Draft Guidelines on the Harmful Substances in Food (Amendment) Regulation 2021

25 June 2021

食物環境衞生署
Food and Environmental Hygiene Department

食物安全中心
Centre for Food Safety

Contents of the draft Guidelines

- Chapter 1: Introduction
- Chapter 2: Interpretation of Maximum Concentration of Harmful Substance in Food under Schedule 1 to the Amendment Regulation
- Chapter 3: Interpretation of the Prohibition of the import and sale of food containing partially hydrogenated oil under the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021
- Chapter 4: Frequently Asked Questions

Chapter 1 - Introduction

Harmful Substances in Food (Amendment) Regulation 2021

- Publication in the Gazette – 11 June 2021
- Tabling at the Legislative Council for negative vetting – 16 June 2021
- Guidelines on the Amendment Regulation 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

The Guidelines:

- **Intended for use as a general reference only – Should be read in conjunction with the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021**
- **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**
- **May be amended or supplemented as necessary from time to time**

Key features of the Amendment Regulation

- Updates the maximum permitted concentration of 3 harmful substances, namely, aflatoxins, erucic acid and melamine, in food
- Introduces 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
- Prohibits the import and sale of food containing partially hydrogenated oil (PHO)
  - Cap. 132W also amended through the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021 to stipulate the labelling requirements of hydrogenated oils in prepackaged foods

Commencement date

- **Provisions relating to PHO and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021: 1 December 2023**
- **Other provisions: 1 June 2023**

Interpretation

- Key technical terms relevant to the Guidelines as defined in the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021, and as appropriate, the Ordinance, have been listed
- New definition
  - **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)
  - **Infant formula** 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** 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.
  - **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

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

Regulation 3

- 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

Extract of Part of Schedule 1

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 – Columns A & B

- **Column A "Item" and Column B "Substance" – List out certain harmful substances governed under Schedule 1**
  - Item 1. Aflatoxin B_1
  - Item 1A. Aflatoxin M_1
  - 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
  - Item 40. 3-monochloropropane-1,2-diol

How to read Schedule 1 – Column C

- **Column C "Description of substance" – Lists out the description of such substance as stated in Column B**
  - **"Aflatoxins, total" refers to "Sum of aflatoxins B_1, B_2, G_1 and G_2"**
  - **"Glycidyl fatty acid esters" refers to "Glycidyl fatty acid esters expressed as glycidol"**

How to read Schedule 1 – Columns D & E

- **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"**

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 under Schedule 1 (1)

- Information on determination of certain harmful substances in foods is available on the websites of the CFS and the Government Laboratory
- 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

Testing and analysis of certain harmful substances under Schedule 1 (2)

- **In general the maximum concentration applies to the edible portion of the food and if applicable, the food in the form specified in a note referred to in Column E of Schedule 1 in relation to the food**

Note 1: The maximum concentration applies to the food that is, or is reconstituted to be, ready for consumption.

Instructions for use (e.g. the amount of water to be used for reconstitution as recommended by the manufacturer)

Note 2: The maximum concentration applies to the dry matter of the food.

Determined on a part of the homogenised sample, using a method that has been demonstrated to determine the dry matter content accurately

Chapter 3 – Interpretation of the Prohibition of the import and sale of food containing partially hydrogenated oil under the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021

Regulation 3A under the Amendment Regulation

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."

- **All foods available in HK should not contain PHO, including:**
  - **Prepackaged and non-prepackaged food**
  - **Edible oils and fats (e.g. margarines and shortenings)**

Schedules 3 and 4 under the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021

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"

- **Food containing hydrogenated oil should be labelled on prepackaged food accordingly**
- **As PHO is regarded as a prohibited substance in food, oil in a product labelled "hydrogenated" in the ingredient list should be fully hydrogenated oil**

Identification of PHOs in food

- **Trader's responsibility**
  - **Provide accurate information on food labels, e.g.**
    - **Information on the ingredient list**
    - **Trans fatty acid content on the nutrition label**
  - **Check with suppliers for the details of ingredients**
  - **Keep proper documentary proofs of ingredient details of products**

Identification of PHOs in food

- CFS makes reference to internationally accepted methods to analyse fatty acids in different food matrices, e.g.
  - AOAC 996.06
  - 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

Identification of PHOs in food

- Estimation of IP-TFA in food by EU approach
- CFS may further investigate the source of trans fatty acids in the food on any hydrogenated oil ingredients if IP-TFAs exceeded 2% of total fat*
- Additional means for single non-blended fats and oils: iodine values (IV) to indicate degree of saturation (not applicable for mixed oils or food products)
  - IV ≤4: Fully hydrogenated oil
  - IV >4: PHO

* Ref: WHO's REPLACE trans fat action package Module 3 (link)

Identification of PHOs in food

- Trader (i.e. importers, manufacturers, distributors and retailers) are advised to keep proper documentary proofs of ingredient details for at least 24 months after the food was acquired or supplied, and provide them for inspection if deemed necessary

- Examples
  - Confirmation letters from the suppliers and their exporting authorities
  - Product specifications
  - Business contracts
  - Ingredient lists
  - Reports from competent laboratories

Chapter 4 -
Frequently Asked Questions

Frequently Asked Questions

- Frequently asked questions relevant to the Amendment Regulation and the Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021, have been listed
- Other information can also be referred to the CFS' website

~ End ~