Consultation Document

Proposed Amendments to the Harmful Substances in Food Regulations (Cap. 132AF)

December 2020

食物及衞生局
Food and Health Bureau

食物環境衞生署
Food and Environmental Hygiene Department

食物安全中心
Centre for Food Safety

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List of Abbreviations

3-MCPD	3-monochloropropane-1,2-diol
Acid-HVPs	Acid-hydrolysed vegetable proteins
B[a]P	Benzo[a]pyrene
CFS	Centre for Food Safety of the Food and Environmental Hygiene Department
Codex	Codex Alimentarius Commission
DON	Deoxynivalenol
FAO	Food and Agriculture Organization of the United Nations
GE	Glycidyl fatty acid esters
General Standard	General Standard for Contaminants and Toxins in Food and Feed
IARC	International Agency for Research on Cancer
IP-TFAs	Industrially-produced trans-fatty acids
ML(s)	Maximum level(s)
PAHs	Polycyclic aromatic hydrocarbons
PHOs	Partially hydrogenated oils
REPLACE action package	Action package to eliminate industrially-produced trans-fatty acids
The Ordinance	Public Health and Municipal Services Ordinance (Cap. 132)
The Regulations	Harmful Substances in Food Regulations (Cap. 132AF)
WHO	World Health Organization

CONTENTS

Chapter 1 Introduction

1.1 Under the Public Health and Municipal Services Ordinance (Cap. 132) ("the Ordinance"), food for sale and intended for human consumption in Hong Kong must be fit for human consumption. Standards relating to food safety are provided in various subsidiary legislations of the Ordinance. In particular, the Harmful Substances in Food Regulations (Cap. 132AF) ("the Regulations") stipulate that 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.

1.2 The Food and Health Bureau and the Centre for Food Safety of the Food and Environmental Hygiene Department ("CFS") have been closely monitoring international developments on the safeguarding of food safety, and reviewing local food safety standards and regulatory arrangements from time to time. Recent initiatives in this regard include –

- enacting the Pesticide Residues in Food Regulation (Cap. 132CM) in 2012 to stipulate residue limits for some 360 pesticides in various foods / food groups and other relevant requirements;

- conducting public consultation on strengthening regulation of edible fats and oils in 2015, covering regulatory proposals on metallic contaminants, mycotoxins and other harmful substances in edible fats and oils; and

- amending the Food Adulteration (Metallic Contamination) Regulations (Cap. 132V) in 2018 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.

1.3 In view of the public health and food safety risks posed by harmful substances (e.g. mycotoxins) in food, the CFS has conducted risk assessments having regard to local dietary practices and reviewed relevant standards under the existing Regulations based on the General Standard for Contaminants and Toxins in Food and Feed ("General Standard") of the Codex Alimentarius Commission

("Codex")[1]. For certain harmful substances and foods / food groups that are of greater food safety risks to the local population but without corresponding Codex standards, the CFS has formulated relevant proposals by making reference to the practices of other places and taking into account the local situation.

1.4 We propose to update and strengthen the regulatory control of three types of mycotoxins in food (detailed in Chapter 2) and set maximum levels ("MLs") for five types of other harmful substances in edible fats and oils, condiments and formula products intended for infants (detailed in Chapter 3) by amending the Regulations. At present, food sold in Hong Kong can generally comply with the requirements under the relevant proposals. 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 for harmful substances in foods / food groups.

1.5 Besides, the 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")[2] in 2018, calling on governments to take actions to eliminate IP-TFAs from the food supply. Various places have successively implemented policies to ban the use of partially hydrogenated oils, the main source of IP-TFAs, in the food supply. In view of these developments, we propose to amend the Regulations to regard partially hydrogenated oils as a prohibited substance in food (detailed in Chapter 4).

1.6 Overview of the proposed amendments to the Regulations is set out in Chapter 5. Members of the public are welcome to offer views on the proposals during the three-month public consultation period.

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[1] Established by the Food and Agriculture Organization of the United Nations ("FAO") and the World Health Organization in 1960s, Codex is the most important international source of reference in developing food associated standards. Information on the Codex standards can be found on the Codex webpage (www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en).

[2] The REPLACE action package can be found on the WHO webpage (www.who.int/teams/nutrition-and-food-safety/replace-trans-fat).

Chapter 2 Mycotoxins in Food

2.1 There are a wide variety of moulds. Moulds are fungi commonly present in the surrounding environment. Most moulds are generally harmless, except for a few which can produce toxins that may cause acute and / or chronic health effects in humans if ingested via food. Currently, the Codex General Standard has provided definitions and set MLs for certain mycotoxins in different foods / food groups.

2.2 The MLs of aflatoxin (i.e. the most toxic kind of mycotoxins) in food have been stipulated under the Regulations since the 1980s. However, they are generally less stringent than the prevailing international standards. We therefore propose to update the relevant standards in this amendment exercise. Taking into account data such as the dietary practices of the local population, we also propose to incorporate two other types of mycotoxins (i.e. deoxynivalenol and patulin) covered by the Codex General Standard into the regulatory framework of the Regulations. Proposed amendments relating to these three types of mycotoxins are set out in the ensuing paragraphs.

Aflatoxin

2.3 Aflatoxin is a group of natural toxins which include four major types, namely aflatoxins B_1, B_2, G_1 and G_2. Among them, aflatoxin B_1 is the most common and the most toxic. Besides, if cows or other ruminant animals consume feeds contaminated with aflatoxin B_1, aflatoxin M_1 will be formed as a result of the metabolic process in the livers of ruminants and be excreted in milk. It may thus exist in milk and milk products produced for human consumption.

2.4 Aflatoxins B_1, B_2, G_1, G_2 and M_1 are classified as "carcinogenic to humans" (Group 1) by the International Agency for Research on Cancer ("IARC") of the WHO. They are also genotoxic. Ingesting a large amount of food contaminated with aflatoxins could result in acute poisoning and cause liver damage. Long-term ingestion of aflatoxins could result in liver cancer. The carcinogenic potency of aflatoxins in hepatitis B virus infected individuals is substantially higher than non-infected ones.

2.5 According to the WHO, hepatitis B prevalence is the highest in the Western Pacific Region (including Hong Kong), where over 6% of the adult

population is infected. In addition, local epidemiological studies gauged 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.). In fact, liver cancer is among the three leading causes of cancer deaths in Hong Kong.

2.6 The MLs of aflatoxin prescribed by the existing Regulations are 20 μg/kg in "peanuts or peanut products" and 15 μg/kg in any other food. The current definition of aflatoxin under the Regulations is different from that in the Codex General Standard[3]. We propose to **update the definition of "aflatoxins, total" under the existing Regulations to ensure consistency with that adopted by Codex**.

2.7 Considering the grave potential food safety risks of aflatoxin to the local population (especially hepatitis B virus carriers), as well as the recommendation of the Joint FAO / WHO Expert Committee on Food Additives that the intake of aflatoxin should be reduced to a level as low as reasonably achievable, we propose to make reference to the practices of some places in the Western Pacific region (e.g. Malaysia and Singapore)[4] to **tighten up the ML for "aflatoxins, total" in any food other than specified food from 15 μg/kg under the existing Regulations to 5 μg/kg**.

2.8 We note that the Codex General Standard has set standards which are as low as reasonably achievable for **"aflatoxins, total" in certain tree nuts, peanuts and dried fruit** that are more susceptible to aflatoxin contamination, **ranging from 10 μg/kg to 15 μg/kg**. We **propose to make reference to the aforesaid standards** to update the ML for "peanuts and peanut products" under the existing Regulations and incorporate other MLs for specified foods set by Codex, with a view to keeping the relevant local standards consistent with the international ones.

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[3] The existing Regulations stipulate that "aflatoxin" includes aflatoxin B_1, B_2, G_1, G_2, M_1, M_2, P_1 and aflatoxicol. In the Codex General Standard, "aflatoxins, total" refers to aflatoxins B_1, B_2, G_1 and G_2, and there is a separate standard for "aflatoxin M_1".

[4] The relevant standard of some neighbouring places such as Malaysia and Singapore for aflatoxin in any food other than specified food is 5 μg/kg. Relevant limit of the United States is 20 μg/kg, and relevant standard of Korea is 15 μg/kg. Japan has set the relevant limit at 10 μg/kg for all food. Australia / New Zealand, Canada, the European Union and the Mainland have not set any relevant standard.

2.9 Besides, the health of infants and young children is affected more easily by harmful substances in food, and manufacturers of food for infants and young children can also achieve a more stringent aflatoxin standard through prudent selection of raw materials. We propose to make reference to the practices of other places (e.g. the European Union, Korea, Malaysia, Singapore and Vietnam)[5] to **set an ML of "aflatoxin B_1"** (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 at 0.1 µg/kg**.

2.10 We also propose to make reference to the Codex General Standard to set an ML of **"aflatoxin M_1" in milk at 0.5 µg/kg**. Considering milk is the major source of nutrients for infants in the first 6 months, and for those who cannot be breastfed or whose parents opt not to do so, formula products will be the substitute, we propose to make reference to the practices of other places (e.g. the European Union, Korea, Malaysia, Singapore and Vietnam)[6] to set a more stringent **ML of 0.025 µg/kg for "aflatoxin M_1" in formula products intended to be consumed principally by infants under the age of 12 months**.

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[5] The relevant standard of some neighbouring places (such as Korea, Malaysia, Singapore and Vietnam) and the European Union is 0.1 µg/kg. The Mainland has set the relevant standard at 0.5 µg/kg. Australia / New Zealand and Canada have not set any relevant standard, while Japan and the United States adopt their respective uniform limits for all food (see footnote 4).

[6] The relevant standard of some neighbouring places (such as Korea, Malaysia, Singapore and Vietnam) and the European Union is 0.025 µg/kg (applicable to products that are, or are reconstituted to be, ready-to-drink). The Mainland has set the relevant standard at 0.5 µg/kg (applicable to products in powdered form). Australia / New Zealand, Canada, Japan and the United States have not set any relevant specified standard.

2.11 Details of the proposed amendments relating to aflatoxin are as follows –

Substance	Food / Food group	Proposed ML	ML under the existing Regulations
Aflatoxins, total (Aflatoxins $B_1+B_2+G_1+G_2$)	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 (Includes aflatoxin B_1, B_2, G_1, G_2, M_1, M_2, P_1 and aflatoxicol)
	Non-ready-to-eat products of the above food		
	Spices		
	Ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios	10 μg/kg	
	Ready-to-eat products of the above food		
	Dried figs		
	Any other food	5 μg/kg	
Aflatoxin B_1	Any food intended to be consumed principally by persons under the age of 36 months	0.1 μg/kg	
Aflatoxin M_1	Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.025 μg/kg	
	Any other milk and dried milk	0.5 μg/kg	

Note: For the proposed MLs in foods / food groups shaded in grey, reference has been made to the standards of other places such as the European Union, Korea, Malaysia, Singapore and Vietnam. Other proposed MLs are set with reference to the Codex General Standard and the existing Regulations.

Deoxynivalenol

2.12 Deoxynivalenol ("DON") (also known as vomitoxin) is mainly produced by moulds in soil. DON-producing moulds are pathogens of cereals, particularly wheat and maize. Infants and young children are more vulnerable to the toxic effects of DON, which may cause decreased appetite and weight loss, possibly leading to reduced growth in the long run. In view of this, we propose to make reference to the standard of DON in cereal food for infants and young children under the Codex General Standard to incorporate in the Regulations **an ML of 200 μg/kg for "DON" in any food containing cereal intended to be consumed principally by infants and young children under the age of 36 months**.

2.13 Based on the local dietary practices and risk assessment results, the dietary intake of DON from cereal products such as pasta / noodles and bread is very low among the Hong Kong population. It is therefore unlikely to pose adverse health effects to the local population groups other than infants and young children (e.g. adults). The CFS will continue to monitor the level of DON in the cereal food concerned and review the results of relevant risk assessments to safeguard food safety.

Patulin

2.14 Patulin is produced by a variety of moulds and mostly occurs in rotten apples. For apple juice made with rotten apples, the patulin contained therein cannot be removed despite heat treatments such as pasteurisation. Excessive intake of patulin through consumption of apple juice could result in symptoms such as nausea, gastrointestinal disturbances and vomiting.

2.15 The CFS has been continuously monitoring the level of patulin in apple juice and other beverages under its Food Surveillance Programme, and noted a number of recent cases involving substantial amounts of patulin found in relevant products. In view of this, we propose to make reference to the standard of patulin in apple juice under the Codex General Standard to incorporate in the Regulations **an ML of 50 μg/kg for "patulin" in apple juice and other beverages to which apple juice has been added.**

Chapter 3 Edible Fats and Oils, Condiments and Formula Products Intended for Infants

3.1 Apart from the mycotoxins mentioned in Chapter 2, we propose to set MLs for five other harmful substances in edible fats and oils, condiments or formula products intended for infants to better protect the health of the local population (including infants). Among these harmful substances, the carcinogenicity[7] of four of them, namely benzo[a]pyrene ("B[a]P"), glycidol (a substance released from hydrolysis of glycidyl fatty acid esters ("GE") in the gastrointestinal tract), melamine and 3-monochloropropane-1,2-diol ("3-MCPD"), have been classified by the IARC of the WHO; whilst the other substance, i.e. erucic acid, has been regulated under the existing Regulations since the 1980s. In relation to these harmful substances, the food groups concerned are closely related to the dietary practices of the local population, and relevant standards have also been set by Codex or other places.

Edible fats and oils and condiments

3.2 Edible fats and oils and condiments are common elements of the local diet, frequently used by the general public for cooking. We propose to set an ML for B[a]P in edible fats and oils and update the existing Regulations to incorporate an ML for erucic acid in a specific type of oil, i.e. "low-erucic acid rapeseed oil". As regards condiments, we propose to set MLs for 3-MCPD in their various forms. Relevant proposals are detailed in paragraphs 3.3 – 3.9 below.

B[a]P

3.3 B[a]P is a kind of polycyclic aromatic hydrocarbons ("PAHs") which are ubiquitous in the environment. B[a]P is classified as "carcinogenic to humans" (Group 1) by the IARC and is toxic to genes. The Joint FAO / WHO Expert Committee on Food Additives has pointed out that vegetable fats and oils

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[7] Under the carcinogenicity classification of the IARC, agents can be categorised into "carcinogenic to humans" (Group 1), "probably carcinogenic to humans" (Group 2A), "possibly carcinogenic to humans" (Group 2B) or "not classifiable as to its carcinogenicity to human" (Group 3).

constitute a major source of the dietary exposure to PAHs (including B[a]P) due to their higher PAH concentrations. Nevertheless, the B[a]P levels of the end products depend on the quality control adopted along the production process.

3.4 Following the incidents of suspected substandard cooking oil in 2011, the CFS set an action level of 10 μg/kg for B[a]P in edible fats and oils in 2013. In the public consultation on strengthening regulation of edible fats and oils in 2015, we proposed to incorporate the level of B[a]P in edible fats and oils at 5 μg/kg into the regulatory framework of the Regulations. During the said consultation, some traders and members of the public considered the proposed ML too stringent, which might have an impact on the production cost and supply of certain edible fats and oils. Meanwhile, there were views that the ML of B[a]P in edible fats and oils should be tightened up substantially to 2 μg/kg with reference to the standard of the European Union.

3.5 After considering a host of factors, including the standards and regulatory arrangements of various places[8], the latest risk assessments and the local situation, as well as the comments received during the earlier public consultation on strengthening regulation of edible fats and oils, we propose to **set an ML of 5 μg/kg for "B[a]P" in edible fats and oils** by amending the Regulations. While the proposed ML is more stringent than the existing action level of the CFS (i.e. 10 μg/kg), it also reflects the outcome of the trade's efforts in reducing the level of B[a]P in edible fats and oils in recent years[9], striking a balance between safeguarding food safety and trade facilitation.

Erucic acid

3.6 Erucic acid is a monounsaturated fatty acid which naturally occurs in oil-rich seeds of species of the mustard family. Unlike some other monounsaturated fatty acids which may reduce the risk of heart disease, studies in experimental animals internationally since the 1970s have revealed that

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[8] The relevant standard in the Mainland is 10 μg/kg, while that in the European Union and Korea is 2 μg/kg. Codex, Australia / New Zealand, Canada, Japan, Singapore and the United States have not set any relevant standard.

[9] According to the CFS's continuous food surveillance, more than 300 samples of edible fats and oils were collected from January 2017 to September 2020, among which some 99% could comply with the proposed ML of B[a]P at 5 μg/kg. This is higher than the rate of about 95% recorded before the 2015 public consultation (i.e. 2012-2014), reflecting an overall reduction of B[a]P in edible fats and oils marketed in Hong Kong in recent years and their ability to comply with the proposed standard (which is more stringent than the current action level of the CFS).

excessive intake of erucic acid may damage heart tissues. Over the years, many places have set standards for erucic acid in edible fats and oils. The existing Regulations have also stipulated the ML of erucic acid in oil or fat (or any mixture thereof) at 5% of their fatty acid content.

3.7 We note that Codex has specified in its Standard for Named Vegetable Oils the level of **"erucic acid"** in **"low erucic acid rapeseed oil"** (i.e. 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) **must be less than 2% of the total fatty acids**. We propose to make reference to the said standard and **incorporate the same ML** by amending the Regulations.

3-MCPD

3.8 One of the ways to produce and process condiments (such as soy sauce, chilli sauce and chicken powder) is to add acid-hydrolysed vegetable proteins ("acid-HVPs") to enhance flavours. However, the production process of acid-HVPs could produce 3-MCPD, which may in turn be present in the final products. According to the IARC, 3-MCPD is classified as "possibly carcinogenic to humans" (Group 2B).

3.9 Currently, the Codex General Standard has a standard for 3-MCPD only in liquid condiments containing acid-HVPs. For solid condiments which are also commonly added to the local diet, only the Mainland has set a relevant standard. Codex and other places[10] have not set any standard for 3-MCPD in solid condiments. Thus, in updating the Regulations, we propose to make reference to the Codex standard for liquid condiments and the Mainland standard for solid condiments to **set MLs for "3-MPCD" in solid condiments and condiments in any other forms (whether liquid, semi-liquid or semi-solid, etc.) at 1 mg/kg and 0.4 mg/kg respectively**[11].

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[10] Including Australia / New Zealand, Canada, the European Union, Japan, Korea, Singapore and the United States.

[11] To ensure that the scope of the proposed standards is easily comprehensible, the proposed amendments will be applicable to all condiments imported to or sold in Hong Kong (regardless of whether they contain acid-HVPs).

Formula products intended for infants

3.10 For infants[12] who cannot be breastfed or whose parents opt not to do so, we propose to enhance the relevant food safety standards with reference to the practices of Codex and the European Union for better protecting their health. Specifically, we propose to set MLs for B[a]P and GE in formula products intended for infants, and update the existing Regulations to incorporate an ML for melamine in liquid formula products. Relevant proposals are detailed in paragraphs 3.11 – 3.15 below.

B[a]P

3.11 B[a]P may be formed in the manufacturing process of the ingredients of formula products. Considering the potential health effects of B[a]P intake on infants (detailed in paragraph 3.3 above), we propose to **set an ML of 1 µg/kg for "B[a]P" in formula products intended to be consumed principally by infants under the age of 12 months** with reference to the relevant standards of the European Union and Korea[13].

GE

3.12 GE are contaminants formed mainly during the deodourisation process in refining vegetable oils. Refined oils and food containing refined oils (e.g. infant formula products) may therefore contain GE. Upon ingestion, GE are hydrolysed into glycidol in the gastrointestinal tract. Glycidol is genotoxic and classified as "probably carcinogenic to humans" (Group 2A) by the IARC. It may also cause toxic effects on the nervous, renal and reproductive systems based on studies in experimental animals.

3.13 While Codex does not have any standard for GE in food at present, the European Union has recently set standards for GE in certain food groups, including infant formula. We propose to update the Regulations by making

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[12] According to the definition of Codex, "infant" means a person under 12 months of age.

[13] The relevant standard of the European Union and Korea is 1 µg/kg. Codex, Australia / New Zealand, Canada, Japan, the Mainland, Singapore and the United States have not set any relevant standard.

reference to the said standards[14] to **set MLs of "GE" in powdered and liquid formula products intended for infants under the age of 12 months at 50 μg/kg and 6 μg/kg respectively**.

Melamine

3.14 Melamine is an industrial chemical and should not be added to any food[15]. Adverse health effects such as urinary problems have occurred among infants and young children who consumed melamine-contaminated infant formula products. Melamine is classified as "possibly carcinogenic to humans" (Group 2B) by the IARC. Subsequent to the incidents of milk products detected with melamine in 2008, we amended the Regulations in the same year to set MLs for melamine in milk, any food intended to be consumed principally by infants and young children under the age of 36 months, and any food intended to be consumed by pregnant or lactating women at 1 mg/kg. These are more stringent than the standard for any food (other than infant formulae) at 2.5 mg/kg set by Codex in its General Standard in 2010.

3.15 In the Codex General Standard, the standard for melamine in "powdered infant formula" is set at 1 mg/kg (i.e. same as the ML under the existing Regulations in Hong Kong), while a separate standard is provided specifically for melamine in "liquid infant formula" at 0.15 mg/kg. Despite the fact that liquid infant formula products are uncommon in the local market, for the purposes of making the local standards in line with the international ones and enhancing food safety for infants, we propose to update the Regulations by making reference to the relevant Codex standard to **set an ML for "melamine" in <u>liquid formula products</u> intended to be consumed by infants under the age of 12 months at 0.15 mg/kg**. All other MLs for melamine under the existing Regulations would remain unchanged.

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[14] The relevant standards of the European Union are 50 μg/kg (applicable to powdered formula products) and 6 μg/kg (applicable to liquid formula products). Codex, Australia / New Zealand, Canada, Japan, Korea, the Mainland, Singapore and the United States have not set any relevant standard.

[15] Melamine is generally used for the production of melamine resins, which are used to produce industrial products such as laminates, glues, paper, textiles etc. Traces of melamine may be present in food due to migration of melamine from utensils / packaging made of melamine-formaldehyde resin and from the environment. However, since melamine is high in nitrogen, adding it illegally to food such as milk can increase the apparent protein content of the food.

Chapter 4 Partially Hydrogenated Oils

4.1 Partially hydrogenated oils ("PHOs") are edible fats and oils (vegetable oils in general) which have undergone the industrial process of hydrogenation. By controlling various elements such as hydrogen pressure, temperature, catalysts, etc. in the hydrogenation process, liquid oils are modified into partially hydrogenated fat products of different hardness (ranging from liquid to solid). Compared with the use of natural animal and vegetable fats (e.g. butter, lard, cocoa butter, etc.), PHOs stand out in terms of lower manufacturing cost, longer product shelf life, higher flavour stability, and making the food produced more resistant to repeated heating. PHOs have thus been widely adopted by the food industry since the early 20th century for manufacturing or adding to food products of different forms and textures such as margarines and vegetable shortenings, pastries, pies, biscuits, cakes and various kinds of baked and fried food.

4.2 PHOs were once believed to be a healthier alternative to animal and some vegetable fats due to the higher content of saturated fatty acids of the latter, which would potentially increase cholesterol levels. Nonetheless, the process of producing PHOs can actually result in a large amount of industrially-produced trans-fatty acids (i.e. IP-TFAs) at a level ranging from 25% to 45% of the total fatty acids generally. There is growing evidence from scientific research that the consumption of IP-TFAs from PHOs is harmful to health caused by the resultant increase in the low-density lipoprotein cholesterol (i.e. the "bad" cholesterol) and decrease in the high-density lipoprotein cholesterol (i.e. the "good" cholesterol), contributing significantly to an increased risk of coronary heart disease.

4.3 The WHO launched the REPLACE action package in 2018, with a goal of eliminating IP-TFAs from the global food supply by 2023. Banning PHOs is one of the policies that the WHO recommended for implementation around the world. The WHO also pointed out that healthier alternatives[16] could be used in lieu of PHOs without affecting the taste or cost of food.

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[16] For healthier alternatives, their total fat should contain as little saturated fat as possible and as much unsaturated fat as possible. Their content of saturated fat should also be less than the sum of saturated fat and trans fat in the PHO-containing products being in use. Edible fats and oils rich in unsaturated fat include corn, sunflower, soybean, canola, olive and peanut oils.

4.4 According to the WHO report released in September 2020, the 12 largest multinational food companies around the world have committed to eliminating IP-TFAs from all their products by 2023. Major oil and fat suppliers worldwide have also been using mature technologies widely to produce PHO-free fats and oils to satisfy market needs. In Hong Kong, 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.

4.5 In recent years, various places have successively formulated policies with reference to the REPLACE action package to prohibit the use of PHOs in food and/or the sale of food containing PHOs, for instance –

- The United States 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; and

- 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. This amendment 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.

4.6 In the "Towards 2025: Strategy and Action Plan to Prevent and Control Non-communicable Diseases in Hong Kong" announced by the Government in 2018, one of the key tasks is to explore the adoption of policies to eliminate PHOs

in the food supply[17], thereby eliminating the food safety risks associated with the consumption of IP-TFAs and protecting the public at source. With reference to the WHO's REPLACE action package and the relevant measures adopted in other places, we propose to **regard "PHOs" as a prohibited substance by prohibiting under the Regulations the import of any edible fats and oils containing "PHOs" and the sale of any food (including edible fats and oils) containing "PHOs"**[18].

4.7 In line with the above proposal, we also propose to stipulate the labelling requirements for hydrogenated oils under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W). Specifically, **if prepackaged foods (including edible fats and oils) contain hydrogenated oils, the latter must be indicated accordingly (e.g. "hydrogenated oil" 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. The relevant labelling requirements, upon implementation, can facilitate the trade to ascertain whether the food products or ingredients that they source contain any hydrogenated oils.

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[17] Details of the "Towards 2025: Strategy and Action Plan to Prevent and Control Non-communicable Diseases in Hong Kong" are accessible on the website of the Department of Health (www.change4health.gov.hk/en/saptowards2025/publications.html).

[18] For the purpose of this proposed amendment to the Regulations, "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. In other words, fully hydrogenated oils should in theory contain no IP-TFAs since all the fatty acids are fully saturated.

Chapter 5 Overview of the Proposed Amendments

5.1 Regarding the proposed amendments to the Regulations set out in Chapters 2 to 4, we consider it appropriate to implement them as soon as practicable, whilst allowing a grace period to provide sufficient time for the food trade and the private testing and laboratory sector to get prepared for the updated food safety standards. To strike a balance between the two and with reference to the experience of previous amendments of food standards, we propose that the Amendment Regulations come into force 18 months after its publication in the Gazette.

5.2 The proposed amendments in relation to the MLs of **mycotoxins and other harmful substances in food** detailed in Chapters 2 and 3 are summarised in the table below:

<table>
<tr><th></th><th>Substance</th><th>Food / Food group</th><th>Proposed ML</th><th>ML under the existing Regulations</th></tr>
<tr><td rowspan="9">1.</td><td rowspan="8">Aflatoxins, total (Note 1)</td><td>Non-ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios</td><td rowspan="3">15 μg/kg (Note 3)</td><td rowspan="9">Peanuts or peanut products: 20 μg/kg

Any other food: 15 μg/kg</td></tr>
<tr><td>Non-ready-to-eat products of the above food</td></tr>
<tr><td>Spices (Note 2)</td></tr>
<tr><td>Ready-to-eat peanuts, almonds, Brazil nuts, hazelnuts and pistachios</td><td rowspan="3">10 μg/kg (Note 4)</td></tr>
<tr><td>Ready-to-eat products of the above food</td></tr>
<tr><td>Dried figs</td></tr>
<tr><td>Any other food</td><td>5 μg/kg</td></tr>
<tr><td>Aflatoxin B_1</td><td>Any food intended to be consumed principally by persons under the age of 36 months</td><td>0.1 μg/kg</td></tr>
</table>

	Substance	Food / Food group	Proposed ML	ML under the existing Regulations
	Aflatoxin M_1	Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.025 μg/kg (Note 5)	
		Any other milk and dried milk	0.5 μg/kg (Note 5)	
2.	Deoxynivalenol	Any food containing cereal intended to be consumed principally by persons under the age of 36 months	200 μg/kg (Note 6)	Nil
3.	Patulin	Apple juice and other beverages to which apple juice has been added	50 μg/kg (Note 7)	
4.	Benzo[a]pyrene	Any oil or fat or any mixture of oil and fat	5 μg/kg	
		Infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1 μg/kg (Note 8)	
5.	Glycidyl fatty acid esters (expressed as glycidol)	Powdered infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	50 μg/kg (Note 8)	
		Liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	6 μg/kg (Note 8)	

	Substance	Food / Food group	Proposed ML	ML under the existing Regulations
6.	Melamine (Note 9)	Liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	0.15 mg/kg (Note 8)	Milk and any food intended to be consumed principally by persons of an age group into which children under the age of 36 months fall: 1mg/kg
		Milk other than liquid infant formula and follow-up formula intended to be consumed principally by persons under the age of 12 months	1 mg/kg (Note 10)	
		Any other food intended to be consumed principally by persons under the age of 36 months		
7.	3-monochloropropane-1,2-diol	Solid condiments	1 mg/kg	Nil
		Any other condiments	0.4 mg/kg (Note 11)	
8.	Erucic acid (Note 12)	Low-erucic acid rapeseed oil	2 per centum by weight of their fatty acid content	Any oil or fat or any mixture thereof: 5 per centum by weight of their fatty acid content
		Any other oil or fat or any mixture of oil and fat	5 per centum by weight of their fatty acid content (Note 10)	

Note 1: "Aflatoxins, total" refers to "aflatoxins B_1+B_2+G_1+G_2" as defined in the Codex General Standard. It is proposed to replace "aflatoxin" and its description (i.e. "group of bis-furanocoumarin compounds and includes aflatoxin B_1, B_2, G_1, G_2, M_1, M_2, P_1 and aflatoxicol") as stipulated in Schedule 1 to the existing Regulations.

Note 2: Codex is drafting an ML for certain spices (i.e. 20 or 30 μg/kg), which is more lenient than that for any food including spices under the existing Regulations (i.e. 15 μg/kg). It is therefore proposed to retain the more stringent standard stipulated under the existing Regulations as the proposed ML.

Note 3: The ML for "non-ready-to-eat" peanuts, almonds, Brazil nuts, hazelnuts and pistachios is proposed with reference to the Codex General Standard in respect of those "intended for further processing". For the non-ready-to-eat products of the above food, the proposed ML is based on the principle that "peanuts or peanut products" is regarded as the same group under the existing Regulations.

Note 4: The ML for "ready-to-eat" almonds, Brazil nuts, hazelnuts and pistachios is proposed with reference to the Codex General Standard, while that for "ready-to-eat" peanuts is based on the existing draft Codex standard. For the ready-to-eat products of the above food, the proposed ML is based on the principle that "peanuts or peanut products" is regarded as the same group under the existing Regulations.

Note 5: The proposed ML applies to products that are, or are reconstituted to be, ready-to-drink.

Note 6: The proposed ML applies to the whole commodity on a dry weight basis.

Note 7: For other beverages to which apple juice has been added, the ML is proposed with reference to the standard for "apple juice" in the Codex General Standard. The proposed ML applies to the whole commodity that is not concentrated, or is reconstituted to be ready-to-drink.

Note 8: The ML applies to products as sold.

Note 9: The MLs of melamine in "any food intended to be consumed principally by pregnant or lactating women" at 1 mg/kg and "any other food" at 2.5 mg/kg stipulated under the existing Regulations would remain unchanged.

Note 10: The ML is the same as that of the existing Regulations; the proposed amendment only involves refinements to the description to the relevant "food / food group".

Note 11: The ML is proposed with reference to the standard for "liquid condiments" containing acid-HVPs in the Codex General Standard.

Note 12: The ML of erucic acid in "any food to which oil or fat or a mixture thereof has been added" at "5 per centum by weight of their fatty acid content of all the oils and fats in the food" under the existing Regulations would remain unchanged.

5.3 The proposed amendments in relation to PHOs in Chapter 4 are summarised as follows –

- To regard "PHOs" as a prohibited substance in food by prohibiting under the Regulations the import of any edible fats and oils containing "PHOs" and the sale of any food (including edible fats and oils) containing "PHOs"; and

- To require that prepackaged foods (including edible fats and oils), if containing hydrogenated oils, 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.

Chapter 6 Views Sought

6.1 We welcome views from members of the public on the proposed amendments to the Regulations detailed in Chapter 5. Please send your comments to the CFS by letter, facsimile or e-mail on or before 15 March 2021 –

Centre for Food Safety
Food and Environmental Hygiene Department
43/F, Queensway Government Offices,
66 Queensway, Hong Kong
Facsimile: (852) 2893 3547
E-mail address: harmful-sub-consultation@fehd.gov.hk

6.2 Members of the public are free to supply their personal data when giving views on the consultation document. Any personal data provided with a submission will only be used for purpose of this consultation exercise.

6.3 The submissions and personal data collected may be sent to the relevant Government bureaux, departments or agencies for purposes directly related to this consultation exercise. The parties receiving the data are bound by such purposes in their subsequent use of the data.

6.4 The names and views of individuals and organisations submitting their views in response to the consultation document ("senders") may be published for public viewing after conclusion of the consultation exercise. The CFS may, either in discussion with others or in any subsequent report, whether privately or publicly, quote the senders and the views they submitted in response to the consultation document. We will respect the wish of senders to remain anonymous and/or keep the views confidential in part or in whole, but if no such wish is indicated, it will be assumed that the sender can be named and his / her views be published for public information.

6.5 Any sender providing personal data to the CFS in his submission will have the right of access and correction with respect to such personal data. Any request for data access or correction of personal data should be made in writing to the focal point of contact specified in paragraph 6.1 above.

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