

***Draft* Guidelines on the Food Adulteration (Metallic Contamination) (Amendment) Regulation 2018**

14 February 2019

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Introduction



Purpose

- The Guidelines aims to assist the trade in having a better understanding of the Amendment Regulation and to answer some frequently asked questions



Disclaimer

● The Guidelines:

- Should be read in conjunction with the Amendment Regulation, is intended for use as a general reference only
- 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
- May be amended or supplemented as necessary from time to time



Key features of the Amendment Regulation (1)

- The Amendment Regulation stipulates updated standards for metallic contamination in food:
 - Total number of metallic contaminants has increased from 7 to 14
 - Stipulates 144 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.



Key features of the Amendment Regulation (2)

- Principles for application of MLs on food in a dried, dehydrated or concentrated form and on compounded food
- For food / food groups without relevant MLs under the Amendment Regulation, CFS will conduct risk assessment to assess whether the food contains the metal concerned in an amount that is dangerous or prejudicial to health
- Provisions to provide a 12-month grace period, from 1 Nov 2019 to 31 Oct 2020 (both dates inclusive), in relation to certain food



Definitions

- Key technical terms relevant to the Guidelines as defined in the Amendment Regulation, and as appropriate, the Ordinance, have been listed



Interpretation of ML of Metal in Food in the Schedule



Regulation 3(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

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

- **Column 1 “Metal”** – lists out the metals specified in the Schedule
- **Column 2 “Food”** – lists out the food / food groups to which the ML applies
- **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
- **Column 4 “Note ”** – specifies the portion of the food or the form of the food for which the ML applies
 - A total of 11 notes
 - e.g. ML of antimony in crabs applies to whole commodity (including the gonads, liver and other digestive organs) after removal of shell and gills



Column 1 – Metals

- 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 4 – Note

- 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.”.

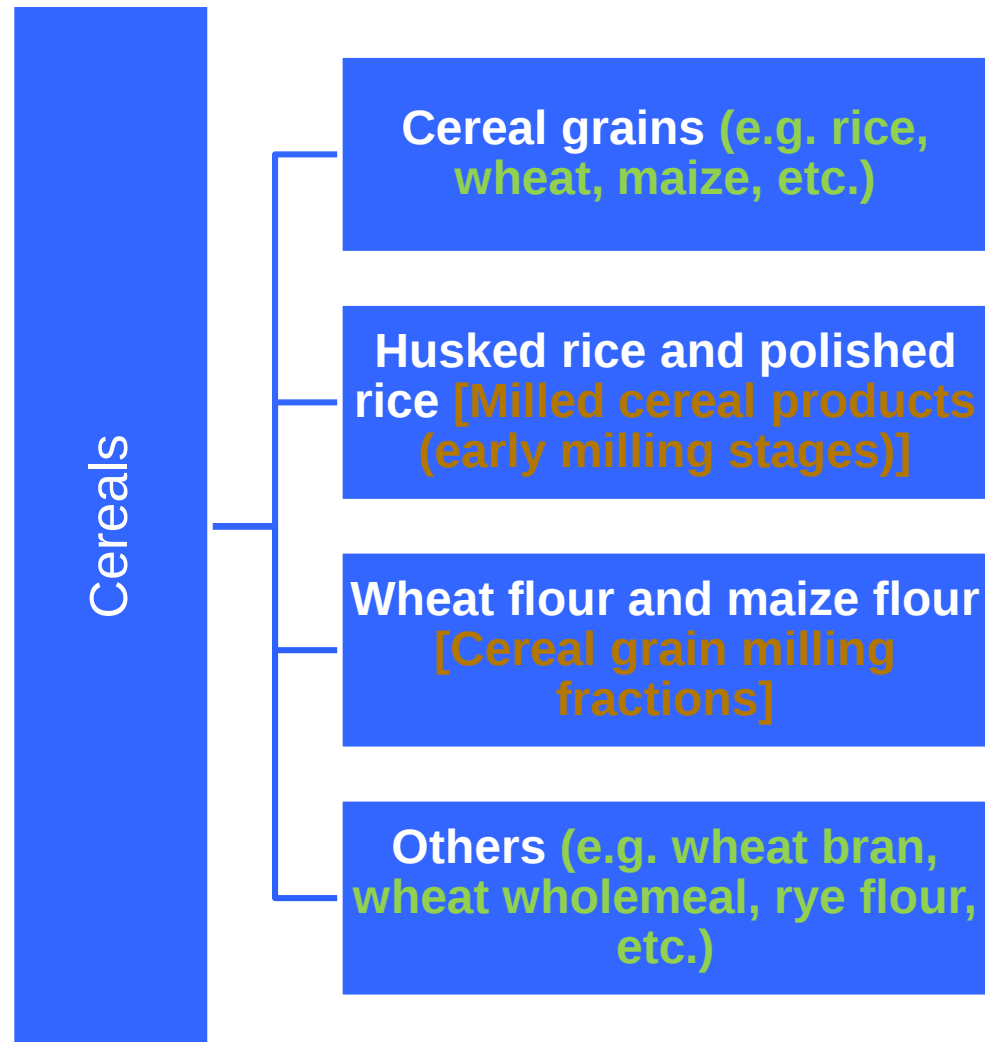


Interpretation of specified food in column 2 of Part 2 of the Schedule (1)

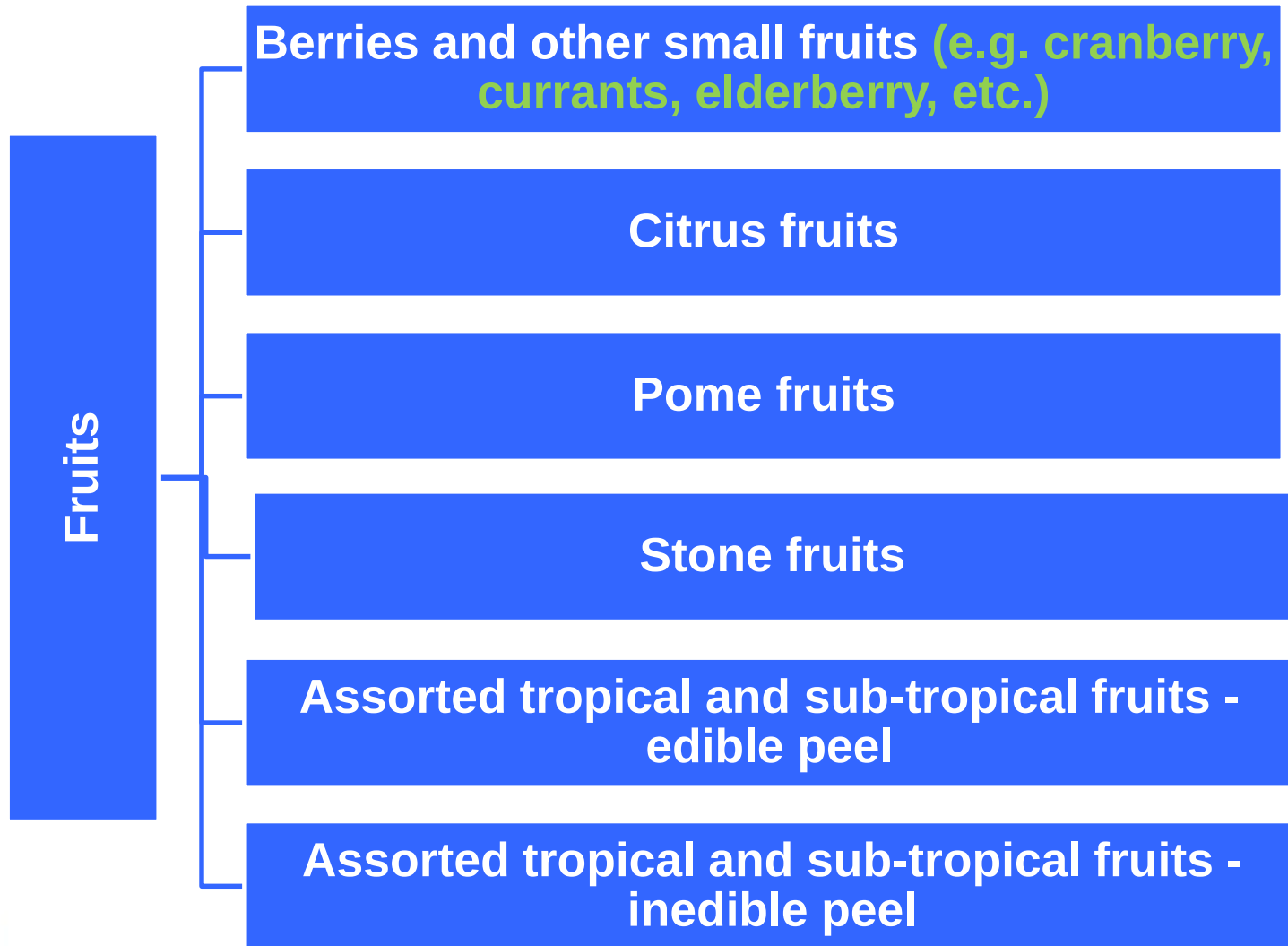
- One of the key features of the Amendment Regulation is the adoption of Codex MLs unless otherwise specified
 - The food descriptions and nomenclatures in the Amendment Regulation also make reference to the Codex food classification and product definitions as appropriate
 - Hierarchy of major types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



Cereals



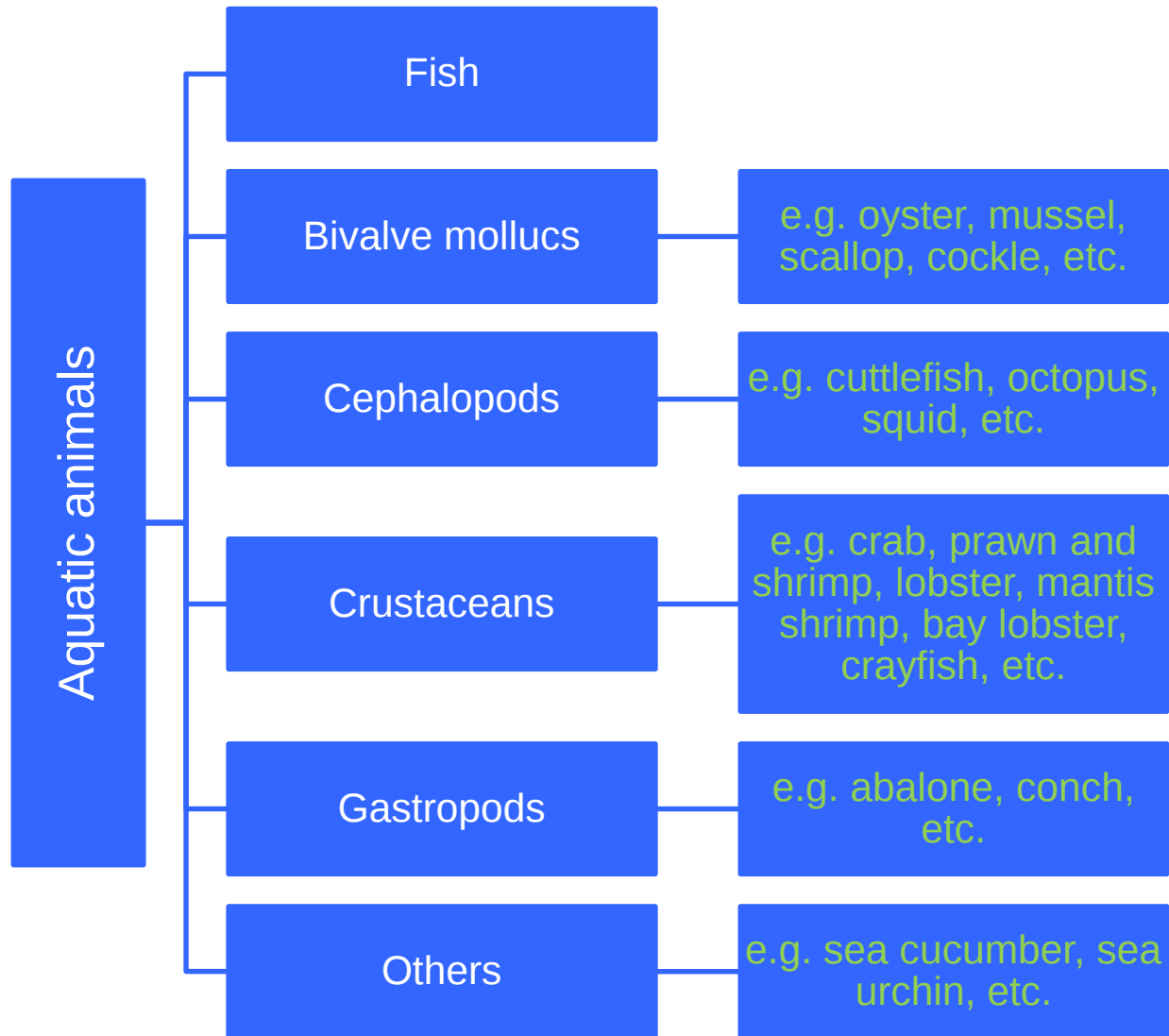
Fruits



Vegetables



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



Specified food that has gone through a process of drying, dehydration or concentration (1)

3(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, 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 (1)

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

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

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



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

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



Specified food that has gone through a process of drying, dehydration or concentration (2)

- 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.



Specified food that has gone through a process of drying, dehydration or concentration (3)

- 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.
 - Direct laboratory analysis of water content of the food sample before and after processing would provide a better estimate of the “conversion factor”.
 - If generally accepted data is used, the trade should ensure that the data sources are accurate and reputable.



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). 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 from: URL: <https://consumer.fda.gov.tw/Food/TFND.aspx?nodeID=178> (in Chinese).



Compounded food

- 3(4) 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) the ML of cadmium in cucumber (i.e. “*fruiting vegetables, Cucurbits*”) = 0.05 mg/kg
 - 2) the ML of cadmium in romaine lettuce (i.e. “*leafy vegetables (including Brassica leafy vegetables)*”) = 0.2 mg/kg
 - 3) the 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
 - = (the ML of cadmium in sliced cucumber) × [% of sliced cucumber in mixed vegetable salad (by weight)] + (the ML of cadmium in romaine lettuce) × [% of romaine lettuce in mixed vegetable salad (by weight)] + (the 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, 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,
⇒ Ingredients: Apricot, sulphur dioxide
- Search for the MLs for lead in each ingredient specified in Part 2 of the Schedule:
 - 1) the ML of lead in apricot (i.e. “*fruits*”) = 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, the lead content of the dried apricot sample concerned can be compared with the ML of 0.1 mg/kg for lead in fruits, with the application of appropriate conversion factor.



Conducting risk assessment

- For food / food groups without relevant MLs under the Amendment Regulation
 - CFS will continue to conduct risk assessment to assess 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 3AA(1): A person must not import, consign, deliver, manufacture or sell for human consumption any food containing any metal in an amount that is dangerous or prejudicial to health
 - Section 54 of the Ordinance stipulates that all food for sale in Hong Kong, locally produced or imported, should be fit for human consumption



Testing or analysis (1)

- **Laboratories are advised to note:**
 - **Portion of the commodity to which the ML applies, i.e.**
 - 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
 - **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.

Testing or analysis (4)

- Further information on determination of metallic contamination in food, particularly the two new elements inorganic arsenic and methylmercury, is available on the websites of CFS and the Government Laboratory



Grace period (1)

- As stated in regulation 7 of the Amendment Regulation, 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 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.



Grace period (2)

- The levels of metallic contamination in food types other than those mentioned above would not contravene the Amendment Regulation if they were complied with the existing maximum permitted concentrations prior to the commencement of the Amendment Regulation
- Eventually all food must comply with the Amendment Regulation starting from 1 Nov 2020



Frequently Asked Questions



Frequently asked questions

- **Chapter 3 of the Guidelines:**
 - **The Amendment Regulation**
 - Definitions, interpretation of MLs, food surveillance and prosecution
 - **Laboratory analysis**



Additional FAQ to be uploaded onto the CFS' website

- **Amendment Regulation**
- **Food descriptions and classification**
- **Conducting risk assessment**
- **Laboratory analysis**
- **Grace period**



Way forward

- The draft guidelines can be downloaded from the website of CFS:

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

- Please send your comments / suggestion on the draft guidelines on or before 20 Feb 2019

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