For Discussion
On 14 June 2011

LegCo Panel on Food Safety and Environmental Hygiene

Proposed amendment to the Harmful Substances in Food Regulations (Cap. 132AF) to prohibit the presence of certain substances in dried milk, condensed milk and reconstituted milk

Purpose

This paper consults Members on our proposal to amend the Harmful Substances in Food Regulations (Cap. 132AF) so that the prohibition on the presence of certain substances specified in the Second Schedule will be extended to cover dried milk, condensed milk and reconstituted milk.

Background

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 estrogens in some infant formulas manufactured in the Mainland which led to suspected cases of precocious puberty in some children in the Mainland last August, we have examined whether there is any specific statutory control governing the presence of hormones of exogenous origin in milk powder.

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 A**. Our conclusion is that, except for the Harmful Substances in Food Regulations (Cap. 132AF), no amendments to other legislation would be necessary since 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.

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 B**.

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 Schedule 2 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.

Proposed Legislative Amendments

13. In light of the review of the current legislation (paragraphs 6-10) and the risk assessment (paragraphs 11-12), we propose to expand the scope of the prohibition on the presence of substances specified in the Second Schedule of Cap. 132AF to cover dried milk, condensed milk and reconstituted milk. We further propose to define the term "dried milk", "condensed milk" and "reconstituted milk" for clarity. "Dried milk" will be defined to cover milk powder for all age groups. When the amendments are passed by LegCo, 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 last August would have been tackled.

Consultation

14. We consulted the Trade Consultation Forum on 12 May 2011. We also arranged a special consultation session for the related traders on 3 June 2011. The traders present (including the six main suppliers of infant formula) did not express any objection to the proposed amendments which aimed to safeguard the safety of these food items. We have also consulted the Advisory Council on Food and Environmental Hygiene and Expert Committee on Food Safety on 25 May and 2 June 2011 respectively, and they also supported the proposed legislative amendments.

15. Subject to Members' comment, we will proceed to consult the Consulate Generals of the countries exporting dried milk, condensed milk and reconstituted milk to Hong Kong.

Legislative Timetable

16. We plan to introduce the Amendment Regulation into the Legislative Council by end 2011.

Advice Sought

17. Members are invited to comment on the proposed amendments to Cap. 132AF.

Food and Health Bureau
Food and Environmental Hygiene Department
Centre for Food Safety
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Annex A

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.

Annex B

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.

	2007	**2008**	**2009**	**2010**	**Total**
Chemical testing	38	450	66	177	731
Microbiological testing	15	8	106	100	229
Total	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