Update on the Regulation of Metallic Contamination in Food in Hong Kong

Seminar on Testing and Certification for Food Safety
5 March 2019

食物環境衞生署
Food and Environmental Hygiene Department

食物安全中心
Centre for Food Safety

Outline

- Regulatory framework for food in Hong Kong
- Food Adulteration (Metallic Contamination) (Amendment) Regulation 2018 ("the Amendment Regulation")

Regulatory framework for food in Hong Kong

Regulatory framework for food in Hong Kong (1)

Local food laws

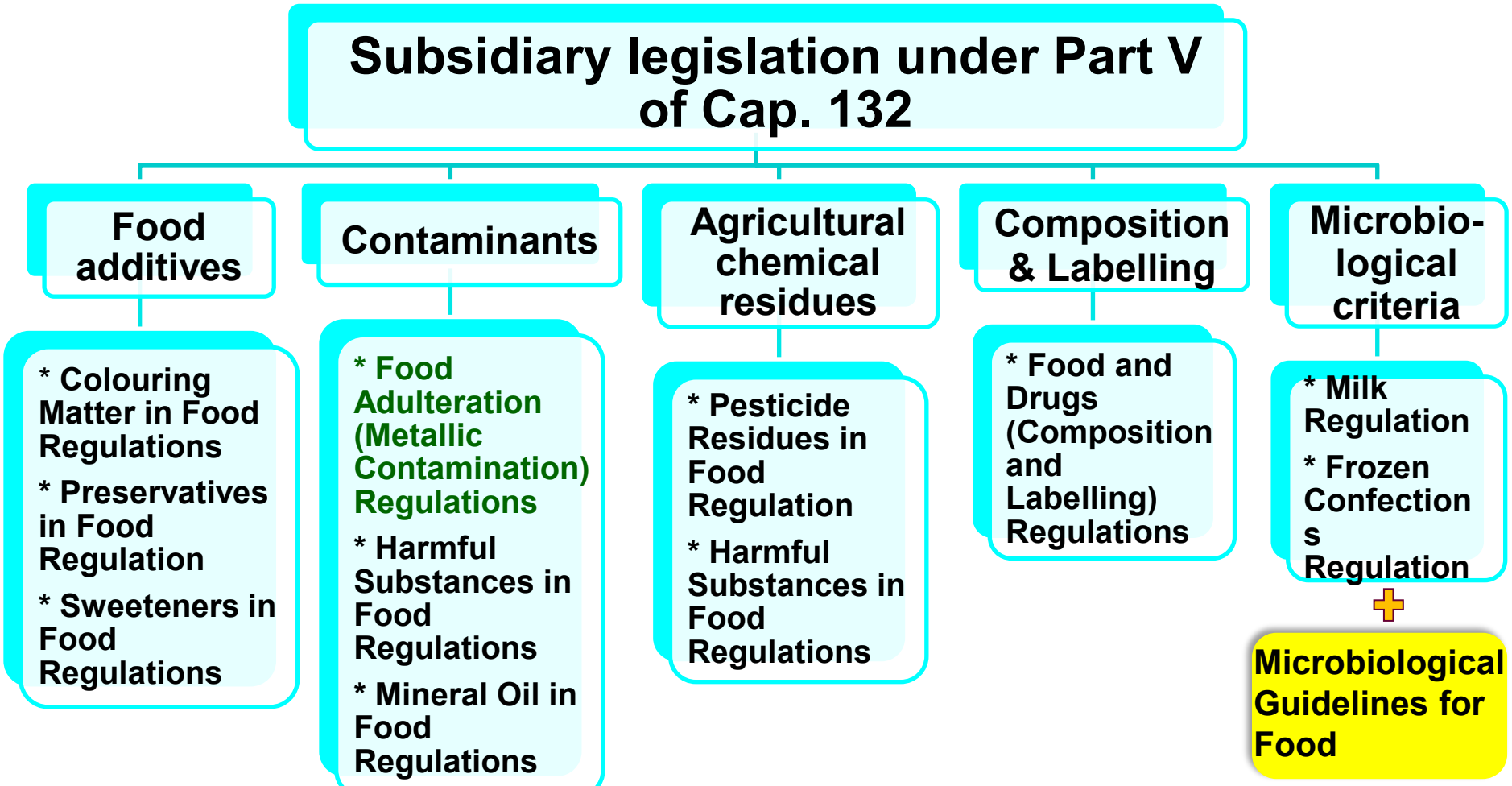
Public Health and Municipal Services Ordinance (Cap. 132) Part V

* Section 52: General protection for food purchasers
* Section 54: Offences in connection with the sale of unfit food
* Subsidiary legislations

Food Safety Ordinance (Cap. 612)

* Registration scheme for food importers and distributors
* Requirement for food traders to maintain proper records
* Empowerment of the authorities to tighten import control on specific food types / make orders to prohibit the import and supply of problem foods and order the recall

Regulatory framework for food in Hong Kong (2)



Review and update of local food safety standards

- **Objectives:**
  - Better protecting public health;
  - Facilitating effective regulation; and
  - Promoting harmonisation between local and international standards.

- **Factors for consideration:**
  - Public health concern (with reference to the local risk assessment results based on local food consumption pattern);
  - Availability of local and international food safety standards;
  - Occurrence data;
  - Stakeholder concern.

Examples of recent amendments (effective dates)

- 1 August 2014: Pesticide Residues in Food Regulation
- 5 December 2015: Imported Game, Meat, Poultry and Eggs Regulations
- 13 December 2015: Requirements on nutritional composition and nutrition labelling of infant formulae (under the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014)
- 13 June 2016: Requirements on nutrition labelling of follow-up formulae and prepackaged food for infants and young children (under the Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014)

Food Adulteration (Metallic Contamination) Regulations (Cap. 132V)

Regulation of metallic contamination in food in Hong Kong (1)

- **Public Health and Municipal Services Ordinance (Cap. 132):**
  - **Section 54: all food for sale must be fit for human consumption.**
- **Food Adulteration (Metallic Contamination) Regulations (Cap. 132V) (the Regulations):**
  - **Regulation 3(1) of the Regulations prohibits the import, consignment, delivery, manufacture or sale, for human consumption, of any food containing any metal in greater concentration than as prescribed in the First or Second Schedule to the Regulations, or in such amount as to be dangerous or prejudicial to health.**

Regulation of metallic contamination in food in Hong Kong (2)

- The First and Second Schedules to the Regulations: 19 maximum permitted concentrations (MPCs) of 7 metallic contaminants, namely arsenic, antimony, cadmium, chromium, lead, mercury and tin, in food.
- Food categories of 4 metallic contaminants (namely arsenic, lead, mercury and tin) cover “all food in solid / liquid form”.

The Regulations

Schedule:	1	MAXIMUM PERMITTED CONCENTRATION OF CERTAIN METALS NATURALLY PRESENT IN SPECIFIED FOODS		30/06/1997

[regulation 3]

A Metal	B Description of food	C Maximum permitted concentration in parts per million
Arsenic (AS_2O_3)	Solids being fish and fish products	6
	Solids being shellfish and shellfish products	10

Schedule:	2	MAXIMUM PERMITTED CONCENTRATION OF CERTAIN METALS PRESENT IN SPECIFIED FOODS		30/06/1997

[regulation 3]

A Metal	B Description of food	C Maximum permitted concentration in parts per million
Antimony (Sb)	Cereals and vegetables	1
	Fish, crab-meat, oysters, prawns and shrimps	1
	Meat of animal and poultry	1
Arsenic (AS_2O_3)	Solids other than- (i) fish and fish products; and (ii) shellfish and shellfish products	1.4
	All food in liquid form	0.14
Cadmium (Cd)	Cereals and vegetables	0.1
	Fish, crab-meat, oysters, prawns and shrimps	2
	Meat of animal and poultry	0.2
Chromium (Cr)	Cereals and vegetables	1
	Fish, crab-meat, oysters, prawns and shrimps	1
	Meat of animal and poultry	1
Lead (Pb)	All food in solid form	6
	All food in liquid form	1
Mercury (Hg)	All food in solid form	0.5
	All food in liquid form	0.5
Tin (Sn)	All food in solid form	230
	All food in liquid form	230

Cover all food in solid/ liquid forms

Principles for amending the Regulations

1) to replace the existing food categories of "all food in solid form" and "all food in liquid form" with specific MLs targeting individual food / food groups, with a view to aligning with the Codex principle and modern international regulatory trends of specifying metallic contamination standards for individual food / food groups of significant dietary exposure;
2) to adopt Codex MLs unless otherwise justified;
3) to establish MLs for food / food groups which are of significance to the population in Hong Kong and for which there are no relevant Codex MLs;
4) to update the food descriptions and nomenclatures in the Regulations, with reference to the available Codex's food descriptions and nomenclatures or those of other economies as appropriate; and
5) to incorporate interpretation of MLs into the Regulations, given that there is currently no interpretation in the Regulations on how the MPCs can be applied to food in a dried, dehydrated or concentrated form; as well as multi-ingredient products (i.e. compounded food).

The Amendment Regulation

(Made by SFH under section 55 of the main Ordinance (Cap. 132))

Timeline

- **Public consultation on the proposed amendments – Jun to Sep 2017**
- **The Amendment Regulation**
  - **Publication in the Gazette – 8 Jun 2018**
  - **Tabling at the Legislative Council (LegCo) for negative vetting – 13 Jun 2018**
  - **Completion of scrutiny of the Amendment Regulation – 10 Oct 2018**
  - **Date of commencement – 1 Nov 2019**

Overview of the Amendment Regulation

- **Total number of metallic contaminants increase from the existing 7 to 14**
  - **Additional metals: barium, boron, copper, manganese, nickel, selenium and uranium**
- **Total number of MLs has increased from the existing 19 to 144**
  - **Of these 144 MLs, 85 made reference to Codex standards.**
  - **New MLs for cadmium in polished rice and methylmercury in predatory fish are more stringent than corresponding Codex standards.**

Key features

- Date of commencement
- Interpretation
- Food prohibited for sale, etc. if its metal content exceeds certain level
  - Specified food that has gone through a process of drying, dehydration or concentration
  - Portion of the commodity to which the ML applies
  - All ingredients of a compounded food are specified food
- Food prohibited for sale, etc. if its metal level is dangerous or prejudicial to health
- Amendment of Schedules
- Provision to provide for a 12-month grace period in relation to certain food

Commencement

- **Comes into operation on 1 November 2019**
  - **For transitional period arrangement, see Regulation 7**

Interpretation

- **Amended definition**
  - **Metal includes antimony, arsenic, boron and selenium**
- **New definition**
  - **Maximum level**
- **Definitions of some other terms can be found in other regulations and Part 1 of the Schedule**

Other definitions

- **Regulation 3**
  - compounded food
  - ingredient
  - specified food
  - specified metal
- **Part 1 of Schedule**
  - aquatic animals
  - follow-up formula
  - infant formula
  - milk
  - secondary milk products

Regulation 3 substituted (1)

(1) 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.

Extract of Part 2 of the Schedule to the Amendment Regulation

Part 2

Maximum Level of Metal in Food

	Column 1 Metal	Column 2 Food	Column 3 Maximum Level (mg/kg)	Column 4 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

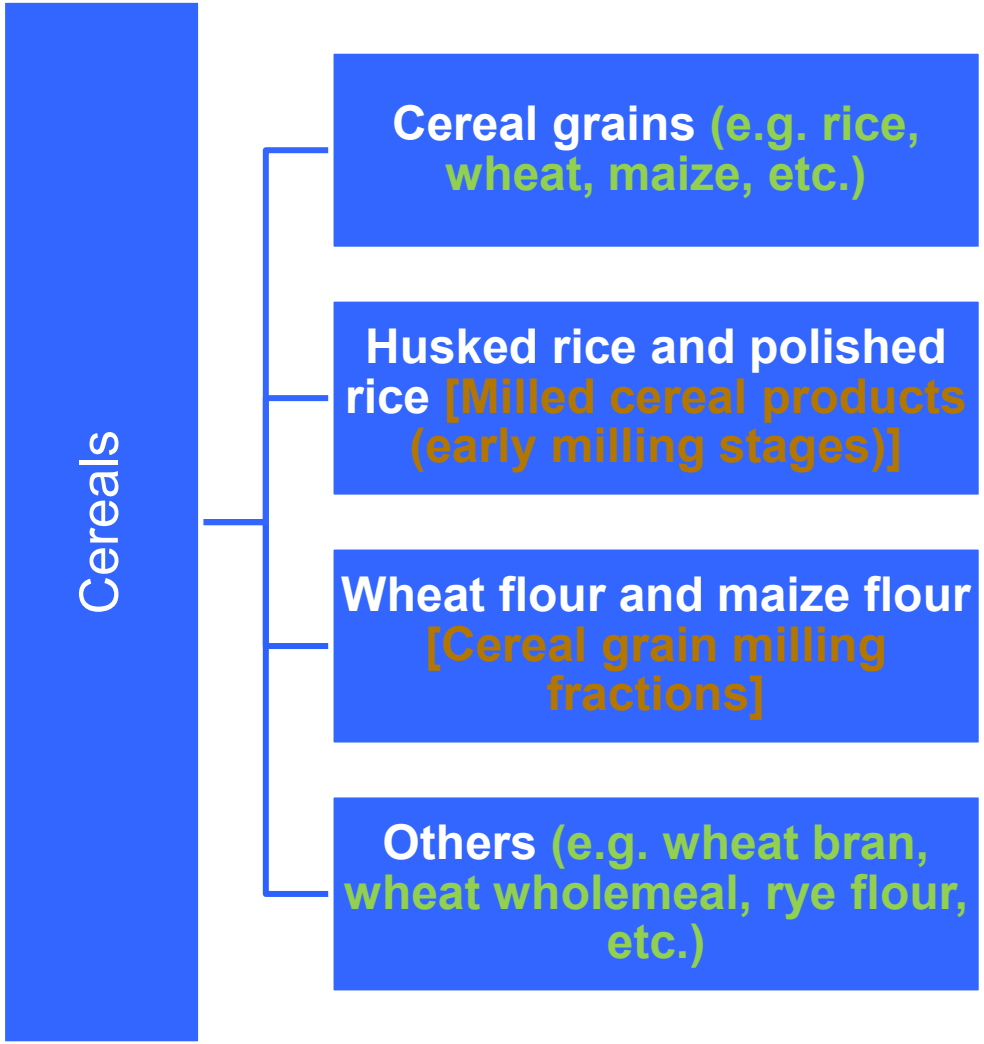
Part 2 of the Schedule

- **Part 2 - Maximum Level of Metal in Food**
  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
  17) Uranium

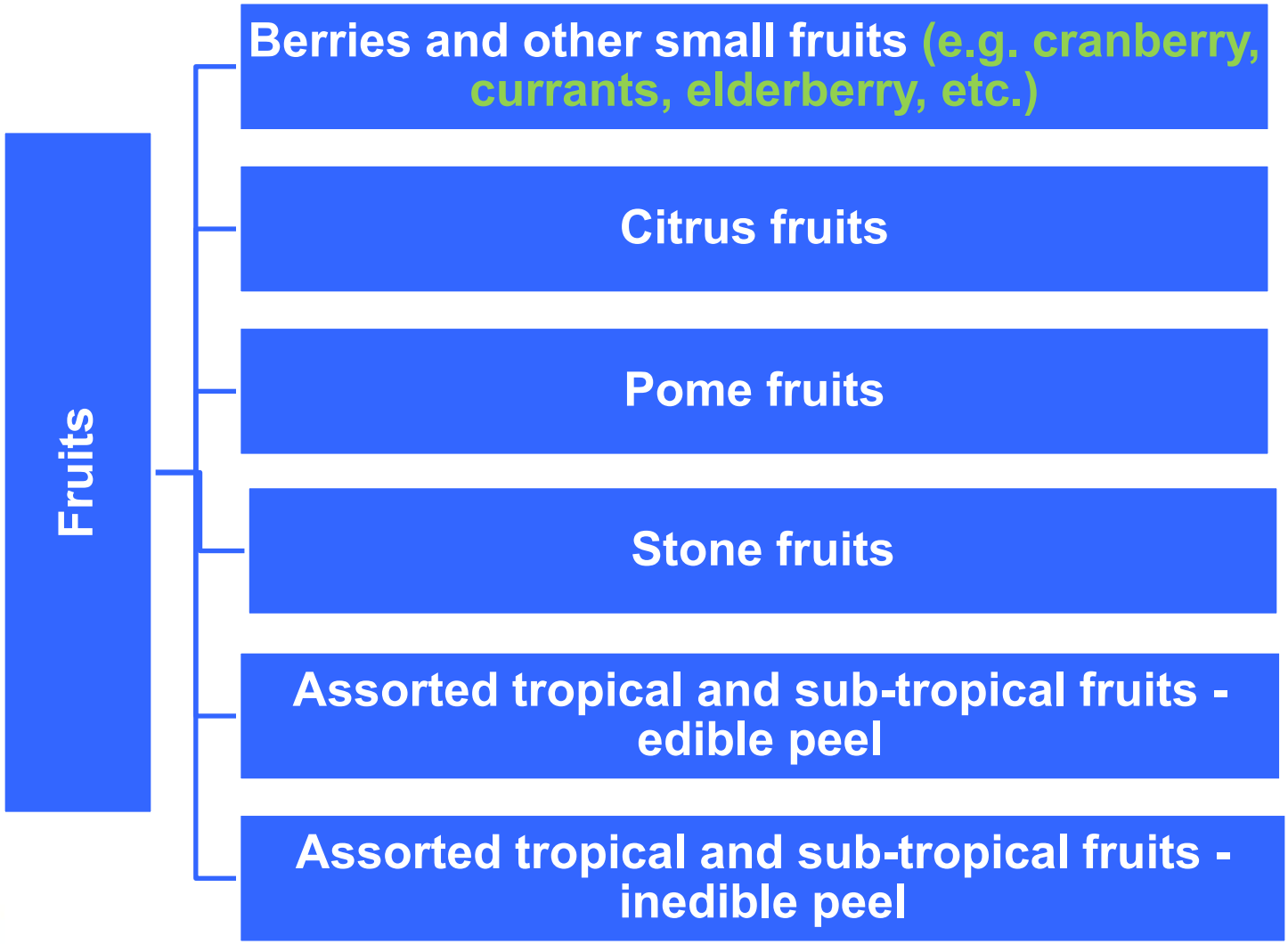
Column 2 – Food

- **One of the key features of the Amendment Regulation is the adoption of Codex MLs, unless otherwise specified**
  - **The food descriptions and nomenclatures in the Amendment Regulation also make reference to the latest Codex food classification and product definitions as appropriate.**
  - **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 to the latest Codex food classification, is illustrated in Annex I of the Guidelines**
  - **Details regarding the latest Codex food classification and definitions of various food commodities are available at the Codex website**

Cereals


Cereals
Cereal grains (e.g. rice, wheat, maize, etc.)
Husked rice and polished rice [Milled cereal products (early milling stages)]
Wheat flour and maize flour [Cereal grain milling fractions]
Others (e.g. wheat bran, wheat wholemeal, rye flour, etc.)

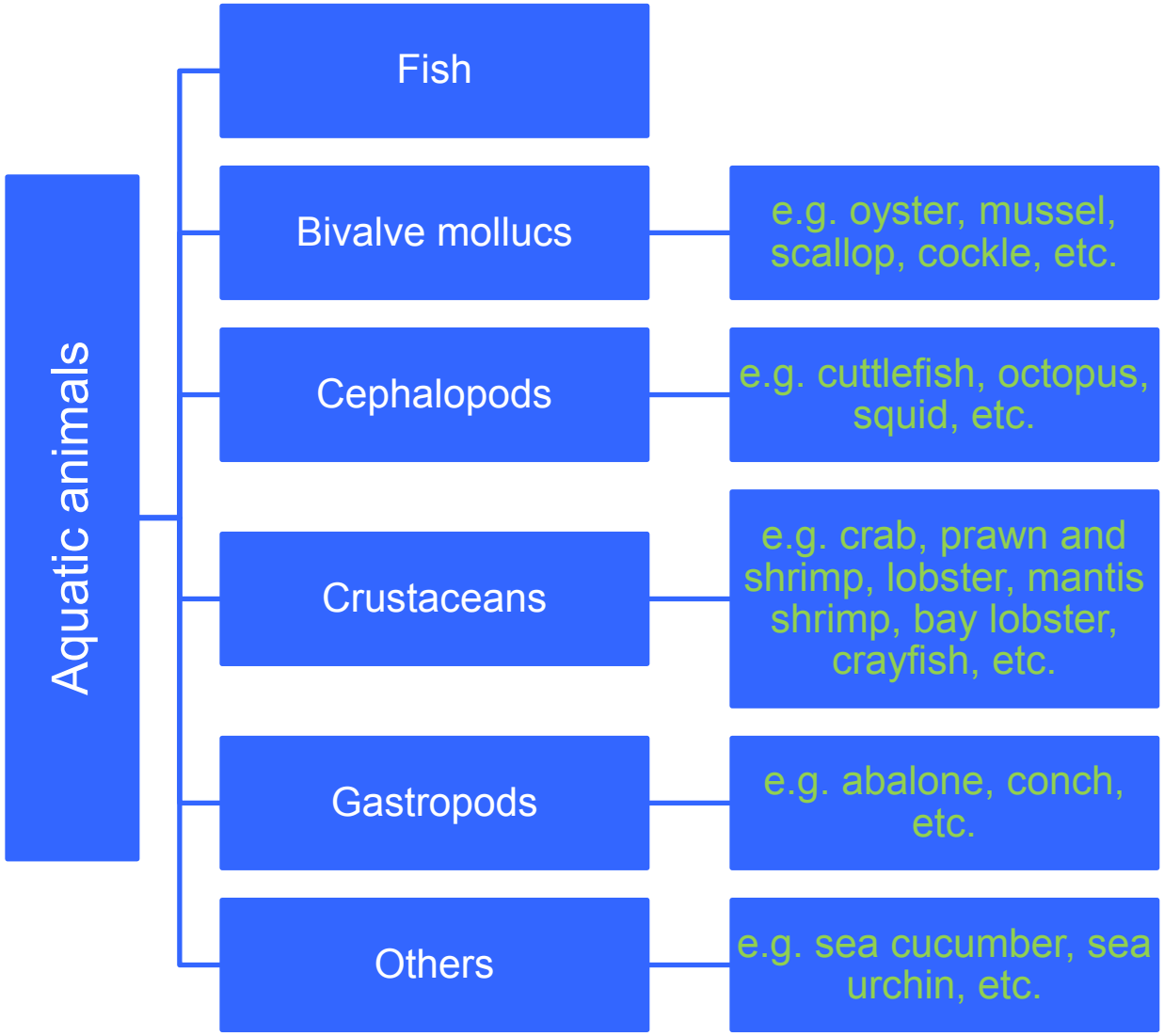
Fruits


Fruits
Berries and other small fruits (e.g. cranberry, currants, elderberry, etc.)
Citrus fruits
Pome fruits
Stone fruits
Assorted tropical and sub-tropical fruits - edible peel
Assorted tropical and sub-tropical fruits - inedible peel

Vegetables


Vegetables
Bulb vegetables
Brassica vegetables, other than Brassica leafy vegetables
Fruiting vegetables, Cucurbits
Fruiting vegetables, other than Cucurbits
Leafy vegetables (including Brassica leafy vegetables)
Legume vegetables
Pulses
Root and tuber vegetables
Stalk and stem vegetables
Edible fungi
Vegetables unless otherwise specified
Cadmium only: applies to edible fungi and tomato

Aquatic animals



Example (1) – Choisum

- **A type of Brassica leafy vegetables**
  - **MLs specified for cadmium and lead in "*leafy vegetables (including Brassica leafy vegetables)*" would be applicable even though there is no specific ML for choisum**
  - **For other metallic contaminants such as antimony, arsenic, chromium and mercury, those MLs specified for "*vegetables*" would apply to "*leafy vegetables (including Brassica leafy vegetables)*" as well as choisum which belongs to the group**

Example (2) – Scallop

- **A type of bivalve molluscs**
  - **MLs specified for cadmium and lead in "*bivalve molluscs*" would be applicable even though here is no ML for scallop specified in the Schedule**
  - **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**

Part 2 of the Schedule

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.".

Regulation 3 substituted (2)

(2)(b) the maximum level 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.

- For example, dried vegetables (including dried mushrooms), dried seafood, concentrated fruit juice, etc.
- Not applicable to any ML that is already established for specified foods in a dried, dehydrated or concentrated form, e.g. husked rice, polished rice, wheat flour, pulses, "*tea, green, black*", etc.

Example 1 – Cadmium in dried oyster

- **Search for the ML of cadmium in oyster laid down in Part 2 of Schedule 1,**
  ⇒ Oyster belongs to *"bivalve molluscs"*;
  ⇒ ML of cadmium in *"bivalve molluscs"* is 2 mg/kg;
  ⇒ i.e. ML of cadmium in oyster is 2 mg/kg.

- **Look up the water content of fresh and dried oyster from reliable database(s) or determine their water content by conducting laboratory analysis, for example,**
  ⇒ water content of fresh oyster = 79.2 – 87.1%
  ⇒ water content of dried oyster 13.1%

- **Calculate the adjusted ML of cadmium in dried oyster:**

$$\frac{\text{(100\% – "Water content in dried oyster" (\%))}}{\text{(100\% – "Water content in fresh oyster" (\%))}} \times \text{ML}$$

= 8.4 to 13.5 mg/kg

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

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

- **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.**

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

- **Search for the ML of lead in orange juice laid down in Part 2 of the Schedule,**
  ⇒ orange juice belongs to the specified food *"fruit juices, other than fruit juices exclusively from berries and other small fruits"*;
  ⇒ ML of lead in *"fruit juices, other than fruit juices exclusively from berries and other small fruits"* is 0.03 mg/kg;
  ⇒ i.e. ML of lead in orange juice is 0.03 mg/kg.

- **Obtain the concentration factor from the food manufacturer/supplier:**
  ⇒ 10X (this example)

- **Calculate the adjusted ML of lead in concentrated (10X) orange juice:**
  ⇒ 0.03 mg/kg × 10 = 0.3 mg/kg

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

Regulation 3 substituted (3)

(3) For paragraph (1), the maximum level of a specified metal in each specified food applies to –

(a) the edible portion of the food; or

(b) if applicable, the portion of the food specified in, or the food in the form specified in, a note referred to column 4 of part 2 of the Schedule in relation to the food.

- **See Notes 1-11 under Part 2 of the Schedule.**
  - Example 1: Scallops – applies to edible portion after removal of shell and viscera;
  - Example 2: Applies to products that are, or are reconstituted to be, ready to drink.

Examples of food composition databases

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

Regulation 3 substituted (4)

(4) For paragraph (1), if all ingredients of a compounded food are specified food, the maximum level of a specified metal in the compounded food is the sum of the maximum level 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).

Example 1: Cadmium in mixed vegetable salad (1)

- **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 ML of cadmium in each of the above ingredient specified in Part 2 of the Schedule, i.e.**
  1) **ML of cadmium in cucumber (i.e. *"fruiting vegetables, Cucurbits"*) = 0.05 mg/kg**
  2) **ML of cadmium in romaine lettuce (i.e. *"leafy vegetables (including Brassica leafy vegetables)"*) = 0.2 mg/kg**
  3) **ML for cadmium in carrot (i.e. *"root and tuber vegetables"*) = 0.1 mg/kg**

Example 1: Cadmium in mixed vegetable salad (2)

- **Calculate the adjusted ML of cadmium in mixed vegetable salad**
  = (ML of cadmium in sliced cucumber) × [% of sliced cucumber in mixed vegetable salad (by weight)] + (ML of cadmium in romaine lettuce) × [% of romaine lettuce in mixed vegetable salad (by weight)] + (ML of cadmium in shredded carrot) × [% of shredded carrot in mixed vegetable salad (by weight)]
  = 0.05 mg/kg × 30% + 0.2 mg/kg × 50% + 0.1 mg/kg × 20%
  = 0.135 mg/kg

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

Example 2: Lead in dried apricot

- **Look up the "List of ingredients" of the concerned food product,**
  ⇒ Ingredients: Apricot, preservative (sulphur dioxide)

- **Search for the MLs of lead in each ingredient specified in Part 2 of the Schedule:**
  1) **ML of lead in apricot (i.e. *"fruits, other than cranberry, currants and elderberry"*) = 0.1 mg/kg**
  2) **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, 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.

Regulation 3AA added

- Similar to existing Regulation 3
- 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

Regulation 7 added (1)

- During the period between 1 Nov 2019 and 31 Oct 2020 (both dates inclusive), a person who does an act in relation to any food (other than any food specified below) that contains a metal at any level is taken not to have contravened regulation 3 if doing the act immediately before 1 Nov 2019 would not have contravened these Regulations as in force immediately before 1 Nov 2019.
- The specified food as mentioned above are fruit and 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.

Regulation 7 added (2)

- Those types of food have shorter durability and shelf life and can be identified easily
- Made reference to Cap. 132X and Cap. 132AK for the interpretation of “fresh”
  - Discussed in previous trade meetings; easier for the trade to understand
- Other food items
  - Normally have a longer shelf / storage life
- All food must comply with the Amendment Regulation starting from 1 Nov 2020

Testing or analysis (1)

- Portion of the commodity to which the ML applies, i.e.
  - 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
- Codex has recommendations on fruit and vegetable samples

Testing or analysis (2)

Food items	Recommendation from Codex: Portion of the commodity to which the ML applies (and which is analysed)
Fruit	Berries and other small fruits, including cranberry and elderberry: whole commodity after removal of caps and stems. Currants: fruit with stem. Pome fruits: whole commodity after removal of stems. 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. Pineapple: whole commodity after removal of crown. Avocado, mango and similar fruit with hard seeds: whole commodity after removal of stone but calculated on whole fruit.
Bulb vegetables	Bulb onions: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached. Green onions: whole vegetables after removal of roots and adhering soil.
Brassica vegetables, other than Brassica leafy vegetables	Head cabbages: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: “buttons” only. Kohlrabi: “tuber-like enlargement of the stem” only.

Testing or analysis (3)

Food items	Recommendation from Codex: Portion of the commodity to which the ML applies (and which is analysed)
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). 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.

Support to the trade

- Designated metal webpage (https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_PA_Food_Adulteration_Metallic_Contamination.html)
- Technical meetings
- Guidelines on the Amendment Regulation
- Frequently asked questions on CFS' website

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