

Guidelines

The Harmful Substances in Food (Amendment) Regulation 2021

January 2022 (Revised)

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Chapter 1 Introduction

Purpose

1.1 The Harmful Substances in Food (Amendment) Regulation 2021 (“the Amendment Regulation”) and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 were published in the Gazette on 11 June 2021 and the Legislative Council completed its scrutiny work in July 2021. This set of Guidelines on the Harmful Substances in Food (Amendment) Regulation 2021 (the Guidelines) aims to assist the trade in having a better understanding of and complying with the relevant requirements under the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021, and to answer some frequently asked questions.

Disclaimer

1.2 The Guidelines, which should be read in conjunction with the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021, is intended for use as a general reference only. Information contained in the Guidelines may not be exhaustive or complete. Specific issues should be considered on a case-by-case basis. The Guidelines does not have the force of the law and should not be interpreted in any manner which would override the provision of the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021. In case of any inconsistency, the statutory provision will prevail. The Guidelines should not be regarded as legal advice. If you need legal advice, you must contact your own lawyer.

1.3 The Guidelines may be amended or supplemented by the Director of Food and Environmental Hygiene as necessary from time to time.

Key features of the Amendment Regulation

1.4 The Amendment Regulation updates the maximum permitted concentration of 3 harmful substances, namely, aflatoxins, erucic acid and melamine, in food and introduces the maximum permitted concentration of 5 harmful substances, namely, benzo[a]pyrene (B[a]P), deoxynivalenol, glycidyl fatty acid esters, patulin and 3-monochloropropane-1,2-diol (3-MCPD), in food.

1.5 The Amendment Regulation also prohibits the import of any edible oil or fat containing partially hydrogenated oil (PHO) and the sale of any food (including edible oil or fat) containing PHO. Correspondingly, an amendment to Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) is also

made through the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 to stipulate the labelling requirements of hydrogenated oils in prepackaged foods.

1.6 The provisions of the Amendment Regulation relating to PHO and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 will come into operation on 1 December 2023. The other provisions of the Amendment Regulation will come into operation on 1 June 2023.

Interpretation

1.7 The followings are some terms as defined in the Amendment Regulation, the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021, the relevant existing Regulations (i.e. the Harmful Substances in Food Regulations and the Food and Drugs (Composition and Labelling) Regulations) as well as the Public Health and Municipal Services Ordinance (Cap. 132) (the Ordinance) —

Catering establishment means a restaurant, canteen, club, public house, school, hospital or other establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer for immediate consumption.

Dried milk 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.

Follow-up formula has the meaning given by regulation 2(1) of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W), i.e. it means—

- (a) a product that, according to its descriptions or instructions for use, is—
 - (i) represented as a replacement for human breast milk or infant formula; and
 - (ii) intended for consumption as a liquid element in a progressively diversified diet by persons of any age from 6 months to under 36 months (even if it is also claimed in the descriptions or instructions, if applicable, to be suitable for consumption by persons of any other age); or
- (b) a product marked or labelled as “follow-up formula” or “較大嬰兒及幼兒配方產品”, or with any other words of similar meaning.

Food includes—

- (a) drink;
- (b) ice;
- (c) chewing gum and other products of a similar nature and use;
- (d) smokeless tobacco products; and
- (e) articles and substances used as ingredients in the preparation of food, but does not include—
 - (f) live animals or live birds, other than live aquatic products;
 - (g) fodder or feeding stuffs for animals, birds or aquatic products; or
 - (h) medicine as defined by section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138) or Chinese herbal medicine or proprietary Chinese medicine as defined by section 2(1) of the Chinese Medicine Ordinance (Cap. 549).

Infant formula has the meaning given by regulation 2(1) of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W), i.e. it means—

- (a) a product that, according to its descriptions or instructions for use, is intended for consumption as a substitute for human breast milk that is specially manufactured to satisfy, by itself, the nutritional requirements of persons of any age up to and including 12 months until the introduction of appropriate complementary feeding (even if it is also claimed in the descriptions or instructions, if applicable, to be suitable for consumption by persons of any age over 12 months); or
- (b) a product marked or labelled as “infant formula” or “嬰兒配方產品”, or with any other words of similar meaning.

Ingredient means any substance, including any additive and any constituent of a compound ingredient, which is used in the manufacture or preparation of a food and which is still present in the finished product, even if in altered form.

Low erucic acid rapeseed oil 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.

Milk, for the purpose of the Harmful Substances in Food Regulations, means cows milk, buffaloes milk and goats milk, and includes cream, separated milk and milk beverage, but does not include dried milk, condensed milk or reconstituted milk.

Oil or fat means oil or fat derived from any animal, bird, fish or plant but does not include any essential oil.

Partially hydrogenated oil means any oil or fat that has undergone the process of hydrogenation but is not fully saturated as a result of that process.

Peanut means groundnut or the seed of *Arachis hypogaea* L.

Peanut products includes oil of peanut or any product containing peanut as its ingredient.

Prepackaged food means any food packaged, whether completely or partially, in such a way that—

- (a) the contents cannot be altered without opening or changing the packaging; and
- (b) the food is ready for presentation to the ultimate consumer or a catering establishment as a single food item.

Sell includes offer or expose for sale or have in possession for sale.

Trans fatty acids means the sum of all unsaturated fatty acids which contains at least one nonconjugated and trans double bond.

Ultimate consumer means any person in Hong Kong who buys otherwise than—

- (a) for the purpose of resale;
- (b) for the purposes of a catering establishment; or
- (c) for the purposes of a manufacturing business

Chapter 2 Interpretation of Maximum Concentration of Harmful Substance in Food under Schedule 1 to the Amendment Regulation

2.1 As stipulated in regulation 3 of the Harmful Substances in Food Regulations, a person must not import, consign, deliver, manufacture or sell, for human consumption, any food of a description specified in Column D of Schedule 1 which contains any substance specified opposite thereto in Column B, or the description of such substance in Column C, in greater concentration than is specified opposite thereto in Column E (see Figure 1).

Figure 1. Extract of Schedule 1 to the Amendment Regulation

Schedule 1

[regs. 3 & 4]

Maximum Concentration of Certain Substances Present in Specified Foods

A	B	C	D	E
Item	Substance	Description of substance	Description of food	Maximum concentration
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	15 micrograms per kilogram of the food.
			Non-ready-to-eat peanut products and products of almonds, Brazil nuts, hazelnuts and pistachios	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.

How to read Schedule 1 to the Amendment Regulation

2.2 Column B, “Substance”, lists out certain harmful substances governed under Schedule 1 to the Amendment Regulation, including “Item 1. Aflatoxin B₁”, “Item 1A. Aflatoxin M₁”, “Item 1B. Aflatoxins, total”, “Item 4A.

Benzo[a]pyrene”, “Item 11A. Deoxynivalenol”, “Item 17. Erucic acid”, “Item 22A. Glycidyl fatty acid esters”, “Item 26B. Melamine”, “Item 30A. Patulin” and “Item 40. 3-monochloropropane-1,2-diol”.

2.3 Column C, “Description of substance”, lists out the description of such substance as stated in Column B e.g., “Aflatoxins, total” refers to “Sum of aflatoxins B₁, B₂, G₁ and G₂” while “Glycidyl fatty acid esters” refers to “Glycidyl fatty acid esters expressed as glycidol”.

2.4 Column D, “Description of food” and Column E, “Maximum concentration” list out the specified food / food products to which the maximum concentration applies. Column E also provides forms of the food which the maximum concentration applies as “Note” (see Figure 2).

Figure 2. Notes under Schedule 1 to the Amendment Regulation

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.

Testing and Analysis of Certain Harmful Substances in Food under Schedule 1 to the Amendment Regulation

2.5 The Government has conducted meetings with the testing laboratories and other stakeholders to discuss the determination of harmful substances in foods as specified in the Amendment Regulation. Information on determination of certain harmful substances in foods is available on the websites of the Centre for Food Safety (CFS)¹ and the Government Laboratory². Based on the actual requirements, equipment and available resources, laboratories may develop testing methods for harmful substances, making reference to international standards, such as AOAC or BS EN ISO or other national technical criteria and reference testing methods.

2.6 Laboratories are advised to note that in general the maximum concentration applies to the edible portion of the food and if applicable, the food

¹ CFS’ website on Harmful Substances in Food Regulations. Available from: URL: https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_Food_Regulations_Harmful_Substances.html

² Government Laboratory’s website on Training and Development Collaborations. Available from: URL: <https://www.govtlab.gov.hk/english/development.htm>

in the form specified in a note referred to in Column E of Schedule 1 in relation to the food.

2.7 For Note 1 “The maximum concentration applies to the food that is, or is reconstituted to be, ready for consumption”, the instructions for use (e.g. the amount of water to be used for reconstitution as recommended by the manufacturer) should be taken into account.

2.8 For Note 2 “The maximum concentration applies to the dry matter of the food”, the dry matter content of the product should be determined on a part of the homogenised sample, using a method that has been demonstrated to determine the dry matter content accurately. Methods on determination of dry matter or moisture content could be referenced to the Codex Recommended Methods of Analysis and Sampling (CXS 234-1999).

Chapter 3 Interpretation of Prohibition of the Import of Any Edible Oil or Fat Containing Partially Hydrogenated Oil (PHO) and the Sale of Any Food Containing PHO under the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021

Interpretation of Prohibition of the Import of Any Edible Oil or Fat Containing PHO and the Sale of Any Food Containing PHO under the Amendment Regulation

3.1 The Amendment Regulation specifies the interpretation of “partially hydrogenated oil”, and amends Regulation 3A as below:

Regulation 3A Prohibition of import and sale of certain food or oil etc. containing prohibited substances

(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.”

3.2 Under the Amendment Regulation, all foods available in Hong Kong, including prepackaged and non-prepackaged food, edible oils and fats such as margarines and shortenings, and ingredients for further food processing such as food additives, should not contain PHO. On the other hand, foods containing fully hydrogenated oil are not covered in this Amendment Regulation.

Interpretation of the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021

3.3 The amendments to Cap. 132W through the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 are as below:

Schedule 3 MARKING AND LABELLING OF PREPACKAGED FOODS

Section 2 List of ingredients

(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”.

Schedule 4 ITEMS EXEMPT FROM SCHEDULE 3

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

3.4 Food containing hydrogenated oil has been taken out from the exemption list in Schedule 4 and should be labelled on prepackaged food accordingly (examples include “hydrogenated”, “hydrogenated oil”, “hydrogenated fat”, “fully hydrogenated oil”, “fully hydrogenated fat”, etc.). As PHO is regarded as a prohibited substance in food, if the oil in a product is labelled “hydrogenated” in the ingredient list, then the product should only contain fully hydrogenated oil.

Identification of PHOs in Food

3.5 The trade are responsible for providing accurate information on food labels, such as information on the ingredient list and the trans fatty acid content on the nutrition label. They should check with suppliers for the details of ingredients.

3.6 For analysing the content of fatty acids in different food matrices, CFS makes reference to internationally accepted methods, such as AOAC 996.06 and AOAC 2012.13/BS EN ISO 16958:2020. Other suitable standardised methods with similar performance characteristics may also be used if they can be proven to deliver equivalent results.

3.7 CFS adopts the EU approach³ to identify the presence of PHO by estimation of industrially produced trans fatty acids (IP-TFAs) level in food. If the level of IP-TFAs exceeded 2% of total fat⁴, CFS may further investigate the source of trans fatty acids in the food on any hydrogenated oil ingredients. The trade (i.e. importers, manufacturers, distributors and retailers) are advised to keep proper documentary proofs (examples including confirmation letters from the suppliers and their exporting authorities, product specifications, business contracts, ingredient lists and reports from competent laboratories) of the ingredient details of the products, for at least 24 months after the food was acquired or supplied, and provide them for inspection if deemed necessary.

³ Analytical approach for checking the compliance of fats and oils against the regulated limit for industrial trans fatty acids (Commission Regulation (EU) 2019/649). Available from: URLs: <https://publications.jrc.ec.europa.eu/repository/handle/JRC125335> (link to pdf document: https://publications.jrc.ec.europa.eu/repository/bitstream/JRC125335/JRC125335_01.pdf)

⁴ The limit of 2% takes reference from: REPLACE trans fat: an action package to eliminate industrially produced trans-fatty acids. Module 3: Legislate or regulate. How-to guide for trans fat policy action. Geneva: World Health Organization; 2020. Available from: URL: <https://apps.who.int/iris/bitstream/handle/10665/324822/WHO-NMH-NHD-19.14-eng.pdf>

3.8 For single non-blended fats and oils, an additional means to identify PHO is by testing their iodine values which indicates their degree of saturation. A fully hydrogenated oil would have an iodine value of 4 or less, whereas PHO would have an iodine value of greater than 4. This means is not for use in mixed oils or food products.

Chapter 4 Frequently Asked Questions

Mycotoxins in Food

1. Will aflatoxins be found in all foods?

Aflatoxins are metabolites produced by certain moulds of the *Aspergillus* genus (including *Aspergillus flavus*, *Aspergillus parasiticus*, etc.). Various moulds of the *Aspergillus* genus are ubiquitous in nature, and the environment with high temperature and high humidity is favourable for their growth. Foods that are more susceptible to aflatoxin contamination include oilseeds (such as peanuts), tree nuts (such as pistachios and almonds) and spices, etc. On the contrary, some foods stored at low temperature (such as frozen food) and those with low water activity (such as sugar and salt) are not likely to be contaminated with aflatoxins.

2. What is “Cereal-based foods intended to be consumed principally by persons under the age of 36 months”?

“Cereal-based foods intended to be consumed principally by persons under the age of 36 months” refers to food intended to fulfil the particular requirements of infants in food health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food. They can be classified into 4 categories, namely, (i) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids, (ii) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, (iii) pastas which are to be used after cooking in boiling water or other appropriate liquids, and (iv) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.

3. Does the maximum concentration for patulin apply to food containing apples?

As stipulated in the Amendment Regulation, the maximum concentration for patulin at 50 µg/kg applies only to apple juice and other beverages to which apple juice has been added.

4. How to calculate the maximum concentration for patulin in concentrated apple juice?

According to Note 1 in column E of Schedule 1 to the Amendment Regulation, the maximum concentration for patulin in “apple juice and other beverages to which apple juice has been added” at 50 µg/kg applies to the food that is, or is reconstituted to be, ready for consumption.

To calculate the maximum concentration for patulin in concentrated apple juice:-

(1) Obtain the concentration factor from the food manufacturer / supplier:

⇒ 10× (for this example)

(2) Calculate the adjusted maximum concentration of patulin in concentrated (10×) apple juice:

⇒ 50 µg/kg × 10 = 500 µg/kg

In other words, the patulin content of concentrated (10×) apple juice shall not exceed 500 µg/kg.

Edible Fats and Oils, Condiments and Formula Products Intended for Infants

5. Does the maximum concentration for B[a]P apply to “cooking oil in use” and oils marketed as “health products”?

The maximum concentration for B[a]P applies to “fresh” or “unused” edible oil or fat, rather than reused oil or cooking oil in use.

There is no internationally accepted nomenclature and definition for so-called “health products”. Depending on the nature, composition and claims of individual products, they may be subject to specific regulatory control under different ordinances and different government departments. For instance, products falling under the definition of pharmaceutical product and medicine under the Pharmacy and Poisons Ordinance (Cap. 138) or the definitions of Chinese herbal medicine or proprietary Chinese medicine in the Chinese Medicine Ordinance (Cap. 549) are governed by the respective ordinances. Similarly, for products fulfilling the definition of “food” as stipulated in the Ordinance, they are governed by the Ordinance and its subsidiary legislation including the Harmful Substances in Food Regulations (Cap. 132AF). Whether an individual product would be considered as food and covered by the Amendment Regulation is required to be analysed and considered on a case-by-case basis having regard to the definitions.

- 6. The Amendment Regulation has stipulated maximum concentrations for various condiments. What are condiments? Why do relevant maximum concentrations only cover all condiments containing acid hydrolysed vegetable proteins (acid-HVPs)?**

Condiments generally refer to products that are added to enhance the taste and flavour of a food.

One of the ways to produce and process condiments is to add acid-HVPs to enhance flavours. However, the production process of acid-HVPs could produce 3-MCPD. Hence, condiments containing acid-HVPs, whether in liquid (such as soy sauce), semi-solid (such as oyster sauce), or solid (such as chicken powder) forms, may in turn be contaminated with 3-MCPD.

On the contrary, condiments like soy sauce made by natural fermentation, sugar and salt do not contain or only contain trace amount of 3-MCPD. Hence, relevant maximum concentrations under the Amendment Regulation only cover all condiments containing acid-HVPs.

- 7. How to classify solid and any other condiments containing acid-HVPs when applying the maximum concentrations for 3-MCPD?**

Under the Amendment Regulation, the maximum concentration for 3-MCPD of 1 mg/kg in solid condiments containing acid-HVPs only applies to condiments in a fully solid state. For any other condiments (including semi-liquid, semi-solid and condiments with both solid and liquid ingredients) containing acid-HVPs, the maximum concentration of 0.4 mg/kg will apply.

- 8. The Amendment Regulation has stipulated a specified maximum concentration for erucic acid in low erucic acid rapeseed oil. What is low erucic acid rapeseed oil?**

Low erucic acid rapeseed oil, also known as low erucic acid turnip rape oil; low erucic acid colza oil; canola oil, 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.

9. What are the maximum concentrations for glycidyl fatty acid esters in formula products intended for infants under the Amendment Regulation? Do you have any recommended testing method?

Under the Amendment Regulation, the maximum concentrations for glycidyl fatty acid esters (**expressed as glycidol**) in “Powdered infant formula and powdered follow-up formula intended to be consumed principally by persons under the age of 12 months” and “Liquid infant formula and liquid follow-up formula intended to be consumed principally by persons under the age of 12 months” are 50 µg/kg and 6 µg/kg respectively.

Testing laboratories should choose a testing method which is validated and applicable to the specified food group i.e. formula products intended for infants.

Partially Hydrogenated Oil (PHO) in Food

10. Will the Amendment Regulation affect products containing natural trans fatty acids from ruminant sources, e.g. milk, cheese?

The Amendment Regulation regards PHO as a prohibited substance in food. Trans fatty acids solely from ruminant sources are of natural origins and do not contain PHO. Products without PHO (e.g. fresh milk, natural cheese, bakery or fried products using non-PHO ingredients) are not affected.

11. Will the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 affect the labelling of trans fatty acids in prepackaged food?

The Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 requires the indication of hydrogenated oil if a prepackaged food contains hydrogenated oil. Labelling of trans fatty acids should be based on their actual contents in food.

12. Is there any food with fully hydrogenated oil prohibited for import and sale?

The Amendment Regulation prohibits the import of any edible oil or fat containing PHO and the sale of any food (including edible oil or fat) containing PHO. Products with fully hydrogenated oil are not affected.

13. What happens if a product is found to contain excessive trans fatty acid content?

The actions to be taken would be considered on a case-by-case basis. The Amendment Regulation prohibits the import of any edible oil or fat containing PHO and the sale of any food (including edible oil or fat) containing PHO. If a product contains IP-TFA more than 2% of total fat, it may trigger further investigation by CFS on the type of oil or fat used for manufacturing the product.

14. How can I know if the food contains PHO or hydrogenated oil?

Hydrogenation of oil requires specific industrial processes which have to be intentionally conducted. The trade shall always check with suppliers for the ingredient details of the products according to needs. For example, if trade obtained the ingredient list containing “vegetable oil (containing partially hydrogenated oil)” before purchase of any edible oil or fat, the product should be prohibited from import. In case the product concerned refers to any food (including edible oil or fat), it should be prohibited from sale in Hong Kong. If in doubt, the trade could also conduct laboratory testing to analyse the fatty acids content of the product (e.g. fatty acid content including but not limited to trans fatty acids).

15. What kind of documentary proofs are needed to show that a product does not contain PHO?

The documentary proofs include confirmation letters from the suppliers and their exporting authorities, product specifications, business contracts, ingredient lists, reports from competent laboratories, etc. For example:

- Ingredient list / product specifications of the food products for trade, specifying the use of oils and fats (if any), and the processing (e.g. blending, hydrogenation);
- Laboratory reports specifying fatty acid contents, including but not limited to trans fatty acids; and
- Business contracts with specifications and descriptions of the products, as appropriate.

16. How can estimation of IP-TFA in food help to identify the presence of PHO?

PHOs are edible fats and oils which have undergone the industrial process of hydrogenation, which is the primary source of IP-TFAs. If IP-TFA does not exceed a certain threshold, e.g. 2% total fat, it is unlikely that PHO is present in the food. On the other hand, estimates of IP-TFA content exceeding such threshold would trigger further investigation on the type of oil/fat used in a product to clarify any PHO origin.

17. For the purpose of regulating PHO, what fatty acids are to be investigated during estimation of IP-TFA levels?

For regulating PHO purpose, CFS adopts the EU approach by estimation of IP-TFAs level in food. If the level of IP-TFAs exceeded 2% of total fat, CFS may further investigate the source of trans fatty acids in the food on any hydrogenated oil ingredients. According to the EU approach, the principle to determine IP-TFA levels comprises the determination of butyric acid $C_{4:0}$, total trans fatty acids (sum of fatty acids with at least one non-conjugated carbon-carbon double bond in the trans configuration, usually the trans-isomers of $C_{16:1T}$, $C_{18:1T}$, $C_{18:2T}$ and $C_{18:3T}$), and conjugated linoleic acid (CLA, $C_{18:2T(9-cis,11-trans)}$).

