

Guidelines

**Food Adulteration
(Metallic Contamination)
(Amendment)
Regulation 2018**

February 2019

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Chapter 1 Introduction

Purpose

1.1 The Legislative Council completed its scrutiny of the Food Adulteration (Metallic Contamination) (Amendment) Regulation 2018 (“the Amendment Regulation”) in October 2018. The Amendment Regulation will come into operation on 1 November 2019. This “Guidelines on the Food Adulteration (Metallic Contamination) (Amendment) Regulation 2018” (“the Guidelines”) aims to assist the trade in having a better understanding of the Amendment Regulation, and to answer some frequently asked questions.

Disclaimer

1.2 The Guidelines, which should be read in conjunction with the Amendment Regulation, 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. 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 stipulates updated standards for metallic contamination in food.

1.5 The total number of metallic contaminants covered by the Amendment Regulation has increased from 7 to 14. On top of the 7 metals currently regulated (i.e. antimony, arsenic, cadmium, chromium, lead, mercury and tin), 7 additional metallic contaminants, namely barium, boron, copper, manganese, nickel, selenium and uranium, are regulated under the Amendment Regulation. The Amendment Regulation stipulates 144 maximum levels (MLs) for the 14 metallic contaminants in respect of different food / food groups in its Schedule, provides where necessary definitions for individual food / food groups, and

replaces / deletes obsolete clauses. A person must not import, consign, deliver, manufacture or sell for human consumption any specified food or compounded food which contains a specified metal in excess of any MLs.

1.6 Regulation 3 of the Amendment Regulation lays down the principles for the application of MLs on food in a dried, dehydrated or concentrated form and on compounded food.

1.7 For food / food groups without relevant MLs under the Amendment Regulation, the Centre for Food Safety (CFS) will conduct risk assessment to determine whether the food contains the metal concerned in an amount that is dangerous or prejudicial to health, thereby contravening regulation 3AA of the Amendment Regulation. Moreover, section 54 of the Public Health and Municipal Services Ordinance (Cap. 132) (“the Ordinance”) stipulates that all food for sale in Hong Kong, locally produced or imported, should be fit for human consumption.

1.8 Regulation 7 of the Amendment Regulation provides a 12-month grace period, from 1 November 2019 to 31 October 2020 (both dates inclusive), in relation to certain food.

Definitions

1.9 The followings are some technical terms relevant to the Guidelines as defined in the Amendment Regulation, and as appropriate, the Ordinance and related subsidiary legislation (sub. leg.) –

Aquatic animals—

- (a) includes—
 - (i) fish;
 - (ii) crustaceans;
 - (iii) molluscs, including bivalve molluscs, cephalopods, gastropods; and
 - (iv) any other aquatic invertebrate animals; but
- (b) does not include amphibians, marine mammals or reptiles.

Compounded food means food containing 2 or more ingredients.

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—

- (a) means any substance which—
 - (i) is used in the manufacture or preparation of food; and
 - (ii) becomes part of the food as finished, even if in altered form; but

- (b) excludes any additive within the meaning of regulation 2(1) of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. leg. W), i.e. any substance, not commonly regarded or used as food, which is added to, or used in or on, food at any stage to affect its keeping qualities, texture, consistency, appearance, taste, odour, alkalinity or acidity, or to serve any other technological function in relation to food, and includes processing aids in so far as they are added to, or used in or on, food as aforesaid, but does not include—
- (i) vitamins, minerals or other nutrients in so far as they are used solely for the purpose of fortifying or enriching food or of restoring the constituents of food;
 - (ii) herbs or spices when used as seasoning;
 - (iii) hops;
 - (iv) salt;
 - (v) yeast or yeast extracts;
 - (vi) the total products of any hydrolysis or autolysis of food protein;
 - (vii) starter cultures;
 - (viii) malt or malt extract;
 - (ix) any substance which is present in food solely as a result of its addition to animal, bird or fish feedingstuffs or its use in a process or treatment carried out in crop husbandry, animal husbandry, veterinary medicine or storage (including any pesticide, fumigant, sprout depressant or veterinary medicine); or
 - (x) air or water.

Metal includes antimony, arsenic, boron and selenium.

Milk means the normal mammary secretion of milking animals that is—

- (a) obtained from one or more milkings without either addition or extraction; and
- (b) intended for consumption as liquid milk or for further processing.

Secondary milk products means skimmed milk, partly skimmed milk, evaporated milk and milk powder.

Specified food means any food specified in column 2 of Part 2 of the Schedule.

Specified metal means a metal specified in column 1 of Part 2 of the Schedule.

Chapter 2 Interpretation of Maximum Level of Metal in Food in the Schedule

2.1 As stipulated in regulation 3(1) of the Amendment Regulation, a person must not import, consign, deliver, manufacture or sell for human consumption any specified food or compounded food which contains a specified metal in excess of the ML. The ML of each specified metal in each specified food is specified in Part 2 of the Schedule (see Figure 1).

Figure 1. Extract of Part 2 of the Schedule to the Amendment Regulation

Part 2			
Maximum Level of Metal in Food			
Column 1	Column 2	Column 3	Column 4
Metal	Food	Maximum Level (mg/kg)	Note
1. Antimony	Vegetables	1	
	Cereals	1	
	Meat of animal	1	Note 1
	Meat of poultry	1	Note 1
	Fish	1	Note 2
	Crabs, prawns and shrimps	1	Note 3

How to read Part 2 of the Schedule

2.2 Column 1, “Metal”, lists out the metals specified in Part 2 of the Schedule, including (1) antimony, (2) arsenic (expressed as total arsenic), (3) arsenic (expressed as inorganic arsenic), (4) barium, (5) boron, (6) cadmium, (7) chromium, (8) copper, (9) lead, (10) manganese, (11) mercury (expressed as methyl-mercury), (12) mercury (expressed as total mercury), (13) mercury (expressed as inorganic mercury), (14) nickel, (15) selenium, (16) tin, and (17) uranium.

2.3 Column 2, “Food”, lists out the food / food groups to which the ML applies.

2.4 Column 3, “Maximum level”, lists out the ML (expressed in the unit of “mg/kg”) of each specified metal in each specified food / food group. The ML applies to the edible portion of the food; or if applicable, the portion of the food specified in, or the food in the form specified in, a note referred to in column 4 of Part 2 of the Schedule in relation to the food. Under column 4, there are a total of 11 notes (see Figure 2 below). For example, the ML of antimony in crabs applies to whole commodity (including the gonads, liver and other digestive organs) after removal of shell and gills.

Figure 2. A list of notes under column 4 of Part 2 of the Schedule to the Amendment Regulation

- | |
|--|
| Note 1: Applies to edible portion after removal of bones (if any) and to fat from the meat. |
| Note 2: Applies to edible portion after removal of the digestive tract. |
| Note 3: Crabs—applies to whole commodity (including the gonads, liver and other digestive organs) after removal of shell and gills. |
| Note 4: Cephalopods—applies to edible portion after removal of shell and viscera. |
| Note 5: Scallops—applies to edible portion after removal of shell and viscera. |
| Note 6: Sea cucumbers—applies to whole commodity after removal of viscera. |
| Note 7: Applies to edible portion after removal of shell (if any) and viscera. |
| Note 8: Applies to fruit juices (not concentrated) or products reconstituted to the original juice concentration that are ready to drink. Also applies to nectars that are ready to drink. |
| Note 9: Applies to fruits or vegetables (as the case may be). |
| Note 10: Applies to products that are, or are reconstituted to be, ready to drink. |
| Note 11: Applies to beverages that are, or are reconstituted to be, ready to drink. |

Interpretation of specified food in column 2 of Part 2 of the Schedule

2.5 One of the key features of the Amendment Regulation is the adoption of the MLs of Codex Alimentarius Commission (Codex) unless otherwise specified. The food descriptions and nomenclatures in the Amendment Regulation also make reference to the Codex food classification and product definitions as appropriate. Details regarding the Codex food classification and definitions of various food commodities are available at the Codex website¹.

2.6 The hierarchy of major types of food listed in Part 2 of the Schedule to the Amendment Regulation as well as their respective food groups and relevant food items, drawing reference from the Codex food classification, is illustrated in Annex I. For example, since choisum (flowering white cabbage) is a type of “*Brassica leafy vegetables*”, the MLs specified for cadmium and lead in “*leafy vegetables (including Brassica leafy vegetables)*” are applicable to choisum even though there is no specific ML for choisum. For other metallic contaminants such as antimony, arsenic, chromium and mercury, there are no specific MLs for “*leafy vegetables (including Brassica leafy vegetables)*” in the Schedule. In such cases, since “*leafy vegetables (including Brassica leafy vegetables)*” falls under “*vegetables*”, those MLs specified for “*vegetables*” apply to “*leafy vegetables (including Brassica leafy vegetables)*” as well as choisum which belongs to the group.

2.7 Scallop is another example. Since scallop belongs to “*bivalve molluscs*”, the MLs specified for cadmium and lead in “*bivalve molluscs*” are applicable to scallop, even though there is no ML for scallop specified in the Schedule. On the other hand, the MLs of arsenic and mercury in “*bivalve molluscs*” are not specified in the Schedule whereas those for inorganic arsenic and total mercury in “*aquatic animals, other than fish*” are listed. Since “*bivalve molluscs*” belongs to “*aquatic animals*”, the MLs of inorganic arsenic and total mercury in “*aquatic animals, other than fish*” are applicable to “*bivalve molluscs*” as well as scallop which belongs to the group. Furthermore, note 5, i.e. “*scallops—applies to edible portion after removal of shell and viscera*”, is listed in column 4 opposite to the MLs for “*bivalve molluscs*” and “*aquatic animals, other than fish*”. Relevant MLs are therefore applicable to edible portion, i.e. adductor muscle of scallop *only*, but not its viscera including gill and digestive gland, as well as its gonad.

¹ Codex standards for various food commodities as well as its food classification are available at the Codex website under Codex texts (<http://www.fao.org/fao-who-codexalimentarius/home/en/>).

Regarding the Codex Classification of Foods and Animal Feeds (Second Edition) (CAC/MISC 4-1993), the latest revisions adopted by Codex (e.g. the revised classification on fruits adopted in 2012 and the revised classification on vegetables and cereal grains adopted in 2017) have not been incorporated in the aforementioned food classification document.

2.8 Interpretation of certain other specified food is also laid down in Part 1 of the Schedule, as set out under paragraph 1.9 of the Guidelines.

Specified food that has gone through a process of drying, dehydration or concentration

2.9 According to regulation 3(2)(b) of the Amendment Regulation, “the ML of a specified metal in a specified food that has gone through a process of drying, dehydration or concentration is to be proportionally adjusted according to the change in the concentration of the metal in the food caused by the process.” Dried seafood, dried vegetables (including dried mushrooms) and concentrated fruit juice are common examples of food that have gone through a process of drying, dehydration or concentration.

2.10 The above principle is not applicable to any ML that is already established for specified food in a dried, dehydrated or concentrated form, e.g. husked rice, polished rice, wheat flour, pulses, “*tea, green, black*”, etc.

2.11 Two examples are provided below to illustrate the application of the above principle:

Example 1 – cadmium in dried oyster

- Search for the ML of cadmium in oyster laid down in Part 2 of the Schedule,
 - ⇒ oyster belongs to “*bivalve molluscs*”;
 - ⇒ the ML of cadmium in “*bivalve molluscs*” is 2 mg/kg;
 - ⇒ i.e. the ML of cadmium in oyster is 2 mg/kg.
- Look up the water content of fresh and dried oysters from reliable database(s) or determine their water content by conducting laboratory analysis, for example,
 - ⇒ water content of fresh oyster = 79.2 to 87.1%²
 - ⇒ water content of dried oyster = 13.1%³

² References: ASEAN Food Composition Database (Electronic version 1, February 2014); China Food Composition (Book 1, 2nd Edition) (available in Chinese); Taiwan Food and Drug Administration Food Nutrients & Composition Database (available in Chinese).

³ Laboratory test result of water content of dried oyster sample.

- Calculate the adjusted ML of cadmium in dried oyster:

$$\frac{(100\% - \text{“Water content in dried oyster” } (\%))}{(100\% - \text{“Water content in fresh oyster” } (\%))} \times \text{ML}$$

$$= 8.4 \text{ to } 13.5 \text{ mg/kg}$$

In order words, the cadmium content of the dried oyster sample concerned shall not exceed 13.5 mg/kg.

- On the other hand, the laboratory test result of cadmium in dried oyster may be proportionally adjusted based on the formula below for comparison with the ML of 2 mg/kg for cadmium in fresh oyster:

$$\frac{(100\% - \text{“Water content in fresh oyster” } (\%))}{(100\% - \text{“Water content in dried oyster” } (\%))} \times \text{Laboratory test result (mg/kg)}$$

Example 2 – Lead in concentrated (ten times (10X)) orange juice

- Search for the ML of lead in orange juice laid down in Part 2 of the Schedule,
 \Rightarrow orange juice belongs to “*fruit juices, other than fruit juices exclusively from berries and other small fruits*”;
 \Rightarrow the ML of lead in “*fruit juices, other than fruit juices exclusively from berries and other small fruits*” is 0.03 mg/kg;
 \Rightarrow i.e. the ML of lead in orange juice is 0.03 mg/kg.
- Obtain the concentration factor from the food manufacturer / supplier:
 \Rightarrow 10X (for this example)
- Calculate the adjusted ML of lead in concentrated (10X) orange juice:
 $\Rightarrow 0.03 \text{ mg/kg} \times 10 = \underline{0.3 \text{ mg/kg}}$

In other words, the lead content of concentrated (10X) orange juice shall not exceed 0.3 mg/kg.

2.12 The water content of the primary food commodity and food in its dried, dehydrated or concentrated form can be derived from:

- (a) laboratory test results of water content of a food sample before and after drying, dehydration or concentration; and / or
- (b) generally accepted data (e.g. food composition database) regarding the water content of the processed food and its unprocessed counterparts.

2.13 It is important to note that water content of a food sample before and

after drying or dehydration may vary with a number of factors including species, seasons, geographical locations, processing requirements, etc. Therefore, direct laboratory analysis of water content of the food sample before and after processing will provide a better estimate of the “conversion factor”⁴ for adjusting the change in the concentration of the metal in the food concerned caused by the process of drying or dehydration. If generally accepted data is used, the trade should ensure that the data sources are accurate and reputable. Examples of food composition databases from adjacent regions are listed in Annex II.

Compounded food

2.14 As stipulated in regulation 3(4) of the Amendment Regulation, “if all ingredients of a compounded food are specified food, the ML of a specified metal in the compounded food is the sum of the ML of the specified metal in each ingredient multiplied by the proportion, by weight, of the ingredient in the compounded food.” Ingredient means any substance which is used in the manufacture or preparation of food and becomes part of the food as finished, even if in altered form, but excludes any additive within the meaning of regulation 2(1) of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132 sub. Leg. W).

2.15 Two examples to illustrate the above principle are provided below –

Example 1: Cadmium in mixed vegetable salad

- Look up the recipe of the concerned food product,
 - ⇒ assuming that a 100 g mixed vegetable salad sample contains 30 g of sliced cucumber (i.e. 30% of the mixed salad by weight), 50 g of romaine lettuce (i.e. 50% of the mixed salad by weight) and 20 g of shredded carrot (i.e. 20% of the mixed salad by weight).
- Search for the MLs of cadmium in each of the above ingredients specified in Part 2 of the Schedule, i.e.
 - (i) the ML of cadmium in cucumber (i.e. “*fruiting vegetables, Cucurbits*”) = 0.05 mg/kg
 - (ii) the ML of cadmium in romaine lettuce (i.e. “*leafy vegetables (including Brassica leafy vegetables)*”) = 0.2 mg/kg
 - (iii) the ML of cadmium in carrot (i.e. “*root and tuber vegetables*”) = 0.1 mg/kg

⁴ Conversion factor =
 $(100\% - \text{“Water content in the fresh food” } (\%)) / (100\% - \text{“Water content in the dried food” } (\%))$

- Calculate the adjusted ML of cadmium in mixed vegetable salad

$$= (\text{the ML of cadmium in sliced cucumber}) \times [\% \text{ of sliced cucumber in mixed vegetable salad (by weight)}] + (\text{the ML of cadmium in romaine lettuce}) \times [\% \text{ of romaine lettuce in mixed vegetable salad (by weight)}] + (\text{the ML of cadmium in shredded carrot}) \times [\% \text{ of shredded carrot in mixed vegetable salad (by weight)}]$$

$$= 0.05 \text{ mg/kg} \times 30\% + 0.2 \text{ mg/kg} \times 50\% + 0.1 \text{ mg/kg} \times 20\%$$

$$= \underline{0.135 \text{ mg/kg}}$$

In other words, the cadmium content of the mixed vegetable salad sample concerned shall not exceed 0.135 mg/kg.

Example 2: Lead in dried apricot

- Look up the “List of ingredients” of the concerned food product,
 \Rightarrow Ingredients: Apricot, preservative (sulphur dioxide)
- Search for the MLs of lead in each ingredient specified in Part 2 of the Schedule:
 - (i) the ML of lead in apricot (i.e. “fruits, other than cranberry, currants and elderberry”) = 0.1 mg/kg
 - (ii) Sulphur dioxide is not considered to be an ingredient under regulation 3 of the Amendment Regulation since it is used as an additive.

In other words, the lead content of the dried apricot sample concerned can be compared with the ML of 0.1 mg/kg for lead in “fruits, other than cranberry, currants and elderberry”, with the application of appropriate conversion factor as mentioned in paragraph 2.13.

Conducting risk assessment

2.16 For food / food groups without relevant MLs under the Amendment Regulation, CFS will continue to conduct risk assessment to determine whether the food contains the metal concerned in an amount that is dangerous or prejudicial to health, thereby contravening regulation 3AA of the Amendment Regulation. Moreover, section 54 of the Ordinance stipulates that all food for sale in Hong Kong, locally produced or imported, should be fit for human consumption. MLs have not been set for each and every type of food that may contain a metallic contaminant. Rather, following the Codex’s principle that MLs should only be set for food / food groups in which the contaminants may be found in amounts that are significant for the total exposure of the consumer, i.e. the general population, MLs have been set for those types of food on an absolutely

necessary basis only, so as to strike a balance between safeguarding public health and avoiding undue regulation.

2.17 Risk assessment is a science-based method which is well-recognised in the international arena. The acceptability of the potential risks upon consumption of a food sample containing metallic contaminants is judged on the basis of comparison of relevant health-based guidance values (HBGVs)⁵ or reference end-points, with the dietary exposure estimates as appropriate, i.e., the outcome of risk assessment process. CFS conducts risk assessment on the reported level of metallic contaminants in a food sample based on the available local food consumption pattern⁶ and the appropriate HBGVs.

2.18 International food safety authorities such as the Joint Food and Agriculture Organization of the United Nations (FAO) / World Health Organization (WHO) Expert Committee on Food Additives (JECFA) have conducted extensive evaluations on the possible adverse health effects of various metallic contaminants and established appropriate HBGVs based on the available toxicological data.

Testing or analysis of metallic contamination in food

2.19 During the analysis of metallic contamination in food, laboratories are advised to note that the portion of the commodity to which the ML applies. As mentioned in paragraph 2.4, the ML of a specified metal in each specified food applies to the edible portion of the food; or if applicable, the portion of the food specified in, or the food in the form specified in, a note referred to in column 4 of Part 2 of the Schedule in relation to the food.

2.20 In addition, for the treatment of fruit or vegetable samples, Codex has the following recommendations:

⁵ HBGV is an estimate of the amount of a chemical that can be ingested over a defined time period (e.g. 24 hours or lifetime) without any appreciable health risks. For example, acute reference dose, acceptable daily intake, provisional tolerable monthly intake, etc.

⁶ The Food and Environmental Hygiene Department (FEHD) conducted “The First Hong Kong Population-based Food Consumption Survey” in 2005-2007. CFS has commenced “The Second Hong Kong Population-based Food Consumption Survey” in April 2018. Report of the first survey and other relevant information are available at the CFS’ website (https://www.cfs.gov.hk/english/programme/programme_firm/programme_fcs.html).

Table 1. Portion of the Commodity to Which the ML Applies

Food items	Recommendations from Codex: Portion of the commodity to which the ML applies (and which is analysed)
Fruit	<p>Berries and other small fruits, including cranberry and elderberry: whole commodity after removal of caps and stems.</p> <p>Currants: fruit with stem.</p> <p>Pome fruits: whole commodity after removal of stems.</p> <p>Stone fruits, dates and olives: whole commodity after removal of stems and stones, but the level calculated and expressed on the whole commodity without stem.</p> <p>Pineapple: whole commodity after removal of crown.</p> <p>Avocado, mango and similar fruit with hard seeds: whole commodity after removal of stone but calculated on whole fruit.</p>
Bulb vegetables	<p>Bulb onions: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.</p> <p>Green onions: whole vegetables after removal of roots and adhering soil.</p>
Brassica vegetables, other than Brassica leafy vegetables	<p>Head cabbages: whole commodity as marketed, after removal of obviously decomposed or withered leaves.</p> <p>Cauliflower and broccoli: flower heads (immature inflorescence only).</p> <p>Brussels sprouts: “buttons” only.</p> <p>Kohlrabi: “tuber-like enlargement of the stem” only.</p>
Fruiting vegetables, Cucurbits and Fruiting vegetables, other than Cucurbits	Whole commodity after removal of stems.
Leafy vegetables (including Brassica leafy vegetables)	Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.
Legume vegetables	Whole commodity, unless otherwise specified.
Pulses	Whole commodity.
Root and tuber vegetables	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity).

Food items	Recommendations from Codex: Portion of the commodity to which the ML applies (and which is analysed)
	Potato: peeled potato.
Stalk and stem vegetables	Whole commodity as marketed after removal of obviously decomposed or withered leaves. Rhubarb: leafy stem only. Globe artichoke: flower head only. Celery and asparagus: removing adhering soil.

2.21 Further information on determination of metallic contamination in food, particularly inorganic arsenic and methylmercury, is available on the websites of CFS⁷ and the Government Laboratory (GL)⁸.

Grace period

2.22 To strike a balance between the public expectation that the Amendment Regulation should be in place as soon as practicable, and the need to allow sufficient time for the trade to get prepared for the changes brought about by the Amendment Regulation, the Amendment Regulation will come into operation on 1 November 2019.

2.23 Nevertheless, as stated in regulation 7 of the Amendment Regulation, “during the period between 1 November 2019 and 31 October 2020 (both dates inclusive), a person who does an act in relation to any food (other than any food specified in paragraph 2.24 below) that contains a metal at any level is taken not to have contravened regulation 3 if doing the act immediately before 1 November 2019 would not have contravened these Regulations as in force immediately before 1 November 2019.” For food specified in paragraph 2.24 below, if it contains a metal at a level that does not exceed the existing maximum permitted concentration but exceeds relevant ML under the Amendment Regulation, it will contravene regulation 3 on or after 1 November 2019, and therefore that food must not be imported, consigned, delivered, manufactured or sold for human consumption from 1 November 2019 onwards.

2.24 The specified food as mentioned in paragraph 2.23 above are fruit and

⁷ CFS’ website on Food Adulteration (Metallic Contamination) Regulations. Available from: URL: https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_PA_Food_Adulteration_Metallic_Contamination.html

⁸ GL’s website on Training and Development Collaborations. Available from: URL: <https://www.govtlab.gov.hk/english/development.htm>

vegetable and their juice, meat and edible offal and animal and poultry, aquatic animal and poultry egg which—

- (a) has not been subjected to a process of preservation; or
- (b) has been preserved by chilling but not freezing.

2.25 In other words, given that food types other than those specified in paragraph 2.24 normally have a longer shelf / storage life, during the period between 1 November 2019 and 31 October 2020 (both dates inclusive), their levels of metallic contamination would not contravene the Amendment Regulation if they comply with the existing maximum permitted concentrations prior to the commencement of the Amendment Regulation. In any event, all food must comply with the Amendment Regulation starting from 1 November 2020 when the 12-month grace period has ended.

Chapter 3 Frequently Asked Questions

The Amendment Regulation

- 1. Why haven't the existing maximum permitted concentrations for food categories of "all food in solid / liquid form" been retained under the Amendment Regulation? Would retaining existing food categories of "all food in solid / liquid form" provide more comprehensive control over the metallic contamination in food than replacing the existing food categories of "all food in solid / liquid form" with specific MLs targeting individual food / food groups?**

Most jurisdictions nowadays do not set MLs for all types of food (including food in solid and liquid forms). This practice is in line with Codex's principle that MLs should only be set for food / food groups in which the contaminants may be found in amounts that are significant for the total exposure of the consumer, i.e. the general local population.

Setting specific MLs targeting individual food / food groups will be conducive to a more focused, tailor-made and proportionate regulation over metallic contamination in food, calibrated in accordance with the known risks associated with the food item concerned.

For food / food groups without relevant MLs under the Amendment Regulation, CFS will continue to conduct risk assessment to determine whether the food contains the metal concerned in an amount that is dangerous or prejudicial to health, thereby contravening regulation 3AA of the Amendment Regulation. Moreover, section 54 of the Ordinance stipulates that all food for sale in Hong Kong, locally produced or imported, should be fit for human consumption.

- 2. Are "health products" subject to regulation under the Amendment Regulation?**

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 Food Adulteration (Metallic Contamination) Regulations (Cap. 132V). According to the Ordinance, food includes articles and substances used as ingredients in the preparation of food. 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.

3. What is the definition of “food” under the Amendment Regulation? Are food ingredients that would not be directly consumed (such as dried monk fruit or Lo han guo which would generally be used for the preparation of tea or soup) subject to regulation under the Amendment Regulation?

The definition of “food” in the Amendment Regulation will be the same as that adopted in the Ordinance. “Food” (食物) 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).

According to the definition of food mentioned above, “food” includes articles and substances used as ingredients in the preparation of food. Therefore, if the relevant article or substance can be proved to be used for the preparation of food, it can be considered as food. On the other hand, products falling under the definitions of Chinese herbal medicine or proprietary Chinese medicine in the Chinese Medicine Ordinance (Cap. 549) are governed by that Ordinance.

For example, “Luo han guo” is not listed in Schedule 1 or 2 to Cap. 549. It is not considered as Chinese herbal medicine. “Luo han guo” or beverage solely prepared from “Luo han guo” would therefore be considered as food and subject to the Amendment Regulation. On the other hand, “Luo han guo” is not considered as fruit or tea according to the Codex food

classification. In other words, the relevant MLs of metal listed in Part 2 of the Schedule to the Amendment Regulation do not apply to “Luo han guo”. For food / food groups without relevant MLs under the Amendment Regulation, CFS will conduct risk assessment to determine whether the food contains the metal concerned in an amount that is dangerous or prejudicial to health, thereby contravening regulation 3AA of the Amendment Regulation. Moreover, section 54 of the Ordinance stipulates that all food for sale in Hong Kong, locally produced or imported, should be fit for human consumption.

4. According to the Amendment Regulation, do edible fungi only have MLs for lead and mercury?

According to the Codex food classification, edible fungi are vegetables. Therefore, MLs set for vegetables are applicable to edible fungi unless otherwise specified. In other words, MLs applicable to vegetables under the Amendment Regulation in respect of antimony, arsenic, cadmium and chromium cover edible fungi. There are also specific MLs for edible fungi for lead and mercury. On the other hand, the ML of tin in canned food are also applicable to canned edible fungi products. As for dried edible fungi, use of conversion factor is generally appropriate in order to obtain a primary judgement of the levels of metallic contamination in these products (see paragraphs 2.9 to 2.13 for details).

5. Do canned foods refer to “foods in metal cans” only under the Amendment Regulation?

According to the Codex food definitions, canned foods are generally referred to food products which are processed in an appropriate manner, before or after being hermetically sealed in a container. Therefore, canned foods do not necessarily limit to foods in metal cans only (please refer to the Codex website for details).

6. Will it be an offence under the Amendment Regulation if a specified metal is detected in a specified food at level exceeding the prescribed ML?

It will be an offence under the Amendment Regulation when a person imports, consigns, delivers, manufactures or sells for human consumption any specified food or compounded food which contains a specified metal in excess of the ML or any metal in an amount that is dangerous or prejudicial to health. Offenders are liable to a maximum fine of \$50,000 and six months' imprisonment upon conviction.

7. Will it be an offence under the Amendment Regulation if a specified metal is detected in a food apparently without relevant ML laid down in Part 2 of the Schedule to the Amendment Regulation?

The trade may wish to check whether the food concerned is (a) a specified food that has gone through a process of drying, dehydration or concentration; or (b) a compounded food with all ingredients being specified food first. If (a), the trade should ascertain the corresponding food / food group of the food concerned prior to the process of drying, dehydration or concentration and then the ML of a specified metal in the food concerned is to be proportionally adjusted according to the change in the concentration of the metal in the food caused by the process (see paragraphs 2.9 to 2.13 for details). If (b), then the ML of the specified metal in the compounded food is the sum of the ML of the specified metal in each ingredient multiplied by the proportion by weight, of the ingredient in the compounded food (see paragraphs 2.14 to 2.15 for details).

If the food concerned is neither (a) nor (b) above, the general principle for food / food groups without relevant MLs, as set out in regulation 3AA of the Amendment Regulation, is that the import, consignment, delivery, manufacture or sale of the concerned food for human consumption will only be allowed if the consumption of the food concerned is not dangerous or prejudicial to health. In deciding whether the consumption of the food concerned is dangerous or prejudicial to health, CFS will conduct risk assessment.

8. At what levels will CFS collect food samples for conducting surveillance for the Amendment Regulation?

Through the Food Surveillance Programme, CFS takes food samples at import, wholesale and retail levels for microbiological testing and chemical analysis to ensure that food for sale is fit for human consumption and in compliance with relevant food safety regulations, including the Amendment Regulation.

9. Will the Government provide recommended testing methods for all the metallic contaminants specified in the Amendment Regulation?

The Government has conducted meetings with the testing laboratories and other stakeholders to discuss the determination of metallic contaminants, particularly inorganic arsenic and methylmercury, in food. Relevant information can be found at the websites of CFS and GL. Based on the actual requirements, equipment, resources available, laboratories may develop testing methods, making reference to international or national technical criteria and reference testing methods.

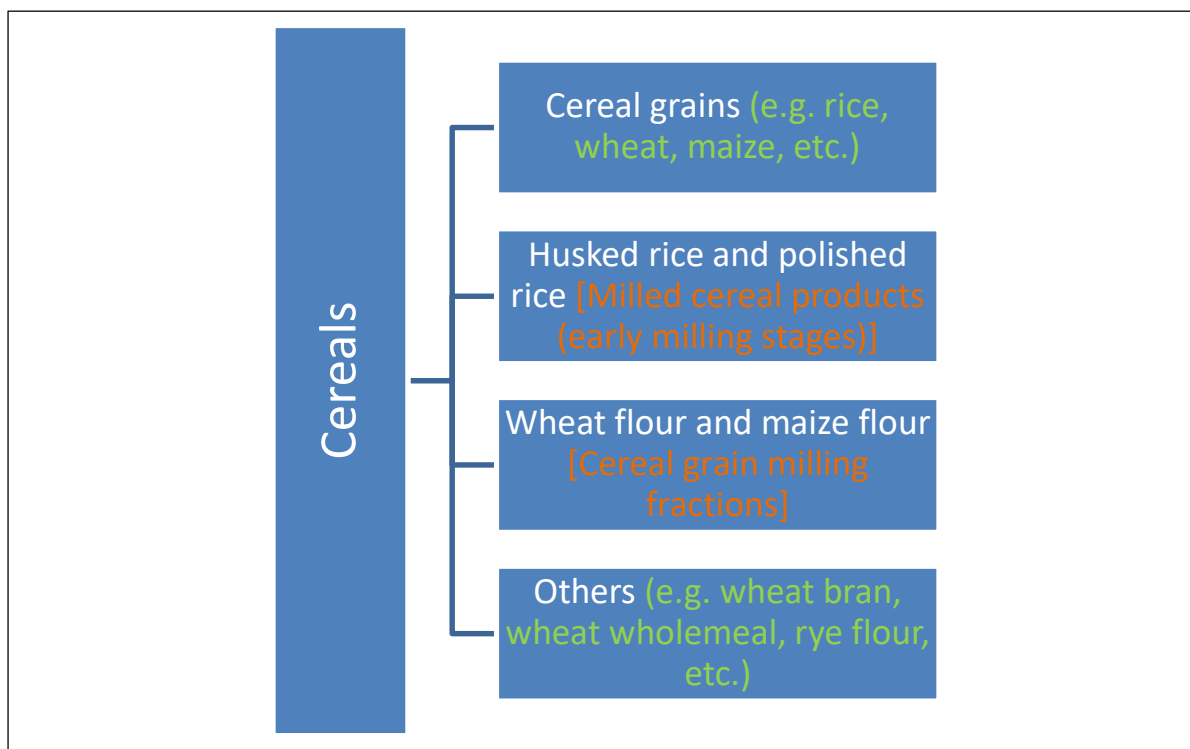
For MLs expressed as methylmercury, the trade may decide to use their own screening when applying the ML for methylmercury by analysing total mercury in the food sample concerned. In general, if the level of total mercury is below or equal to the ML expressed as methylmercury, no further testing is required and the sample is determined to be in compliance with the ML expressed as methylmercury. If the level of total mercury is above the ML expressed as methylmercury, further testing is necessary to determine if the level of methylmercury in the food sample concerned is above the ML. The aforesaid principle may also be applicable to inorganic arsenic.

10. Is it appropriate if I only test the edible portion (e.g. orange pulp) of a food sample?

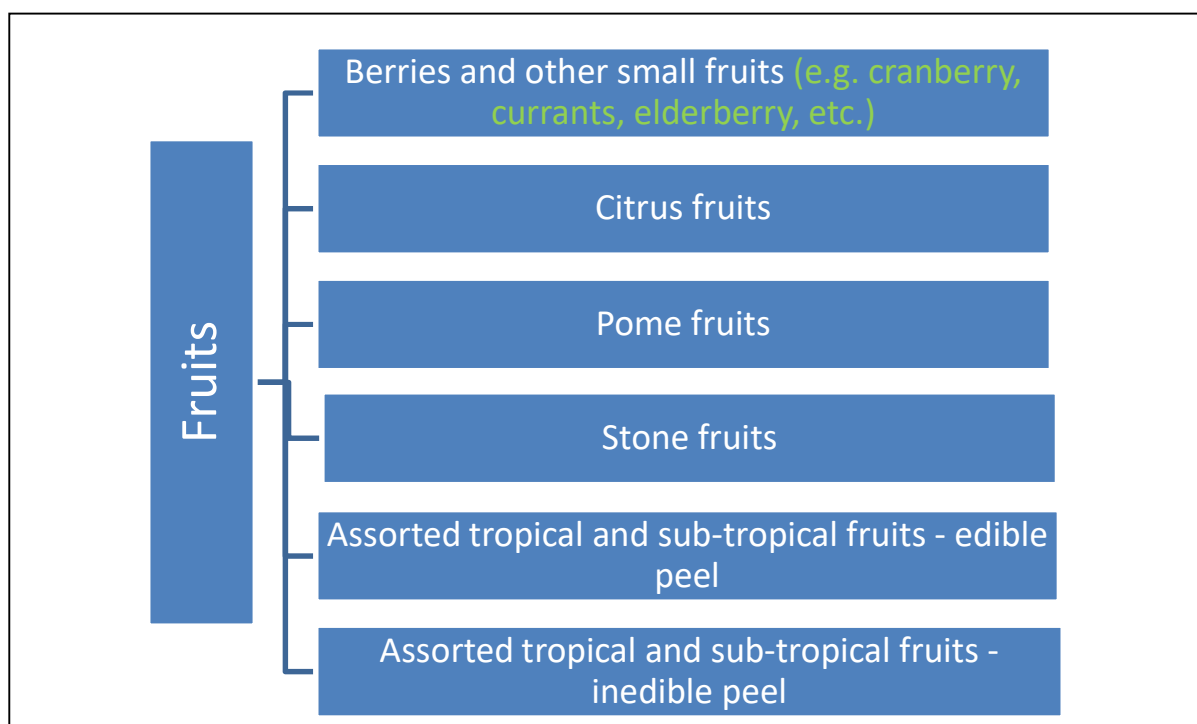
During the analysis of metallic contamination in food, laboratories are advised to note the portion of the commodity to which the ML applies. As stipulated in regulation 3(3), the ML of a specified metal in each specified food applies to the edible portion of the food; or if applicable, the portion of the food specified in, or the food in the form specified in, a note referred to in column 4 of Part 2 of the Schedule in relation to the food. In addition, Codex has provided recommendations regarding the analysis of fruit and vegetable samples (see paragraphs 2.19 and 2.20 for details).

Hierarchy of Food Grouping under the Amendment Regulation

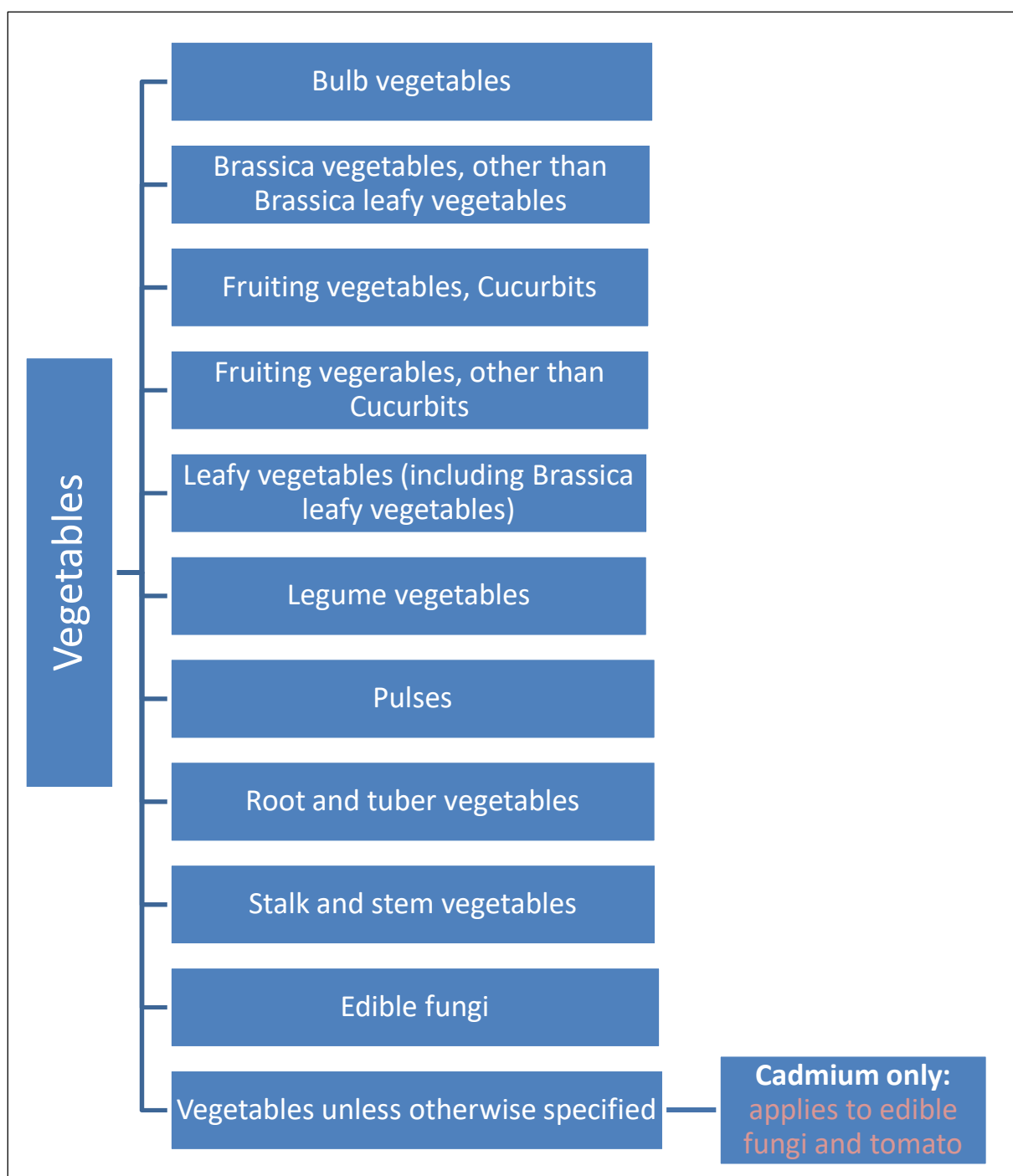
I. Cereals



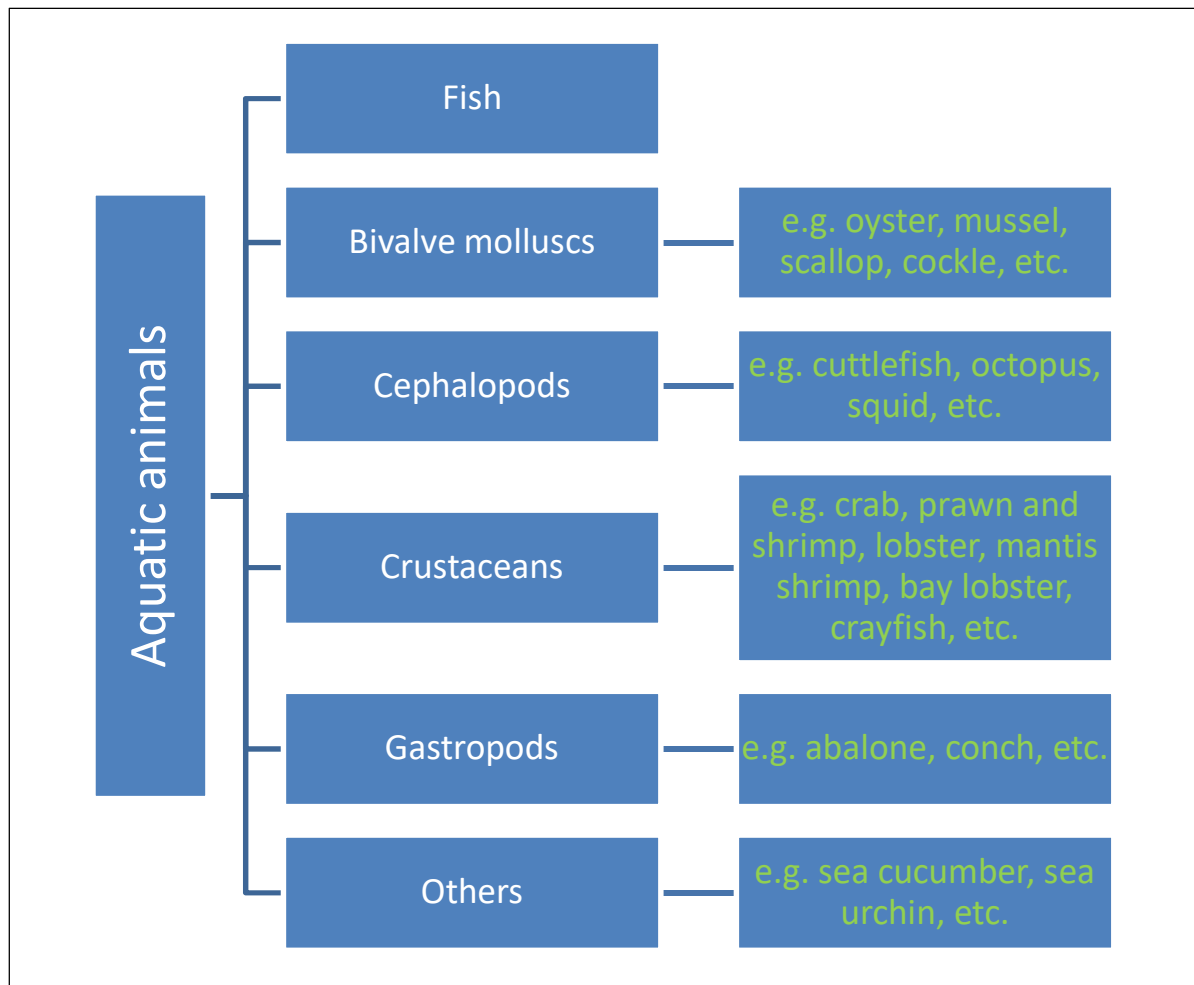
II. Fruits



III. Vegetables



IV. Aquatic animals



Examples of Food Composition Databases from Adjacent Regions

1. ASEAN – Institute of Nutrition, Mahidol University (2014). ASEAN Food Composition Database, Electronic version 1, February 2014, Thailand. Available from: URL: http://www.inmu.mahidol.ac.th/aseanfoods/composition_data.html
2. The Mainland – National Institute of Nutrition and Food Safety, China CDC (2009). China Food Composition (Book 1, 2nd Edition) (available in Chinese). Beijing: Peking University Medical Press.
3. Japan – Ministry of Education, Culture, Sports, Science and Technology (2015). Standard Tables of Food Composition in Japan, Seventh Revised Edition. Available from: URL: http://www.mext.go.jp/en/policy/science_technology/policy/title01/detail01/sdetail01/sdetail01/1385122.htm
4. Korea – National Institute of Agricultural Sciences. Korean Standard Food Composition Table, The 9th Revision. Available from: URL: <http://koreanfood.rda.go.kr/eng/fctFoodSrchEng/engMain>
5. Taiwan - Taiwan Food and Drug Administration. Food Nutrients & Composition Database (New Edition) (available in Chinese). Available from: URL: <https://consumer.fda.gov.tw/Food/TFND.aspx?nodeID=178>

