

# Public Consultation on the Proposed Amendments to the Harmful Substances in Food Regulations (Cap. 132AF)

17 January 2021

# Background

- **To safeguard food safety, we have been closely monitoring international developments and having regard to local dietary practices and risk assessments to review local food safety standards and regulatory arrangements from time to time on the basis of scientific evidence**
- **Recent initiatives on strengthening local food safety standards and regulatory arrangements**
  - **2012** Enacting the Pesticide Residues in Food Regulation (Cap. 132CM) to stipulate residue limits for some 360 pesticides in various foods / food groups and other relevant requirements
  - **2015** Conducting public consultation on strengthening the regulation of edible fats and oils (covering regulatory proposals on metallic contaminants, mycotoxins and other harmful substances)
  - **2018** Amending the Food Adulteration (Metallic Contamination) Regulations (Cap. 132V) to increase the number of metallic contaminants covered from seven to 14 and update the statutory standards for arsenic and lead in edible fats and oils

# Harmful Substances in Food Regulations (Cap. 132AF)

- Enacted in 1983
- Any specified food containing prohibited substances or specified harmful substances in excessive concentrations is not allowed to be imported to or sold in Hong Kong



# Directions of the Proposed Amendments

In view of the **public health** and **food safety** risks posed by certain harmful substances in food, and after conducting risk assessments having regard to local dietary practices –

- Based on the **Codex** General Standard for Contaminants and Toxins in Food and Feed
- For certain harmful substances and food groups (particularly formula products intended for infants), make reference to the practices of **other places** when there is no corresponding Codex standard
- **World Health Organization** (WHO) put forward an action package to eliminate industrially-produced trans fatty acids (IP-TFAs) from the global food supply (REPLACE action package) in 2018



# Scopes of the Proposed Amendments

- A. Strengthen the regulation on **three types of mycotoxins**
  - Aflatoxins, deoxynivalenol and patulin
  
- B. Set standards for **five types of other harmful substances** in **edible fats and oils, condiments or formula products intended for infants**
  - Benzo[a]pyrene, glycidyl fatty acid esters, melamine, 3-monochloropropane-1,2-diol and erucic acid
  
- C. Regard **partially hydrogenated oils (PHOs)**, the main source of IP-TFAs, as a **prohibited substance** in food



# Aflatoxins (I)

- Toxins produced by a number of mould of the *Aspergillus* family (including *A. flavus* etc.); include **four major types**, namely **aflatoxins B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub>**; **Aflatoxin B<sub>1</sub> is the most common and the most toxic**
- **Aflatoxin M<sub>1</sub> will be formed** as a result of the **metabolic process** in cows and other ruminant animals, and thus exist in milk and milk products produced for human consumption



# Aflatoxins (II)

- **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**
- **Hepatitis B prevalence is the highest in the Western Pacific Region (including Hong Kong)**
  - A prevalence of 7.2% for hepatitis B virus infection in the Hong Kong population, higher than the average rates of the Western Pacific Region and many neighbouring places (e.g. 4.4% in Korea, 3.6% in Singapore, etc.)

Considering the grave potential food safety risks of aflatoxin to the local population (especially hepatitis B virus carriers); intake of aflatoxin should be reduced to a level as low as reasonably achievable



# Aflatoxins - Proposed Amendments

**Make reference to the practices of Codex and some other places and propose to:**

- 1) Lower the maximum level (ML) for “aflatoxins, total” in any food other than specified foods from 15 µg/kg under the existing Regulations to 5 µg/kg
- 2) Tighten up the MLs of “aflatoxins, total” in certain tree nuts, peanuts and dried fruit from 15-20 µg/kg under the existing Regulations to 10-15 µg/kg, with a view to keeping the local standards consistent with the international ones
- 3) Set standard for “aflatoxin B<sub>1</sub>” (i.e. the most potent aflatoxin) in any food intended to be consumed principally by infants and young children under the age of 36 months
- 4) Set standard for “aflatoxin M<sub>1</sub>” in milk and milk products (including formula products intended to be consumed principally by infants under the age of 12 months)

# Aflatoxins, Total

## Aflatoxins, total \* - propose to update the existing Regulations

Food / Food group	Proposed ML	Existing ML
Non-ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios	15 µg/kg	Peanuts or peanut products: 20 µg/kg  Any other food: 15 µg/kg
Non-ready-to-eat products of the above food		
Spices		
Ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios	10 µg/kg	(Includes aflatoxin B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> , G <sub>2</sub> , M <sub>1</sub> , M <sub>2</sub> , P <sub>1</sub> and aflatoxicol)
Ready-to-eat products of the above food		
Dried figs		
Any other food	5 µg/kg	

\* Definition of “aflatoxins, total” will be updated as “aflatoxin B<sub>1</sub>+B<sub>2</sub>+G<sub>1</sub>+G<sub>2</sub>” to keep it in line with Codex

Make reference to Codex and existing Regulations

Make reference to other places

# Aflatoxin B<sub>1</sub> & M<sub>1</sub>

## Aflatoxins B<sub>1</sub> - proposed new standard

Food / Food group	Proposed ML
Any food intended to be consumed principally by persons under the age of 36 months	0.1µg/kg

## Aflatoxins M<sub>1</sub> - proposed new standards

Food / Food group	Proposed ML
Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.025µg/kg
Any other milk and dried milk	0.5µg/kg

Make reference to  
Codex

Make reference to  
other places



# Deoxynivalenol (DON)

- **Mainly found in cereals**
- **Food safety risk**
  - Infants and young children are more vulnerable to this vomitoxin, which may cause decreased appetite and weight loss, possibly leading to reduced growth in the long run
- **Proposed new standard**

Food / Food group	Proposed ML
Any food containing cereal intended to be consumed principally by persons under the age of 36 months	200µg/kg

Make reference to Codex



# Patulin

- **Mostly occurs in rotten apples; presents in apple juice made with rotten apples**
- **Food safety risk**
  - Could result in symptoms such as nausea, gastrointestinal disturbances and vomiting
- **CFS noted a number of recent cases involving substantial amounts of patulin found in relevant products**
- **Proposed new standard**

Food / Food group	Proposed ML
Apple juice and other beverages to which apple juice has been added	50 µg/kg

Make reference to Codex

# Edible Fats and Oils

- **Common elements of the local diet, frequently used by the general public for cooking**
- **Make reference to the proposal in the 2015 public consultation on strengthening regulation of edible fats and oils, propose to add / update the standards of the following:**
  - 1) Benzo[a]pyrene (B[a]P)
  - 2) Erucic acid



# B[a]P in Edible Fats and Oils

- “Carcinogenic to humans” (Group 1) ; 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
- Proposed new standard

Food / Food group	Proposed ML
Any oil or fat or any mixture of oil and fat	5 µg/kg

Make reference to the standards and regulatory arrangements of various places, the latest risk assessments and the local situation, as well as comments received during the earlier public consultation on strengthening regulation of edible fats and oils etc.

# Erucic Acid in Edible Fats and Oils

- A monounsaturated fatty acid; excessive intake may damage heart tissues of animals
- MLs in the existing Regulations would remain unchanged
  - Any oil or fat (or any mixture thereof) } 5 per centum by weight of their fatty acid content
- Propose to add the following standard for specified vegetable oil

Food / Food group	Proposed ML
Low erucic acid rapeseed oil	2 per centum by weight of their fatty acid content

Make reference to Codex

# 3-MCPD in Condiments

- “Possibly carcinogenic to humans” (Group 2B); 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
- Proposed new standards

Food / Food group	Proposed ML
Solid condiments	1 mg/kg
Any other condiments	0.4 mg/kg

Make reference to Codex

Make reference to the Mainland

# Formula Products Intended for Infants

- **For infants who cannot be breastfed or whose parents opt not to do so, we propose to add/update the standards of the following in formula products intended to be consumed principally by infants under the age of 12 months with reference to the practices of Codex and the EU for better protecting their health:**
  - 1) Benzo[a]pyrene (B[a]P)
  - 2) Glycidyl fatty acid esters (GE)
  - 3) Melamine



# B[a]P and GE in Formula Products Intended for Infants

- B[a]P and GE may exist in formula products
- Proposed new standard – B[a]P

Food / Food group	Proposed ML
Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1 µg/kg

- Proposed new standards – GE (expressed as glycidol); Upon ingestion, GE are hydrolysed into glycidol in the gastrointestinal tract; Glycidol is “probably carcinogenic to humans” (Group 2A)

Food / Food group	Proposed ML
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

Make reference to EU

# Melamine in Formula Products Intended for Infants

- An industrial chemical and should not be added to any food; adverse health effects such as urinary problems have occurred among infants and young children who consumed melamine-contaminated infant formula products
- MLs in the existing Regulations would remain unchanged
  - Milk and formula products: 1 mg/kg
- Propose to add standard for liquid formula products

Food / Food group	Proposed ML
<u>Liquid</u> infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.15 mg/kg

Make reference to Codex

# Partially Hydrogenated Oils (PHOs) (I)

## (the main source of IP-TFAs)

- **Tran fatty acids**

- Naturally present in the meat and dairy products of ruminant animals (e.g. cow, goat)
- Also produced during food processing, of which edible oils/fats undergone the process of partially hydrogenation is the main source of IP-TFAs
- Increase the low-density lipoprotein (“bad”) cholesterol and decrease the high-density lipoprotein (“good”) cholesterol in blood, contributing significantly to an increased risk of coronary heart disease



# Partially Hydrogenated Oils (PHOs) (II)

## (the main source of IP-TFAs)

- **Sources of PHOs**

- Edible oils/fat undergone the industrial process of hydrogenation are modified into PHOs by controlling various elements (e.g. hydrogen pressure, temperature, catalysts, etc.) in the hydrogenation process
- The aim of partial hydrogenation is to produce PHOs-containing products of different hardness which will have a longer product shelf life, higher flavour stability, and more resistant to repeated heating

- **Common food products possibly made with PHOs**

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

# Partially Hydrogenated Oils (PHOs) – WHO's REPLACE action package

- Launched in 2018, with a goal of eliminating IP-TFAs from the global food supply by 2023
- 12 large-scale multinational food companies have committed to achieving the WHO's goal
- Banning PHOs is one of the policies that the WHO recommended for implementation



Action package to eliminate industrially-produced trans-fatty acids



# PHOs – International Development

- Various places have implemented the relevant policies

Countries	Policy
USA	Released its final determination in 2015 that PHOs are not Generally Recognized as Safe, prohibiting the addition of PHOs to food by food manufacturers by the end of 2020
Canada	Added PHOs to the List of Contaminants and Other Adulterating Substances in Foods in 2017, prohibiting the sale of any food containing PHOs from 2018 onwards
Thailand	Amended its legislation in 2018 to prohibit the production, import or sale of PHOs and food containing PHOs from 2019 onwards
Singapore	Amended its legislation in June 2020* to prohibit the import of edible fats and oils containing PHOs for manufacturing other edible fats or oils or prepackaged food, or the use of edible fats and oils containing PHOs for manufacturing other edible fats or oils or prepackaged food (*will take effect in June 2021 to supersede its existing legislation enacted in 2013 which set an ML of trans-fatty acids in oils and fats)

# PHOs – Local Policy Objective

- Government announced in 2018 an Action Plan to Prevent and Control Non-communicable Diseases in Hong Kong; one of the key tasks is **to explore the adoption of policies to eliminate PHOs in the food supply**
- Eliminate the food safety risks associated with the consumption of IP-TFAs by protecting public health at source



**TOWARDS  
2025**

Strategy and Action Plan to  
Prevent and Control NCD in Hong Kong



# PHOs – Proposed Amendments

## To regard PHOs as a prohibited substance

### Harmful Substances in Food Regulations (Cap. 132AF)\*

- Prohibiting the sale of any food (including edible fats and oils) containing “PHOs”; and prohibiting the import of any edible fats and oils containing “PHOs”

*\*“PHOs” means any edible oils or fats that have undergone the process of hydrogenation but are not fully saturated as a result of that process.*

## Prepackaged food labelling requirement

### Food and Drugs (Composition and Labelling) Regulations (Cap. 132W)

- Prepackaged foods (including edible fats and oils), if containing hydrogenated oils, must 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.

# Grace Period

- **The Amendment Regulations are proposed to come into force 18 months after their publication in the Gazette**
  - **To implement as soon as practicable**
    - According to the testing results of the samples collected by the CFS under its Food Surveillance Programme and relevant risk assessments in recent years, more than 95% of the relevant samples could meet the proposed MLs
    - PHO-free margarines, vegetable shortenings and other edible fats and oils are currently available in the local market, and many catering and baking industries have already chosen these PHO-free products for food production
  - **To provide sufficient time for the food trade and the private testing and laboratory sector to get prepared for the updated food safety standards**
  - **In line with WHO's goal of eliminating IP-TFAs from the global food supply by 2023**

# Public Consultation

- **Members of the public are welcome to offer views on the proposals during the three-month public consultation period (11 December 2020 - 15 March 2021)**
- **Please visit this webpage for details:  
[www.cfs.gov.hk/harmfulsubstance](http://www.cfs.gov.hk/harmfulsubstance)**



**Thank you**

