

*Consultation Paper*



# Amendment to Preservatives in Food Regulations

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**Consultation Paper on**

**Amendment to**

**Preservatives in Food Regulations**

**CENTRE FOR FOOD SAFETY**

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## **CHAPTER 1            INTRODUCTION**

1.1            Food is a perishable commodity. It is affected by a range of physical, chemical and biological processes and under certain conditions it may deteriorate. Besides spoiling many desirable properties of foods, deterioration, together with the growth of microorganisms, may produce toxic substances which have harmful effects on the health of consumers. Through inhibiting the growth of harmful microorganisms and preventing spoilage, food preservatives and antioxidants improve the safety and palatability of foods.

1.2            Preserving techniques to keep food fresh or palatable have a very long history of use. Since ancient times, it has been necessary to keep supplies of harvested food edible over unfavourable periods of time such as winter, rainy periods and drought, and a number of preservative methods had been invented to cope with the need. These include drying, smoking, salting, etc. As regards chemical preservatives, salt was likely the first antimicrobial chemical that has been used.

1.3            Over the past two decades, food preservatives and antioxidants played more important roles in food processing due to the increased production of prepared, processed, and convenience foods. Preservatives and antioxidants are required to prolong the shelf-life of many foods so that they can be transported over long distances, for example from one continent to another continent. Without preservatives and antioxidants, many foods would be prohibitively expensive and much would be wasted, not to mention the possibility of many food-related poisonings that might have been caused.

1.4            To protect public health, food preservatives and antioxidants have to undergo stringent evaluation by international authorities. In general, preservatives and antioxidants are permitted for food use only when they are proved to present no hazard to the health at the level of use proposed and a reasonable technological need can be demonstrated and the purpose cannot be achieved by other means which are economically and technologically practicable. Furthermore, their uses should not mislead the consumer.

1.5 The justification for the use of acceptable food additives including preservatives and antioxidants had been endorsed by the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA). Preservatives and antioxidants can (i) improve the safety of a food as well as prevent the wastage of seasonal surplus by making it last longer on the shelf or in the fridge, for example, the use of a preservative to prevent the growth of bacteria; (ii) improve the keeping quality of a food, for example, the use of an antioxidant to prevent fats and oils in foods from combining with oxygen in the air and making the foods rancid; and (iii) improve the appearance of a food, for example the use of an antioxidant to prevent colour changes caused by oxidation.

1.6 Another benefit of preservatives and antioxidants is that consumers can be offered a wider choice of foods. Many processed foods contain these additives. Some common examples are bacon, margarine, sauce and bread.

## CHAPTER 2 BACKGROUND

2.1 In Hong Kong, most food safety related rules and regulations are contained in the Public Health and Municipal Services Ordinance, Cap. 132. The Ordinance stipulates that all food on sale must be wholesome, unadulterated and fit for human consumption. There is also a set of subsidiary legislations (at **Annex 1**) which spells out the standards for specific food products or substances allowed in food.

2.2 The control on the use of preservatives and antioxidants in food is governed by the Preservatives in Food Regulations, Cap. 132BD (the Regulations). The Regulations stipulate that any food being imported, manufactured for sale, or sold should only contain permitted preservatives or antioxidants and in the proportion specified.

2.3 “Preservative”, as defined by the Regulations, means “any substance which is capable of inhibiting, retarding or arresting the process of fermentation, acidification or other deterioration of food or of masking any of the evidence of putrefaction”. “Antioxidant” means “any substance which delays, retards or prevents the development in food of rancidity or other flavour deterioration due to oxidation”.

2.4 “Preservatives” and “antioxidants” are commonly used in various kinds of food, such as meat products, juices and soft drinks. At present, there are a total of 12 permitted preservatives and 91 specified foods in Part I of the First Schedule to the Regulations, and 7 permitted antioxidants and 8 specified foods in Part II of the First Schedule. The list of permitted preservatives (and their alternative forms) and permitted antioxidants are given in **Annex 2** and **Annex 3**.

2.5 The Regulations stipulate which preservatives and antioxidants are permitted for use and for sale to use in food, as well as conditions of use of preservatives and antioxidants including the maximum levels that the specified food may contain.

2.6 A minor amendment to the First Schedule of the Regulations was made in late 2005 and it is noted that further amendments should be made to the Regulations in order to reflect the latest development in food

science and technology and keep abreast of international standards. The Government now considers that there is a need to review and update the Regulations. The following lists the major areas of the Regulations that are not in line with other national or international standards:

- (a) antioxidants under the Regulations do not include those additives which protect foodstuffs against colour changes caused by oxidation;
- (b) permitted preservatives and antioxidants under the Regulations are a simple combination of the permitted additives and the specified food items (i.e. product-specific). Similar specified foods are not grouped together to form major food categories;
- (c) the Regulations do not acknowledge the multifunctional property of additives, i.e. an additive can only be considered as either a preservative or an antioxidant but cannot be both even though it can technologically serve both functions; and
- (d) some common preservatives and antioxidants which were proven safe by JECFA and included in Codex's standards are not included in the Regulations.

## **CHAPTER 3            CODEX GENERAL STANDARD ON FOOD ADDITIVES (GSFA)**

3.1            The Codex Alimentarius Commission (Codex), established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations in the 1960s, has become the single most important international reference point for developments associated with food standards.

3.2            The Codex Alimentarius, or the food code, contains wide-ranging standards, guidelines, codes of practice for the protection of consumers and has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade.

3.3            As regards the standards for the use of preservatives and antioxidants, Codex published a document entitled General Standard on Food Additives (GSFA). The document contains a list of food additives including preservatives and antioxidants for use in foods and sets forth the conditions under which these additives can be used.

3.4            The preservatives and antioxidants included in the GSFA have the following features –

- (a) they have been evaluated by JECFA and are found acceptable for use in food; and
- (b) their permitted levels of use in various foods ensure that the intake of these additives does not exceed the safety reference value.

3.5            In addition, food items are grouped under major food categories and sub-categories in the GSFA. This reflects an international trend of removing away from so-called ‘product-specific’ legislation to horizontal provisions aimed at all food types.

3.6            The food additive provisions for the GSFA are reviewed on a regular basis and revised as necessary in light of new scientific information on safety, changing technological need and justification for use. The most recent update of the GSFA, *CODEX STAN 192-1995 (Rev. 7-2006)*, was conducted in September 2006.

## CHAPTER 4 PROPOSED AMENDMENT TO THE PRESERVATIVES IN FOOD REGULATIONS

4.1 During the last decade, there have been an increasing number of preservatives and antioxidants being evaluated as safe and permitted for food use internationally.

4.2 As part of the Government's ongoing efforts to enhance food safety for the protection of public health and consumer interest, the Administration conducts regular review on legal provisions on food standards and requirements for food labelling. Effort is also made to keep the local food legislation abreast of international development and advancement of food science and technology, and as far as possible tie in with those adopted by Codex.

4.3 To address the needs, the Administration proposes to amend the Regulations by making reference to Codex standards, including the GSFA and relevant commodity standards. The major amendment will include the following -

- (a) amendment of the *definitions* of preservatives and antioxidants;
- (b) incorporation of those preservatives and antioxidants, as well as their permitted levels of use, that are listed in the GSFA into the Regulations;
- (c) combining Part I and Part II of the First Schedule to the Regulations; and
- (d) introduction of a food category system.

### *Definitions of preservatives and antioxidants*

4.4 We propose to amend the definitions of preservatives and antioxidants to make them in line with the corresponding definitions contained in the Codex document entitled **Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989, Rev. 6-2001, Amd. 2005)**. The major difference between the proposed and the existing definitions is that the proposed definition of antioxidants includes those additives which protect foodstuffs against colour changes caused by oxidation.

4.5 The proposed definitions will continually not include substances such as lecithin, ascorbic acid, citric acid, common salt, acetic acid and so on which are currently not included in the definitions of antioxidants or preservatives of the Regulations. A summary of the substances that are not included in the definitions of antioxidants and preservatives in the Regulations is given in **Annex 4**.

#### *Incorporation of GSFA into the Regulations*

4.6 We propose to incorporate those preservatives and antioxidants, as well as their permitted levels of use, in the GSFA into the Regulations.

4.7 In situation where there are local standards for specific preservatives and antioxidants in specified food items but there are no corresponding Codex standards, we propose that those permitted ones currently in the Regulations will continue, where appropriate, to be allowed. The proposed amendment, an amalgamation of the GSFA standards with those of the existing Regulations, will allow the trade to use a much wider choice of preservatives and antioxidants (**Annex 5**).

4.8 If there are discrepancies of permitted levels between the GSFA and the Regulations, the ones listed in the GSFA will be considered for the sake of harmonisation of local and international standards, unless there are strong justifications to adopt a different standard.

#### *Combining Part I and Part II of the First Schedule*

4.9 Some permitted additives under the GSFA are multi-functional which can serve, for example, as antioxidant and preservative. On the contrary, preservatives and antioxidants are mutually exclusive under the Regulations. In terms of food safety, it is considered unnecessary to regulate preservatives and antioxidants separately. We propose to combine Part I and Part II of the First Schedule to the Regulations.

### *A food category system*

4.10 We propose to develop a food category system which will be used in the proposed amendment based upon the food category system adopted by the Codex Committee on Food Additives and Contaminants for use in the GSFA. The food category system is designed to allow the specific identification of individual foods or classes of foods to which preservatives and antioxidants may be added. An extract of the food category system in the GSFA is given in **Annex 6** for illustration purpose.

4.11 The amendment reflects the international trend of removing away from so-called ‘product-specific’ legislation to horizontal provisions aimed at all food types. It is also intended that the new system is easier to understand and will increase clarity in the use of preservatives and antioxidants.

4.12 The food category system is hierarchical, meaning that when the use of an additive is permitted in a general category, it is automatically permitted in all its sub-categories, unless otherwise stated. Similarly, when an additive is permitted in a sub-category, its use is also allowed in any further sub-categories and individual foodstuffs mentioned in a sub-category.

4.13 Currently, the food category system used in the Australia and New Zealand General Standard for Food Additives (Standard 1.3.1 of the Food Standards Code) adopted a similar format. In the Mainland, a food category system is also proposed in the consultation document for the revision of Hygienic Standards for the Use of Food Additives. It is expected that more countries will adopt the food category system of GFSA in the years to come.

4.14 As certain food items in the Regulations are unique to the local setting and may not fit the relevant Codex food category system, new food groups will need to be created to accommodate these food items.

## **CHAPTER 5            PRINCIPLES IN MAKING THE PROPOSED AMENDMENT**

5.1            The review of the Regulations is carried out in accordance with the following principles:

- protection of public health;
- provision of adequate information relating to food to enable consumers to make informed choices about food; and
- promotion of harmonisation between local and international food standards.

5.2            In addition, the Administration expects to achieve the following outcomes when proposing the amendment of the Regulations:

- public health would continue to be protected at a level which could be justified against internationally recognised risk assessment and management yardsticks;
- consumer confidence in food safety would be enhanced by the amendment;
- regulation of preservatives and antioxidants would be consistent with standards adopted already by Codex;
- stakeholders will find the amended regulations more user friendly.

### *Protection of public health*

5.3            Only those preservatives and antioxidants in the GSFA, which have been evaluated by JECFA and found acceptable for use in foods, are included in the amendment. In addition, the permitted levels of preservatives and antioxidants in the GSFA have been established by appropriate methods which verify that the intake of these additives does not exceed the safety reference level.

### *Adequate consumer information*

5.4            The labelling of preservatives and antioxidants is not the subject of this proposal; however, according to the Food and Drugs (Composition and Labelling) Regulations, the presence of food additives

(such as colour, raising agent, preservative, etc.) in prepackaged food must be identified by their functional categories (i.e. colour or preservative) and their names or numbers in the international numbering system on the label of the food after July 2007. This enables consumers who may have concerns about sensitivities to specific preservatives and antioxidants to identify and avoid them.

### *Promotion of harmonisation*

5.5 The format of the amendment (i.e. introduction of the food classification system and the inclusion of preservatives and antioxidants in the GFSA) is consistent with policy applied by the Codex Committee on Food Additives and Contaminants. In addition, similar approach has been adopted by other countries, such as Australia and New Zealand. The Mainland is currently revising its food additive regulations in order to incorporate the Codex's format. Hence, harmonising local and international standards will also allow stakeholders to make rapid comparisons between local and international regulations.

## CHAPTER 6 VIEWS SOUGHT

6.1 The Administration proposes to amend the Regulations by making reference to Codex standards, including the GSFA and other commodity standards. The scope of the proposed amendment will include the following -

- (a) amendment of the *definitions* of preservatives and antioxidants;
- (b) amalgamation of the preservatives and antioxidants in GSFA with those in the Regulations;
- (c) combining Part I and Part II of the First Schedule to the Regulations; and
- (d) introduction of a food category system.

6.2 The proposal entails a major technical amendment exercise to the existing Regulations. The Administration needs to consult stakeholders, i.e. the trade, on the proposed amendment, review the lists of permitted additives, and try to include the existing specified food items in the Regulations to the food categories under the GSFA. As certain food items in the Regulations are unique to the local setting and may not have an available food category under the relevant Codex food category, new food categories would need to be created.

### *Views sought*

6.3 The Administration invites you to let us have your views on the following issues:

- (a) Do you agree with the proposal to amend the *definitions* of preservatives and antioxidants to be in line with Codex definitions, the international standards, and, if yes, do you agree with the proposed definitions? (Paragraphs 4.4 and 4.5)
- (b) Do you agree with the proposal to amalgamate the preservatives and antioxidants in GSFA with those in the Regulations so that the food trade can have a wider choice of safe preservatives and antioxidants at their disposal? (Paragraphs 4.6 to 4.8)
- (c) Do you agree with the proposal to combine Part I and Part II of the First Schedule to the Regulations to simplify the legal requirements; (Paragraph 4.9)
- (d) Do you agree with the introduction of a food category system for

more user-friendly categorisation of food? (Paragraphs 4.10 to 4.14)

6.4 Please send your views and comments by letter, facsimile or e-mail to the Centre for Food Safety at the following address:

Centre for Food Safety  
(Attn: Risk Assessment Section)  
43/F, Queensway Government Offices,  
66 Queensway,  
Hong Kong  
Facsimile : 2893 3547  
E-mail address : [preserve\\_consultation@fehd.gov.hk](mailto:preserve_consultation@fehd.gov.hk)  
Enquiry tel. no. : 2867 5699

6.5 The Administration will take full account of the views received before finalising the proposed amendment to the Preservatives in Food Regulations.

**Subsidiary Legislations under Cap. 132 on Food Standards**

Colouring Matter in Food Regulations (Cap 132 H)

Dried Milk Regulations (Cap 132 R)

Sweeteners in Food Regulations (Cap 132 U)

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

Food and Drugs (Composition and Labelling) Regulations (Cap 132 W)

Frozen Confections Regulation (Cap 132 AC)

Harmful Substances in Food Regulations (Cap 132 AF)

Imported Game, Meat and Poultry Regulations (Cap 132 AK)

Milk Regulation (Cap 132 AQ)

Mineral Oil in Food Regulations (Cap 132 AR)

Preservatives in Food Regulations (Cap 132 BD)

**List of permitted preservatives  
under the Preservatives in Food Regulations (Cap. 132BD)**

Permitted preservatives under Part I of the First Schedule	Alternative form of the permitted preservative under Part III of the First Schedule
1. Sodium nitrate	Potassium nitrate
2. Sodium nitrite	Potassium nitrite
3. Sulphur dioxide	Sulphurous acid / sodium sulphite / sodium hydrogen sulphite / sodium metabisulphite / potassium sulphite / potassium metabisulphite / calcium sulphite / calcium hydrogen sulphite
4. Benzoic acid	Sodium benzoate / potassium benzoate / calcium benzoate
5. Methyl para-hydroxybenzoate	Methyl para-hydroxybenzoate, sodium salt
6. Ethyl para-hydroxybenzoate	Ethyl para-hydroxybenzoate, sodium salt
7. Propyl para-hydroxybenzoate	Propyl para-hydroxybenzoate, sodium salt
8. Propionic acid	Sodium propionate / calcium propionate / potassium propionate
9. Sorbic acid	Sodium sorbate / potassium sorbate / calcium sorbate
10. Diphenyl	N/A
11. Ortho-phenylphenol	Sodium ortho-phenylphenate
12. Copper carbonate	N/A

\* Apart from the First Schedule, regulation (3) of the Preservatives in Food Regulations allows the use of certain preservatives in specific food products without stipulating the permitted levels, e.g.

- The skin, but not flesh, of a banana may contain nystatin;
- Cheese, clotted cream or any canned food may contain nisin.

**List of permitted antioxidants under the  
Preservatives in Food Regulations (Cap. 132BD)**

1. Propyl gallate
2. Octyl gallate
3. Dodecyl gallate
4. Butylated hydroxyanisole (BHA)
5. Butylated hydroxytoluene (BHT)
6. Ethoxyquin
7. Ethylene Diamine Tetraacetate (EDTA)

Note:

- Propyl gallate, octyl gallate and dodecyl gallate can be used together as a mixture.
- BHA and BHT can be used together as a mixture.

**Substances not considered as preservatives or antioxidants  
in the Regulations (Cap. 132BD)**

1. lecithin
2. ascorbic acid, or its salts or esters
3. tocopherols
4. sodium chloride
5. sugars
6. nicotine acid or its amide
7. acetic acid, or its calcium, potassium or sodium salts
8. lactic acid, or its calcium, potassium or sodium salts
9. citric acid, or its calcium, potassium or sodium salts
10. malic acid, or its calcium, potassium or sodium salts
11. phosphoric acid, or its calcium, potassium or sodium salts
12. polyphosphoric acid, or its calcium, potassium or sodium salts
13. tartaric acid, or its calcium, potassium or sodium salts
14. glycerol
15. alcohol or potable spirits
16. isopropyl alcohol
17. propylene glycol
18. monoacetin
19. diacetin
20. triacetin
21. herbs or hop extract
22. spices or essential oils when used for flavouring purposes
23. any substance added to food by the process of curing known as smoking
24. carbon dioxide, nitrogen or hydrogen when used in the packing of food in hermetically sealed containers
25. nitrous oxide when used in the making of whipped cream

**Additional preservatives and antioxidants  
permitted for food use in the proposed amendment**

1. Guaiac resin
2. Isopropyl Citrates
3. Stannous Chloride
4. Tertiary Butylhydroquinone (TBHQ)
5. Thiodipropionates
6. Dimethyl Dicarbonate
7. Ferrous Gluconate
8. Formates
9. Hexamethylene Tetramine
10. Lysozome
11. Pimaricin

Note: The above preservatives and antioxidants are permitted for food use in the Codex General Standard For Food Additives (*CODEX STAN 192-1995 (Rev. 7-2006)*). These additives have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and found acceptable for use in foods.

**FOOD CATEGORY SYSTEM**

(extract from *CODEX STAN 192-1995 (Rev. 7-2006)*)

**PART I: Food Category System**

- 01.0 Dairy products and analogues, excluding products of food category 02.0
  - 01.1 Milk and dairy-based drinks
    - 01.1.1 Milk and buttermilk (plain)
      - 01.1.1.1 Milk (plain)
      - 01.1.1.2 Buttermilk (plain)
    - 01.1.2 Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)
  - 01.2 Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy based drinks)
    - 01.2.1 Fermented milks (plain)
      - 01.2.1.1 Fermented milks (plain), not heat-treated after fermentation
      - 01.2.1.2 Fermented milks (plain), heat-treated after fermentation
    - 01.2.2 Renneted milk (plain)
  - 01.3 Condensed milk and analogues (plain)
    - 01.3.1 Condensed milk (plain)
    - 01.3.2 Beverage whiteners
  - 01.4 Cream (plain) and the like
    - 01.4.1 Pasteurized cream (plain)
    - 01.4.2 Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)
    - 01.4.3 Clotted cream (plain)
    - 01.4.4 Cream analogues
  - 01.5 Milk powder and cream powder and powder analogues (plain)
    - 01.5.1 Milk powder and cream powder (plain)
    - 01.5.2 Milk and cream powder analogues
  - 01.6 Cheese and analogues
    - 01.6.1 Unripened cheese
    - 01.6.2 Ripened cheese
      - 01.6.2.1 Ripened cheese, includes rind
      - 01.6.2.2 Rind of ripened cheese
      - 01.6.2.3 Cheese powder (for reconstitution; e.g., for cheese sauces)
    - 01.6.3 Whey cheese

- 01.6.4 Processed cheese
  - 01.6.4.1 Plain processed cheese
  - 01.6.4.2 Flavoured processed cheese, including containing fruit, vegetables, meat, etc.
- 01.6.5 Cheese analogues
- 01.6.6 Whey protein cheese
- 01.7 Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)
- 01.8 Whey and whey products, excluding whey cheeses
  - 01.8.1 Liquid whey and whey products, excluding whey cheeses
  - 01.8.2 Dried whey and whey products, excluding whey cheeses
- 02.0 Fats and oils, and fat emulsions
  - 02.1 Fats and oils essentially free from water
    - 02.1.1 Butter oil, anhydrous milkfat, ghee
    - 02.1.2 Vegetable oils and fats
    - 02.1.3 Lard, tallow, fish oil, and other animal fats
  - 02.2 Fat emulsions mainly of type water-in-oil
    - 02.2.1 Emulsions containing at least 80% fat
      - 02.2.1.1 Butter and concentrated butter
      - 02.2.1.2 Margarine and similar products
      - 02.2.1.3 Blends of butter and margarine
    - 02.2.2 Emulsions containing less than 80% fat
  - 02.3 Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions
  - 02.4 Fat-based desserts excluding dairy-based dessert products of food category 01.7

Note: “General Standard for Food Additives *CODEX STAN 192-1995 (Rev. 7-2006)*” is a 186-page document and can be found in Codex’s website.

[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en)

