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Panel on Food Safety and Environmental Hygiene

Background brief prepared by the Legislative Council Secretariat for the meeting on 20 April 2021

Administration's proposals to amend the Harmful Substances in Food Regulations

Purpose

This paper provides background information on the Administration's proposals to amend the Harmful Substances in Food Regulations (Cap. 132AF) ("the Regulations") for strengthening the regulation of certain harmful substances (such as industrially-produced trans fats and mycotoxins) in food, and summarizes major views and concerns of members of the Panel on Food Safety and Environmental Hygiene ("the Panel") on the proposals.

Background

2. Under the Public Health and Municipal Services Ordinance (Cap. 132), food for sale and intended for human consumption in Hong Kong must be fit for human consumption. Standards relating to food safety are provided in various pieces of subsidiary legislation. Specifically, the Regulations stipulate that any specified food containing prohibited substances or specified harmful substances in excessive concentrations is not allowed to be imported to or sold in Hong Kong.

3. According to the Administration, the Food and Health Bureau and the Centre for Food Safety ("CFS") of the Food and Environmental Hygiene Department have been closely monitoring international developments on the safeguarding of food safety (including making reference to the food safety standards of the Codex Alimentarius Commission ("Codex") and other places) and considering local dietary practices as well as risk assessment results, with a view to reviewing and updating from time to time the local food safety standards and regulatory arrangements based on scientific evidence.

Proposed amendments to the Regulations

Strengthening regulation of three mycotoxins

4. The Regulations have prescribed the permitted maximum levels ("MLs") of aflatoxins in food since the 1980s. Considering the grave food safety risks posed by aflatoxins¹ to the local population, the Administration proposes to tighten up the permitted MLs of "aflatoxins, total" (from 15-20 µg/kg to 10-15 µg/kg) for certain tree nuts, peanuts and dried fruit which are more susceptible to aflatoxin contamination. Having regard to the substantially higher carcinogenic potency of aflatoxins in hepatitis B virus-infected than non-infected individuals, and the higher prevalence of hepatitis B virus infection in the Hong Kong population compared with that in many neighbouring places, the Administration also proposes to lower the permitted ML for "aflatoxins, total" in any other food except specified foods (from 15 µg/kg to 5 µg/kg). The Administration also proposes to strengthen the regulation of two other types of mycotoxins, i.e. deoxynivalenol (also known as vomitoxin) and patulin, in specified foods with reference to the standards adopted by Codex. The proposed MLs in relation to these substances are set out in **Appendix I**.

Strengthening regulation of five harmful substances in edible fats and oils, condiments and formula products intended for infants

5. To better protect the health of the local population (including infants), the Administration proposes to set or update MLs for five harmful substances (i.e. benzo[a]pyrene ("B[a]P"), glycidyl fatty acid esters (expressed as glycidol), melamine, 3-monochloropropane-1,2-diol and erucic acid) in edible fats and oils, condiments or formula products intended for infants. Details of the proposed amendments are also set out in **Appendix I**.

Regarding "partially hydrogenated oils" as a prohibited substance in food

6. "Partially hydrogenated oils" ("PHOs") are the main source of industrially-produced trans fatty acids, which are relatively common in margarines, vegetable shortenings and various kinds of food with margarines or vegetable shortenings as ingredients (e.g. baked food). Scientific research has revealed that industrially-produced trans fatty acids are harmful to health, contributing significantly to an increased risk of coronary heart diseases. To protect public health at source, the Administration proposes to regard PHOs as a prohibited substance in food with reference to the recommendation of the World Health Organization. Under the legislative proposal, the import of any edible fats and oils containing PHOs and the sale of any food (including edible

¹ According to information provided by the Administration to the Panel in January 2021, long-term ingestion of aflatoxins, the most toxic kind of mycotoxin, could result in liver cancer.

fats and oils) containing PHOs will be prohibited. The Administration also proposes that any prepackaged food containing hydrogenated oils must be indicated accordingly in the list of ingredients.

Members' concerns

7. The Administration briefed members on its proposals to amend the Regulations at the Panel meeting on 25 January 2021. Members' major views and concerns on the proposals are summarized below.

Strengthening the regulation of harmful substances in food

8. Members generally supported the Administration's proposals to amend the Regulations for strengthening the regulation of harmful substances. Some members noted with concern that some mycotoxins and harmful substances such as aflatoxin, B[a]P and melamine were involved in major food incidents occurred in Hong Kong several years ago. They questioned why it took so long for CFS to complete the review on the safety standards of those harmful substances in food. Information was sought under what circumstances the Administration would review the regulatory control over other harmful substances in food.

9. According to the Administration, in updating the regulatory arrangements for harmful substances in food including aflatoxin, B[a]P and melamine, CFS had made reference to the food safety standards adopted by Codex and overseas jurisdictions as well as the dietary practices of the local population and risk assessment results. For instance, as Codex had provided a specific ML for melamine in "liquid infant formula" at 0.15 mg/kg in its General Standard for Contaminants and Toxins in Food and Feed ("General Standard"), the Administration proposed to adopt the same standard by updating the existing Regulations. The Administration stressed that CFS would continue to update local food safety standards and regulatory arrangements based on scientific evidence.

10. In response to members' follow-up question about the existing regulatory control over formula products intended for infants, the Administration advised that CFS had been regularly collecting samples of formula products for (a) testing of harmful substances and metallic contaminants as well as (b) monitoring the nutrient content. CFS also conducted compliance checks in respect of the labelling requirements for formula products.

11. Question was raised on why an ML of patulin (excessive intake of which might cause symptoms such as nausea, gastrointestinal disturbance and vomiting) was proposed for apple juice and other beverages to which apple juice had been added, but not apple itself.

12. The Administration explained that patulin was produced by a variety of moulds and mostly occurred in rotten apples. As the amount of patulin found in rotten apples in food was normally lower than the amount found in apple juice, and having noted a number of recent cases involving substantial amount of patulin found in relevant juice products, the Administration proposed to make reference to the standard of patulin in apple juice under the Codex General Standard to incorporate in the Regulations an ML of 50µg/kg for "patulin" in apple juice and other beverages to which apple juice had been added.

Impact of implementing the proposed amendments

13. Concerns were expressed about the impact of setting MLs for harmful substances (including B[a]P, glycidyl fatty acid esters and melamine) in formula products intended for infants on the supply of such products; and how consumers would be informed of the food safety risks posed by infant formula products which failed to meet the updated standards.

14. The Administration advised that as infants who could not be breastfed or whose parents opted not to do so were fed with formula products, it proposed to enhance the food safety standards of formula products intended for infants by making reference to the practices of Codex and the European Union. At present, food sold in Hong Kong (including formula products) could generally comply with the proposed new standards. According to the testing results of the samples collected by CFS under its regular Food Surveillance Programme and relevant risk assessments in recent years, more than 95% of the relevant samples could meet the proposed MLs for harmful substances in foods/food groups. CFS would assess the food safety risks of infant formula products after the implementation of the new food safety standards and regulatory arrangements, and would take appropriate actions (e.g. instructing vendors to stop selling the products) if immediate health risks in food samples were detected.

Proposed grace period

15. Some members were of the view that the proposed grace period should be shortened for early implementation of the updated standards of the harmful substances under discussion.

16. In response, the Administration advised that to provide sufficient time for the food trade as well as the private testing and laboratory sector to get prepared for the updated food safety standards, it proposed to allow a grace period of 18 months for the Amendment Regulations to be gazetted to come into force. The Administration further advised that it had been maintaining close liaison with relevant stakeholders of the trade, including suppliers of formula products, on the proposed amendments and the implementation arrangements (e.g. applicable standards for different types of food products, the testing methods, the length of the grace period and the potential impact on food supply).

Recent developments

17. The Administration conducted a public consultation exercise on the proposals to amend the Regulations between 11 December 2020 and 15 March 2021.² The Administration will report on the results of the public consultation exercise at the Panel meeting on 20 April 2021.

Relevant papers

18. A list of the relevant papers on the Legislative Council website is in **Appendix II**.

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² The relevant consultation document (Annex to LC Paper No. CB(2)599/20-21(03)) is available on the Legislative Council website at <https://www.legco.gov.hk/yr20-21/english/panels/fseh/papers/fseh20210125cb2-599-3-e.pdf>

Overview of the Proposed Amendments

The proposed amendments in relation to the MLs of **mycotoxins and other harmful substances in food** are summarised in the table below:

	Substance	Food / Food group	Proposed ML	ML under the existing Regulations
1.	Aflatoxins, total (Note 1)	Non-ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios	15 µg/kg (Note 3)	Peanuts or peanut products: 20 µg/kg Any other food: 15 µg/kg
		Non-ready-to-eat products of the above food		
		Spices (Note 2)		
		Ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios	10 µg/kg (Note 4)	
		Ready-to-eat products of the above food		
		Dried figs		
		Any other food	5 µg/kg	
	Aflatoxin B ₁	Any food intended to be consumed principally by persons under the age of 36 months	0.1 µg/kg	

	Substance	Food / Food group	Proposed ML	ML under the existing Regulations
	Aflatoxin M ₁	Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.025 µg/kg (Note 5)	
		Any other milk and dried milk	0.5 µg/kg (Note 5)	
2.	Deoxynivalenol	Any food containing cereal intended to be consumed principally by persons under the age of 36 months	200 µg/kg (Note 6)	Nil
3.	Patulin	Apple juice and other beverages to which apple juice has been added	50 µg/kg (Note 7)	
	Benzo[a]pyrene	Any oil or fat or any mixture of oil and fat	5 µg/kg	
4.		Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1 µg/kg (Note 8)	
5.	Glycidyl fatty acid esters (expressed as glycidol)	Powdered infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	50 µg/kg (Note 8)	
		Liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	6 µg/kg (Note 8)	

	Substance	Food / Food group	Proposed ML	ML under the existing Regulations
6.	Melamine (Note 9)	Liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.15 mg/kg (Note 8)	Milk and any food intended to be consumed principally by persons of an age group into which children under the age of 36 months fall: 1mg/kg
		Milk other than liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1 mg/kg (Note 10)	
		Any other food intended to be consumed principally by persons under the age of 36 months		
7.	3-monochloropropane-1,2-diol	Solid condiments	1 mg/kg	Nil
		Any other condiments	0.4 mg/kg (Note 11)	
8.	Erucic acid (Note 12)	Low-erucic acid rapeseed oil	2 per centum by weight of their fatty acid content	Any oil or fat or any mixture thereof:
		Any other oil or fat or any mixture of oil and fat	5 per centum by weight of their fatty acid content (Note 10)	5 per centum by weight of their fatty acid content

Note 1: “Aflatoxins, total” refers to “aflatoxins B₁+B₂+G₁+G₂” as defined in the Codex General Standard. It is proposed to replace “aflatoxin” and its description (i.e. “group of bis-furanocoumarin compounds and includes aflatoxin B₁, B₂, G₁, G₂, M₁, M₂, P₁ and aflatoxicol”) as stipulated in Schedule 1 to the existing Regulations.

Note 2: Codex is drafting an ML for certain spices (i.e. 20 or 30 µg/kg), which is more lenient than that for any food including spices under the existing Regulations (i.e. 15 µg/kg). It is therefore proposed to retain the more stringent standard stipulated under the existing Regulations as the proposed ML.

Note 3: The ML for “non-ready-to-eat” peanuts, almonds, Brazil nuts, hazelnuts and pistachios is proposed with reference to the Codex General Standard in respect of those “intended for further processing”. For the non-ready-to-eat products of the above food, the proposed ML is based on the principle that “peanuts or peanut products” is regarded as the same group under the existing Regulations.

Note 4: The ML for “ready-to-eat” almonds, Brazil nuts, hazelnuts and pistachios is proposed with reference to the Codex General Standard, while that for “ready-to-eat” peanuts is based on the existing draft Codex standard. For the ready-to-eat products of the above food, the proposed ML is based on the principle that “peanuts or peanut products” is regarded as the same group under the existing Regulations.

Note 5: The proposed ML applies to products that are, or are reconstituted to be, ready-to-drink.

Note 6: The proposed ML applies to the whole commodity on a dry weight basis.

Note 7: For other beverages to which apple juice has been added, the ML is proposed with reference to the standard for “apple juice” in the Codex General Standard. The proposed ML applies to the whole commodity that is not concentrated, or is reconstituted to be ready-to-drink.

Note 8: The ML applies to products as sold.

Note 9: The MLs of melamine in “any food intended to be consumed principally by pregnant or lactating women” at 1 mg/kg and “any other food” at 2.5 mg/kg stipulated under the existing Regulations would remain unchanged.

Note 10: The ML is the same as that of the existing Regulations; the proposed amendment only involves refinements to the description to the relevant “food / food group”.

Note 11: The ML is proposed with reference to the standard for “liquid condiments” containing acid-HVPs in the Codex General Standard.

Note 12: The ML of erucic acid in “any food to which oil or fat or a mixture thereof has been added” at “5 per centum by weight of their fatty acid content of all the oils and fats in the food” under the existing Regulations would remain unchanged.

Source: Extracted from the Administration's paper entitled "Public Consultation on Strengthening Regulation of Harmful Substances in Food" provided for the meeting of the Panel on Food Safety and Environmental Hygiene held on 25 January 2021 (Annex to LC Paper No. CB(2)599/20-21(03))

**Relevant papers on the
Administration's proposals to amend the
Harmful Substances in Food Regulations**

Committee	Date of meeting	Paper
Panel on Food Safety and Environmental Hygiene	25.1.2021 (Item VI)	<u>Agenda</u> <u>Minutes</u>

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