CONSULTATION ON DRAFT FOOD (AMENDMENT) REGULATIONS 2024 (FOOD ADDITIVES AND INGREDIENTS)

Posted on: *31 January 2024* | ***Closing Date:*** *31 March 2024*

Aim

The Singapore Food Agency (SFA) is seeking feedback from the food industry, as well as interested parties on the draft Food (Amendment) Regulations 2024, which is targeted to come into effect in the second quarter of 2024.

Summary of amendments

The draft Food (Amendment) Regulations 2024 contains amendments to the Food Regulations, mainly to extend the use of permitted food additives, as well as to allow the use of new ingredients in infant formula.

A detailed description of the proposed changes can be found in the **ANNEX**. The legal text of the amendments can be downloaded from SFA's website at:

> https://www.sfa.gov.sg/food-information/public-consultation
> *(Click on "Draft Food (Amendment) Regulations 2024 (Food additives and ingredients)" and "Consultation on Draft Food (Amendment) Regulations 2024 (Food additives and ingredients)")*

Request for comments

SFA invites views and comments on the draft Food (Amendment) Regulations 2024. All submissions should be clearly and concisely written and should provide a reasoned explanation for any proposed revisions.

Submissions should reach SFA no later than 5:00 p.m. (Singapore time; UTC+8), 31 March 2024, through email, to the following address: toh_kian_han@sfa.gov.sg

ANNEX

PROPOSED AMENDMENTS TO THE FOOD REGULATIONS

(A) CHANGES TO THE PERMITTED FORMS OF STEVIOL GLYCOSIDES

1. SFA proposes to make amendments to Regulation 18(1) of the Food Regulations to replace the current forms of steviol glycosides with the four types of steviol glycosides produced by different methods, so as to align with the Codex Alimentarius Commission. **There is no change to the Thirteenth Schedule of the Food Regulations with respect to the food categories which may be added with steviol glycosides, or the maximum levels of steviol glycosides allowed for use in food imported/manufactured for sale in Singapore**.

Current Regulation 18(1)	Proposed Regulation 18(1)
18.—(1) In these Regulations — "steviol glycosides" means any of the following: (a) steviol glycosides from *Stevia rebaudiana* Bertoni; (b) Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*; (c) Rebaudioside M produced by enzymatic modification of Rebaudioside A extracted from Stevia leaf, using the enzymes UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13), produced by genetically modified strains of *Escherichia coli* K-12 W311; (d) Rebaudioside M produced by enzymatic conversion of purified Stevia leaf extract, using the enzymes UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13), produced by	**18**.—(1) In these Regulations — "steviol glycosides" means any of the following: (a) steviol glycosides from *Stevia rebaudiana* Bertoni (steviol glycosides from Stevia); (b) steviol glycosides from fermentation[1]; (c) enzymatically produced steviol glycosides (including steviol glycosides produced using the enzyme uridine triphosphate (UTP)-glucose-1-phosphate uridyltransferase (EC 2.7.7.9) from the source organism *Bifidobacterium bifidum*; (d) glucosylated steviol glycosides;

[1] In the revised JECFA specifications, "steviol glycoside produced from fermentation" includes rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*. Moreover, the name of this form of steviol glycosides reflected in the Codex General Standard for Food Additives (CXS 192-1995) and the Class Names and the International Numbering System for Food Additives (CXG 36-1989) is "steviol glycoside produced from fermentation". Therefore, there is no need to separately list "rebaudioside A from multiple gene donors expressed in Yarrowia lipolytica" in the Food Regulations.

genetically modified strains of *Pichia pastoris*; (e) Rebaudioside D produced by enzymatic conversion of purified Stevia leaf extract using the enzymes UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13), produced by genetically modified strains of *Pichia pastoris*; (f) Rebaudioside E produced by enzymatic conversion of purified Stevia leaf extract using the enzymes UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13), produced by genetically modified strains of *Pichia pastoris*; (g) Rebaudioside AM produced by enzymatic conversion of stevioside extracted from Stevia leaf using the enzymes UDP-glucosyltransferase (EC2.4.1.17) and sucrose synthase (EC 2.4.1.13), produced by genetically modified strains of *Escherichia coli* K-12 W311;	

2. Steviol glycosides were first included into the Food Regulations as permitted sweetening agents under Regulation 18 of the Food Regulations in 2011. At that time, the only form of steviol glycosides used by industry was obtained through extraction from the Stevia plant (i.e., *Stevia rebaudiana* Bertoni). As the industry developed newer technologies to produce steviol glycosides, such as the use of precision fermentation and enzyme modification, the use of such steviol glycosides were evaluated by then-AVA and later, SFA, on a case-by-case basis and approved new forms of steviol glycosides were added into Regulation 18(1), with the result that there are currently seven forms of steviol glycosides listed as permitted sweetening agents under the Food Regulations.

3. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has, in recent years, established a revised specification to cover the different forms of steviol glycosides produced by different methods. In JECFA's revised specifications, the different forms of steviol glycosides are grouped into four

types based on the different production methods (refer to Annexes 1 to 4 of the enclosed document on JECFA's specifications). The Acceptable Daily Intake (ADI) for steviol glycosides (expressed as steviol equivalent) remains unchanged at 0 – 4 mg/kg body weight. Codex has adopted the revised JECFA specifications (Download JECFA's revised specifications for steviol glycosides here).

4. SFA has assessed that the revised JECFA specifications are able to cover the seven forms of steviol glycosides that have been allowed under Regulation 18(1). There will be no impact on food safety as the ADI and **maximum permitted levels for steviol glycosides in the Thirteenth Schedule remain unchanged**.

5. SFA also proposes additional changes to Regulation 18(1)(c) to include provisions for the use of a new enzymatically produced steviol glycoside that is produced using the enzyme uridine triphosphate (UTP)-glucose-1-phosphate uridyltransferase (EC 2.7.7.9) from the source organism *Bifidobacterium bifidum*. This enzymatically produced steviol glycoside is not covered by the revised JECFA specifications. However, SFA has assessed the safety of this form of steviol glycoside and recommends approval for its use in food.

(B) TO EXTEND THE USE OF PERMITTED FOOD ADDITIVES

6. **L-theanine**, a permitted flavour enhancer, is currently allowed to be used in various types of foods listed in Regulation 23(2)(e). SFA proposes to extend the use of L-theanine to salt substitutes, up to a maximum level of 15000 ppm.

7. Salt substitutes are products with reduced sodium content and are meant for use in foods in place of salt. The use of L-theanine in salt substitutes is permitted in Japan and Korea. SFA has assessed that the estimated dietary intake of L-theanine from the proposed use in foods (including salt substitutes) is safe.

8. SFA also proposes to extend the use of **sucralose**, a permitted sweetening agent, to soybean-based beverage, up to a maximum permitted level of 400 ppm. At present, the only sweetening agent permitted to be used in soybean-based beverage is steviol glycosides. Codex has adopted provisions for the use of sucralose in soybean-based beverages, up to a maximum level of 400 ppm. The use of sucralose in soybean-based beverages is also permitted in major developed countries such as Australia, New Zealand and Japan.

(C) TO ALLOW NEW INGREDIENTS IN INFANT FORMULA

9. SFA proposes to make amendments to Regulation 252(6) to allow the following new ingredients to be added to infant formula:
    a. **Sodium salt of 3'-sialyllactose**, up to
        i. 20 mg per 100 ml (as 3'- sialyllactose (3'-SL)), in the case of infant formula for an infant of or below 6 months of age
        ii. 15 mg per 100 ml (as 3'- sialyllactose (3'-SL)), in the case of infant formula for an infant above the age of 6 months but not more than 12 months of age

    b. **Sodium salt of 6'-sialyllactose**, up to
        i. 40 mg per 100 ml (as 6'- sialyllactose (6'-SL)), in the case of infant formula for an infant of or below 6 months of age
        ii. 30 mg per 100 ml (as 6'- sialyllactose (6'-SL)), in the case of infant formula for an infant above the age of 6 months but not more than 12 months of age

    c. **3-fucosyllactose** (3-FL), up to 44 mg per 100 ml

10. Sodium salts of 3'-SL, 6'-SL and 3-FL have been allowed for use in infant formula in the European Union and the United States up to the proposed maximum levels. Considering the positive evidence backing the safe uses of sodium salts of 3'-SL and 6'-SL, as well as 3-FL in infant formula, SFA has reviewed and approved the use of these new ingredients in infant formula.

(D) TO INCREASE THE MAXIMUM LEVELS OF PERMITTED INGREDIENTS IN INFANT FORMULA

11. SFA proposes to make amendments to Regulation 252(6) to increase the maximum levels of **2'-fucosyllactose** (2'-FL) and **Lactose-N-tetraose** (LNT) for use in infant formula:
    a. In the case of 2'-FL, to increase the maximum level from the current 120 mg per 100 ml to **240 mg per 100 ml**
    b. In the case of LNT, to increase the maximum level for use in infant formula for an infant above the age of 6 months but not more than 12 months of age from the current 60 mg per 100 ml to **80 mg per 100 ml**.

12. The increased levels of 2'-FL and LNT in infant formula are comparable to levels that naturally occur in human milk. The proposed levels are also permitted in Australia, New Zealand and the United States (in the case of 2'-FL), and in the European Union and the US (in the case of LNT). Considering the positive evidence backing the safe use of 2'-FL and LNT up to the increased levels in infant formula, SFA proposes to allow such use.

~~~~~~
~~~~~~