

Preservatives in Food (Amendment) Regulation 2024

Preservatives and Antioxidants

Draft User Guidelines

3rd Technical Meeting
15 November 2024

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1 Introduction

- 1.1 Purpose
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- 1.3 Disclaimer
- 1.4 Definition (Already introduced in the ppt for Amendment Regulation)

1.1 Purpose

- To assist the trade in having a better understanding of the amended Cap. 132BD, and to answer some of the frequently asked questions
 - Also provide detailed description of the categories and sub-categories under the updated food category system

1.3 Disclaimer

- The Guidelines:

- Should be read in conjunction with Cap. 132BD and the Amendment Regulation
- Intended for use as a general reference
- Do not have the force of the law and should not be interpreted in any manner which would override the provisions of the Amendment Regulation and the amended Cap. 132BD
- In case of any inconsistency, the statutory provisions will prevail
- Should not be regarded as legal advice; if legal advice is needed, please contact your own lawyer
- May be amended or supplemented by DFEH as necessary from time to time

2 Conditions of Use of Preservatives and Antioxidants

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2.1 Permitted Preservatives and Antioxidants

- Refer to food additives specified in column 2 of Schedule 1 or column 2 of Schedule 1B to the amended Cap. 132BD

2.2 Foods Permitted to Contain Preservatives and Antioxidants

- Preservatives and antioxidants listed in Schedule 1 to the amended Cap. 132BD may be used in the food categories specified
 - Their use must observe the MPLs and the notes (if available) specified in Schedule 1
- Preservatives and antioxidants listed in Schedule 1B to the amended Cap. 132BD are permitted to be added to food in accordance with GMP principles (i.e. GMP additives)
 - Except any relevant food of a scheduled food category that is specified in Schedule 1C

Updated Schedule 1 (Extract)

With reference to the Codex standards to update the food category system

Including food additive groups

"Schedule 1

[ss. 2, 3, 4 & 11 & Sch. 1C]

Food which may Contain Food Additive and the Description and Proportion of Food Additive in Each Case

Column 1		Column 2		Column 3	Column 4
No.	Food category or sub-category	Permitted food additives		Maximum permitted level (mg/kg, unless otherwise specified)	(Note)
		INS nos.	Name		
1.6.2.1	Ripened cheese, including rind	200-203	Sorbates	3 000	Note 9
		234	Nisin	12.5	
		235	Natamycin (pimaricin)	40	Notes 16 and 17
		239	Hexamethylene tetramine	25	Notes 24 and 25

Note 1 As phosphorus.

Note 2 For use in sterilized and ultra-heat treated (UHT) milks only.

Note 3 Excluding lactose reduced milks.

Note 4 Excluding all fluid milks that are not vitamin or mineral fortified.

Note 5 Except that the maximum permitted level for use in lactose reduced milks is 500 mg/kg.



New Schedules 1B / 1C (Extract)

“Schedule 1B

[ss. 2 & 3]

Food Additives Permitted under Section 3(2A) for Use in Food in accordance with GMP Principles

Column 1	Column 2
Item	Permitted food additive (INS no.)
1.	Acetic acid, glacial (260)
2.	Potassium acetate (261(i))
3.	Sodium acetate (262(i))
4.	Calcium acetate (263)
5.	Propionic acid (280)
6.	Sodium propionate (281)
7.	Calcium propionate (282)
8.	Potassium propionate (283)

i.e. GMP additives can be applied to the food sub-category “1.1.4 Flavoured fluid milk drinks”

1.1.4 not listed



Schedule 1C

[s. 3]

Food Excluded from Operation of Section 3(2A)

Column 1	Column 2
Food category no. (as assigned by Schedule 1)	Food category or sub-category
1.1.1	Fluid milk (plain), including skimmed, partly skimmed and whole milk
1.1.2	Other fluid milk (plain) (e.g. plain reconstituted fluid milks, non-flavoured vitamin and mineral fortified fluid milks, lactose reduced milk and plain milk-based beverages), excluding products of food categories 1.1.1, 1.1.3 and 1.2 and their sub-categories (if applicable)
1.1.3	Fluid buttermilk (plain)
1.2	Fermented and renneted milk products (plain), excluding flavoured products of food category 1.1.4 and its sub-categories (if applicable), and desserts of food category 1.7 and its sub-categories (if applicable)

2.3 Maximum Permitted Levels (MPLs)

- Mean the greatest proportion of a permitted preservative or antioxidant, specified in column 3 of Schedule 1, that is allowed to be present in the relevant food
- Attention: the relevant “participating additives” in relation to the “food additive groups” under Schedule 1A
- Generally expressed as “mg additive/ kg of food”
 - Exceptions, e.g.
 - MPLs for natamycin (pimaricin) in cheese may be expressed as “mg additive/ dm²” (surface area) of food
 - MPLs for food category “13.1 Infant formulae and follow-up formulae” are expressed as “mg additive/ L of food”

Schedule 1A (Extract)

- MPL for that food additive group means the proportion applicable to the total amount of the participating additives in that group

“Schedule 1A

[s. 2]

Participating Additives of Food Additive Groups

Item	Column 1 Food additive group (INS nos.)	Column 2 Participating additives (INS nos.)
1.	Sorbates (200–203)	Sorbic acid (200) Sodium sorbate (201) Potassium sorbate (202) Calcium sorbate (203)
2.	Benzoates (210–213)	Benzoic acid (210) Sodium benzoate (211) Potassium benzoate (212) Calcium benzoate (213)
3.	Hydroxybenzoates, para- (214, 215, 218 & 219)	Ethyl para-hydroxybenzoate (214) Sodium ethyl para- hydroxybenzoate (215) Methyl para- hydroxybenzoate (218)

2.4 Good Manufacturing Practice (GMP)

- MPLs for certain “preservatives / antioxidants – food pairs” are set at GMP in Schedule 1
- Preservatives and antioxidants listed in Schedule 1B are permitted to be added to food in accordance with GMP principles (except any relevant food of a scheduled food category that is also specified in Schedule 1C)

The **GMP** principles governing the use of preservatives and antioxidants refer to good manufacturing practice that complies with the following:

- (a) the quantity of the food additive added to the food is limited to the lowest possible level necessary to accomplish the desired effect of adding it;
- (b) the quantity of the food additive that becomes a component of the food as a result of its use in the manufacturing, processing or packaging of a food and that is not intended to accomplish any physical or other technical effect in the food itself, is reduced to a reasonably possible extent; and
- (c) the food additive is prepared and handled in the same way as a food ingredient.

The above definition of **GMP** is the same as the existing Cap. 132BD

2.5 Use of Two or More Preservatives and Antioxidants

- Unless specified otherwise, the use of two or more preservatives and/ or antioxidants in a food is generally permitted
 - Provided that all relevant preservatives and/ or antioxidants are permitted for use in the relevant food category
 - MPLs are observed
- In some cases, specific provisions made in Column 4 (i.e. Note) of Schedule 1 concerning combined use of preservatives and/ or antioxidants must be observed

Column 1		Column 2		Column 3	Column 4
No.	Food category or sub-category	Permitted food additives		Maximum permitted level (mg/kg, unless otherwise specified)	Note
		INS nos.	Name		
7.2.3	Mixes for fine bakery wares (e.g. cake mix, flour confectionery mix, pancake mix, pie mix and waffle mix)	310	Propyl gallate	200	Notes 12 and 14
		320	Butylated hydroxyanisole	200	Notes 12 and 14
		321	Butylated hydroxytoluene	200	Notes 12 and 14

Note 14: in relation to BHA, BHT, propyl gallate, octyl gallate, dodecyl gallate and TBHQ, 2 or more of these food additives can be used in combination only if the following condition is satisfied: when the quantity of each such food additive present in that food is expressed as a percentage of the MPL, the sum of those percentages does not exceed 100

2.6 Nisin in Canned Food

- Principles of section 3(8) of Cap. 132BD:
 - ① Any canned food (including canned compounded food) to contain nisin, and
 - ② Any other food to contain nisin where it is introduced in the preparation by the use of nisin-containing canned food
- After the update:
 - Proportion of nisin that may be present is limited to the applicable MPL
- Examples provided in the draft guidelines:
 - If MPL for the applicable “nisin-food” pair is specified in the updated Schedule 1 (e.g. canned tomato, canned condensed milk): the proportion of nisin shall not exceed the relevant MPL
 - If the updated Schedule 1 has not specified the “nisin-food” pair (e.g. canned fruit salad, canned double-cooked pork (回鍋肉)): the canned food product may contain nisin – and in such case, nisin should be used in accordance with GMP principles

2.7 Carry-over of Preservatives and Antioxidants into Compounded Food

- Compounded food: Prepared using 2 or more ingredients, e.g. pizza
- It is impractical to specify permitted preservatives and antioxidants for all compounded foods and their MPLs
- The carry-over principles under the existing Cap. 132BD have been amended under the Amendment Regulation:
 - A compounded food is permitted to contain preservatives and/ or antioxidants, if they are permitted to be used in the individual ingredients of the compounded food
 - For a permitted preservative or antioxidant specified in Schedule 1 for an ingredient of a compounded food, its proportion present in the compounded food should not exceed, in relation to the quantity of the ingredient used, the MPL
 - For a permitted preservative or antioxidant specified in Schedule 1B, it should be used in an ingredient of the compounded food in accordance with GMP principles, provided that the ingredient is not a relevant food of a scheduled food category that is also specified in Schedule 1C

2.8 Specifications on the Usage of Permitted Preservatives and Antioxidants

- Notes (if available) in Column 4 of Schedule 1 and must be observed

Column 1		Column 2		Column 3	Column 4
No.	Food category or sub-category	Permitted food additives		Maximum permitted level (mg/kg, unless otherwise specified)	Note
		INS nos.	Name		
1.7	Dairy-based desserts, including ready-to-eat flavoured dairy dessert products and dessert mixes (e.g. ice cream, pudding and fruit or flavoured yoghurt), excluding plain fermented milks (e.g. plain yoghurt) of food category 1.2.1 and its sub-categories (if applicable)	310	Propyl gallate	90	Notes 12 and 28

Note 28 The levels of food additives concerned are calculated on the dry ingredient, dry weight, dry mix or concentrate basis.

Column 1		Column 2		Column 3	Column 4
No.	Food category or sub-category	Permitted food additives		Maximum permitted level (mg/kg, unless otherwise specified)	Note
		INS nos.	Name		
8.2.1.2	Cured (including salted) and dried non-heat treated processed meat, poultry and game products in whole pieces or cuts	200–203	Sorbates	2 000	Notes 9 and 16
		210–213	Benzoates	1 000	Notes 6 and 16
		234	Nisin	12.5	
		235	Natamycin (pimaricin)	6	

Note 16 For use in surface treatment only.

2.9 Preservatives and Antioxidants That Are Naturally Present in Food

- Section 3(10) of Cap. 132BD:
 - subsection (1) does not apply to an article of food containing any food additive that is naturally present in that food
 - **Unchanged** under the Amendment Regulation
- Possible natural occurrence of certain preservatives or antioxidants and their levels in the food concerned would be taken into account during the routine food surveillance and enforcement
 - e.g. benzoic acid, acetic acid, phosphates, ascorbic acid, tocopherols, etc.

2.10 Exemption

- The Amendment Regulation adds a new definition of food to exclude food for special medical purposes (FSMPs) from the application of Cap. 132BD
- Codex has defined FSMPs as a category of food for special dietary uses “which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two”

FSMPs – Examples

- Include "formulae for special medical purposes for infants and young children"
 - e.g. formulae for infants and young children suffering from metabolic disorders (e.g. maple diabetes or phenylketonuria), and formulae for preterm infants or infants and young children suffering from specific groups of diseases such as lactose intolerance
- Other FSMPs
 - include products for dietary management of patients with diseases
 - e.g. formulae for cancer treatment, formulae for impaired gastrointestinal functions and products for patients with swallowing difficulties

FSMPs – Labelling

- FSMP is recommended to be marked or labelled with following conspicuously on the package:
 - (i) the words “food for special medical purposes” or “特殊醫用食品”, or any other words of similar meaning;
 - (ii) the words "USE UNDER MEDICAL SUPERVISION" or "在醫生指示下使用", or any other words of similar meaning; and
 - (iii) a statement stating "For the dietary management of (*fill in the disease, disorder or medical condition for which the food is intended to be used or known to be effective*)", or showing any other words of similar meaning.

2.11 Use of Antioxidants in “Food Intended to be Consumed Principally by Persons Under the Age of 36 Months”

Before the amendments

- Section 4 of Cap. 132BD:
 - prohibited the description or advertisement of any food as being food intended mainly for babies and young children if it has in it or on it any added antioxidant

Amendment Regulation

- Section 4 of Cap. 132BD is amended to exclude from its application any food falling within food categories or its sub-categories
 - e.g. infant formula containing ascorbic acid as an antioxidant
- Other antioxidant-containing foods e.g. fruit juice-based beverages (under food category 14.1.4), are still not allowed to be described or advertised as being food product intended mainly for babies and children

Amendment Regulation

- Certain antioxidants, originally falling outside the definition of “antioxidant” before the amendments, are included as permitted antioxidants (e.g. acetic acid, ascorbic acid, citric acid, etc.)
 - Permitted to be added to the food category “13 food intended to be consumed principally by persons under the age of 36 months”

For example:

Column 1		Column 2		Column 3	Column 4	Column 1		Column 2		Column 3	Column 4
No.	Food category or sub-category	Permitted food additives		Maximum permitted level (mg/kg, unless otherwise specified)	Note	No.	Food category or sub-category	Permitted food additives		Maximum permitted level (mg/kg, unless otherwise specified)	Note
		INS nos.	Name					INS nos.	Name		
13.1	Infant formulae and follow-up formulae					13.2	Complementary foods for infants and young children, excluding products of food category 13.1 and its sub-categories (if applicable)	260	Acetic acid, glacial	5 000	Note 141
13.1.1	Infant formulae	290	Carbon dioxide	GMP				261(i)	Potassium acetate	GMP	
		301	Sodium ascorbate	75	Notes 128 and 136			262(i)	Sodium acetate	GMP	
		304 & 305	Ascorbyl esters	10	Notes 128, 136 and 137			263	Calcium acetate	GMP	
		307a, b & c	Tocopherols	10	Notes 128 and 136			290	Carbon dioxide	GMP	
		322	Lecithins	5 000	Notes 128 and 136			300	Ascorbic acid, L-	500	
		330	Citric acid	GMP				301	Sodium ascorbate	500	Note 140

2.12 Transitional arrangement

- Transitional period: **30 December 2024 to 29 December 2026**
- During the transitional period, any single food item may be legally imported or sold if it complies wholly with the requirements of either the existing or the amended Cap. 132BD
 - If 2 food additives are added to a particular food item it is not acceptable for one to comply with the requirements of the existing Cap. 132BD and the other to comply with the requirements of the amended Cap. 132BD
 - Food products which comply with the existing Cap. 132BD and are already on the shelf before commencement of the Amendment Regulation would be allowed to be sold until the end of the transitional period
 - May introduce new food products (including products that have undergone reformulation) that are in compliance with the amended Cap. 132BD
- After the end of the transitional period, the trade should fully comply with the requirements of the amended Cap. 132BD

3 The Food Category System

3.1 Principles of the Food Category System
(unchanged)

3.2 The Food Category Descriptors (updated
with reference to Codex standards)

3.2 The Food Category Descriptors

- Provide detailed information on selected food categories and their sub-categories provided in the updated Schedule 1 to the amended Cap. 132BD

1 Dairy products and analogues, excluding infant formulae and follow-up formulae of food categories 13.1.1 and 13.1.2 and their sub-categories (if applicable), and products of food category 2 and its sub-categories (if applicable)

This major category includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, with the exception of food category 1.1.4, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.

1.1 Fluid milk and milk products, excluding plain fermented milk products and plain renneted milk products of food category 1.2 and its sub-categories (if applicable)

This category includes all plain and flavoured fluid milks based on skimmed, partly skimmed and whole milk, excluding plain fermented products and plain renneted milk products of food category 1.2. Fluid milks are “milk products” that are obtained by the processing of milk, and may contain food additives and other ingredients functionally necessary for processing. Raw milk shall not contain any food additives.

1.1.1 Fluid milk (plain), including skimmed, partly skimmed and whole milk

This category refers to plain fluid milk obtained from milking animals (e.g. cows, sheep, goats, buffalo) that has been processed. It includes pasteurized, ultra-heat treated (UHT), sterilized, homogenized, or fat adjusted milk. It also includes, but is not limited to, skimmed, partly skimmed and whole milk.

1.1.2 Other fluid milk (plain) (e.g. plain reconstituted fluid milks, non-flavoured vitamin and mineral fortified fluid milks, lactose reduced milk and plain milk-based beverages), excluding products of food categories 1.1.1, 1.1.3 and 1.2 and their sub-categories (if applicable)

This category includes all plain fluid milk, excluding products of food categories 1.1.1 Fluid milk (plain), 1.1.3 Fluid buttermilk (plain), and 1.2 Fermented and renneted milk products (plain). It includes, but is not limited to, plain recombined fluid milks, plain reconstituted fluid milks, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks, lactose reduced milk, and plain milk-based beverages. In this food category, plain products contain no added flavouring nor other ingredients that intentionally impart flavour, but may contain other non-dairy ingredients.

4 Frequently Asked Questions

- Include:
 - How is the use of preservatives and antioxidants regulated in Hong Kong
 - Major amendments made by the Amendment Regulation
 - Definitions of preservatives and antioxidants, MPL
 - The list of permitted preservatives / permitted antioxidants
 - Transitional period

Additional Frequently Asked Questions

- Include:
 - Update of MPLs and the food category system
 - Section 4 of Cap. 132BD concerning food containing antioxidant not to be recommended for babies and young children
 - Labelling of preservatives and antioxidants (including the use of “no preservative added” / “no antioxidant added” wordings on food package)
 - Regulation of multi-functional food additives under Cap. 132BD
 - Exemption of food for special medical purposes from the regulatory arrangement under the amended Cap. 132BD
 - Use of phosphates in sweetened condensed or evaporated milk, butter and cream
 - Testing methods

Way forward

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

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

- You are welcome to provide your comments / suggestion on the draft User Guidelines on or before 22 November 2024:
 - Email: ra@fehd.gov.hk
 - Fax: (852) 2803 0534

Thank you