

LEGISLATIVE COUNCIL BRIEF

Public Health and Municipal Services Ordinance
(Chapter 132)

HARMFUL SUBSTANCES IN FOOD (AMENDMENT) REGULATION 2021

FOOD AND DRUGS (COMPOSITION AND LABELLING) (AMENDMENT) REGULATION 2021

INTRODUCTION

The Secretary for Food and Health, in exercise of the power under section 55 of the Public Health and Municipal Services Ordinance (Cap. 132) (“the Ordinance”), made the Harmful Substances in Food (Amendment) Regulation 2021 at **Annex A**.

JUSTIFICATIONS

2. The Harmful Substances in Food Regulations (Cap. 132AF) govern, among other things, the presence of harmful substances in food imported to and sold in Hong Kong. The First Schedule to Cap. 132AF stipulates the maximum amount of harmful substances which may be present in specified foods. Any person who imports, consigns, delivers, manufactures or sells for human consumption any food containing substances in greater concentration than that stipulated in the First Schedule to Cap. 132AF commits an offence.

3. The Food and Health Bureau and the Centre for Food Safety 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”)¹ and other places, with a view to reviewing local

¹ Established by the Food and Agriculture Organization of the United Nations and the World Health Organization in 1960s, Codex is the most important international source of reference in developing food associated standards.

standards and regulatory arrangements from time to time. The Centre for Food Safety has conducted risk assessments having regard to the dietary practices of the local population and the risks to public health posed by the respective harmful substances, and formulated proposals to update the current legislation based on scientific evidence.

Strengthening regulation of three mycotoxins

4. The regulatory control of three types of mycotoxins in food, namely aflatoxin, deoxynivalenol and patulin, is proposed to be strengthened. For aflatoxins, the most toxic kind of mycotoxins, maximum levels (“MLs”) in different foods have been stipulated under Cap. 132AF since the 1980s and are generally less stringent than the prevailing international standards. We therefore propose to update the relevant MLs by amending Cap. 132AF. Taking into account data including the dietary practices of the local population, we also propose to incorporate MLs of two other types of mycotoxins in specified foods, i.e. deoxynivalenol in cereal-based foods for infants and young children and patulin in apple juice, into the regulatory framework of Cap. 132AF by making reference to the relevant standards covered by the Codex General Standard for Contaminants and Toxins in Food and Feed.

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

5. Edible fats and oils, condiments and formula products intended for infants are closely related to the dietary practices of the local population. Codex or other places have also set standards in relation to these food groups for five harmful substances concerned. Two of these harmful substances, namely erucic acid and melamine, have been regulated under Cap.132AF since the 1980s and 2008 respectively; whilst the other three, namely benzo[a]pyrene, glycidol (a substance released from hydrolysis of glycidyl fatty acid esters in the gastrointestinal tract) and 3-monochloropropane-1,2-diol, have been classified by the International Agency for Research on Cancer of the World Health Organization (“WHO”) as “carcinogenic to humans”, “probably carcinogenic to humans” and “possibly carcinogenic to humans” respectively. To better protect the health of the local population, we propose to update or set the MLs for the five harmful substances in the relevant food groups.

Regarding “partially hydrogenated oil” as a prohibited substance in food

6. The WHO put forward an action package called “REPLACE” in 2018, with a goal of eliminating industrially-produced trans-fatty acids (“IP-TFAs”) from the global food supply by 2023. Banning partially hydrogenated oil (“PHO”), the main source of IP-TFAs in food, is one of the policies recommended by the WHO and provided under the “Towards 2025: Strategy and Action Plan to Prevent and Control Non-Communicable Disease in Hong Kong” announced by the Government in 2018. To eliminate the food safety risks associated with the consumption of IP-TFAs and protect public health at source, we propose to make reference to the WHO’s recommendation and the relevant measures adopted in other places to prohibit under Cap. 132AF the import of any edible oil or fat containing PHO and the sale of any food (including edible oil or fat) containing PHO.

7. Pursuant to the Air Cargo Transshipment (Facilitation) Ordinance, an import prohibition provision of Cap. 132AF was, among other relevant ordinances and regulations, amended in 2000 to facilitate air transit cargo and air transshipment cargo to the effect that such prohibition with regard to food containing certain harmful substances in excessive concentrations would not apply if the food is air transit cargo or air transshipment cargo as referred to in the Import and Export Ordinance (Cap. 60). By the same token, similar facilitation for air transit cargo and air transshipment cargo is proposed in respect of import prohibition of edible oil or fat containing PHO, and any other food containing prohibited substances specified in the existing Cap. 132AF for the sake of consistency.

8. To align with the Codex standards and the prevailing practice of many other places, we also propose that any prepackaged food containing hydrogenated oils, e.g. fully hydrogenated oil, must be indicated accordingly in the list of ingredients to provide more precise information on edible oils used in these food products. Accordingly, the Director of Food and Environmental Hygiene exercised the power under section 55(1) of the Ordinance to make separate amendments to two relevant schedules to the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) through the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 at **Annex B** to provide for the marking and labelling requirement for prepackaged foods containing hydrogenated oil.

Grace Period

9. We put forward in the public consultation document (paragraph 17 below refers) a proposal for the Amendment Regulations to come into force

18 months after their publication in the Gazette. While some respondents suggested that the Amendment Regulations should be implemented as soon as possible, particularly regarding the MLs applicable to infant formula for better protection of infants' health, most traders requested that the grace period be extended to a duration ranging from 24 to 36 months to allow sufficient time for the trade to make necessary preparation, especially with respect to the labelling requirement for prepackaged foods containing hydrogenated oil. The trade considered a longer grace period necessary on the following grounds:-

- (a) the trade needs to perform calibration of the composition of their products with the new requirements to ensure compliance with the Amendment Regulations;
- (b) calibration results may require their products to be reformulated. Product reformulation involves product development, trial production and stability tests, as well as re-labelling of the products;
- (c) the trade needs sufficient time to phase out old products following the existing requirements before introducing new ones into the market; and
- (d) many products, including formula products for infants and young children, are not manufactured in Hong Kong and need to be transported to Hong Kong upon production.

10. We agree that the Amendment Regulations, including the enhanced food safety standards for infant formula, should be implemented as soon as practicable. Meanwhile, in view of the business environment under the COVID-19 pandemic, we also have to duly consider the need of allowing sufficient time for the trade to get prepared for the updated food safety standards, as well as for the local testing and laboratory sector to establish the capability for performing the related food tests. On balance, and having regard to the arrangement of relevant legislative amendments in the past and the aforementioned 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 Amendment Regulations in **two phases** for the provisions relating to hydrogenated oil and the related marking and labelling requirement (paragraphs 6 and 8 above refer) to come into operation on **1 December 2023**, and the rest to come into operation on **1 June 2023**.

THE AMENDMENT REGULATIONS

11. The principal sections of the Harmful Substances in Food (Amendment) Regulation 2021 are as follows –

- (a) **Section 1** provides for the commencement of the Amendment Regulation (paragraph 10 above refers).
- (b) **Section 3** defines certain terms used in the Amendment Regulation, including PHO.
- (c) **Section 4** amends Regulation 3A of Cap.132AF by adding the prohibition on the import for human consumption of oil or fat, or a mixture of both, that contains PHO; and the sale or consignment or delivery for sale for human consumption of any food containing PHO (paragraph 6 above refers).
- (d) **Section 5** amends Regulation 3B of Cap.132AF to extend the application of facilitation to air transit or air transshipment cargo to cover Regulation 3A in addition to the existing Regulation 3 (paragraph 7 above refers).
- (e) **Section 6** amends the First Schedule to Cap. 132AF to update the MLs of three substances (i.e. aflatoxins, erucic acid and melamine) and introduce the MLs of five substances (i.e. deoxynivalenol, patulin, benzo[a]pyrene, glycidyl fatty acid esters and 3-monochloropropane-1,2-diol) in food (paragraphs 4-5 above refer).

12. The principal sections of the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 are as follows –

- (a) **Section 1** provides for the commencement of the Amendment Regulation (paragraph 10 above refers).
- (b) **Sections 3 and 4** amend the Third and Fourth Schedules to Cap. 132W to provide for a marking and labelling requirement for prepackaged foods containing hydrogenated oil (paragraph 8 above refers).

LEGISLATIVE TIMETABLE

13. The legislative timetable is as follows –

Publication in the Gazette	11 June 2021
Tabling at the Legislative Council for negative vetting	16 June 2021

IMPLICATIONS OF THE PROPOSALS

14. The Amendment Regulations are in conformity with the Basic Law, including the provisions concerning human rights. They will not affect the binding effect of the Ordinance.

15. The proposals would enhance food safety and is in line with the sustainability principle of pursuing policies which promote and protect the health and safety of the people of Hong Kong. They would at the same time increase the transparency in respect of the prohibition or legally permitted MLs of harmful substances in food, and in consequence facilitate trade of food products. On economic implications, the proposed labelling requirement for prepackaged foods containing hydrogenated oils would entail some compliance costs for the trade as they would need to undertake preparatory work, including laboratory testing, product reformulation and re-labelling. The increase in costs should not be significant as the proposed requirement is devised with reference to Codex standard and prevailing international practice.

16. Additional staffing and financial implications arising from the implementation of the Amendment Regulations, if any, will be absorbed from within the existing resources of the departments concerned or, where necessary, sought in accordance with the established mechanism. The proposals have no productivity, environmental, family or gender implications.

PUBLIC CONSULTATION

17. We conducted a three-month public consultation from 11 December 2020 to 15 March 2021 to collect public views on the legislative amendment proposals, including organising two consultation forums and some other meetings with stakeholders of the trade. We also

consulted the Advisory Council on Food and Environmental Hygiene, as well as the Wholesale and Retail Task Force and the Food Business and Related Services Task Force under the Business Facilitation Advisory Committee. The respondents generally welcomed and supported the proposed amendments and considered that the proposals could better protect public health.

18. The legislative amendment proposals were discussed at the meeting of the Legislative Council Panel on Food Safety and Environmental Hygiene (“the Panel”) on 25 January 2021. We briefed the Panel on the results of public consultation and the updated proposals on 20 April 2021. Members supported the updated proposals, which have addressed several technical comments raised by some respondents, and the same has been reflected in the Amendment Regulations.

PUBLICITY

19. A press release will be issued. A spokesperson will be available to answer press enquiries.

ENQUIRY

20. Any enquiry on this brief can be addressed to Ms Chelsea Wong, Principal Assistant Secretary for Food and Health (Food)1, at 3509 8925.

Food and Health Bureau
Food and Environmental Hygiene Department
June 2021

Harmful Substances in Food (Amendment) Regulation 2021

(Made by the Secretary for Food and Health under section 55 of the Public Health and Municipal Services Ordinance (Cap. 132))

1. Commencement

- (1) Subject to subsection (2), this Regulation comes into operation on 1 June 2023.
- (2) Sections 3(3), 4 and 5 come into operation on 1 December 2023.

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 6.

3. Regulation 2 amended (interpretation)

- (1) Regulation 2, Chinese text, definition of ~~機場貨物轉運區~~

Repeal

“涵義。”

Substitute

“涵義；”

- (2) Regulation 2—

Add in alphabetical order

“*follow-up formula* (較大嬰兒及幼兒配方產品) has the meaning given by regulation 2(1) of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W);

infant formula (嬰兒配方產品) has the meaning given by regulation 2(1) of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W);

low erucic acid rapeseed oil (低芥酸菜籽油) means any vegetable oil produced from low erucic acid oil-bearing seeds of varieties derived from the *Brassica napus* L., *Brassica rapa* L. and *Brassica juncea* L., species;”.

- (3) Regulation 2—

Add in alphabetical order

“*partially hydrogenated oil* (部分氫化油) means any oil or fat that has undergone the process of hydrogenation but is not fully saturated as a result of that process;”.

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

- (1) Regulation 3A, heading—

Repeal

“fish, meat or milk”

Substitute

“certain food or oil”.

- (2) Regulation 3A—

Renumber the regulation as regulation 3A(1).

- (3) After regulation 3A(1)—

Add

“(2) A person must not import for human consumption any oil or fat or a mixture of oil and fat containing partially hydrogenated oil.

(3) A person must not sell, or consign or deliver for sale, for human consumption any food (including any oil or fat or

a mixture of oil and fat) containing partially hydrogenated oil.”.

5. Regulation 3B amended (application to air transit or air transshipment cargo)

- (1) Regulation 3B(1)—
Repeal
 “Regulation 3 does”
Substitute
 “Regulations 3 and 3A do”.
- (2) Regulation 3B(1)—
Repeal
 “in that regulation”
Substitute
 “in those regulations”.
- (3) Regulation 3B(1)—
Repeal
 “of regulation 3”
Substitute
 “of regulations 3 and 3A”.
- (4) Regulation 3B(1)—
Repeal
 “that regulation has”
Substitute
 “those regulations have”.
- (5) Regulation 3B(2)(a)—
Repeal

“regulation 3”
Substitute
 “regulation 3 or 3A”.

6. Schedule 1 amended (maximum concentration of certain substances present in specified foods)

- (1) Schedule 1—
Repeal item 1
Substitute
- | | | |
|------------------------------|---|--|
| “1. Aflatoxin B ₁ | Infant formula and follow-up formula other than formula manufactured from milk proteins

Any other food intended to be consumed principally by persons under the age of 36 months other than infant formula and follow-up formula manufactured from milk proteins | 0.1 microgram per kilogram of the food.
(Note 1)

0.1 microgram per kilogram of the food.
(Note 2) |
|------------------------------|---|--|

1A.	Aflatoxin M ₁	Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.025 microgram per kilogram of the food. (Note 1)
		Any other milk or dried milk	0.5 microgram per kilogram of the food. (Note 1)
1B.	Aflatoxins, total	Sum of aflatoxins B ₁ , B ₂ , G ₁ and G ₂	Non-ready-to-eat almonds, Brazil nuts, hazelnuts, peanuts and pistachios Non-ready-to-eat peanut products and products of almonds, Brazil nuts, hazelnuts and pistachios
			15 micrograms per kilogram of the food. 15 micrograms per kilogram of the food.

Spices	15 micrograms per kilogram of the food.
Any other food	10 micrograms per kilogram of the food.”.
(2) Schedule 1, after item 4— Add	
“4A. Benzo[a]pyrene	Oil or fat or any mixture of oil and fat
	5 micrograms per kilogram of the food.
	Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months
	1 microgram per kilogram of the food.”.
(3) Schedule 1, after item 11— Add	

“11A. Deoxynivalenol Cereal-based foods intended to be consumed principally by persons under the age of 36 months 200 micrograms per kilogram of the food. (Note 2)”.

(4) Schedule 1—
Repeal item 17
Substitute

“17. Erucic acid The fatty acid cis-docos-13-enoic acid Low erucic acid rapeseed oil 2 per centum by weight of its fatty acid content.

Any other oil or fat or any mixture of oil and fat 5 per centum by weight of its fatty acid content.

Any food to which oil or fat or a mixture of oil and fat has been added 5 per centum by weight of its fatty acid content of all the oils and fats in the food.”.

(5) Schedule 1, after item 22—

Add

“22A. Glycidyl fatty acid esters Glycidyl fatty acid esters expressed as glycidol Powdered infant formula and powdered follow-up formula intended to be consumed principally by persons under the age of 12 months 50 micrograms per kilogram of the food.

Liquid infant formula and liquid follow-up formula intended to be consumed principally by persons under the age of 12 months 6 micrograms per kilogram of the food.”.

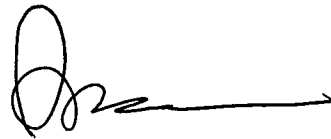
(6) Schedule 1—
Repeal item 26B
Substitute

“26B. Melamine Liquid infant formula and liquid follow-up formula intended to be consumed principally by 0.15 milligram per kilogram of the food.

persons under the age of 12 months	
Milk other than liquid infant formula and liquid follow-up formula intended to be consumed principally by persons under the age of 12 months	1 milligram per kilogram of the food.
Any other food intended to be consumed principally by persons under the age of 36 months	1 milligram per kilogram of the food.
Any food intended to be consumed principally by pregnant or lactating women	1 milligram per kilogram of the food.

	Any other food	2.5 milligrams per kilogram of the food.”.
(7) Schedule 1, after item 30—		
Add		
“30A. Patulin	Apple juice and other beverages to which apple juice has been added	50 micrograms per kilogram of the food. (Note 1)”.
(8) Schedule 1, after item 39—		
Add		
“40. 3-monochloropropane-1,2-diol	Solid condiments containing acid hydrolysed vegetable proteins	1 milligram per kilogram of the food.
	Any other condiments containing acid hydrolysed vegetable proteins	0.4 milligram per kilogram of the food.”.
(9) At the end of Schedule 1—		
Add		

- “Note 1: The maximum concentration applies to the food that is, or is reconstituted to be, ready for consumption.
- Note 2: The maximum concentration applies to the dry matter of the food.”



Secretary for Food and Health

7 June 2021

Explanatory Note

This Regulation is made under section 55 of the Public Health and Municipal Services Ordinance (Cap. 132) to amend the Harmful Substances in Food Regulations (Cap. 132 sub. leg. AF) (*principal Regulations*). The purposes of the Regulation are to—

- (a) amend Schedule 1 to the principal Regulations to—
 - (i) update the maximum permitted concentration of 3 harmful substances, namely, aflatoxins, erucic acid and melamine, in food; and
 - (ii) introduce the maximum permitted concentration of 5 harmful substances, namely, benzo[a]pyrene, deoxynivalenol, glycidyl fatty acid esters, patulin and 3-monochloropropane-1,2-diol, in food; and
 - (b) amend regulation 3A of the principal Regulations to prohibit—
 - (i) the import for human consumption of oil or fat, or a mixture of both, that contains partially hydrogenated oil; and
 - (ii) the sale or consignment or delivery for sale for human consumption of any food containing partially hydrogenated oil,and consequentially amend regulation 3B of the principal Regulations.
2. The provisions of the Regulation relating to partially hydrogenated oil will come into operation on 1 December 2023. The other provisions of the Regulation will come into operation on 1 June 2023.

**Food and Drugs (Composition and Labelling)
(Amendment) Regulation 2021**

(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 December 2023.

2. Food and Drugs (Composition and Labelling) Regulations amended

The Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W) are amended as set out in sections 3 and 4.

3. Schedule 3 amended (marking and labelling of prepackaged foods)

Schedule 3, after section 2(4E)—

Add

“(4F) If a food consists of or contains hydrogenated oil—

- (a) the list of ingredients must contain a reference to “hydrogenated oil”; or
- (b) the name of the oil, as appearing in the list of ingredients, must be qualified by the word “hydrogenated”.”.

4. Schedule 4 amended (items exempt from Schedule 3)

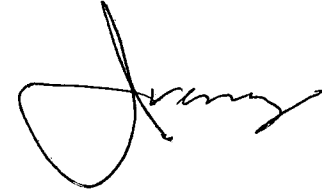
Schedule 4—

Repeal

“Any food consisting of a single ingredient”

Substitute

“Any food consisting of a single ingredient other than hydrogenated oil”.



Director of Food and Environmental
Hygiene

7 June 2021

Explanatory Note

This Regulation amends the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W) to provide for a marking and labelling requirement for prepackaged foods containing hydrogenated oil.