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Preservatives in Food (Amendment) Regulation 2024
Additional Frequently Asked Questions

Disclaimer

This set of Additional Frequently Asked Questions (FAQs), which should be read in conjunction with Cap. 132BD and the Amendment Regulation, are intended for use as a general reference only. Information contained in this set of FAQs may not be exhaustive or complete. Specific issues should be considered on a case-by-case basis. This set of FAQs does 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. This set of FAQs should not be regarded as legal advice. If you need legal advice, you must contact your own lawyer.

This set of FAQs may be amended or supplemented by the Director of Food and Environmental Hygiene as necessary from time to time.

Q1. What are the major amendments made by the Preservatives in Food (Amendment) Regulation 2024 (Amendment Regulation)?

A1. The major amendments include –

(A) the definitions of "preservative" and "antioxidant" have been updated with reference to the corresponding definitions adopted by the Codex Alimentarius Commission (Codex);

(B) the total number of permitted preservatives and antioxidants has increased from 32 to 58; among them, 24 are food additives that are acceptable for general use in foods when used in accordance with the principles of good manufacturing practice (GMP), which have been set out in a separate list (i.e. Schedule 1B) in the amended Cap. 132BD;

(C) the maximum permitted levels (MPLs) of the permitted preservatives / antioxidants in specific food categories have been updated / stipulated in Schedule 1; and the number of "additive-

food" pairs has increased from around 900 to around 2 000; and

(D) the food category system has been updated in light of the latest Codex standard.

Q2. Under the Amendment Regulation, what are the "additive-food" pairs whose maximum permitted levels (MPLs) are more stringent than those laid down in the existing Regulation?

A2. Members of the public may browse the Amendment Regulation for details of the amendments, including the MPLs for "additive-food" pairs. The Amendment Regulation can be downloaded from the following website: https://www.gld.gov.hk/egazette/english/gazette/file.php?year=2024&vol=28&no=41&extra=0&type=2&number=130

Under the Amendment Regulation, three currently permitted preservatives (i.e. copper carbonate, diphenyl, formic acid) have been removed. Consequently, the trade would not be permitted to use them as preservatives. In addition, the MPLs for 12 major "additive-food" pairs are more stringent in comparison with those laid down in the Preservatives in Food Regulation (Cap. 132BD) before the amendments. For details, please refer to slides 28-34 of the powerpoint: https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/files/Cap132BD_ppt.pdf.

Q3. What are the changes made to the food category system under Schedule 1 to the Amendment Regulation?

A3. The food category system of the Cap. 132BD before the amendments was mainly based on the Codex General Standard for Food Additives (GSFA) as revised in 2007. In the current exercise, the food category system has been updated with reference to the latest Codex GSFA and the major changes include but not limited to:

- Update of food sub-categories under food categories "1.1 Fluid milk and milk products" and "2.2 Fat emulsions mainly of water-in-oil type";
- Establishment of new food sub-categories under food category "6.8 Soybean products" and relocation of food sub-category "Fermented soybeans" from under food category 12 to under food category 6;

- Update of food sub-categories under food category 12, including the addition of new food sub-category "12.9 Soybean-based seasonings and condiments"; and
- Addition of new food category "13 Food intended to be consumed principally by persons under the age of 36 months" and its sub-categories.

In addition, "Liquid foam headings" and "Gelatin capsules" under food category "16 Miscellaneous" have been removed as neither Codex nor our major food trading partners such as the Mainland, the European Union, Singapore, Australia/New Zealand, United States and Canada have set any maximum levels for food additives in these two items.

Q4. What are the reasons for changing the unit of MPL for specified "additive-food" pair from "ppm" to "mg/kg" under the Amendment Regulation?

A4. Under the Amendment Regulation, the unit of MPL for specified "additive-food" pair has been changed from "ppm" to "mg/kg". Such amendment has been made with reference to the Codex standards and would not affect the actual numerical value of the MPL. Besides, the MPLs for permitted preservatives or antioxidants in food category "13.1 Infant formulae and follow-up formulae" are expressed as "mg additive/L of food".

Q5. In Schedule 1 to the amended Cap. 132BD, MPLs for certain permitted antioxidants in food category "13 Food intended to be consumed principally by persons under the age of 36 months" have been established. On the other hand, section 4 of Cap. 132BD before the amendments specifies that food containing antioxidant is not to be recommended for babies and young children. So would the trade be allowed to use antioxidants in food for infants and young children under the amended Cap. 132BD?

A5. Section 4 of Cap. 132BD before the amendments prohibited the description or advertisement of <u>any food</u> as being food intended mainly for babies and young children (i.e. persons under the age of 36 months) if it has in it or on it any added antioxidant. In the amended Cap. 132BD, certain antioxidants, originally falling outside the definition of "antioxidant" before the amendments, are included as permitted

antioxidants in the updated definitions. Some of these (e.g. acetic acid, ascorbic acid, citric acid, etc.) are permitted to be added to the food category "13 food intended to be consumed principally by persons under the age of 36 months" or its sub-categories as specified in the updated Schedule 1. Section 4 of Cap. 132BD is amended to exclude from its application any food falling within food category 13 or its sub-categories in the updated Schedule 1. In other words, the description and advertisement of such food (e.g. infant formula containing ascorbic acid as an antioxidant) would continue to be unaffected by section 4 of the amended Cap. 132BD. On the other hand, antioxidant-containing foods falling under food categories other than food category 13 (e.g. fruit juice-based beverage categorised under food category "14.1.4 Water-based flavoured drinks" containing thiodipropionic acid as an antioxidant), are still not allowed to be described or advertised as food product intended mainly for babies and young children.

Q6. We noted that the term "alternative form" has been changed to "participating additive" in Schedule 1A to the amended Cap. 132BD. What are the reasons for such amendment? Will it affect the regulatory scope of the Amendment Regulation?

A6. Column 1 of Schedule 1A to Cap. 132BD before the amendments lists "permitted food additives specified for it in Schedule 1", whilst column 2 lists "alternative form in which the permitted food additives may be used". With reference to the latest practice of listing food additives in the Codex GSFA, certain permitted preservatives and antioxidants specified in the updated Schedule 1 to the amended Cap. 132BD are listed in the form of "food additive group" (such as benzoates); and all the permitted food additives that constitute the "food additive group" (i.e. "participating additives" such as benzoic acid, sodium benzoate, potassium benzoate and calcium benzoate) are listed in Column 2 of the updated Schedule 1A, opposite to the corresponding "food additive group" in Column 1. In relation to the permitted food additives that are participating additives of a food additive group, the "maximum permitted level" for that group means the proportion applicable to the total amount of the participating additives in that group. With the adoption of such terms and practice, the affiliation between the "food additive group" and its "participating additives" is clearly shown. The above amendments would not affect the regulatory scope of the amended Cap. 132BD, the list of permitted preservatives / antioxidants and their MPLs in specified foods.

Q7. Would there be any impact to the marking and labelling of prepackaged food under the Amendment Regulation? Would there be any changes to the labelling of food additives on the package?

A7. The Amendment Regulation aims to update the permitted list of preservatives and antioxidants and their MPLs under Cap. 132BD. The labelling requirements for prepackaged food under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W), including the labelling of food additives, have not been affected.

According to paragraph 2(5) and 2(6) of Schedule 3 to Cap. 132W, an additive constituting one of the ingredients of a prepackaged food shall be listed by its functional class and-

(a) its specific name; or
(b) its identification number under the International Numbering System for Food Additives; or
(c) its identification number under the International Numbering System for Food Additives with the prefix "E" or "e".

For example, if the trade has applied benzoic acid in a specified food, its name and functional class, e.g. benzoic acid (preservative), should be appropriately indicated on the product label.

Q8. Would wordings such as "no preservative added" or "no antioxidant added" be allowed on the food package if a multi-functional food additive is added for a function other than preservation or antioxidation?

A8. According to labelling requirements stipulated in Cap. 132W, the functional class of the additive should be suitably indicated on the product label based on the technical effect intended to be achieved upon the use of the additive in food. On this basis, we propose to keep the current practice of allowing the use of "no added preservatives" / "no added antioxidants" wordings on food package, provided that the intended functions (i.e. any functions other than preservation / antioxidation) of such multi-functional additives in food are stated clearly on the food label. For example, the newly added permitted food additive, citric acid, is a multi-functional additive which can be used as acidity regulator, antioxidant or colour retention agent in food. The trade is allowed to use "no antioxidant added" wordings on the package

of an ice-cream product if citric acid is added in the product for regulation of acidity, and the intended function is properly indicated in the ingredient list, i.e. "citric acid (acidity regulator)".

The trade can follow the relevant Codex documents (e.g. GSFA and the International Numbering System for Food additives) regarding the functional class of the concerned food additive; and they can provide the above Codex documents as a documentary proof of the intended functions (i.e. any functions other than preservation / antioxidation) of such multi-functional additives in their products. After all, the documentary proof provided by the trade should be in line with the information provided by the manufacturer; the trade should ensure consistency between the labelling of functional class of food additive in the ingredient list and the use of "no added preservatives" / "no added antioxidants" wordings on the food package.

In addition, the food concerned must comply with section 61(1) of the Public Health and Municipal Services Ordinance (Cap. 132), which stipulates that no person shall give or display a label which falsely describes the food or is calculated to mislead as to its nature, substance or quality.

Q9. Some preservatives / antioxidants permitted under the Amendment Regulation have multiple technological functions. If the trade uses these additives in food for function(s) other than preservative or antioxidant (e.g. using acetic acid as an acidity regulator), do the trade need to comply with the relevant MPLs in the Regulation?

A9. A total of 58 preservatives and antioxidants are permitted under the amended Cap. 132BD, some of which have various technological functions, e.g. apart from preservative and antioxidant functions, ethylenediaminetetraacetates can also be used as colour retention agent and sequestrant whilst acetic acid can be used as an acidity regulator or a preservative. In fact, the definitions of antioxidant and preservative cover multi-functional food additives that are capable of functioning as preservative or antioxidant in food. As such, their usage has to comply with the statutory standards specified in Cap. 132BD, regardless of their actual function in a particular food.

Q10. How can I know whether a product belongs to "food for special medical purposes (FSMP)"?

A10. Codex[1] has defined FSMP as a category of food for special dietary uses[2] "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."

To ensure that the patients are well-informed about the product is **for special medical purpose** (i.e. for dietary management of patients) and may be **used only under medical supervision**, FSMP is recommended to be marked or labelled with following conspicuously on the package—

(a) the words "food for special medical purposes" or "特殊醫用食品", or any other words of similar meaning;
(b) the words "USE UNDER MEDICAL SUPERVISION" or "在醫生指示下使用", or any other words of similar meaning; and
(c) 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.

The table below (which is not exhaustive) lists out some wordings that are considered to be of similar meaning with "food for special medical purposes" (特殊醫用食品) and "USE UNDER MEDICAL SUPERVISON" (在醫生指示下使用):

	Words with similar meanings (Examples)
food for special medical purposes	• "Food / product / formula" for

[1] Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (Codex Stan 180-1991).

[2] Food for special dietary use is those specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific disease and disorders and which are presented as such. The composition of these food stuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist. It should be noted that the presentation of the product as a food for special dietary use needs to observe relevant provisions in existing law of Hong Kong, including the Undesirable Medical Advertisements Ordinance (Cap. 231) and general food labeling requirements. For details please visit: https://www.cfs.gov.hk/english/programme/programme_nifl/programme_nifl_faq.html

(特殊醫用食品)	special medical uses • Special medical purpose "food / product / formula" • Special medical use "food / product / formula" • 特殊醫療用途"食品／產品／配方產品"
USE UNDER MEDICAL SUPERVISON (在醫生指示下使用)	• USE UNDER MEDICAL ADVICE • USE UNDER SUPERVISION OF A MEDICAL PROFESSIONAL • USE AS DIRECTED BY A MEDICAL PROFESSIONAL • 在醫生監督下使用 • 在醫護人員指導下使用

In addition, it should be noted that the presentation of FSMPs needs to comply with relevant requirements of the laws of Hong Kong (including the Undesirable Medical Advertisements Ordinance (Cap. 231) and the general food labelling requirements) as appropriate.

Q11. What are the examples of "food for special medical purposes (FSMP)"?

A11. Codex has defined FSMP as a category of foods for special dietary uses which "which are specially processed or formulated and presented for the **dietary management of patients** and may be **used only under medical supervision**. FSMP includes "formulae for special medical purposes for infants and young children", such as 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, such as formulae for cancer treatment, formulae for impaired gastrointestinal functions and products for patients with swallowing difficulties.

Generally speaking, products (e.g. products solely for tube feeding) are

considered to be FSMP if they are specially processed / formulated and marketed / labelled as for special medical purposes (i.e. for dietary management of patients), as well as being used only under medical supervision.

On the other hand, products that are not considered to be food for special dietary uses would also not be considered to be FSMP. For example, if a product is targeted at a particular group of consumers (e.g. the elderly population) only as marketing strategy, but the composition is not significantly different from ordinary food, or if the product is added with nutrients which are of interest to a particular group of consumers who actually do not have special requirement for these nutrients as compared to the general population, the product is not considered as a food for special dietary use or FSMP. In addition, food for special dietary uses (including FSMP) should not have any information or advertisement suggesting or implying that the product is also recommended or suitable for the general population or other population subgroups which do not have that specific disease or condition (e.g. "for health-conscious people", "for maintaining well-being and help you stay energetic", "for picky-eaters").

Another example is “milk specially formulated for pregnant women and lactating mother” and presented as such, which is considered to be food for special dietary uses but NOT FSMP with reference to the Codex definitions. Also, protein powder products that are intended for general population are NOT considered to be food for special dietary uses or FSMP.

Q12. Does the amended Cap. 132BD apply to “health products”?

A12. There are various types of “health products” with different ingredients and properties. The international community currently has no consistent definition and regulation of “health products”. Cap. 132BD regulates preservatives and antioxidants in food. Whether a product is regarded as “food” should be determined by a case-by-case analysis, taking into account factors including its nature, composition, content of the claims made, etc.

Q13. Is the use of phosphates in sweetened condensed or evaporated milk, butter and cream permitted under the Amendment Regulation?

Q13. There is no proposed change to Cap. 132W in the current exercise. In order words, maximum levels for certain additives such as phosphates in certain milk products as stipulated in Part III of Schedule 1 to Cap. 132W are still valid after the amendments of Cap. 132BD. Please refer to Part III of Schedule 1 to Cap. 132W for the use of phosphates in sweetened condensed or evaporated milk, butter or cream and the relevant maximum levels.

Q14. Will the Government provide recommended testing methods for all the preservatives and antioxidants specified in the Amendment Regulation?

Q14. The Government has conducted technical meetings to discuss various technical issues related to the Amendment Regulation, including the testing approach to preservatives and antioxidants listed in the amendments. Please refer to the presentation materials for the 2nd Technical Meeting available at the CFS' website (https://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_Proposed_Amendments_Preservatives_Food_Regulation.html) for details. Based on the actual requirements, equipment and resources available, laboratories may develop testing methods, making reference to national or international technical criteria and reference testing methods.