

## **LEGISLATIVE COUNCIL BRIEF**

### **Public Health and Municipal Services Ordinance**

**(Cap. 132)**

#### **HARMFUL SUBSTANCES IN FOOD (AMENDMENT)**

#### **REGULATION 2011**

#### **INTRODUCTION**

On 5 December 2011, the Director of Food and Environmental Hygiene (DFEH), in exercise of the power under section 55(1) of the Public Health and Municipal Services Ordinance (Cap. 132), made the Harmful Substances in Food (Amendment) Regulation 2011 (“the Amendment Regulation”) at **Annex A**.

**A**

#### **JUSTIFICATIONS**

2. In recent years, food incidents involving infant formulas in the Mainland had been widely reported in Hong Kong such as the detection of melamine in infant formulas in end 2008. There has been concern about the spillover of these problem infant formulas into Hong Kong. These incidents also focus public attention on whether the current regulatory regime in Hong Kong has provided sufficient control over this food item.

3. Codex Alimentarius Commission (Codex) defines

“infant formula” as a breast-milk substitute for infants during the first months of life up to the introduction of appropriate complementary feeding and “infant” means a person not more than 12 months of age. It should, however, be noted that there exists in the market other powdered milk for all age groups and for usage as food ingredients. Unlike infant formulas for babies, the latter is normally not meant for consumption as a main food item but as a supplement.

4. Currently, the safety of infant formulas is regulated by section 54 of the Public Health and Municipal Services Ordinance (Cap. 132), which stipulates that all food for sale must be fit for human consumption. As food includes infant formulas, we can regulate its safety through section 54 and take prosecution action in cases where the infant formula is found to be unfit for human consumption.

5. To address the public concern over the suspected presence of harmful hormones in some infant formulas manufactured in the Mainland which led to suspected cases of precocious puberty in some children in the Mainland in August 2010, we have examined whether there is any specific statutory control governing the presence of hormones of exogenous origin in milk powder.

#### **(A) Review of the relevant legislation**

6. Accordingly, we have reviewed the adequacy of the current legislation regulating the food safety of the dried milk, condensed milk and reconstituted milk in Hong Kong. Our detailed analysis is at **Annex B**. Our conclusion is that, except for the Harmful Substances in Food Regulations (Cap. 132AF), no amendments to other legislation would be necessary. The definition of food in Cap. 132 already covers dried milk, condensed milk and reconstituted milk which means that they are regulated under the current regime on food safety

7. At present, Cap. 132AF governs the import and sale of food containing harmful substances, most of which are veterinary drugs. Under Regulation 3A of Cap. 132AF, prohibited substances (most of which are veterinary drugs) in the Second Schedule are not allowed in milk. As the definition of “milk” in Cap. 132AF excludes dried milk, condensed milk and reconstituted milk, the prohibition under Regulation 3A does not apply to dried milk, condensed milk and reconstituted milk. As a result, the presence of the exogenous estrogens specified in the Second Schedule, namely, Dienoestrol, Diethylstilboestrol and Hexoestrol, in infant formula is not prohibited by Cap. 132AF. We need to plug this loophole.

8. Apart from the Second Schedule of Cap. 132AF, we have also explored whether we should set the Maximum Residue Limits (MRLs) for dried milk under Regulation 3 of Cap. 132AF. Under Regulation 3, no person shall import, consign, deliver, manufacture or sell, for human consumption, any food specified in the First Schedule that exceeds the maximum concentration set for the substances (which also covers mostly veterinary drugs) therein. In this connection, it should be noted that melamine, item 26B in the First Schedule, applies to any food intended to be consumed principally by children under the age of 36 months. As such, it will cover infant formula.

9. According to expert advice of the Working Group on Standard Setting for Veterinary Drug Residues in Food, they are not aware of any country that has established veterinary drug residues standard specifically for infant formula. Apart from the lack of an international standard, the Working Group is of the view that it would be very difficult to establish such standards because the manufacturing process of milk powder may change the veterinary drug residues in many ways. For example, the dehydration process may either

concentrate or decrease the residue level depending on the solubility of the veterinary drug. In case the veterinary drug is fat soluble (e.g. cypermethrin), it will be concentrated. For water soluble drug (e.g. imidocarb), a large proportion of the residues may be removed with the water during the drying process. The same applies to condensed milk and reconstituted milk.

10. Without the support of scientific data and international standards, we would not be able to set MRLs for dried milk, condensed milk and reconstituted milk in relation to those veterinary drugs specified in the First Schedule. If we do, we may not be able to withstand possible challenge by other World Trade Organisation members that such standards are not based on scientific evidence and hence should be regarded as trade barriers. We have therefore decided not to set MRLs for dried milk, condensed milk or reconstituted milk in relation to those veterinary drugs specified in the First Schedule of Cap. 132AF. We will, however, still be able to regulate those veterinary drug residues found in dried milk, condensed milk and reconstituted milk if they are found to be unfit for human consumption under section 54 of Cap. 132.

## **(B) Risk Assessment**

11. The Centre for Food Safety (CFS) collects samples of milk powder (mostly infant formula) for test every year, with satisfactory results in 2007-2010. The results of food surveillance on milk powder in recent years did not reveal any use of the prohibited substances in the Second Schedule of Cap. 132AF. Details are at **Annex C**.

**C**

12. When compared with milk, dried milk is not as perishable. The manufacturing process has already reduced the presence of pathogens in dried milk. While the risk of having pathogens in dried milk is low, it is possible

that it may contain prohibited veterinary drugs as prescribed in the Second Schedule of Cap. 132AF. From a risk assessment point of view, it is unacceptable to find the presence of the prohibited veterinary drugs in dried milk, condensed milk and reconstituted milk. As infant formula is the main food item for babies, the public would expect stringent control by the Government given babies' vulnerability.

13. In light of the review of the current legislation (paragraphs 6-10) and the risk assessment (paragraphs 11-12), we propose to extend the prohibition on the presence of substances specified in the Second Schedule of Cap. 132AF in food to dried milk, condensed milk and reconstituted milk. When the amendments are passed by the Legislative Council, the three exogenous estrogens specified in the Second Schedule would be prohibited in dried milk, including infant formula. The potential problem highlighted by the suspected contaminated infant formula in the Mainland in August 2010 would have been tackled.

## **THE AMENDMENT REGULATION**

14. The Amendment Regulation at Annex A amends the Harmful Substances in Food Regulations (Cap. 132AF) to extend the prohibition on the presence of substances specified in its Second Schedule in food to dried milk, condensed milk and reconstituted milk. Such substances include three exogenous estrogens specified in items 1-3 of the Second Schedule. The main provisions of the Amendment Regulation are as follows-

- (a) Section 1 provides for the commencement of the Amendment Regulation.
- (b) Section 2 provides that the Harmful substances in Food Regulations (Cap. 132AF) are amended as set out in sections 3 to 5 of the Amendment Regulation.

- (c) Section 3 adds the definition of condensed milk, dried milk, reconstituted milk and skimmed milk to Regulation 2 of Cap. 132AF.
- (d) Section 4 amends the English text of Regulation 3 of Cap. 132AF by replacing “No person shall” with “A person must not”.
- (e) Section 5 amends Regulation 3A of Cap. 132AF by adding “dried milk, condensed milk or reconstituted milk” to extend the prohibition on the presence of substances specified in its Second Schedule in food to dried milk, condensed milk and reconstituted milk. In the English text, the phrase “No person shall” will also be replaced by “A person must not” in Regulation 3A of Cap. 132AF.

## **LEGISLATIVE TIMETABLE**

15. The legislative timetable is as follows –

Publication in gazette	9 December 2011
Tabling at the Legislative Council	14 December 2011

## **IMPLICATIONS OF THE PROPOSAL**

16. The Amendment Regulation is in conformity with the Basic Law, including the provisions concerning human rights. It will not affect the binding effect of the Public Health and Municipal Services Ordinance (Cap. 132). Additional staffing and financial implications arising from the implementation of the proposal will be absorbed by the Food and Environmental Hygiene Department. As these prohibited substances are not supposed to be found in dried milk, condensed milk and reconstituted milk in Hong Kong, the Amendment Regulation will have no economic, productivity, environmental implications.

**D**

17. The Amendment Regulation has sustainability implications as set out in **Annex D**.

**PUBLIC CONSULTATION**

18. We consulted members of the trade through a Trade Consultation Forum on 12 May 2011 and a special consultation session on 3 June 2011. The traders present were content. We have also consulted the Advisory Council on Food and Environmental Hygiene and the Expert Committee on Food Safety on 25 May and 2 June 2011 respectively. Both supported the proposal.

19. The Legislative Council Panel on Food Safety and Environmental Hygiene supported the proposal at the meeting on 14 June 2011.

**PUBLICITY**

20. A press release will be issued. A spokesman will be available to answer media enquiries.

**ENQUIRIES**

21. Any enquiry on this brief can be addressed to Mr Kevin Yeung, Principal Assistant Secretary for Food and Health (Food)1, on 2973 8297.

**Food and Health Bureau  
Food and Environmental Hygiene Department  
December 2011**

## Harmful Substances in Food (Amendment) Regulation 2011

(Made by the Director of Food and Environmental Hygiene under section 55(1) of the Public Health and Municipal Services Ordinance (Cap. 132))

### 1. Commencement

This Regulation comes into operation on 1 March 2012.

### 2. Harmful Substances in Food Regulations amended

The Harmful Substances in Food Regulations (Cap. 132 sub. leg. AF) are amended as set out in sections 3 to 5.

### 3. Regulation 2 amended (interpretation)

(1) Regulation 2, English text, definition of *sell*—

**Repeal the full stop**

**Substitute a semicolon.**

(2) Regulation 2—

**Add in alphabetical order**

“*condensed milk* (煉奶) means milk which has been condensed by the evaporation of a portion of its water content, whether or not sugar has been added, and includes—

- (a) any such milk made from skimmed milk or partly skimmed milk; and
- (b) evaporated milk;

*dried milk* (奶粉) means milk which has been concentrated in the form of solid or powder by removal of water, whether or not it has been sweetened, modified or compounded, and includes any such milk made from skimmed milk or partly skimmed milk;

*reconstituted milk* (再造奶) means products resulting from the recombining with water of milk constituents, namely, milk fat and other solids derived from milk exclusive of any other substance, and includes the products resulting from the melting of frozen concentrated milk;

*skimmed milk* (脫脂奶) includes separated milk and machine skimmed milk.”.

### 4. Regulation 3 amended (prohibition of import and sale of food containing certain substances in excessive concentrations)

Regulation 3, English text—

**Repeal**

“No person shall”

**Substitute**

“A person must not”.

### 5. Regulation 3A amended (prohibition of import and sale of fish, meat or milk containing prohibited substances)

(1) Regulation 3A, heading—

**Repeal**

“milk”

**Substitute**

“milk etc.”.

(2) Regulation 3A, English text—

**Repeal**

“No person shall”

**Substitute**

“A person must not”.

(3) Regulation 3A—

**Repeal**



“meat or milk”

**Substitute**

“meat, milk, dried milk, condensed milk or reconstituted milk”.



Director of Food and Environmental  
Hygiene

5 Dec. 2011

---

**Explanatory Note**

The purpose of this Regulation is to amend the Harmful Substances in Food Regulations (Cap. 132 sub. leg. AF) to extend the prohibition of the presence of certain substances in food to dried milk, condensed milk and reconstituted milk.

## **Review of the Relevant Legislation**

Colouring Matter in Food Regulations (Cap. 132H) and Sweeteners in Food Regulations (Cap. 132U) regulate the presence of colouring matters and sweeteners in food. Permitted colouring matters and sweeteners are listed in the Regulations without specifying any limits on the food type. As dried milk, condensed milk and reconstituted milk are already covered by the broad definition of food, and there is no exclusion of them from any provision of Cap. 132H and Cap. 132U, no amendments to Cap. 132H and Cap. 132U would be necessary.

2. The Food Adulteration (Metallic Contamination) Regulations (Cap. 132V) regulates the level of metallic contaminants in food and prescribes the maximum permitted concentration of 7 specified metals present in specific food types. Similarly, the Mineral Oil in Food Regulations (Cap. 132AR) limits the amount of mineral oil to 0.2 parts by weight per 100 parts by weight of the article of food. As dried milk, condensed milk and reconstituted milk are already covered in the general definition of food, and there is no exclusion of them from any provision of Cap. 132V and Cap. 132AR, no amendments would be necessary.

3. The Preservatives in Food Regulation (Cap. 132BD) regulates the use of additives (ie preservatives or antioxidants) in food. Section 4 of Cap. 132BD prohibits the supply of food intended mainly for babies and young children that contains antioxidants. No amendments to the Regulation would be necessary.

**Current food surveillance on milk powder**

CFS collects samples of milk powder (including infant formula and others, but most of them are infant formula) for testing every year. The number of samples taken in the past 4 years is shown below. All testing results were satisfactory. The number of samples taken in 2008 was relatively large because of melamine incidents.

	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>Total</b>
Chemical testing	38	450	66	177	731
Microbiological testing	15	8	106	100	229
<b>Total</b>	53	458	172	277	960

Testing parameters include:

Chemical Testing: Antibiotics, Anti-oxidants, Colouring Matter, Metallic Contamination, Composition, Radioactive contaminants, Mineral Oil (Hydrocarbon), Pesticides (Organo-chlorine pesticides), Preservatives, Sweeteners, Toxins, Dioxins, Melamine, Food Spoilage, Foreign Matter, Allergen, Hormones

Microbiological Testing: Indicator organisms, Pathogens, Enterobacter sakazakii

**IMPLICATIONS OF THE PROPOSAL**  
**HARMFUL SUBSTANCES IN FOOD (AMENDMENT)**  
**REGULATION 2011**

The sustainability implications of the Harmful Substances in Food (Amendment) Regulation 2011 are as follows.

**Sustainability Implications**

2. The proposal would strengthen the Government's capability to ensure food safety. It is in line with the sustainability principle of pursuing policies which promote and protect the physical and mental health and safety of the people of Hong Kong