

《食物內有害物質規例》(第132AF章) 的最新修訂

The Latest Amendments to the Harmful Substances in Food Regulations (Cap 132 AF)

2023食物安全研討會
Food Safety Seminar for Trade 2023

2023年12月7日
7 December 2023



《2021年食物內有害物質(修訂)規例》

The Harmful Substances in Food (Amendment) Regulation 2021

《修訂規例》

- 刊憲: 2021年6月11日
- 分兩階段實施
 - 訂明食物內**有害物質最高濃度**的條文：2023年6月1日生效；
 - 將部分**氫化油**列為食物中的**違禁物質**及相關**標示**規定的條文：2023年12月1日生效

The Amendment Regulation

- Published in the Gazette: 11 June 2021
- Came into force in two phases
 - Maximum **concentrations (MCs)** of **harmful substances**: from 1 June 2023;
 - Specifying **partially hydrogenated oils (PHOs)** as a **prohibited substance** and the related **marking and labelling** requirement: from 1 Dec 2023.

方向 Directions

- 以食品法典委員會的《**食品和飼料中污染物和毒素通用標準**》為基礎
- 對香港市民有較大食物安全風險的**有害物質及食物組別**，參考其他司法管轄區的做法訂定**相關建議**
- 全球和本地目標：**消除食品供應中工業生產的反式脂肪和部
分氫化油**
 - 世界衛生組織《**消除工業生產的反式脂肪酸—攬子行動方案**》
 - 政府《**邁向2025：香港非傳染病防控策略及行動計劃**》
- Based on the Codex General Standard for Contaminants and Toxins in Food and Feed
- For certain harmful substances and food groups with higher concern, made reference to the practices of other places
- Global and local goal on eliminating industrially-produced trans fatty acids (**IP-TFAs**) and **PHOs** in food supply
 - World Health Organization (WHO)'s REPLACE action package
 - HK Government's Action Plan to Prevent and Control Non-communicable Diseases



範圍 Scopes

- 更新及加強對三類霉菌毒素的規管
- 訂定或更新五類其他有害物質在食用油脂、調味品及擬供嬰兒食用的配方產品的標準
- 將「部分氫化油」（即工業生產的反式脂肪酸的主要來源）列為食物中的違禁物質
- Update and strengthen the regulation on three types of mycotoxins
- Set or update standards for five types of other harmful substances in edible fats and oils, condiments or formula products intended for infants
- Regard **PHOs**, the main source of **IP-TFAs**, as a prohibited substance in food

黃曲霉毒素 Aflatoxins

● 食物安全風險

- 「令人類患癌」(即第1類)物質：可引致肝癌，對乙型肝炎病毒感染人士的致癌性尤高
- 本港乙型肝炎病毒感染人口比例約7.2%，高於不少鄰近地區(例如新加坡、南韓等)

● Food safety risk

- “Carcinogenic to humans” (Group 1): could result in liver cancer; its carcinogenic potency in hepatitis B virus infected individuals is substantially higher
- A prevalence of 7.2% for hepatitis B virus infection in the Hong Kong population, higher than the rates of many neighbouring places (e.g. Korea and Singapore, etc.)



總黃曲霉毒素 Aflatoxins, Total (1)

食物 / 食物組別 Food / Food group	現行最高濃度 Existing MC (微克/公斤 µg/kg)	舊例最高濃度 Previous MC (微克/公斤 µg/kg)
非即食的杏仁、巴西堅果、榛子、花生及開心果 Non-ready-to-eat almonds, Brazil nuts, hazelnuts, peanuts and pistachios	15	花生或花生產品 Peanuts or peanut products 20
非即食的花生產品及杏仁、巴西堅果、榛子及 開心果產品 Non-ready-to-eat peanut products and products of almonds, Brazil nuts, hazelnuts and pistachios		
香料 Spices		任何其他食物 Any other food
任何其他食物 Any other food	10	15

總黃曲霉毒素 Aflatoxins, Total (2)

「總黃曲霉毒素」的定義

➤ 舊例的定義

- 黃曲霉毒素B1、B2、G1、G2、M1、M2、P1及黃曲霉毒素醇

➤ 現例的定義

- 黃 曲 霉 毒 素
B1+B2+G1+G2
- 與食品法典委員會一致

Definition of aflatoxins, total

➤ Previous definition:

- **aflatoxin B₁, B₂, G₁, G₂, M₁, M₂, P₁ and aflatoxicol**

➤ Existing definition:

- **aflatoxin B₁+B₂+G₁+G₂”**
- to keep it in line with Codex



黃曲霉毒素 Aflatoxins

● 新增最高濃度

- 為擬供36個月以下嬰幼兒食用的任何食物訂定「黃曲霉毒素B1」的標準
- 就奶類等產品（包括擬供12個月以下嬰兒食用的配方產品）訂定「黃曲霉毒素M1」的標準

● New MCs

- “aflatoxin B₁” in any food intended to be consumed principally by infants and young children under the age of 36 months
- “aflatoxin M₁” in milk and milk products (including formula products intended to be consumed principally by infants under the age of 12 months)



黃曲霉毒素B₁ Aflatoxin B₁

新增最高濃度 New MCs

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/公斤µg/kg)
嬰兒配方產品及較大嬰兒及幼兒配方產品 (以奶類蛋白質製造的 配方產品除外) Infant formula and follow-up formula other than formula manufactured from milk proteins	0.1 (註1 Note 1)
任何其他擬主要供不足36個月大的人食用的食物(以奶類蛋白質 製造的嬰兒配方產品及較大嬰兒及幼兒配方產品除外) 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 (註2 Note 2)

註1：最高濃度適用於已調配至可即時食用狀態的食物

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

註2：最高濃度適用於食物的乾物質

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



黃曲霉毒素M₁ Aflatoxin M₁

新增最高濃度 New MCs

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/公斤 µg/kg)
擬主要供不足12個月大的人食用的嬰兒配方產品及較大嬰兒及幼兒配方產品 Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.025 (註1 Note 1)
任何其他奶類或奶粉 Any other milk or dried milk	0.5 (註1 Note 1)

註1：最高濃度適用於已調配至可即時食用狀態的食物

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



脱氧雪腐镰刀菌烯醇 Deoxynivalenol (DON)

- 主要存在於穀物
- 食物安全風險
 - 嘔吐毒素
 - 嬰幼兒屬高危群組
- Mainly found in cereals
- Food safety risk
 - vomitoxin
 - Infants and young children are more vulnerable

新增最高濃度 New MC

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/ 公斤 $\mu\text{g}/\text{kg}$)
擬主要供不足36個月大的人食用的穀基類食物 Cereal-based foods intended to be consumed principally by persons under the age of 36 months	200 (註2 Note 2)

註2：最高濃度適用於食物的乾物質 ¹¹

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



棒曲霉素 Patulin

- 主要源自腐爛的蘋果
- 食物安全風險
 - 可引致噁心、胃腸道不適及嘔吐等徵狀
- Mostly occurs in rotten apples
- Food safety risk
 - Could result in symptoms such as nausea, gastrointestinal disturbances and vomiting

新增最高濃度 New MC

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/公斤 $\mu\text{g}/\text{kg}$)
蘋果汁及加有蘋果汁的其他飲品 Apple juice and other beverages to which apple juice has been added	50 (註1 Note 1)

註1：最高濃度適用於已調配至可即時食用狀態的食物

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

食用油脂中的苯並[a]芘

Benzo[a]pyrene (B[a]P) in Edible Fats and Oils

- 植物油脂是膳食中攝入苯並[a]芘的主要來源之一
- 食安中心於2013年已就苯並[a]芘在食用油脂中的含量制定行動水平
 - 10微克/公斤
- Vegetable fats and oils constitute a major source of the dietary exposure to B[a]P
- CFS set an action level for B[a]P in edible fats and oils in 2013
 - 10 µg/kg

新增最高濃度 New MC

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/公斤 µg/kg)
油或脂肪或兩者的混合物 Oil or fat or any mixture of oil and fat	5

食用油脂中的芥酸

Erucic Acid in Edible Fats and Oils

- 舊例中的標準維持不變 (所含脂肪酸的5%)
 - 油或脂肪 (或兩者的混合物)
 - 加有油或脂肪 (或兩者的混合物) 的任何食物
- MCs in the previous Regulations would remain unchanged (5 per centum by weight of their fatty acid content)
 - Any oil or fat or any mixture thereof
 - Any food to which oil or fat or a mixture thereof has been added

加入最高濃度 Add MC

食物 / 食物組別 Food / Food group	最高濃度 MC
低芥酸菜籽油 Low erucic acid rapeseed oil	以重量計其所含脂肪酸的2% 2 per centum by weight of its fatty acid content

調味品中的氯丙二醇

3-MCPD in Condiments

- 調味品的製造 / 加工過程如使用加酸水解植物蛋白增加其鮮味，可令氯丙二醇存在於製成品中
- acid-hydrolysed vegetable proteins (acid-HVPs) may be added to enhance the flavour of condiments in the production process; the production process of acid-HVPs could produce 3-MCPD, which may in turn be present in the final products

新增最高濃度 New MCs

食物 / 食物組別 Food / Food group	最高濃度 MC (毫克/公斤 mg/kg)
含有酸水解植物蛋白的固體調味品 Solid condiments containing acid hydrolysed vegetable proteins	1
任何其他含有酸水解植物蛋白的調味品 Any other condiments containing acid hydrolysed vegetable proteins	0.4

配方產品中的苯並[a]芘

Benzo[a]pyren in Formula Products Intended for Infants

- 配方產品可能含有苯並[a]芘
- Benzo[a]pyren (B[a]P) may exist in formula products

新增最高濃度 New MC

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/公斤 µg/kg)
擬主要供不足12個月大的人食用的嬰兒配方產品 及較大嬰兒及幼兒配方產品 Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1

配方產品中的縮水甘油脂肪酸酯 Glycidyl fatty acid esters in Formula Products Intended for Infants

新增最高濃度-縮水甘油脂肪酸酯 (以環氧丙醇表示)

New MCs - Glycidyl fatty acid esters (GE) (expressed as glycidol)

食物 / 食物組別 Food / Food group	最高濃度 MC (微克/公斤 µg/kg)
擬主要供不足12個月大的人食用的粉狀嬰兒配方產品及粉狀較大嬰兒及幼兒配方產品 Powdered infant formula and powdered follow-up formula intended to be consumed principally by persons under the age of 12 months	50
擬主要供不足12個月大的人食用的液態嬰兒配方產品及液態較大嬰兒及幼兒配方產品 Liquid infant formula and liquid follow-up formula intended to be consumed principally by persons under the age of 12 months	6

配方產品中的三聚氰胺

Melamine in Formula Products Intended for Infants (1)

- 舊例中的標準維持不變

- 奶類、任何擬供36個月以下的人食用的食物、擬主要供懷孕或授乳的女性食用的任何食物：
1毫克/公斤
- 任何其他食物：2.5毫克/公斤

- The MCs in previous regulation remain unchanged

- Milk; Any food intended to be consumed principally by persons of an age group into which children under the age of 36 months fall; Any food intended to be consumed principally by pregnant or lactating women: 1 mg/kg
- “Any other food”; 2.5 mg/kg

配方產品中的三聚氰胺

Melamine in Formula Products Intended for Infants (2)

加入液態配方產品最高濃度

Add MC for liquid formula products

食物 / 食物組別 Food / Food group	最高濃度 MC (毫克/公斤 mg/kg)
擬主要供不足12個月大的人食用的 <u>液態</u> 嬰兒配方產品及 <u>液態</u> 較大嬰兒及幼兒配方產品 Liquid infant formula and liquid follow-up formula intended to be consumed principally by persons under the age of 12 months	0.15



食物內部分氫化油的規管

Regulating PHOs in food

- 《修訂規例》：
 - 禁止輸入含有部分氫化油的油脂，以及售賣含有部分氫化油的任何食物（包括食用油脂）
- 《2021年食物及藥物（成分組合及標籤）（修訂）規例》
 - 規定預先包裝食物如含有氫化油（例如完全氫化油）必須在其配料表中作出相應標示
- **The Amendment Regulation**
 - To prohibit the import of any **edible oil or fat** containing **PHO** and the **sale** of any **food** (including edible oil or fat) **containing PHO**
- **The Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021**
 - To stipulate that any **prepackaged food** containing **hydrogenated oils, e.g. fully hydrogenated oil**, must be indicated accordingly in the **list of ingredients**

部分氫化油是工業生產的反式脂肪酸的主要來源

PHOs as the main source of IP-TFAs (1)

● 反式脂肪酸

- 增加血液內「壞」膽固醇，同時減少「好」膽固醇的水平，提高患冠心病的風險
- **少量**：天然存在於反芻動物的肉及奶製品等
- **大量**：經過「部分氫化」過程的食用油脂是工業生產的反式脂肪酸的主要來源

● Tran fatty acids (TFAs)

- Increase “bad” cholesterol and decrease “good” cholesterol in blood, contributing to an increased risk of coronary heart disease
- **Small amount: Naturally** present in the meat and dairy products of ruminant animals
- **Large amount: Partial hydrogenation** of edible oils/fats is the main source of IP-TFAs

部分氫化油是工業生產的反式脂肪酸的主要來源

PHOs as the main source of IP-TFAs (2)

● 部分氫化油

- 透過氫化的工業生產過程，控制氫氣壓力、溫度、催化劑等元素，把食用油脂轉變成部份氫化油
 - 製造不同硬度的部分氫化油脂產品，以延長產品的保質期、提升味道穩定性，以及令食品更為耐受反覆加熱

● 常見採用了「部分氫化油」製造的食物:

- 人造牛油/ 植物起酥油、酥皮、批、餅乾、蛋糕及烘焙食品等等

● PHOs

- In the industrial process of hydrogenation, edible oils/ fats are modified into PHOs by controlling various elements (e.g. hydrogen pressure, temperature, catalysts, etc.)
 - Produce PHOs-containing products of different hardness: for longer product shelf life, higher flavour stability, and food more resistant to repeated heating

● Common PHO-containing food products:

- Margarines/ Vegetable shortenings, pastries, pies, biscuits, cakes and various kinds of baked food

《修訂規例》第3A條及釋義

Regulation 3A of the Amendment Regulation & its interpretation

第3A條 禁止輸入和出售含有違禁物質的某些食物或油等

- (2) 任何人不得輸入含有部分氫化油的油或脂肪或兩者的混合物以供人食用。
- (3) 任何人不得售賣或為供出售而託付或交付含有部分氫化油的食物（包括油或脂肪或兩者的混合物）以供人食用。

- 所有在香港供應的食物均不得含有部分氫化油，包括：
 - 預先包裝和非預先包裝食物
 - 食用油脂(例如人造牛油和起酥油等)

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)



《2021年食物及藥物(成分組合及標籤)(修訂)規例》 Food and Drugs (Composition and Labelling) (Amendment) Regulation 2021

附表3 預先包裝食物的標記及標籤 第2條 配料表

(4F) 如食物由氫化油組成，或含有氫化油—

- (a) 配料表須載有“氫化油”的提述；或
- (b) 配料表上所顯示的該油名稱，須以“氫化”一詞修飾。

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”.

附表4 獲豁免遵從附表3規定的項目

“含有單一種配料（不包括氫化油）的食物”

Schedule 4 ITEMS EXEMPT FROM SCHEDULE 3

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

附表3及4的釋義

Interpretation of Schedules 3 & 4

- 預先包裝食物如含有氫化油，須相應作出標示
 - 例子：
「氫化」、「氫化油」、
「氫化脂肪 / 氫化脂 / 氫化油脂」、「完全氫化油 / 全氫化油」、「完全氫化脂 / 全氫化脂」等
- 由於部分氫化油已列為食品中的違禁物質，產品中的油在配料表中被標示為“氫化”即為完全氫化油
- Food containing hydrogenated oil should be labelled on prepackaged food accordingly
 - Examples:
“hydrogenated”,
“hydrogenated oil”,
“hydrogenated fat”, “fully hydrogenated oil”, “fully hydrogenated fat”, etc..
- As PHO is regarded as a prohibited substance in food, oil in a product labelled "hydrogenated" in the ingredient list means fully hydrogenated oil

業界的責任 Trader's responsibility

- 在食物標籤上提供準確的資料，例如：
 - 配料表的資料
 - 營養標籤的反式脂肪酸含量
- 向供應商查詢食品的成分詳情
- 妥善保存食品成分詳情的證明文件

- Provide accurate information on food labels, e.g.
 - Information on the ingredient list
 - TFA content on the nutrition label
- Check with suppliers for the details of ingredients
- Keep proper documentary proofs of ingredient details of products

識別食物中的部分氫化油

Identification of PHOs in food

- 業界（即進口商、製造商、分銷商和零售商）在獲取或獲供應有關食物後至少24個月內，妥善保存食品成分詳情的證明文件，並在有需要時供有關機構查核
- 例子：
 - 供應商及其出口當局的确認信
 - 產品規格
 - 商業合約
 - 配料表
 - 合資格化驗所發出的報告
- Trader (i.e. importers, manufacturers, distributors and retailers) 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

專題網頁 Designated webpage (1)

「取代食物中工業生產反式脂肪的指引」

https://www.cfs.gov.hk/tc_chi/food_leg/food_leg_Guidance_to_REPLACE_Trans_Fats_in_Food.html

“Guidance to Replace Industrially-produced Trans Fats in Food”

https://www.cfs.gov.hk/english/food_leg/food_leg_Guidance_to_REPLACE_Trans_Fats_in_Food.html

The screenshot shows the Chinese version of the Centre for Food Safety website. The header includes the CFS logo and the text '香港特別行政區政府 食物安全中心'. A search bar is present. The main navigation menu on the left lists various categories like '最新消息', '關於我們', '新聞稿', etc. The main content area is titled '食物規例 / 指引' and features a prominent article titled '取代食物中工業生產反式脂肪的指引' with a sub-image of butter. Below the title, there is a paragraph of text in Chinese and a smaller image showing a person's hands working with food.

The screenshot shows the English version of the Centre for Food Safety website. The header includes the CFS logo and the text 'Centre for Food Safety The Government of the Hong Kong Special Administrative Region'. A search bar is present. The main navigation menu on the left lists various categories like 'What's New', 'About Us', 'Press Release', etc. The main content area is titled 'Food Legislation / Guidelines' and features a prominent article titled 'Guidance to Replace Industrially-produced Trans Fats in Food' with a sub-image of butter. Below the title, there is a paragraph of text in English and a smaller image showing a person's hands working with food.

專題網頁 Designated webpage (2)

「《2021年食物內有害物質(修訂)規例》」

https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_Food_Regulations_Harmful_Substances.html

“Harmful Substances in Food (Amendment) Regulation 2021”

https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_Food_Regulations_Harmful_Substances.html

The screenshot shows the Chinese version of the webpage. At the top, it features the logo of the Centre for Food Safety and the text '食物安全中心'. Below the logo, there is a search bar and navigation icons. The main heading is '《2021年食物內有害物質(修訂)規例》'. A prominent orange banner contains the text '食物內有害物質規例'. Below the banner, there is an 'Introduction' section with several paragraphs of text. At the bottom, there is a list of links and a date '2021年6月11日'.

The screenshot shows the English version of the webpage. At the top, it features the logo of the Centre for Food Safety and the text 'The Government of the Hong Kong Special Administrative Region'. Below the logo, there is a search bar and navigation icons. The main heading is 'Harmful Substances in Food (Amendment) Regulation 2021'. A prominent orange banner contains the text 'Harmful Substances in Food Regulations'. Below the banner, there is an 'Introduction' section with several paragraphs of text. At the bottom, there is a list of links and a date '2021年6月11日'.



相關指引 Related guidelines

- 「《2021年食物內有害物質(修訂)規例》指引(二零二二年一月更新)」

➢ 旨在協助業界進一步了解和遵守《修訂規例》的相關規定，並解答一些常見的問題

https://www.cfs.gov.hk/tc_chi/whatsnew/whatsnew_fstr/files/Combined_Guideline.pdf

- 「取代食物中工業生產反式脂肪的指引」

➢ 旨在鼓勵和協助業界減少食物中的反式脂肪及取代工業生產的反式脂肪，為市民提供較健康的食物

https://www.cfs.gov.hk/english/food_leg/files/Industrially_produced_booklet_2_web.pdf

- “Guidelines on the Harmful Substances in Food (Amendment) Regulation 2021 (Updated in Jan 2022)”

➢ Aims to assist the trade in having a better understanding of and complying with the relevant requirements under the Amendment Regulations, and to answer some FAQs

https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/files/Combined_Guideline.pdf

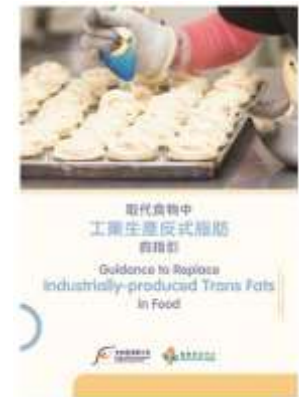
- “Guidance to Replace Industrially-produced Trans Fats in Food”

➢ Aims at encouraging and assisting trade to provide healthier food with respect to reducing trans fats and replacing industrially-produced trans fats

https://www.cfs.gov.hk/english/food_leg/files/Industrially_produced_booklet_2_web.pdf

更多查詢 Further enquiries:

- https://www.cfs.gov.hk/tc_chi/contactus/enquiry.html
- <https://www.cfs.gov.hk/english/contactus/enquiry.html>



Thank you!
謝謝!

