1985) and the Guidelines for Use of Nutrition and Health Claims (1997).*

## Importance of nutrition labelling for infant and special dietary foods

2.8 Good nutrition is very important in every stage of life. Infants need energy and nutrients for growth and development. Well-nourished children grow and learn better. Pregnant women and lactating mothers require additional nutrients to support a normal pregnancy and lactation for the babies respectively. Older adults require different nutrients in balanced amount to maintain good health and prevent diseases. Infants, young children and people with special dietary needs are generally more vulnerable. As a result, foods for them have to be more strictly regulated.

2.9 The dietary requirements of infants, young children and people with special dietary needs are different from those of the general public. Apart from the fact that the general standards and guidelines on nutrition labelling, developed by Codex, generally apply to infant and special dietary foods (Notes 8 and 9), Codex has developed specific additional standards to govern such foods (see Appendix C).

2.10 Taking **infant formula** as an example, because it is a breast-milk substitute specially manufactured to satisfy the nutritional requirements of infants during their first months of life up to the introduction of appropriate complementary feeding, Codex has laid down comprehensive standards on the formula's compositional, quality and safety requirements, to ensure its nutritional safety and adequacy to support the growth and development of infants. Such standards cover **nutritional composition and labelling** of infant formula. Examples of such standards are shown below.

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**Note 9:** *For example, the Codex Guidelines for Use of Nutrition and Health Claims (which apply to all foods for which nutrition and health claims are made) have provided that the use of nutrition and health claims on foods for infants and young children is prohibited, except where specifically provided for in relevant Codex standards or national legislation.*

### *Scope*

- (a) The application of the Codex Standard for infant formula should take into account, among others, the recommendations made by the World Health Organization (WHO) in its International Code of Marketing of Breast-milk Substitutes issued in 1981 (the 1981 WHO Code).
- (b) Only products that comply with the criteria laid down in the Codex Standard would be accepted for marketing as infant formula.

### *Essential composition and quality factors*

- (c) The nutritional safety and adequacy of infant formula should be scientifically demonstrated to support growth and development of infants. All ingredients and food additives should be gluten-free.
- (d) Infant formula prepared ready for consumption in accordance with the instructions of the manufacturer should contain, per 100 millilitres (mL), not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy.
- (e) **Infant formula prepared ready for consumption should contain, per 100 kcal (or 100 kJ), 33 essential nutrients which include protein, fat, carbohydrates, vitamins and minerals, with the minimum and maximum levels set for each nutrient (more details are at Appendix D).** For example, for every 100 kcal (or 100 kJ) of infant formula prepared ready for consumption, its protein content should reach at least 1.8 grams (g) (or 0.45g) and should not exceed 3g (or 0.7g).
- (f) Ratios of essential nutrients:

| Essential nutrient                  | Minimum | Maximum |
|-------------------------------------|---------|---------|
| Calcium : phosphorus                | 1:1     | 2:1     |
| Linoleic : $\alpha$ -linolenic acid | 5:1     | 15:1    |

### *Optional ingredients*

- (g) In addition to the compositional requirements set for essential nutrients, other 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.
- (h) **The suitability for the particular nutritional uses of infants and the safety of these substances should be scientifically demonstrated.**

(To be continued)



(Cont'd)

***Food additives***

- (i) Only food additives listed in the Codex Standard or in the Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (1979) are acceptable for use in the preparation of infant formulae. The amount of the food additive in the raw materials or other ingredients (including food additives) should not exceed the maximum level specified.

***Labelling***

- (j) **The use of nutrition and health claims (Note) for foods for infants and young children is prohibited, except where specifically provided for in relevant Codex standards or national legislation.**
- (k) The declaration of nutrition information should show the amount/quantity of energy, protein, carbohydrate, fat, vitamins, minerals and choline, and any other ingredients in specified order.
- (l) Labels should not discourage breastfeeding. Each container label should have a clear, conspicuous and easily readable message which includes, among others, the statement of “Breast milk is the best food for your baby” or a similar statement as to the superiority of breastfeeding or breast milk.
- (m) **The label should have no pictures of infants and women nor any other picture or text which idealises the use of infant formula.**
- (n) The products should be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.

Legend: kcal = kilocalories  
kJ = kilojoules

*Source:* Section A “Revised standard for infant formula” of the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (first issued in 1981)

*Note:* According to Codex, nutrition claims are claims which suggest that a food has particular nutritional properties (see para. 1.11), whereas health claims are claims that imply or suggest a relationship between a food (or a constituent of that food) and health.

2.11 In the case of **special dietary foods**, Codex has developed specific additional standards for their labelling and claims which are more stringent than the standards applicable to ordinary foods. For such special dietary foods (including foods for infants and young children), examples of additional mandatory labelling requirements suggested by Codex include the following:

***The name of the food***

- (a) The designation “special dietary”, “special dietetic” or an appropriate equivalent term, may be used in conjunction with the name only when the product meets the definition of “food for special dietary uses”.
- (b) The characterising essential feature should be stated in appropriate descriptive terms in close proximity to the name of the food.

***Nutrition labelling***

- (c) The following information should be declared as per 100g or 100 mL of the food as sold and where appropriate per specified quantity of the food as suggested for consumption:
  - (i) the amount of energy (expressed in kcal and kJ);
  - (ii) the number of grams of protein, available carbohydrate and fat; and
  - (iii) the total quantity of those specific nutrients or other components which provide the characterising essential feature for the special dietary use (see (b) above).

*Source: Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (first issued in 1985)*

Similar to other prepackaged foods, Codex prohibits certain types of claims (Note 10) made on foods for special dietary uses including, for example, claims which cannot be substantiated and claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients. According to Codex, the principle is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect. Food traders should be able to justify the claims they made.

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**Note 10:** *Claims are representations which state, suggest or imply that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.*

## Audit observations

### *Compliance with Codex standards and guidelines not mandatory*

2.12 Audit notes that Codex has gained international recognition on setting food-related standards, but compliance with the Codex standards and guidelines is not mandatory. It is up to individual governments to develop their own nutritional composition and labelling requirements (with reference to the Codex standards and guidelines) to suit their needs.

2.13 Although the Administration repeatedly informed LegCo that the nutrition labelling scheme would not apply to infant and special dietary foods because they were regulated by different Codex standards and guidelines (see paras. 2.3 and 2.4), Audit has some reservations on the desirability of deferring consideration for including infant and special dietary foods under the scheme. **This is because compliance with the Codex standards and guidelines is not mandatory. Given this, unless compliance is made as a requirement, infant and special dietary foods marketed in Hong Kong cannot be effectively regulated by the Codex standards and guidelines.**

2.14 The fact remains that despite the importance of regulating infant and special dietary foods, the nutrition labelling scheme does not apply to them. **The Administration has however neither set any separate law or regulations to govern nutrition labelling (including nutrition and health claims) of infant and special dietary foods marketed in Hong Kong, nor required such foods to comply with relevant Codex standards and guidelines.**

### *Audit examination of selected infant and special dietary foods*

2.15 Against the above background, Audit conducted an examination of selected infant and special dietary foods marketed in Hong Kong (Note 11). The objective of the examination was to ascertain the extent to which such foods had followed the Codex standards and guidelines. The results are set out in paragraphs 2.16 to 2.21.

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**Note 11:** *Owing to resource constraints, only limited samples relating to two types of infant and special dietary foods had been examined. They were, namely, formulae intended to be consumed by children under the age of 36 months and other foods for special dietary uses (see para. 1.13(a) and (c)).*

*Formulae for infant and young children*

2.16 Audit found that a few of such infant and follow-up formulae marketed in Hong Kong did not strictly follow the Codex standards and guidelines. Such non-compliances included:

- (a) deviations from the Codex standards and guidelines in nutritional composition and labelling (examples are shown in Case 1); and
- (b) although Codex has prohibited the use of nutrition and health claims for foods for infants and young children (see para. 2.10(j)), nutrition and health claims, and other claims were commonly used by formula traders to promote infant and follow-up formulae marketed in Hong Kong (see examples in Case 2). It is worth noting that the 1981 WHO Code has also recommended that there should be no advertising or other form of promotion to the general public of breast-milk substitutes (see para. 4.2(b)).

## Case 1

### Deviations from Codex standards and guidelines in nutritional composition and labelling

1. According to Codex, infant formula has to contain 33 essential nutrients and follow-up formula 25 essential nutrients. Minimum and maximum levels are set for each nutrient. They aim to provide a product intended for use as a substitute for human milk in meeting the normal nutritional requirements of infants.

2. All infant and follow-up formulae marketed in Hong Kong are imported. Based on an examination in mid-2011 of the general food and nutrition labels for a number of foreign infant formulae marketed in Hong Kong, Audit found that two popular brands of such formulae, Formula 1 and Formula 2 (Note 1), imported from Country A, differed from the Codex standards and guidelines in their nutritional composition and labelling in the following areas:

- (a) Codex stipulates that whenever docosahexaenoic acid (DHA) has been added to infant formulae, the arachidonic acid (AA/ARA) contents of the formulae should reach at least the same concentration as the DHA, i.e. a ratio of **“≥ 1 : 1” for AA/ARA to DHA**. Audit however found that the ratios of AA/ARA to DHA in Formulae 1 and 2 were “1 : 2” and “1 : 3.8” respectively (Note 2);
- (b) although iodine (Note 3) and biotin are two essential nutrients according to the Codex standards (see Appendix D), they were however not shown on the nutrition labels of Formulae 1 and 2 (Note 4); and
- (c) although Codex prohibits the use of infants’ pictures on the container labels (see para. 2.10(m)), the picture of an infant was displayed on the container labels of Formulae 1 and 2.

3. According to Codex, other ingredients may be added provided that their suitability for the particular nutritional uses of infants and their safety have been scientifically demonstrated (see para. 2.10(h)). Audit noted that some ingredients which were not classified as essential nutrients under the Codex standards, were included in the formulae. However, it is not known whether their suitability for our infants has been scientifically demonstrated. Examples are shown below:

| Formula 1   | Formula 2                                      |
|---|--|
| Lactulose and Raffinose, both with a declared value of 500mg/100g | Cholesterol with a declared value of 74mg/100g |

(To be continued)

(Cont'd)

**Audit comments**

4. Importing countries might have set different nutritional requirements for their infants in order to meet the health needs of their infants. However, in the absence of specific nutritional composition and labelling requirements laid down in Hong Kong, our people will have to accept the imported formulae, yet without knowing if they are appropriate for our infants. It is worth noting that the mainland of China has generally followed the Codex standards in its 2010 revision of the nutritional composition and labelling requirements for infant formula (see Appendix D).

*Source: Audit research*

*Note 1: Audit also found that Formula 2 and three other brands of infant formulae imported from Country A had their nutrition information displayed in a foreign language only (which was neither English nor Chinese).*

*Note 2: In early October 2011, the CFS informed Audit that: (a) national authorities may deviate from the Codex requirements, as appropriate for the nutritional needs of their people; (b) according to Country A's regulation, there was no requirement on the ratio of AA/ARA to DHA; and (c) the requirement on the ratio of AA/ARA to DHA (" $\geq 1 : 1$ ") was adopted by Codex in 2007 but was not supported by Country A (and some other delegations) at the 28th Session (held in 2006) of the Codex Committee on Nutrition and Foods for Special Dietary Uses because Country A considered that there was insufficient scientific evidence.*

*Note 3: Iodine is an essential nutrient for human. According to the result of a risk assessment study on "Dietary Iodine Intake in Hong Kong Adults" published by the CFS in July 2011, iodine played a key role in regulating various metabolic functions in the body. It was also reported that iodine deficiency might lead to goitre, hypothyroidism, abnormalities in the growth and development of the brain and central nervous system in infants and children. Infants and young children were particularly vulnerable to iodine deficiency disorders. According to the study, the WHO recommended the intake per person of iodine for different age groups from 90 micrograms ( $\mu\text{g}$ ) to 250 $\mu\text{g}$  per day.*

*Note 4: Although iodine and biotin are essential nutrients for infant formula under the Codex standards, they were not regarded as such in Country A.*

## Case 2

### Common use of claims to promote infant and follow-up formulae

1. Audit found that nutrition and health claims, and other claims were commonly used by formula traders to promote their infant and follow-up formulae marketed in Hong Kong. Some examples are shown below.

- (a) “17mg DHA, 34mg ARA, Prebiotics and Antioxidants : 醫學研究顯示有助支持腦部及免疫系統發展” (17 milligrams (mg) DHA, 34mg ARA, Prebiotics and Antioxidants : Medical studies show that they help the development of the brain and the immune system) (see Photograph 1)
- (b) “添加 DHA 及 Nucleotide , 添加低聚醣 促進腸道健康 , 含 Sialic Acid 及色氨酸” (Added DHA and Nucleotide, added Oligosaccharide which promotes healthy intestinal tracts, contains Sialic Acid and Tryptophan) (see Photograph 2)
- (c) “It now contains higher levels of Phospholipids. Phospholipids are essential for the functioning of brain cells”
- (d) “And, added lutein, a nutrient important to the retina to support your baby’s eye health.”
- (e) “DHA and ARA are two special fatty acids found in breast milk and are important for your baby’s defense system, contributing to the development of the brain and vision.” (see Photograph 3)
- (f) “Prebiotics — Galacto-oligosaccharides (GOS) stimulates the growth of beneficial intestinal flora to maintain a healthy digestive system”
- (g) “Contains a unique vegetable fat blend without palm olein oil to support calcium absorption for strong bones and healthy teeth”
- (h) “PhD 有助傳遞大腦訊息” (PhD helps transmit brain messages)
- (i) “添加水溶性膳食纖維 , 幫助健康的腸道益菌生長 , 有助軟化便便及減少腸道熱氣” (Added water-soluble dietary fibre helps the growth of healthy probiotics in intestinal tracts, thereby softening faeces and reducing intestinal heatiness)
- (j) The picture of an infant and a woman in the advertisement, together with a statement of “最健康天然的選擇原來是 XX (某品牌的嬰兒奶粉)” (The most healthy and natural choice turns out to be XX — a brand name of infant formula) (see Photograph 4)

(To be continued)

(Cont'd)

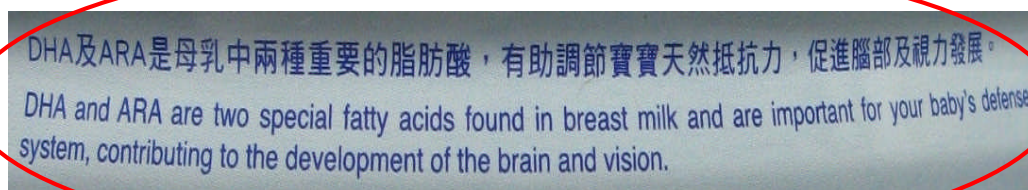
Photograph 1



Photograph 2



Photograph 3



Photograph 4



2. It would appear that the above claims might not be in line with the Codex standards and guidelines.

Legend:  Nutrition and health claims, and other claims

Source: Audit research



2.17 The deviations from the Codex standards and guidelines in Cases 1 and 2 are causes for concern. Such deviations have arisen apparently because the Administration has not developed any nutritional composition and labelling requirements (by law or regulations) to govern infant and follow-up formulae marketed in Hong Kong. In the absence of these, coupled with the fact that compliance with the Codex standards is not mandatory, there is inadequate assurance of the nutritional safety and adequacy of infant and follow-up formulae marketed in Hong Kong (PART 3 on the regulation of nutrition information is also relevant).

2.18 For benchmarking, it is worth noting that many countries, including China, have developed comprehensive laws or regulations governing the nutritional composition and labelling of infant and follow-up formulae to be marketed in their countries. Most of them have made reference to the Codex standards and guidelines in developing their local laws and regulations, and have included various degrees of restrictions on the use of nutrition and health claims to promote foods for infant and young children (Note 12). In particular, the mainland of China (not including Hong Kong) has generally followed the Codex standards in its 2010 revision of the nutritional composition and labelling requirements for infant formula. A summary benchmarking some of these countries' nutritional composition and labelling requirements for infant formula against the Codex standards is shown at Appendix D.

### *Food for special dietary uses*

2.19 The Regulations have not provided any definition of “food for special dietary uses” (see para. 2.6(c)). To assist the trade and consumers to determine whether a food product should be classified as “food for special dietary uses”, the CFS has specified some principles and guidelines on its website (see Appendix E). However, the CFS has further indicated that individual products have to be considered **on a case-by-case basis** for determining whether they are foods for special dietary uses.

2.20 Furthermore, because Hong Kong relies heavily on imported foods, in the absence of specific nutritional composition and labelling requirements having been set for special dietary foods marketed in Hong Kong, the nutrition labels of such imported foods will vary with importing countries. However, different jurisdictions may have set different nutritional composition and labelling requirements for different types of foods. **As such, the interest of the special population subgroups in Hong Kong may not have been adequately safeguarded.**

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**Note 12:** *Based on a research paper (August 2011) of the CFS and the DH, for infant formula, many countries have developed specific regulations on claims, with some having pre-market approval/registration systems (e.g. the United States and the European Union) under which formula traders intending to make claims have to submit details (such as lists of ingredients, claims statements and scientific evidence) of the products to the regulatory authorities for approval/registration.*

2.21 Audit examination of selected special dietary foods indicated that some of such products contained claims which might not be in line with the Codex standards and guidelines (see para. 2.11). Examples are shown in Case 3.

### Case 3

#### Common use of claims in special dietary foods

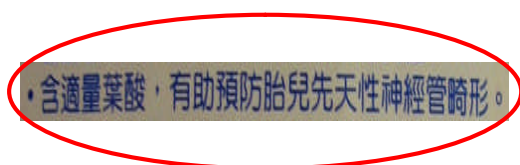
1. Audit examined three special dietary food products, namely:
  - (a) a popular brand of powder product for pregnant and lactating women (Product 1);
  - (b) a popular brand of powder product for diabetics (Product 2); and
  - (c) a brand of powder product for cancer patients (Product 3).
2. Products 1 to 3 did not show any designation of “special dietary”, “special dietetic” or an appropriate equivalent term, in conjunction with the product names (see para. 2.11(a)).
3. Many claims were found on Products 1 to 3. Examples included the following:
  - (a) “含適量葉酸，有助預防胎兒先天性神經管畸形” (Contains the right amount of folic acid, helps prevent congenital anomaly in neural tube of foetus) (Photograph 5);
  - (b) “Foods with low GI help control blood glucose because they produce less of an elevation of blood glucose after eating. A GI less of 55 is considered low. Product 2 helps control your blood glucose as it has a GI of 22”;
  - (c) “Product 2 is a complete balanced diet specifically formulated to produce a lower glycaemic response”;
  - (d) “含豐富 DHA，有助胎兒腦部及視力發育” (High in DHA, helps the development of the brain and the eyesight in foetus);
  - (e) “含豐富鐵質，有助預防孕婦缺鐵性貧血” (High in iron, helps prevent iron deficiency anemia in pregnant women);
  - (f) “複合性糖份及纖維有助穩定餐後血糖” (Complex carbohydrate and fibre help stabilise blood sugar level after meals) (Photograph 6);
  - (g) “含天然胡蘿蔔素，有助增強母親的免疫能力” (Contains natural carotenes, strengthens the immunity of mothers);
  - (h) “High energy, high protein therapeutic nutrition with EPA”;

(To be continued)

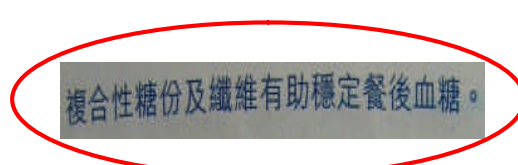
(Cont'd)

- (i) “提供豐富的蛋白質、熱量及各種礦物質及維生素，適合有體重驟降人士使用” (High in protein, calorie and different types of minerals and vitamins, suitable for those who have sudden weight drop);
- (j) “醫學證實，癌症病人透過每天飲用 2 杯 Product 3，可顯著增進體重” (Medical studies confirm that 2 cups of Product 3 for cancer patients daily will help them gain substantial body weight); and
- (k) “每日 2 克 EPA，能減低蛋白質分裂因子的產生及炎症反應，改善胃口，提升體重” (2g of EPA daily will reduce the formation of protein degradation factors and the effects of inflammation, thereby improving appetite and regaining body weight) (Photograph 7).

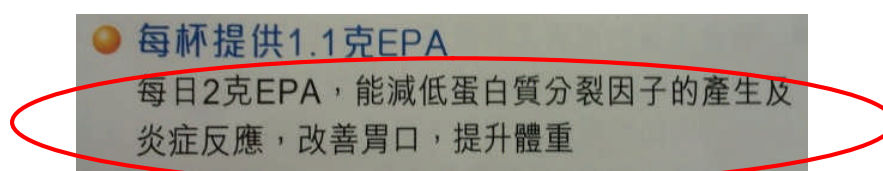
Photograph 5



Photograph 6



Photograph 7



4. It would appear that some of the above claims might not be in line with the Codex standards and guidelines (Note).

Legend:  Claims

Source: Audit research

Note: In September 2011, the CFS further informed Audit that because there was no international consensus on many of the claims, a wide range of claims was allowed to be used on foods for special dietary uses in different jurisdictions. The CFS said that some of the claims listed in this case study might be allowed provided that certain specified conditions were met.

*Need for review to introduce appropriate law or regulations*

2.22 To safeguard public health and noting the various deviations from the Codex standards and guidelines (see paras. 2.16 to 2.21), Audit considers that the Administration needs to critically consider whether it is in the public interest for the Government to continue relying on the trade to comply with the Codex standards and guidelines at their discretion. Given that six years have passed since the Administration undertook in 2005 to review the need for introducing nutrition labelling requirements for infant and special dietary foods in the future (see para. 2.3), it is high time for the Administration to consider introducing appropriate law or regulations to govern them.

## **PART 3: REGULATION OF NUTRITION INFORMATION**

3.1 This PART examines the Government's regulation of nutrition information on food labels for infant and special dietary foods. Nine case studies are reported in this PART, as summarised below:

| <b>Case</b> | <b>Paragraph no.</b>  | <b>Particulars</b>   |
|-------------|-----------------------|--|
| 4           | 3.3(d)                | Follow-up of an enquiry made in 2007 by the Hospital Authority (HA) on infant formulae imported from Country A   |
| 5           | 3.3(d)                | Follow-up of a complaint on the nutrient contents of three foreign food products for diabetics   |
| 6           | 3.3(d) and Appendix F | Follow-up of several complaints on the use of claims by one formula trader on food labels or in advertisements to promote his brand of infant and follow-up formulae |
| 7           | 3.3(d) and Appendix G | Follow-up of complaints referred by the Broadcasting Authority (BA) on the use of two claims in TV advertisements  |
| 8           | 3.6                   | Audit examination of four popular brands of foreign infant formulae (manufactured in different countries)  |
| 9           | 3.6                   | Audit examination of a food product for young children (suitable for children of 12 to 36 months old)  |
| 10          | 3.6                   | Audit examination of a special dietary food product for diabetics  |
| 11          | 3.8                   | Audit examination of a food product for "diabetic & people concern with diabetes" which was not considered by the CFS as "food for special dietary uses"             |
| 12          | 3.8                   | Audit examination of a food product for a specified age group of people which was not considered by the CFS as "food for special dietary uses"                       |

### **Background**

3.2 Given that infants, young children and other people with special dietary needs are generally more vulnerable, their foods have to be more strictly regulated (see para. 2.8). The regulation of nutrition information for such foods is important,

although the health impacts as a result of improper dietary intake may not always be immediate. Six years have however passed since the Administration undertook in 2005 to review the need for introducing nutrition labelling requirements for infant and special dietary foods.

## **Audit observations**

### ***Inadequacies in regulation of nutrition information***

3.3 Apart from the deviations from the Codex standards and guidelines identified in PART 2, Audit has also found the following inadequacies in the Government's regulation of nutrition information displayed on food labels of infant and special dietary foods marketed in Hong Kong:

- (a) ***No verification of nutrition information.*** Since its establishment in 2006 and up to mid-2011, the CFS had not conducted any risk assessment studies on nutrition of infant and special dietary foods (Note 13). As at September 2011, the CFS was working on a joint study with the Consumer Council on nutrition labelling and nutrition claims on prepackaged foods for infants and young children (excluding infant and follow-up formulae). The result was expected to be available in early 2012. Taking infant and follow-up formulae as an example, in the absence of proper import control (such as import licences/permits) to regulate their importation, the CFS had not developed any special programme to ensure the nutritional safety and adequacy of infant and follow-up formulae marketed in Hong Kong. In its food surveillance, the CFS had **not** selected any infant and special dietary foods for verifying the correctness of the nutrition information declared, other than selecting samples for chemical and microbiological testing (Note 14);

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**Note 13:** *Each year, the CFS conducted a number of food-related risk assessment studies. Such studies completed in recent years on nutrition included those on Dietary Iodine Intake in Hong Kong Adults (2011), Sugars Content of Prepackaged Non-alcoholic Beverages in Hong Kong (2009) and Sodium Content of Savoury Snacks in Hong Kong (2009).*

**Note 14:** *As part of its food surveillance, the CFS would select milk powder samples (including infant formulae) for chemical and microbiological testing. Chemical testing covers testing for food additives, contaminants, toxins and other harmful residues whereas microbiological testing covers testing for bacteria and viruses. The CFS would also conduct enhanced surveillance in response to local and overseas food incidents. Such incidents included the testing of infant formula for Melamine and Enterobacter Sakazakii. In 2010, the CFS conducted chemical and microbiological testing of 227 samples of infant formula.*

- (b) ***Powers under section 61 not invoked.*** In the absence of specific law or regulations, the Administration mainly relies on the general provisions of the PHMSO to regulate infant and special dietary foods marketed in Hong Kong. Section 61 of the PHMSO, which disallows a label or advertisement that falsely describes the food or misleads as to the nutritional or dietary value of the food, can be invoked against malpractices identified in relation to infant and special dietary foods. However, as far as Audit could ascertain, the CFS, as the food safety authority, had so far not invoked section 61 in any case in relation to infant and special dietary foods apart from the issue of warning/enquiry letters on a few occasions advising food traders of the initiation of enforcement actions under section 61 if they continued with the use of improper claims to promote infant formulae (see examples in para. 2(c) of Case 6 at Appendix F);
- (c) ***Proactive actions not taken.*** Codex has prohibited the use of nutrition and health claims for foods for infants and young children (see para. 2.10(j)). The 1981 WHO Code has also recommended no advertisement or other form of promotion of breast-milk substitutes (see para. 4.2(b)). Audit however notes that the use of claims to promote foods for infants and young children is common in Hong Kong (see Case 2 in para. 2.16(b)). **There was however no evidence that the CFS had taken proactive actions to verify the validity of claims by seeking scientific evidence from the food traders, or to stop them from using the claims (Note 15).** The possible use of misleading or exaggerated claims in foods for infants and young children is a cause for concern. Taking infant and follow-up formulae as an example, the use of misleading or exaggerated claims might cause undue influence to parents in formula selection. If such practices are allowed to persist, consumers may be misled by invalid claims. In fact, over-reliance on infant and follow-up formulae to meet the nutritional requirements of infants after the first months of life is not recommended. Both Codex and the WHO have suggested the feeding of infants after the age of six months with complementary foods in order to gain optimal nutrient intake; and
- (d) ***Enquiries/complaints not always properly followed through.*** Cases 4 to 7 are examples. The inadequacies in the follow-up of the various enquiries and complaints might result in the Government's delay or inability to timely detect potential threats to public health.

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**Note 15:** *It is worth pointing out that health claims on all conventional foods, including infant and special dietary foods, are not governed by any specific law or regulations in Hong Kong. This is highlighted in PART 3 of Chapter 3 of the Director of Audit's Report No. 57 on "Food labelling".*

## Case 4

### An enquiry from Hospital Authority

1. In **September 2007**, the HA informed the FEHD that:
  - (a) some foreign infant formulae (from Country A) had become popular in Hong Kong, but the HA had concerns, among others, that some “novel ingredients” with health claims might have been added to these formulae and the claims might need clarification on the adequacy and strength of scientific evidence for substantiation; and
  - (b) it had concerns that these infant formulae might not have complied with the international food standards.

The HA also noted that some parents brought in such infant formulae to the hospitals and requested the hospitals to reconstitute them. For the sake of ensuring the safety of children and the public, the HA requested the FEHD to look into the matter and take appropriate action, if necessary, and keep the HA informed.

2. In **November 2007**, the FEHD informed the HA that:
  - (a) CFS staff carried out label checks (Note) on prepackaged foods, including infant formulae, in retail outlets and took food samples for analysis or examination at import, wholesale and retail levels according to the CFS food surveillance programmes; and
  - (b) the CFS would continue to advise the public to purchase food from reliable sources and to read the food labels, and to advise the trade to comply with the relevant food regulations.
3. Based on the FEHD records, in **November 2007**, the CFS reported internally that its front-line staff had conducted routine label checks (Note) of the foreign infant formulae imported from Country A, but no irregularity was detected.

#### Audit comments

4. In this case, there was no evidence that the FEHD had conducted investigation on the HA’s concerns raised in 2007 about the inclusion of some “novel ingredients” with health claims in some foreign infant formulae (from Country A) and their possible non-compliance with international food standards.
5. It is worth noting that in Case 1 in paragraph 2.16(a), Audit also found in mid-2011 that a few popular brands of foreign infant formulae marketed in Hong Kong had deviated from the Codex standards and guidelines in their nutritional composition and labelling.

Source: FEHD records

Note: As at November 2007, the nutrition labelling scheme had not yet been implemented. Therefore, the label checks referred to checking the compliance with the general food labelling requirements (see paras. 1.3 and 1.4).



## Case 5

## Complaint on nutrient contents of food products for diabetics (Products 4 to 6)

1. In **April 2011**, the CFS received an anonymous complaint about the sale at a retail outlet in Wan Chai of three foreign food products for diabetics (Products 4 to 6). The complainant noted that the food labels of the three products contained no list of ingredients, but the nutrition labels indicated that over 50g of sugars were contained in every 100g of the products. The complainant was very concerned whether such products were really suitable for diabetics.

2. During **May and June 2011**, the FEHD staff visited the retail outlet several times, but could not find Products 4 to 6 for sale until 15 June 2011. On **27 June 2011**, the staff reported that one of the products under complaint (together with two other related products of the same brand — Note 1) had been checked and proper food labels were affixed.

3. On **10 June 2011**, Audit also visited the retail outlet and found that Products 4 to 6 were available for sale (Note 2). Audit then bought the three products for examination on **14 June and 8 July 2011**. Audit found that in this case:

- (a) there was no follow-up of the complaint to ascertain whether Products 4 to 6 were really suitable for diabetics (Note 3);
- (b) Audit's laboratory test (see Note 16 to para. 3.5) indicated that there were obvious variances for a number of nutrients between their declared values and the contents (see below). For each product, at least one nutrient was found to have discrepancies falling outside the CFS's tolerance limits (see Note 17 to para. 3.6);

| Nutrient                     | Declared value<br>(a) | Nutrient value per<br>Audit's laboratory test<br>(b) | Nutrient value<br>as a percentage of<br>declared value<br>(Note 4)<br>(c) = (b)/(a) × 100% |
|------------------------------|-----------------------|--|--|
| <i>Product 4 (syrup):</i>    |                       |  |  |
| <b>Total fat</b>             | 0.1g/100mL            | 1.5g/100mL   | <b>*1,500%</b>   |
| <b>Sugars</b>                | 75g/100mL             | 80.7g/100mL  | <b>108%</b>  |
| <b>Sodium</b>                | 10mg/100mL            | < 3mg/100mL  | <b>&lt; 30%</b>  |
| <b>Protein</b>               | 1.1g/100mL            | 0.4g/100mL   | <b>*36%</b>  |
| <i>Product 5 (preserve):</i> |                       |  |  |
| <b>Sugars</b>                | 56.8g/100g            | 6.1g/100g  | <b>11%</b>   |
| <b>Sodium</b>                | 0mg/100g<br>(Note 5)  | 7mg/100g   | <b>*140%</b><br>(Note 5)   |
| <i>Product 6 (syrup):</i>    |                       |  |  |
| <b>Total fat</b>             | 0.1g/100mL            | 2.4g/100mL   | <b>*2,400%</b>   |

(To be continued)

(Cont'd)

- (c) had the nutrition labelling scheme been applied to special dietary foods:
  - (i) the discrepancies falling outside the CFS's tolerance limits in (b) above would have triggered the issue of warning/enquiry letters and enforcement actions (see Note 18 to para. 3.6); and
  - (ii) Product 6 would have breached the scheme requirements in that there was no English or Chinese nutrition label (see para. 1.10), and no value for trans fat was declared in the nutrition information displayed in German; and
- (d) the general food labelling information on Products 4 to 6 (e.g. food name, list of ingredients, and instructions for use) was displayed in German. This did not conform with the Regulations which stipulate that food labels should be displayed in English or Chinese (see para. 1.3).

*Source: FEHD records and Audit research*

*Note 1: Audit noted that the retail outlet had two series of similar products for sale, one with the designation of "Diabetics" (in German) and another without.*

*Note 2: In the absence of any designation of "special dietary" or "special dietetic" on the container labels (see para. 2.11(a)), Audit regarded Products 4 to 6 as special dietary foods because the word "Diabetics" (in German) was clearly displayed in conjunction with the food name.*

*Note 3: In September 2011, the CFS informed Audit that its staff had conducted another follow-up visit in August 2011 with a view to taking samples for testing of nutrient contents, but found that Products 4 to 6 were out of stock.*

*Note 4: Nutrients marked with \* would have gone outside the CFS's tolerance limit had the nutrition labelling scheme been applied to these products.*

*Note 5: In accordance with the CFS Technical Guidance Notes, whenever sodium (per 100g) is  $\leq 5$  mg, its declared value can be stated as "0".*

3.3(d) **Cases 6 and 7**, as detailed at Appendices F and G respectively, are summarised (Cont'd) below. In Case 6, the FEHD had not adequately followed through several complaints over the years 2003 to 2010 on the use of claims by one formula trader on food labels or in advertisements to promote his brand of infant and follow-up formulae. In Case 7, the Broadcasting Authority (BA) referred five complaints, relating to two claims used by another formula trader in TV advertisements, to the FEHD for advice. Audit considers that the FEHD should have provided more input to help the BA verify the validity of the claims. In

particular, the FEHD should have followed through the complaints to see if similar claims were also found on food labels or in other advertisements and verified them by seeking scientific evidence from the formula trader. As at August 2011, Audit found that the two formula traders (Cases 6 and 7) were still using many claims, similar to the claims under complaint, on food labels and on their websites to promote their brands of formulae.

### *Need for enhanced regulation of nutrition information*

3.4 **Audit considers that the CFS needs to step up the Government's regulatory controls of nutrition information displayed on food labels for infant and special dietary foods.** In particular, it needs to step up its food surveillance to cover infant and follow-up formulae marketed in Hong Kong to ensure their nutritional safety and adequacy (see para. 3.3(a)). Before specific law or regulations are introduced to prohibit the use of nutrition and health claims in foods for infants and young children, the CFS should take proactive actions to verify the validity of claims used by food traders and discourage them from using invalid claims to promote their foods (see para. 3.3(c)). The CFS should also step up its efforts in following through enquiries/complaints it received (see para. 3.3(d)).

### *Audit examination of selected infant and special dietary foods*

3.5 Given the inadequacies in regulatory controls of nutrition information (see para. 3.3) and because the nutrition labelling scheme did not apply to infant and special dietary foods, Audit conducted an examination (Note 16) of selected infant and special dietary foods marketed in Hong Kong. The objective of the examination was to ascertain the accuracy of the nutrition information displayed on their food labels. Owing to resource constraints, laboratory tests of only a few nutrients in each food product were conducted.

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**Note 16:** *Audit has commissioned a local university to provide accredited laboratory services in the independent laboratory tests (see para. 1.15).*

3.6 For such foods which serve special population subgroups who are more vulnerable, one would expect minimal deviations between the nutrition information displayed on the nutrition labels (declared values) and the nutrient contents. However, for some of the infant and special dietary foods examined, Audit found that there were obvious deviations, some of which would have fallen outside the CFS's tolerance limits (Note 17) had the nutrition labelling scheme been applied to them. Besides, the products examined did not meet some of the requirements in the nutrition labelling scheme (such as labelling the value of the "1+7" core nutrients and any other nutrient for which a claim is made). It would appear that had these products been covered by the nutrition labelling scheme, some of the deviations and non-compliances identified would have triggered the issue of warning/enquiry letters and enforcement actions (Note 18). Case 5 in paragraph 3.3(d) above and Cases 8 to 10 below are examples.

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**Note 17:** *For considering enforcement action, the CFS has set tolerance limits to help assess whether a food product had complied with the nutrition labelling scheme (e.g. a tolerance limit of " $\leq 120\%$  of declared value" is set for energy, total fat, saturated fat, trans fat, cholesterol, sodium or sugars).*

**Note 18:** *For irregularities detected from visual checking, the CFS would issue warning letters to the food traders requiring remedial action within 60 days. If the food traders fail to do so, the CFS would initiate prosecution. For irregularities detected from chemical analysis of nutrient contents, the CFS would issue enquiry letters to allow the food traders to explain within 21 days. If the explanations are not acceptable, the CFS would issue warning letters requesting the traders to rectify within 39 days. If the irregularities remain unrectified, the CFS would initiate prosecution.*

## Case 8

## Four popular brands of infant formulae

1. From May to July 2011, Audit selected the following four popular brands of foreign infant formulae (manufactured in different countries) for laboratory test:

- (a) Formula 1 (0-9 months)
- (b) Formula 4 (0-6 months)
- (c) Formula 5 (0-6 months)
- (d) Formula 6 (0-6 months)

2. Audit examination showed that calcium contained in the four infant formulae were “96%”, “110%”, “82%” and “86%” respectively of their declared values. Although calcium is scientifically proven to aid in the development of strong bones and teeth, and may help to improve bone density, Audit found that the calcium contents contained in two of the four infant formulae were significantly less than their declared values.

3. Audit also found that had the nutrition labelling scheme been applied to infant formulae, the scheme requirements might not have been complied with, as follows:

- (a) for Formulae 1, 5 and 6, the deviations would have fallen outside the CFS’s tolerance limit of “ $\geq$  declared value” and would have triggered the issue of warning/enquiry letters and enforcement actions; and
- (b) for all four infant formulae, many nutrition claims that might not be permitted under the scheme were found. Examples included:
  - (i) claims on “DHA/ARA” and “AA/DHA”;
  - (ii) “5 種主要核苷酸及 Alpha 蛋白(母乳所含的主要乳清蛋白) 幫助促進嬰兒消化系統健康” (5 major types of nucleotide and alpha protein (the major whey protein in breast milk) help to promote a healthy digestive system in babies); and
  - (iii) “The bifidogenic effect is a nutrient combination that helps to enhance babies’ natural immunity by supporting a healthy gut flora”.

Source: Audit research

## Case 9

### A food product for young children (Product 7)

1. In July 2011, Audit purchased one popular brand of foreign biscuits suitable for children of 12 to 36 months old (Product 7) for examination and found that protein and saturated fat were declared as 0g per serving (i.e. 0g/7g). However, Audit's laboratory test showed that protein and saturated fat contained in the product were "7.8g/100g" and "0.9g/100g" respectively.
2. Audit also found that had the nutrition labelling scheme been applied to Product 7, the scheme requirements might not have been complied with, as follows:
  - (a) although all "1+7" core nutrients had been declared, protein and saturated fat of "7.8g/100g" and "0.9g/100g" respectively (see para. 1 above) should not have been declared as "0g per serving" on the nutrition label. This is because, according to the CFS Technical Guidance Notes, an amount of " $\leq 0.5\text{g}$ " is required for protein or saturated fat with a declared value of "0g" per 100g of food; and
  - (b) a nutrition claim of "Good Source of Calcium, Iron, Vitamin E & Zinc" was displayed on the product package (Note). The absolute amounts of the four nutrients in the claim, namely calcium, iron, vitamin E and zinc, should have been declared on the nutrition label.

*Source: Audit research*

*Note: For such a "High" claim on calcium, iron, vitamin E and zinc under the scheme, the product should have contained "not less than 30%" of the Nutrient Reference Value (as listed in Schedule 7 of the 2008 Amendment Regulation) of the vitamin or mineral concerned per 100g of food.*

## Case 10

## A special dietary food product (Product 8)

1. In June 2011, Audit purchased one can of popular brand of foreign nutrition powder for diabetics (Product 8 — Note) for examination.
2. Audit's laboratory test revealed that there were obvious variances for the following nutrients between the declared values and their content values, as shown below:

| Nutrient       | Declared value<br>(a) | Nutrient value per<br>Audit's laboratory test<br>(b) | Nutrient value<br>as a percentage of<br>declared value<br>(c) = (b)/(a) × 100% |
|----------------|-----------------------|--|--|
| <b>Sugars</b>  | <b>Not declared</b>   | <b>12.3g/100g</b>                                    | <b>Not applicable</b>  |
| <b>Calcium</b> | 481mg/100g            | 554mg/100g   | <b>115%</b>  |
| <b>Sodium</b>  | 404mg/100g            | 462mg/100g   | <b>114%</b>  |

For a special dietary food product for diabetics, it is a cause for concern that there was no declared value for sugars, but laboratory test revealed that Product 8 contained sugars of 12.3g/100g.

3. Audit also found that had the nutrition labelling scheme been applied to Product 8, the scheme requirements might not have been complied with, as follows:
  - (a) the product had no declared values for three core nutrients, namely sugars, saturated fat and trans fat;
  - (b) the product contained a “low calorie” claim which did not meet the claim condition that the food should contain no more than 40 kcal of energy per 100g of food because energy had a declared value of 424 kcal/100g; and
  - (c) the product contained a nutrition claim of “In addition to fibre content, a Mono-Unsaturated Fatty Acid Lipid System is ideally suited for Cardiovascular Health” which was not permitted under the scheme.

Source: Audit research

Note: In the absence of any designation of “special dietary” or “special dietetic” on the container label (see para. 2.11(a)), Audit regarded Product 8 as a special dietary food because the container label clearly presented the following statements:

- (i) “Diabetic Nutrition” used in conjunction with the food name;
- (ii) “Formulated with a Slow Release energy system to assist in stabilizing blood sugar”;
- (iii) “Product 8 as part of a diabetes management program has been clinically shown to enhance A1c, Blood Pressure and Cholesterol profiles”;
- (iv) “Managing A1c, Blood Pressure and Cholesterol at optimal levels lower the risk for diabetic complications”; and
- (v) “Not intended for use in children unless recommended by a physician or other qualified healthcare professional”.

*Need for review to introduce appropriate law or regulations*

3.7 Noting the non-compliances with the Codex standards and guidelines in some of the infant and special dietary foods (see paras. 2.16 and 2.21) and the deviations found in Cases 5 and 8 to 10 in some of the nutrients examined between their declared values and the nutrient contents, Audit considers that the Administration needs to critically consider whether it is in the public interest to continue relying on the trade to self-regulate. Paragraph 2.22 is also relevant.

*Difficulties to differentiate special dietary food from others*

3.8 It is also a cause for concern that in the absence of a legal definition for “food for special dietary uses” (see para. 2.6(c)), there were food products serving special population subgroups, but not regarded by the CFS as “food for special dietary uses” under its principles and guidelines. As such, they should have fallen within the scope of the nutrition labelling scheme. However, Audit found that some of these products might not have complied with the nutrition labelling scheme in various areas. Cases 11 and 12 are examples.



## Case 11

## Product 9 for “diabetic &amp; people concern with diabetes”

1. In June 2011, Audit purchased a can of popular brand of foreign milk powder for “diabetic & people concern with diabetes” (Product 9) for examination.

2. Audit’s laboratory test revealed that for three nutrients, there were obvious variances between declared values and their content values, as shown below:

| Nutrient      | Declared value<br>(a) | Nutrient value per<br>Audit’s laboratory test<br>(b) | Nutrient value<br>as a percentage of<br>declared value<br>(c) = (b)/(a) × 100% |
|---------------|-----------------------|--|--|
| Saturated fat | 19g/100g              | 11.9g/100g   | 63%  |
| Sugars        | 14.2g/100g            | 28.9g/100g   | 204%   |
| Calcium       | 472mg/100g            | 799mg/100g   | 169%   |

For a food product for diabetics, it is a cause for concern that the sugars content was twice its declared value.

3. Audit found that Product 9 did not bear any designation of “special dietary” or “special dietetic” on the container label (see para. 2.11(a)), but it clearly presented the following statements on its container label:

- (a) for “diabetic & people concern with diabetes” used in conjunction with the food name;
- (b) “meets International Diabetic Guidelines”;
- (c) “Low Glycemic Index (GI)”;
- (d) “GI below 55 is regarded low and Product 9 is effectively in control of your blood glucose as it is much below GI 55”;
- (e) “can be used as staple source of diabetic diet or as a supplement”; and
- (f) **“Warning: Use under medical supervision”.**

4. Upon enquiry, the CFS informed Audit in September 2011 that Product 9 should **not** have been considered as “food for special dietary uses” because according to the food trader’s website, the product was practically suitable for everybody, including health-conscious people.

(To be continued)

(Cont'd)

5. Audit was however concerned that, in the absence of any requirement for specifying the designation of “special dietary” on the food label, consumers might find it difficult to differentiate Product 9 (an “alleged” special dietary food which should have been covered by the nutrition labelling scheme) from a special dietary food (not covered by the scheme). Consumers might also have relied on claims on such products (whether they were classified as special dietary foods or otherwise) in making their food choices.

6. Audit further found that Product 9 did **not** comply with the nutrition labelling scheme in that:

- (a) there was no declared value for trans fat; and
- (b) the product’s sugars might have fallen outside the CFS’s tolerance limit of “ $\leq 120\%$ ” of the declared value.

*Source: Audit research*

## Case 12

## Product 10 for a specified age group of people

1. In May 2011, Audit purchased one package of foreign “high calcium, low fat” milk powder of popular brand for a specified age group of people (Product 10) for examination.

2. Audit’s laboratory test revealed that for three nutrients, their content values were obviously different from the declared values, as shown below:

| Nutrient         | Declared value<br>(a) | Nutrient value per<br>Audit’s laboratory test<br>(b) | Nutrient value<br>as a percentage of<br>declared value<br>(c) = (b)/(a) × 100% |
|------------------|-----------------------|--|--|
| <b>Total fat</b> | 2.8g/100g             | 3.3g/100g  | <b>118%</b>  |
| <b>Sodium</b>    | 300mg/100g            | 260mg/100g   | <b>87%</b>   |
| <b>Calcium</b>   | 2,000mg/100g          | 2,601mg/100g   | <b>130%</b>  |

Given that the product was claimed to be “low fat”, it is a cause for concern that the fat content was significantly higher than its declared value.

3. Audit found that Product 10 did not bear any designation of “special dietary” or “special dietetic” on the food label, but it clearly presented three times on its package that it was specially formulated for a specified age group of people to emphasise that it served a special target subgroup of people, apparently differentiating it from a similar product under the same brand that was formulated for a younger age group.

4. Upon enquiry, the CFS informed Audit in September 2011 that Product 10 should **not** have been considered as “food for special dietary uses” because it was indicated on the food trader’s website that people other than the specified age group could consume the product.

5. Audit was concerned that, in the absence of any requirement for specifying the designation of “special dietary” on the food label, consumers might find it difficult to differentiate Product 10 from other special dietary foods and might not be able to make informed food choices.

6. Audit also found that Product 10 might not have complied with the nutrition labelling scheme in that:

(To be continued)

(Cont'd)

- (a) given that laboratory test revealed that the product had a content value of 3.3g of fat per 100g of food (see para. 2 above), it might not have complied with the “Low fat” claim condition which only allowed not more than 3g of fat per 100g of food; and
- (b) a nutrition claim of “Contains Nano-Calcium, which is more than 100 times smaller than normal calcium. The revolutionary formula provides important nutrient needed by your bones” was not included in the CFS list of acceptable nutrient function claims (Note).

*Source: Audit research*

*Note: Such claims may be accepted by the CFS if they are based on scientific substantiation and scientific consensus.*

### ***Need for clarifications and enhanced publicity efforts***

3.9 As the CFS indicates that whether a product should be classified as a “food for special dietary uses” has to be considered on a case-by-case basis (see para. 2.19), Audit considers that the CFS needs to provide further clarifications and step up its publicity efforts to help the trade and consumers determine whether or not a particular food product that serves a special population subgroup is a “food for special dietary uses” (that falls outside the scope of the nutrition labelling scheme). There is also a need for the Administration to consider how to step up the Government’s regulatory controls of nutrition information on food labels for such foods, e.g. extending the CFS’s checking in its food surveillance to cover more of such foods.

## **PART 4: DEVELOPMENT OF A HONG KONG CODE OF MARKETING OF BREAST-MILK SUBSTITUTES**

4.1 This PART examines the development of the Hong Kong Code of Marketing of Breast-milk Substitutes (the Hong Kong Code).

### **Background**

4.2 Codex has laid down standards to govern the compositional, quality and safety requirements for infant formula. It has also stipulated that the application of the Codex standards for infant formula should take into account the recommendations in the 1981 WHO Code (see para. 2.10(a)). The aim of the WHO Code is to contribute to the provision of safe and adequate nutrition for infants by the protection and promotion of breast-feeding and ensuring the proper use of breast-milk substitutes, including infant formula, on the basis of adequate information and through appropriate marketing and distribution. The WHO Code contains recommendations (see examples below) to regulate the advertising and marketing of breast-milk substitutes and on the ways governments should implement the Code.

- (a) Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition.
- (b) **There should be no advertising or other form of promotion to the general public of breast-milk substitutes.**
- (c) Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of breast-milk substitutes.
- (d) There should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums and special sales.
- (e) Samples of infant formula or other products within the scope of the WHO Code should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level.
- (f) Manufacturers and distributors should not distribute to pregnant women or mothers or infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.
- (g) Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealise the use of infant formula.
- (h) **Governments should take action to give effect to the principles and aim of the WHO Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures.**

*Source: WHO Code (1981)*

4.3 The WHO updated or enhanced its Code by way of resolution at the World Health Assembly (WHA) which was held once every one to two years in the light of scientific and market developments. In May 2005, the WHO was concerned that nutrition and health claims might be used to promote breast-milk substitutes as superior to breastfeeding and urged its member states to ensure that such claims were not permitted for breast-milk substitutes, except where specifically provided for in national legislation. In May 2010, the WHO again urged its member states to end all forms of inappropriate promotion of foods for infants and young children, and ensure that nutrition and health claims should not be permitted for such foods, except where specifically provided for in relevant Codex standards or national legislation.

4.4 With reference to the WHO Code, many countries (e.g. Australia, New Zealand, Singapore and Malaysia) have developed their advertising and marketing guidelines applicable to their own countries for compliance by the trade. China has also adopted the WHO Code by enacting the “Chinese Rules Governing the Administration of Marketing of Breast-milk Substitutes” in October 1995. **In Hong Kong, the Government has not yet made it a mandatory requirement for the trade to comply with the WHO Code and the relevant WHA resolutions.** In other words, the Government mainly relies on the trade to self-regulate.

### **Setting up a task force to develop the Hong Kong Code**

4.5 In **June 2010**, the Administration set up a task force (Note 19) to develop the Hong Kong Code. The objective of the Hong Kong Code was to regulate the manufacturers and distributors of breast-milk substitutes and related products, and to prohibit malpractices in advertising and marketing such products. According to the Food and Health Bureau, in developing the Hong Kong Code, the task force would take into account the details and scope of regulation recommended in the WHO Code and the WHA resolutions.

4.6 In **June 2011**, the Secretary for Food and Health further informed LegCo that:

- (a) the drafting of the Hong Kong Code would be completed by the end of 2011. Upon completion of the drafting of the Hong Kong Code, the DH would consult the trade and collect the views of various parties. It was expected that the Hong Kong Code would be put into implementation within 2012; and
- (b) in the light of many countries’ experience, control of undesirable marketing practices would be more effective if appropriate monitoring and sanction mechanisms were put in place in tandem with the implementation of the Code. In Hong Kong, after the Hong Kong Code had been implemented, the DH would monitor the situation and canvass the views of various parties to consider if there would be a need to step up enforcement and regulation.

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**Note 19:** *The task force, set up under the DH, is comprised of members from different sectors of the community, including representatives from the HA, Consumer Council, specialist groups, academia, non-governmental organisations, and other major local partners.*

## Audit observations

4.7 Audit welcomes the Administration's recent efforts to develop the Hong Kong Code, which will help regulate the advertising and marketing of breast-milk substitutes in future. Audit also shares the Administration's view that proper monitoring and sanction mechanisms need to be put in place for the effective implementation of the Hong Kong Code.

4.8 However, the development of the Hong Kong Code alone may not be sufficient for regulating the nutritional composition of foods for infants and young children, including infant and follow-up formulae (Note 20). As mentioned in paragraphs 2.22 and 3.7, to address this, the Administration needs to conduct a review to critically consider introducing appropriate law or regulations to govern nutritional composition and labelling of infant and special dietary foods marketed in Hong Kong.

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**Note 20:** *Based on a draft of the Hong Kong Code (August 2011), it was noted that:*

- (a) the Hong Kong Code (compliance of which would be **voluntary**) had **not** specified requirements for the nutritional composition of various foods for infants and young children, and the trade would be encouraged to follow the relevant Codex standards and guidelines, or other national guidelines in manufacturing the foods, where available; and*
- (b) the trade would be advised to adhere to the Hong Kong Code, including making claims which might be regulated by relevant laws, such as the PHMSO and the Trade Descriptions Ordinance (Cap. 362).*



## **PART 5: THE WAY FORWARD AND AUDIT RECOMMENDATIONS**

5.1 This PART examines the way forward for nutrition labelling of infant and special dietary foods, and makes audit recommendations to address issues identified in this review.

### **The way forward**

5.2 Audit welcomes the implementation of the nutrition labelling scheme. It facilitates consumers to make healthy food choices, encourages food manufacturers to apply sound nutrition principles in the formulation of foods which would benefit public health, and regulates misleading or deceptive labels and claims. However, the nutrition labelling scheme introduced under the 2008 Amendment Regulation does not apply to infant and special dietary foods. This audit has revealed various inadequacies in the nutritional composition and labelling of infant and special dietary foods marketed in Hong Kong (see PARTs 2 to 4). There is a need for the Administration to take actions to address these issues as a matter of urgency.

### **Audit recommendations**

5.3 **Audit has *recommended* that the Secretary for Food and Health should, in collaboration with the Director of Food and Environmental Hygiene and the Director of Health:**

- (a) **conduct a review to critically consider introducing appropriate law or regulations to govern nutritional composition and labelling of infant and special dietary foods marketed in Hong Kong;**
- (b) **step up the regulation of nutrition information on infant and special dietary foods marketed in Hong Kong, including enhancing the CFS food surveillance programme to cover laboratory tests of more infant and follow-up formulae marketed in Hong Kong to ensure their nutritional safety and adequacy;**
- (c) **urge the CFS to:**
  - (i) **take appropriate follow-up actions on the various deviations from the Codex standards and guidelines as identified in Cases 1 to 3 in PART 2;**

- (ii) before specific law or regulations in (a) above is/are introduced, take appropriate actions to encourage food traders' compliance with the Codex standards and guidelines as far as possible, educate them on the importance of food products' compliance with the Codex standards and guidelines and, where necessary, take appropriate action under section 61 of the PHMSO against the food traders;
  - (iii) before specific law or regulations in (a) above is/are introduced to prohibit the use of nutrition and health claims in foods for infants and young children, take proactive actions to verify the validity of claims used by food traders, discourage them from using invalid claims to promote their foods and, where necessary, take appropriate action under section 61 of the PHMSO;
  - (iv) step up its actions to follow through enquiries/complaints;
  - (v) take appropriate follow-up actions on the audit observations in Cases 4 to 12 in PART 3 including, for example, taking more samples for verification of nutrition information and seeking explanations from food traders, if necessary;
  - (vi) extend checking to cover other infant and special dietary foods marketed in Hong Kong to ascertain if there are problems/deviations similar to those found in Cases 4 to 10 in PART 3;
  - (vii) provide further clarifications on the definition of "foods for special dietary uses" and step up its publicity efforts to help the trade and consumers determine whether a food product is a "food for special dietary uses" that falls outside the scope of the nutrition labelling scheme; and
  - (viii) extend checking in its food surveillance to cover "alleged" special dietary foods (such as Cases 11 and 12 in PART 3) to ensure that they comply with the nutrition labelling scheme;
- (d) introduce appropriate monitoring and sanction mechanisms to support the effective implementation of the Hong Kong Code (see PART 4), taking into account the development of specific law or regulations in (a) above; and
- (e) closely monitor the implementation of the Hong Kong Code and plan for the conduct of a post-implementation review in due course.

## Response from the Administration

5.4 The **Secretary for Food and Health**, in collaboration with the **Director of Food and Environmental Hygiene** and the **Director of Health**, welcomes the audit recommendations in paragraph 5.3(a) and (b). He has said that:

- (a) the 1981 WHO Code has set out the basic requirements of advertising and marketing practices of breast-milk substitutes. The WHO also updated these requirements and enhanced the relevant regulation by way of resolution at its subsequent WHA in the light of scientific and market developments. At the 63rd WHA held in 2010, the WHO urged its member states to end all forms of inappropriate promotion of foods for infants and young children. At present, the Administration mainly relies on milk powder manufacturers and distributors in Hong Kong to exercise self-discipline in compliance with the WHO Code and requirements in the relevant WHA resolutions in monitoring their marketing practices. Where non-compliance of the WHO Code was noted, the DH would issue warning letters to the manufacturers involved;
- (b) to further regulate the advertising and marketing of breast-milk substitutes, the DH has set up the task force in June 2010 to develop the Hong Kong Code (see para. 4.5). The task force has been working out the details and coverage of the Hong Kong Code, having regard to the details and scope of regulation recommended in the WHO Code and the WHA resolutions. It is expected that the drafting of the Hong Kong Code will be completed by the end of 2011. Upon completion of the drafting of the Hong Kong Code, the DH will consult the trade and collect the views of various parties. It is expected that the Hong Kong Code will be put into implementation within 2012 (see para. 4.6(a)). The CFS will work closely with the DH to actively consider incorporating requirements on nutritional composition and labelling of infant and follow-up formulae marketed in Hong Kong into the Hong Kong Code, and to monitor the trade's adherence to it;
- (c) subject to the responses of the trade to the Hong Kong Code, the Government will consider whether specific law or regulation governing nutritional composition and labelling of infant foods is necessary;
- (d) as regards special dietary foods, it should be noted that the dietary needs of most people with various health conditions can be met by conventional food, which is already regulated under the PHMSO and its food-related regulations. Since there is a wide range of foods for special dietary use, Codex has not established compositional requirements for all types of special dietary foods. The CFS will study the current situation regarding labelling of these foods and make recommendations regarding the priority of regulating these products; and

- (e) the CFS food surveillance programme regularly monitors foods offered for sale in Hong Kong (including infant and special dietary foods) to ensure their fitness for human consumption under the PHMSO. Samples are collected at import, wholesale and retail levels for chemical and microbiological testing (see Note 14 to para. 3.3(a)). For example, the CFS collects samples of milk powder (most of them being infant formulae) for a wide range of chemical and microbiological testing every year (Note 21). 960 samples were taken from 2007 to 2010. All testing results were satisfactory. The CFS will continue to improve the food surveillance programme to cover chemical analysis of more infant and follow-up formulae marketed in Hong Kong.

5.5 The **Director of Food and Environmental Hygiene** agrees with the audit recommendations in paragraph 5.3(c). He has said that:

- (a) the CFS will follow up on cases identified by Audit;
- (b) the CFS will take actions against those products that are suspected to have violated section 61 of the PHMSO. Although the Codex standards and guidelines governing infant and special dietary foods are currently not legally binding, the CFS would encourage food traders to comply with such standards and guidelines as a matter of good practice. With the launching of Hong Kong Code, such good practices could be further promoted;
- (c) the CFS has thoroughly discussed the definition of “foods for special dietary uses” with the trade at various meetings and workshops and the relevant information is available on the CFS website for their reference. The CFS will step up its publicity efforts to enhance the understanding of the trade and consumers on this issue (Note 22); and
- (d) while Cases 11 and 12 are not considered as special dietary foods, the CFS will continue to take actions against products that are found to have violated the nutrition labelling requirements.

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**Note 21:** *As mentioned in paragraph 3.3(a), in its food surveillance, the CFS had **not** selected any infant and special dietary foods for verifying the correctness of the nutrition information declared. Milk powder samples (including infant formulae) were selected only for chemical and microbiological testing which covers testing for food additives, contaminants, toxins, bacteria and viruses. Note 14 to paragraph 3.3(a) is relevant.*

**Note 22:** *In October 2011, the CFS uploaded additional information relating to the classification of special dietary foods onto its website (see Appendix E).*

5.6 The **Director of Health** agrees with the audit recommendations in paragraph 5.3(d) and (e). He has said that:

- (a) the DH will develop appropriate monitoring and reviewing mechanism, with a view to supporting the effective implementation of the Hong Kong Code; and
- (b) sanction mechanism is being considered by the task force.

### **Codex Alimentarius Commission**

1. Codex was created in 1963 by the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) as an international authority to develop food standards, guidelines and related texts such as codes of practices under the Joint FAO/WHO Food Standards Programme. The primary purposes of this Programme are to protect the health of consumers and to ensure fair trade practices in the food trade. At present, membership of Codex comprises about 180 countries, including China, the United States, the European Union and Australia.

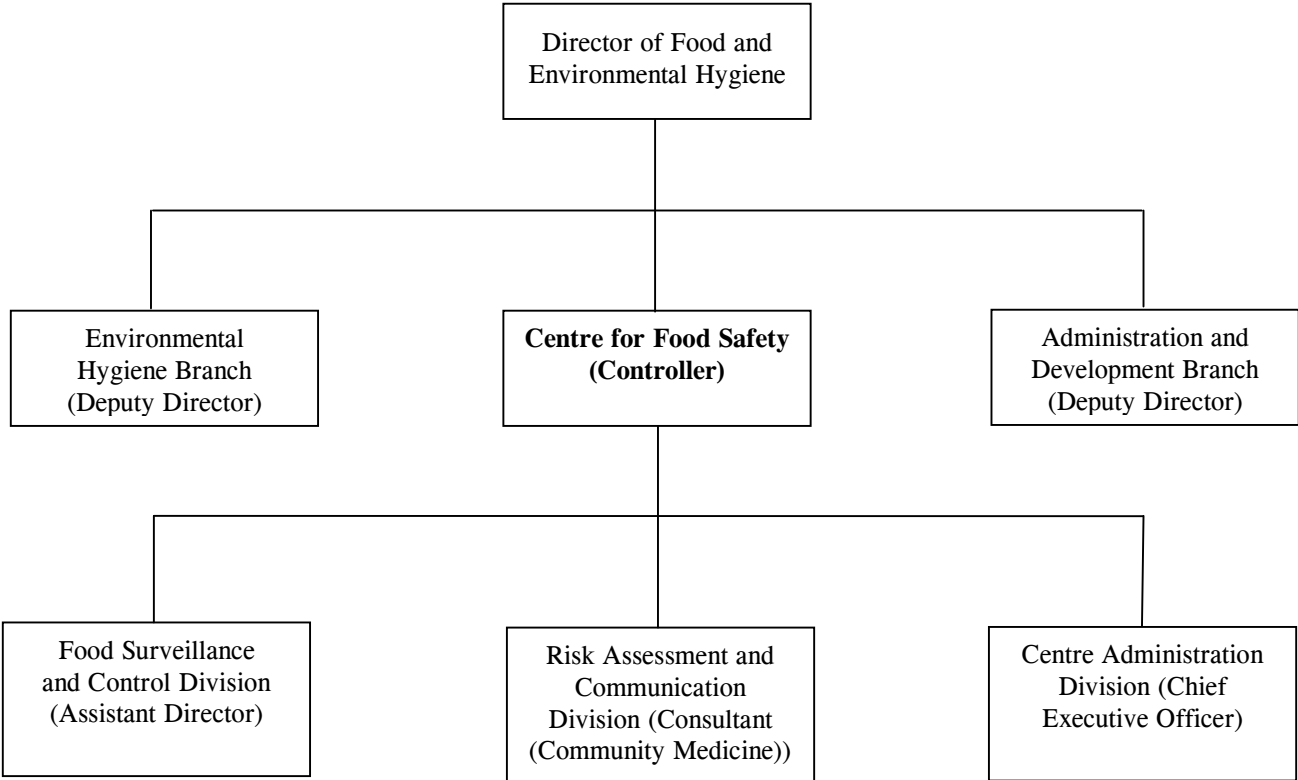
2. Codex has gained international recognition on setting food-related standards. Codex standards are adopted in most cases by consensus and are based on the best scientific and technical knowledge. Codex is the only international forum bringing together scientists, technical experts, government regulators, as well as international consumer and industry organisations. According to Codex, its standards and guidelines are only voluntary and non-binding recommendations (i.e. not mandatory) and hence there is no control over their implementation. Nevertheless, many countries implement them because they see the benefits of complying with the Codex standards and guidelines for their consumers and their trade.

3. Codex adopted the guidelines on nutrition labelling (which were first issued in 1985). These guidelines require that when nutrition label is applied, it should include declarations of energy, protein, available carbohydrate and fat, plus any other nutrients which are considered to be relevant for maintaining a good nutritional status in the population concerned. In addition to core nutrients, the guidelines also require the declaration of the amount of any other nutrient for which a claim is made. According to these guidelines, nutrition labelling is voluntary when nutrition claims have not been made.

4. Codex adopted the guidelines for use of nutrition and health claims (which were first issued in 1997). These guidelines lay down the conditions under which the use of nutrition and health claims on food labels and in advertisements is permitted.

*Source: Audit research*

**Centre for Food Safety  
Organisation chart (extract)  
(1 September 2011)**



*Source: FEHD records*

**Examples of relevant Codex standards  
and guidelines for infant and special dietary foods**

***Standard for infant formula***

1. As early as 1981, Codex adopted the “Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants” to govern the compositional, quality and safety requirements of infant formula. The Codex standard states that only formulae complying with the standards would be accepted for marketing as infant formula and no product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.

***Guidelines on nutrient compounds for use in foods for infants and young children***

2. In 1979, Codex adopted the “Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children”. In 1991, Codex further developed the “Guidelines on Formulated Supplementary Foods for Older Infants and Young Children” to provide guidance on nutritional and technical aspects of the production of formulated supplementary foods for older infants and young children, including the formulation of such foods, processing techniques, hygienic requirements and provisions for labelling and instructions for use.

***Standard for follow-up formula***

3. In 1987, Codex adopted the “Standard for Follow-up Formula” to govern the composition and labelling of follow-up formula to ensure that such formula is nutritionally adequate to contribute to normal growth and development of infants (from the 6th month) and young children. Similar to infant formula, Codex has laid down the requirement for the formula to contain 25 essential nutrients, with minimum and maximum levels set for each nutrient.

***Standard for prepackaged foods for special dietary uses***

4. In 1985, Codex adopted the “General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses”. According to Codex, special dietary foods are specially processed or formulated in order to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. These include foods for infants and young children.

*Source: Audit research*



**Benchmarking of countries' nutritional composition  
and labelling requirements for infant formula**

|   |              | <b>Codex</b>    | <b>European Union</b> | <b>United States</b> | <b>China (Note)</b> |
|---|--------------|-----------------|-----------------------|----------------------|---------------------|
| <b>Energy</b>   | <b>Min.:</b> | 60kcal/100mL    | 60kcal/100mL          | NS                   | 60kcal/100mL        |
|   | <b>Max.:</b> | 70kcal/100mL    | 70kcal/100mL          | NS                   | 70kcal/100mL        |
| <i>Essential nutrient composition (extracts only for demonstration purposes):</i> |              |                 |                       |                      |                     |
| <b>Protein</b>  | <b>Min.:</b> | 1.8g/100kcal    | 1.8g/100kcal          | 1.8g/100kcal         | 1.88g/100kcal       |
|   | <b>Max.:</b> | 3.0g/100kcal    | 3g/100kcal            | 4.5g/100kcal         | 2.93g/100kcal       |
| <b>Fat</b>  | <b>Min.:</b> | 4.4g/100kcal    | 4.4g/100kcal          | 3.3g/100kcal         | 4.39g/100kcal       |
|   | <b>Max.:</b> | 6.0g/100kcal    | 6.0g/100kcal          | 6.0g/100kcal         | 5.86g/100kcal       |
| <b>Linoleic acid</b>  | <b>Min.:</b> | 300mg/100kcal   | 300mg/100kcal         | 300mg/100kcal        | 290mg/100kcal       |
|   | <b>Max.:</b> | 1,400mg/100kcal | 1,200mg/100kcal       | NS                   | 1,380mg/100kcal     |
| <b>Carbohydrates</b>  | <b>Min.:</b> | 9.0g/100kcal    | 9.0g/100kcal          | NS                   | 9.2g/100kcal        |
|   | <b>Max.:</b> | 14.0g/100kcal   | 14g/100kcal           | NS                   | 13.8g/100kcal       |
| <b>Thiamin</b>  | <b>Min.:</b> | 60µg/100kcal    | 60µg/100kcal          | 40µg/100kcal         | 59µg/100kcal        |
|   | <b>Max.:</b> | 300µg/100kcal   | 300µg/100kcal         | NS                   | 301µg/100kcal       |
| <b>Riboflavin</b>   | <b>Min.:</b> | 80µg/100kcal    | 80µg/100kcal          | 60µg/100kcal         | 80µg/100kcal        |
|   | <b>Max.:</b> | 500µg/100kcal   | 400µg/100kcal         | NS                   | 498µg/100kcal       |
| <b>Niacin</b>   | <b>Min.:</b> | 300µg/100kcal   | 300µg/100kcal         | 250µg/100kcal        | 293µg/100kcal       |
|   | <b>Max.:</b> | 1,500µg/100kcal | 1,500µg/100kcal       | NS                   | 1,506µg/100kcal     |
| <b>Pantothenic acid</b>   | <b>Min.:</b> | 400µg/100kcal   | 400µg/100kcal         | 300µg/100kcal        | 402µg/100kcal       |
|   | <b>Max.:</b> | 2,000µg/100kcal | 2,000µg/100kcal       | NS                   | 2,000µg/100kcal     |
| <b>Biotin</b>   | <b>Min.:</b> | 1.5µg/100kcal   | 1.5µg/100kcal         | 1.5µg/100kcal        | 1.5µg/100kcal       |
|   | <b>Max.:</b> | 10µg/100kcal    | 7.5µg/100kcal         | NS                   | 10.0µg/100kcal      |
| <b>Sodium</b>   | <b>Min.:</b> | 20mg/100kcal    | 20mg/100kcal          | 20mg/100kcal         | 21mg/100kcal        |
|   | <b>Max.:</b> | 60mg/100kcal    | 60mg/100kcal          | 60mg/100kcal         | 59mg/100kcal        |

**Appendix D**  
(Cont'd)  
(para. 2.10(e), Case 1 in  
para. 2.16(a) and para. 2.18 refer)

|  |  | Codex  | European Union  | United States  | China (Note)    |
|--|--|--|---|--|-----------------|
| Calcium  | Min.:  | 50mg/100kcal   | 50mg/100kcal  | 60mg/100kcal   | 50mg/100kcal    |
|  | Max.:  | 140mg/100kcal  | 140mg/100kcal   | NS   | 146mg/100kcal   |
| Chloride   | Min.:  | 50mg/100kcal   | 50mg/100kcal  | 55mg/100kcal   | 50mg/100kcal    |
|  | Max.:  | 160mg/100kcal  | 160mg/100kcal   | 150mg/100kcal  | 159mg/100kcal   |
| Potassium  | Min.:  | 60mg/100kcal   | 60mg/100kcal  | 80mg/100kcal   | 59mg/100kcal    |
|  | Max.:  | 180mg/100kcal  | 160mg/100kcal   | 200mg/100kcal  | 180mg/100kcal   |
| Iodine   | Min.:  | 10µg/100kcal   | 10µg/100kcal  | 5µg/100kcal  | 10.5µg/100kcal  |
|  | Max.:  | 60µg/100kcal   | 50µg/100kcal  | 75µg/100kcal   | 58.6µg/100kcal  |
| Copper   | Min.:  | 35µg/100kcal   | 35µg/100kcal  | 60µg/100kcal   | 35.6µg/100kcal  |
|  | Max.:  | 120µg/100kcal  | 100µg/100kcal   | NS   | 121.3µg/100kcal |
| Labelling requirements (extracts only for demonstration purposes): |  |  |   |  |                 |
| Nutrition and health claims  | Prohibited except where specifically provided for in relevant Codex standards or national legislation. | Only certain specified nutrition and health claims were allowed. | Only certain specified nutrition and health claims were allowed. For example, “infant formula with iron” was allowed. | Nutrient content claims and nutrient comparative claims of energy and nutrients were permitted if certain conditions had been met. Certain nutrient function claims were also allowed. |                 |

Legend: Min. = Minimum  
Max. = Maximum  
NS = Not specified

Source: Audit research

Note: The nutritional composition and labelling requirements for China only apply to the Mainland, and not to Hong Kong (see para. 2.18).

### **Principles and guidelines on “food for special dietary uses”**

1. There is no definition of “food for special dietary uses” in the Food and Drugs (Composition and Labelling) Regulations. Nevertheless, according to the CFS Technical Guidance Notes, food for special dietary uses is food specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific disease and disorders and which are presented as such. The composition of these food stuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

#### **Examples of food for special dietary uses**

2. According to the CFS, the following products are generally considered as food for special dietary uses:

- (a) products that must always be used under medical supervision and are presented as such;
- (b) products solely for tube feeding; and
- (c) products that are specially formulated for certain patients or physical conditions and are clearly presented as such, e.g. with statement “specially formulated for cancer patients” (products only marked with “suitable for xx patients” may not fall into this category).

3. According to the CFS’s guidelines (before October 2011), products to be classified as food for special dietary uses should not have any information or advertisement suggesting or implying that the product was also recommended or suitable for the general population or other population subgroups which did not have that specific disease or condition. Other products not mentioned above might also be considered as foods for special dietary uses as long as the principles mentioned in paragraph 1 above were satisfied. In any case, individual products would be **considered on a case-by-case basis** when determining whether they were considered as foods for special dietary uses.

#### **Developments in October 2011**

4. Following the audit review, in October 2011, the CFS uploaded the following additional information onto its website:

**Appendix E**  
(Cont'd)  
(paras. 2.19 and  
5.5(c) refer)

- (a) products with statements such as “for children under age of 3, use under medical supervision only” or “use under medical supervision if use as sole source of nutrition” are not considered as food for special dietary uses;
- (b) if a product is targeted to a particular group of consumers (e.g. the elderly population) only as marketing strategy, but the composition is not significantly different from ordinary food, or if the product is added with nutrients which are of interest to a particular group of consumers who actually do not have special requirement on these nutrients as compared to the general population, the product is not considered as a food for special dietary use;
- (c) a product to be classified as a food for special dietary use should not have any information or advertisement suggesting or implying that the product is also recommended or suitable for the general population or other population subgroups who do not have that specific disease or condition (e.g. “for health-conscious people”, “for maintaining well-being and help you stay energetic” and “for picky-eaters”); and
- (d) in any cases, products would be classified as food for special dietary uses only if the principles in paragraph 1 above are satisfied. In case of uncertainty, relevant information for individual products will be considered to see whether such products are considered as food for special dietary uses.

*Source: CFS website*

Case 6

Complaints on the use of claims to promote infant and follow-up formulae

1. From **December 2003 to April 2010**, the FEHD received six complaints, including two from the Consulate General of a country (the Consulate) and one referred by the BA, on the following claims used by a formula trader on food labels or in advertisements for promoting his brand of infant and follow-up formulae:

- (a) **Claim 1:** “不含棕櫚油，減低排硬便或便秘的機會” (Infants fed on palm olein-free formula have less chance of forming hard stools or constipation);
- (b) **Claim 2:** “不含棕櫚油，寶寶的鈣質吸收更好，骨骼更強健” (Infants fed on palm olein-free formula has a better absorption of calcium than infants fed on palm oil-containing formula);
- (c) **Claim 3:** “不含棕櫚油的嬰兒配方，有助鈣質吸收” (Infant formula without palm/palm olein oil helps calcium absorption);
- (d) **Claim 4:** “不含棕櫚油，增加骨礦物質含量和骨質密度” (Infants fed on formula without palm/palm olein oil have significantly higher bone mineral content and bone mineral density than those fed formula with palm olein oil);
- (e) **Claim 5:** “不含棕櫚油：讓鈣質更好吸收，堅固牙齒和骨骼，寶寶大便稀糊不上火” (Infant formula without palm/palm olein oil helps calcium absorption to support healthy teeth and strong bones, babies to have soft stools); and
- (f) **Claim 6:** “特有嘅 PHD 成分，即係 Phospholipid，對大腦信息傳遞舉足輕重” (The products contained phospholipids (PHD) which could thoroughly release a child's potential).

The complainants considered that the claims were not properly substantiated. The Consulate also advised the FEHD in 2006 that similar claims for promoting palm olein-free formulae had been banned from use in a number of South East Asian countries.

2. The six claims were subsequently dealt with as follows:

- (a) **Claim 1:** the formula trader informed the FEHD that he had stopped using claims on “palm olein-free” for promotion of its formula;
- (b) **Claim 2:** on receiving additional information from the formula trader, the FEHD considered that Claim 2 was substantiated;
- (c) **Claims 3, 4 and 5:** owing to insufficient scientific support for the claims, the FEHD issued warning/enquiry letters urging the formula trader to stop using the claims, else enforcement action under section 61 of the PHMSO would be taken; and

## Appendix F

(Cont'd)

(paras. 3.1, 3.3(b) and (d) and Appendix G refer)

- (d) **Claim 6:** the FEHD informed the BA in **June and September 2010** that based on overseas research, there was no cause and effect relationship between the consumption of phospholipids and normal memory, learning capacity and concentration, and normal function of the nervous system, and that the nutrition labelling scheme did not apply to infant and follow-up formulae. In **January 2011**, the BA ruled that the complaint on Claim 6 was unsubstantiated.

### Audit comments

3. Audit found that the FEHD (or its CFS set up since 2006) had not followed through the complaints adequately. For example, for Claims 3, 4 and 5, the FEHD simply issued warning letters against the formula trader requesting him to stop using the claims for formula promotion, without taking early actions to address the root cause of the problem (e.g. initiating actions to introduce necessary law or regulations to regulate the claims). Although Claim 2 was similar to Claim 3, the FEHD considered that the former was substantiated but not the latter.

4. On the complaint relating to the use of Claim 6 in TV advertisements, Audit considers that the FEHD should have provided more input to help the BA verify the validity of the claim. In particular, the FEHD should have followed through the complaints to see if similar claims were also found on food labels or in other advertisements and verified them by seeking scientific evidence from the formula trader.

5. As at **August 2011**, Audit found that the formula trader was still using many other claims, similar to some of the above claims, on food labels and on his website to promote his brand of formulae.

*Source: FEHD records and Audit research*

Case 7

Complaints on the use of claims to promote infant and follow-up formulae

1. In **May 2010**, BA referred five complaints to the FEHD for advice on the following two claims shown in a TV advertisement to promote a particular brand of infant and follow-up formulae by another formula trader (different from the one in Case 6 — see Appendix F):

- (a) **Claim 7:** “Formula 3 DHA 含量全港最高” (Formula 3 contained the highest DHA content in Hong Kong); and
- (b) **Claim 8:** “Formula 3 DHA 含量最高。喺 6 至 12 個月，腦部急促成長，腦細胞會攝取同儲存大量 DHA” (Formula 3 contained the highest DHA content. The brain cells would absorb and store a large amount of DHA at the infant stage (6-month to 12-month) when the brain developed rapidly).

The complainants considered that the two claims might not have been properly supported and might be untruthful.

2. Regarding Claim 8, in **June 2010**, the FEHD informed the BA that according to the WHO, DHA was present in high concentrations in the central nervous system, in the cell membranes and the visual system, and played a role in optimal neuronal function and visual acuity. The FEHD also informed the BA that the nutrition labelling scheme (then about to be implemented) did not apply to formulae intended to be consumed by children under the age of 36 months (Note).

3. In **September 2010**, the FEHD further informed the BA that:

- (a) **Claim 7:** the FEHD had no information of the DHA content in other brands of formulae; and
- (b) **Claim 8:** the FEHD had no comment from the nutrition angle and could provide no further input (Note).

4. In **March 2011**, the BA ruled that the complaints were unsubstantiated.

**Audit comments**

5. Audit considers that the FEHD should have provided more input to help the BA verify the validity of the claims. In particular, the FEHD should have followed through the complaints to see if similar claims were also found on food labels or other advertisements and verified them by seeking scientific evidence from the formula trader.

6. As at **August 2011**, Audit found that the formula trader was still using many claims, similar to Claims 7 and 8 above, on food labels and on his website to promote his brand of formulae.

Source: FEHD records and Audit research

Note: In June 2010, the FEHD informed the BA that according to Codex, if DHA was added, AA/ARA contents should reach at least the same concentration as DHA. The FEHD then asked the BA to obtain more information about the fatty acids profile (e.g. the DHA content in terms of percentage of fatty acids) in the alleged formulae. In August 2010, the BA provided the necessary product information to the FEHD. In September 2010, the FEHD informed the BA that the product information showed that the alleged formulae were in line with one Codex requirement.

**Acronyms and abbreviations**

|        |  |
|--------|--|
| AA/ARA | Arachidonic acid   |
| Audit  | Audit Commission   |
| BA     | Broadcasting Authority                                   |
| CFS    | Centre for Food Safety                                   |
| Codex  | Codex Alimentarius Commission                            |
| DH     | Department of Health                                     |
| DHA    | Docosahexaenoic acid                                     |
| FAO    | Food and Agricultural Organization of the United Nations |
| FEHD   | Food and Environmental Hygiene Department                |
| g      | Grams  |
| GI     | Glycemic Index   |
| HA     | Hospital Authority                                       |
| kcal   | Kilocalories   |
| kJ     | Kilojoules   |
| LegCo  | Legislative Council                                      |
| mg     | Milligrams   |
| mL     | Millilitres  |
| PHD    | Phospholipids  |
| PHMSO  | Public Health and Municipal Services Ordinance           |
| WHA    | World Health Assembly                                    |
| WHO    | World Health Organization                                |
| µg     | Micrograms   |