

**For discussion
on 20 April 2021**

Legislative Council Panel on Food Safety and Environmental Hygiene

**Result of Public Consultation on
Strengthening Regulation of Harmful Substances in Food**

Purpose

This paper sets out the outcome of the public consultation on strengthening regulation of harmful substances in food and the proposed way forward.

Background

2. The Food and Health Bureau and the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department conducted a public consultation on the proposed amendments to the Harmful Substances in Food Regulations (Cap. 132AF) (the Regulations) between 11 December 2020 and 15 March 2021. The proposals aim to enhance the regulatory control of various harmful substances in food, namely three types of mycotoxins, five types of other harmful substances in edible fats and oils, condiments and formula products intended for infants, and partially hydrogenated oils (i.e. the main source of industrially-produced trans fats), with a view to ensuring food safety in Hong Kong.

3. Members were consulted on the proposed amendments to the Regulations on 25 January 2021 (vide LC Paper No. CB(2)599/20-21(03)). We also consulted several relevant advisory bodies, including the Advisory Council on Food and Environmental Hygiene (ACFEH), as well as the Wholesale and Retail Task Force and the Food Business and Related Services Task Force under the Business Facilitation Advisory Committee. In addition, the CFS organised two consultation forums by videoconferencing with more than 150 participants (including members of

the trade), and some other virtual meetings to facilitate communication with stakeholders of the trade (such as the retail and the laboratory testing sectors) who had expressed concerns over the proposals.

Result of the Public Consultation

4. We received a total of 36 written submissions, of which about two-thirds were from various organisations and stakeholders of the food trade, and the other one-third were from professional groups, political parties, consumer group and individuals. A list of respondents is at **Annex 1**. **The respondents generally welcomed and supported the proposed amendments and considered that the proposals could better protect public health.** Meanwhile, several technical comments were raised by some respondents as summarised in the ensuing paragraphs.

Proposed Standards for Aflatoxins

Aflatoxins, total

5. On the proposal of tightening up the maximum level (ML) of “aflatoxins, total” in any food other than specified foods from 15 µg/kg under the existing Regulations to 5 µg/kg, some respondents considered it too strict as there was no common standard for “aflatoxins, total” in “any food” internationally. While some places had set relevant standards, such standards were generally more lenient than 5 µg/kg. The respondents were concerned that under the regulatory proposal, foods that were compliant with the statutory requirements of the place of origin might not meet the proposed standard upon import into Hong Kong, possibly affecting food imports. In addition, some respondents noted that according to the prevailing international standards, the types of food they produced should fall outside the regulatory scope of “aflatoxins, total”. Meanwhile, another respondent suggested further tightening up the regulatory control of certain foods (e.g. spices) by making reference to the standard of the European Union (EU).

6. While we understand the concerns of the trade, it must be stressed that the ML of “aflatoxins, total” in any food other than specified foods (i.e. peanut or peanut products) has been stipulated under the Regulations since the 1980s. Being the most toxic kind of mycotoxins, aflatoxins pose grave

food safety risks to the local population (especially hepatitis B virus-infected individuals). Nonetheless, as the new regulatory proposals on “aflatoxin B₁” and “aflatoxin M₁” in specified foods will enhance health protection for the public (including high-risk groups) in a targeted manner, members of the ACFEH opined that consideration could be given to setting the ML of “aflatoxins, total” in any other food at 10 µg/kg. Taking into account the above factors, we propose to **tighten up the ML of “aflatoxins, total” in any food other than specified foods to 10 µg/kg**. We will continue to monitor the level of “aflatoxins, total” in different foods and review the relevant standards in a timely manner.

Aflatoxin B₁

7. As regards the proposal of setting an ML of 0.1 µg/kg for “aflatoxin B₁” in any food intended to be consumed by infants and young children under the age of 36 months, some respondents expressed that the relevant EU standard was not applicable to infant and follow-up formula. They considered that the regulatory scope should be clarified.

8. The proposed ML of “aflatoxin B₁” is based on the practice of various places such as the EU and Singapore. However, we agree that for **formula products with milk as the ingredient**, it will be more practical and effective to make reference to the practice of the EU to focus on regulating their “aflatoxin M₁” (a toxin formed as a result of the metabolic process in the livers of cows or other ruminant animals if they consume feeds contaminated with “aflatoxin B₁” and excreted in milk). Therefore, on the basis that the new standard for “aflatoxin M₁” remains unchanged, we propose to adjust the regulatory scope for “aflatoxin B₁” to “any food intended to be consumed by infants and young children under the age of 36 months **except infant formula and follow-up formula manufactured from milk proteins**”.

Coverage of MLs for Other Harmful Substances

9. Some respondents commented on the coverage of the newly proposed standards for two harmful substances. On the proposal of setting the coverage of the standard for “deoxynivalenol” (DON) (also known as vomitoxin) as “any food containing cereal intended to be consumed by infants and young children under the age of 36 months”, a respondent

pointed out that the prevailing international standard only applied to “cereal-based foods intended to be consumed by infants and young children under the age of 36 months”. As for the proposal of setting the coverage of the standards of “3-monochloropropane-1,2-diol” (3-MCPD) as “any condiments”, some respondents stated that the prevailing international standard was only applicable to “condiments containing acid hydrolysed vegetable proteins (acid-HVPs)”.

10. On the other hand, some respondents suggested enhancing the regulation of specific harmful substances by making reference to the EU standards, such as expanding the regulatory scope for DON to all cereal-containing foods; expanding the regulatory scope for 3-MCPD to infant formula; expanding the regulatory scope for glycidyl fatty acid esters to edible fats and oils; further tightening up the ML of benzo[a]pyrene in edible oils and fats from the proposed level of 5 µg/kg to 2 µg/kg; and introducing regulation of ochratoxin A in spices.

11. Regarding the comments in paragraph 9 above, having considered the relevant standards of the Codex Alimentarius Commission (Codex) and the related scientific evidence, we agree that the coverage of the MLs for “**DON**” and “**3-MCPD**” can be more clearly stipulated as “cereal-based foods intended to be consumed by infants and young children under the age of 36 months” and “condiments containing acid-HVPs” respectively. In fact, condiments not containing acid-HVPs such as naturally fermented soy sauce, sugar and salt should not contain, or only contain trace amounts of, 3-MCPD. As for the comments in paragraph 10 above, the suggestions involve certain harmful substances and foods/food groups not covered by the Codex standards. The CFS will closely monitor international developments (including the practice of other places) and take into account the local situation to review the relevant standards based on scientific evidence in a timely manner.

Partially Hydrogenated Oils (PHOs)

12. As far as PHOs are concerned, respondents **generally supported regarding PHOs as a prohibited substance in food** to better protect public health by reducing the risk of coronary heart diseases and align with international practice. Many respondents from the trade indicated that they and/or their food suppliers were taking, or had already taken, measures to

stop using PHOs in their products, with a view to meeting the goal of the World Health Organization (WHO) to eliminate industrially-produced trans-fatty acids (IP-TFAs) from the global food supply by 2023.

13. As for the proposal of requiring prepackaged foods containing hydrogenated oils be indicated accordingly in the ingredient list, a respondent from the trade considered the labelling requirement unnecessary since the fats and oils in prepackaged foods should either be fully hydrogenated or non-hydrogenated, both of which would be permitted for use, after the listing of PHOs as a prohibited substance. Nonetheless, it must be pointed out that the proposed labelling requirement for prepacked foods containing “hydrogenated oils” is intended to provide more precise information on edible oils used in these food products. This is in line with the Codex standards and the prevailing practice of many other places.

Other Comments

14. Other comments from the respondents mainly concerned with testing matters, such as whether the MLs of specific harmful substances should be applied to food as sold or as consumed, the importance for private laboratories to be capable of conducting tests on the relevant substances and to provide accurate testing results within a reasonable timeframe and price range, as well as the provision of information on qualified independent laboratories to the trade.

15. To ensure food safety, it is crucial for the trade to conduct sampling tests on food products that they supply to the market to ensure compliance with the local regulation. Since January 2021, the CFS has conducted two technical meetings with private laboratories and the related sectors of the trade to introduce the testing methods for the relevant substances and address enquiries from the trade directly. The CFS will continue to organise a series of technical meetings and issue technical guidelines on the proposed amendments by the end of this year to assist the trade in understanding and adapting to the updated food safety standards. Meanwhile, the Hong Kong Accreditation Service of the Innovation and Technology Commission (ITC) will continue to provide accreditation services for local private laboratories through the Hong Kong Laboratory

Accreditation Scheme. Traders may refer to the ITC's website¹ for the list of laboratories accredited for performing different food tests.

Grace Period

16. Diverse views were received on the proposal for the Amendment Regulations to come into force 18 months after their publication in the Gazette as put forward in the consultation document. Some respondents suggested that the Amendment Regulations should be implemented as soon as possible to better protect public health. On the other hand, a number of respondents (including trade organisations) considered that the proposed grace period could not provide sufficient time for the trade to make necessary preparation, especially with respect to the **labelling requirement for prepackaged foods containing hydrogenated oils**. They requested that the grace period be extended to a duration ranging from 24 to 36 months. The relevant views are extracted in **Annex 2**.

17. We agree that the Amendment Regulations should be implemented as soon as practicable. Meanwhile, in view of the business environment of the trade under the COVID-19 pandemic, we should duly consider the need of allowing a more ample grace period for the trade to get prepared for the updated food safety standards and for the local testing and laboratory sector to establish the relevant testing capability. Members of the ACFEH also concurred that consideration could be given to extending the grace period suitably. Having regard to the arrangement of relevant legislative amendments in the past and the WHO's goal (i.e. eliminating IP-TFAs from the global food supply by 2023), we propose to **extend the grace period** and implement the proposed amendments **in two phases** –

1 June 2023	Commencement of all proposed amendments except the prohibition of PHOs in food and the labelling requirement for hydrogenated oils
1 December 2023	Commencement of the proposed amendments concerning the prohibition of PHOs in food and the labelling requirement for hydrogenated oils

¹ Website: www.itc.gov.hk/en/quality/hkas/conformity_assessment_bodies/hoklas.html#t_services

Way Forward

18. We plan to update the proposed amendments to the Regulations (see **Annex 3** for an overview) and commencement dates along the aforementioned direction. We will formulate the relevant Amendment Regulations for gazettal and tabling at the Legislative Council in mid-2021 for negative vetting, with a view to enabling the Amendment Regulations to take effect by phases by the end of 2023.

Views Sought

19. Members are invited to note the outcome of public consultation and offer views on the updated amendments and the proposed way forward.

Food and Health Bureau

Food and Environmental Hygiene Department

April 2021

**List of Respondents to the Public Consultation
(in order of date of receipt)**

1	SGS Hong Kong Limited
2	Mr Chan
3	Orient Resources Company (o/b China Business Ltd.)
4	The Association for Hong Kong Catering Services Management Ltd.
5	Hong Kong College of Community Medicine
6	Hong Kong Dried Seafood & Grocery Merchants Association Ltd.
7	Mr John Chong
8	Hong Kong Retail Management Association
9	Taikoo Sugar Limited
10	Hong Kong Federation of Restaurants & Related Trades
11	The Garden Company Limited
12	Ming Dou Bakery Catering Co., Ltd
13	Consumer Council
14	Hong Kong Dietitians Association
15	Ms Yeung
16	Hong Kong Nutrition Association Ltd.
17	Kellogg Company
18	Anonymous
19	Dr CHIA Chi Fung
20	Respondent requested keeping name confidential
21	HiPP
22	Unilever Hong Kong Limited
23	Hong Kong Infant and Young Child Nutrition Association
24	Wyeth (Hong Kong) Holding Company Limited
25	Nestlé Hong Kong Limited
26	Hong Kong Suppliers Association Ltd.
27	Hong Kong College of Cardiology
28	Respondent requested keeping name confidential
29	Respondent requested keeping name confidential
30	New People's Party
31	PepsiCo Beverages HK Limited
32	Ms Irene LW Lam
33	Respondent requested keeping name confidential
34	Mondelēz Hong Kong Limited
35	Liberal Party
36	F&N Global Marketing Pte. Ltd.

Extract of Views received on Grace Period

(1) Hong Kong Retail Management Association (Serial No. 8)

“The grace period is an important time that allows the trade to implement the proposed regulatory amendment before enforcement action and we propose this can be considered in two parts:

	Proposed Grace Period
Non- Labelling: Mycotoxins & PHOs	24 months
Labelling: Fully Hydrogenated Vegetable Oils	36 months

For mycotoxins & PHOs, this will require members to contact all of their suppliers around the world and give them time to make any formulation adjustments or the selection of alternative products. Organoleptic testing, nutrition content and shelf life will have to reassess and validate. Products already produced may have a long shelf life and may take some considerable time to clear given some products may have a shelf life of 18 months (most frozen foods) or two to three years (canned foods). We need to avoid producing food waste and the environmental and cost consequences.

For any changes to foods labelling, the information must first be obtained from all suppliers around the world and for those products produced in packaging specifically for the Hong Kong market, the packaging needs to be changed if the product contains fully hydrogenated oils and this is a very time consuming process which involves.....to avoid food and food packaging waste, we request a 36 months grace period for the labelling of ‘fully hydrogenated oils’ on each pack.”

(2) Consumer Council (Serial No. 13) [English translation]

“Understand that it is necessary to allow reasonable time for the trade to improve their products as needed to comply with the new statutory requirements. However, relevant regulatory controls are already in place in many food exporting countries or regions. Besides, the testing items related to the proposals do not involve the use of instruments with a high

level of precision, and are able to be dealt with by most private laboratories with their existing equipment. Therefore, the proposals should be implemented as soon as possible to better safeguard the health of consumers.”

(3) New People’s Party (Serial No. 30) [English translation]

“The proposed amendments may affect the supply of products that are subject to regulation. In order to maintain steady market supply for avoiding an upsurge in prices of daily necessities, facilitate the trade in adapting to the new legislation and identifying other sources of products as needed, as well as enable local laboratories to establish the capability of providing testing services having regard to the new maximum levels, we agree with the importance of providing a reasonable grace period. However, considering the fact that infant formula (either powdered or liquid) is the main source of food for infants under the age of 12 months, and the experience of other places, we opine that the Government should adopt a more stringent approach to ensure the safety of these products. As such, the Government may consider a shorter grace period for infant formula products while keeping the grace period for other products unchanged.”

(4) Liberal Party (Serial No. 35) [English translation]

“On grace period, notwithstanding the Government’s claims that more than 95% of samples could meet the proposed maximum levels for the relevant harmful substances and foods according to the results of food surveillance and relevant risk assessments in recent years, and that substitutes for some affected food ingredients are available in the market, we consider the grace period of 18 months proposed in the consultation document still insufficient.

To comply with the latest food safety standards, traders often have to make a lot of preparation. For example, they need to contact suppliers from all over the world, select substitutes, modify recipes and conduct tests on quality and taste. It is also necessary to reexamine and reassess the nutritional content and shelf life of the products. For food products that require labelling, importers have to obtain necessary information from relevant suppliers around the world and make changes to the labels as required under Hong Kong’s legislation. It involves multiple procedures such as redesign, manufacture and packaging.

In addition, the shelf life of different food products may vary from 18 months (such as some frozen foods) to two or three years (such as canned foods). The proposed 18-month grace period may not be sufficient for traders to clear their stock, resulting in financial loss and food wastage. Therefore, we suggest that the Government consider extending the grace period, such as setting a grace period of 24 months and 36 months for non-labelled food and labelled food respectively as proposed by some traders.”

- Ends -

Overview of the Updated Proposed Amendments**I. Maximum levels (MLs) of mycotoxins and other harmful substances in food**

	Substance	Food / Food group	Proposed ML
1.	Aflatoxins, total	Non-ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios	15 µg/kg
		Non-ready-to-eat peanut products and products of almonds, Brazil nuts, hazelnuts and pistachios	
		Spices	
		Any other food	10 µg/kg
	Aflatoxin B ₁	Infant formula and follow-up formula other than formula products manufactured from milk proteins (Note 1)	0.1 µg/kg
		Any other food intended to be consumed principally by persons under the age of 36 months (Note 2)	
Aflatoxin M ₁	Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months (Note 1)	0.025 µg/kg	
	Any other milk and dried milk (Note 1)	0.5 µg/kg	
2.	Deoxynivalenol	Cereal-based foods intended to be consumed principally by persons under the age of 36 months (Note 2)	200 µg/kg
3.	Patulin	Apple juice and other beverages to which apple juice has been added (Note 1)	50 µg/kg
4.	Benzo[a]pyrene	Any oil or fat or any mixture of oil and fat	5 µg/kg
		Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1 µg/kg

	Substance	Food / Food group	Proposed ML
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
		Liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	6 µg/kg
6.	Melamine	Liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.15 mg/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
		Any other food intended to be consumed principally by persons under the age of 36 months	
7.	3-monochloropropane-1,2-diol	Solid condiments containing acid hydrolysed vegetable proteins	1 mg/kg
		Any other condiments containing acid hydrolysed vegetable proteins	0.4 mg/kg
8.	Erucic acid	Low erucic acid rapeseed oil	2 per centum by weight of their fatty acid content
		Any other oil or fat or any mixture of oil and fat	5 per centum by weight of their fatty acid content

Note 1: The proposed ML applies to products that are, or are reconstituted to be, ready-to-drink.

Note 2: The proposed ML applies to the dry matter.

II. Ban on partially hydrogenated oils (PHOs) and labelling requirements for hydrogenated oils

- To regard “PHOs” as a prohibited substance in food by prohibiting under the Regulations the import of any edible fats and oils containing “PHOs” and the sale of any food (including edible fats and oils) containing “PHOs”; and
- To require that prepackaged foods (including edible fats and oils), if containing hydrogenated oils, be indicated accordingly (e.g. “hydrogenated oils” or the name of the oil qualified by the word “hydrogenated”) in the list of ingredients. Prepackaged foods containing hydrogenated oils as the only single ingredient are also required to provide an ingredient list and comply with the labelling requirement for hydrogenated oils.

- Ends -