

CONSULTATION ON DRAFT FOOD (AMENDMENT) REGULATIONS 2019

Aim

The Agri-Food and Veterinary Authority (AVA) is seeking feedback from the food industry (local food manufacturers and importers, as well as interested parties) on the draft Food (Amendment) Regulations 2019, which are targeted to come into effect in the first quarter of 2019.

Summary of amendments

The draft Food (Amendment) Regulations 2019 contains trade facilitating measures, such as provisions for the use of new additives in food, extension of use of existing food additives, extension of use of a permitted health claim to a new food constituent, removal of copper from the list of incidental constituents and removal of the labelling requirement for eggs treated with mineral hydrocarbons. A new maximum limit for inorganic arsenic in husked rice will also be included in the Food Regulations.

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

<http://www.ava.gov.sg/legislation> (select "Sale of Food Act", then click on "Draft Food (Amendment) Regulations 2019")

Request for comments

AVA invites views and comments on the draft Food (Amendment) Regulations 2019. All submissions should be clearly and concisely written, and should provide a reasoned explanation for any proposed revisions.

Submissions should reach AVA no later than 6:00 p.m., 05 November 2018, through mail, or email, to the following addresses:

Mail:

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PROPOSED AMENDMENTS TO THE FOOD REGULATIONS

(A) TO ALLOW THE USE OF NEW ADDITIVES

1. 1,3-propanediol will be included under Regulation 22 as a permitted carrier solvent for flavouring agents, for use under good manufacturing practice. 1,3-propanediol is generally recognised as safe (GRAS) for use as a carrier solvent for flavouring agents in the United States, and is also permitted as a flavouring agent in a number of countries such as Australia, New Zealand, Mexico, Brazil, Argentina, Chile, and Peru.
2. Four new salts of currently permitted amino acids (listed below) will be included under Part III of the Seventh Schedule of the Food Regulations. These amino acids have been approved for use in food in the major developed countries, including Japan, the European Union and the United States. The nomenclature for permitted amino acids will also include a prefix “L-” to align with the nomenclature used by the Codex Alimentarius Commission and major developed countries.
 - L-Isoleucine monohydrochloride
 - L-Leucine monohydrochloride
 - L-Lysine monohydrochloride
 - L-Lysine acetate
3. Seven new enzymes (listed below) will be permitted for use in food under good manufacturing practice. These enzymes have a long history of usage by the food industry, and have been approved for use in food in several countries, including Australia, Brazil, Canada, China, Denmark, France, Japan, Mexico, New Zealand and the United States. In addition, the existing footnote for serine proteinase (EC 3.4.21.14) will be amended to specify that serine proteinase includes subtilisin (EC 3.4.21.62), to be in line with the classification of subtilisin in international scientific enzyme databases.

Enzyme	EC Number	Production organism	Donor organism	Donor gene
Alpha-acetolactate decarboxylase	4.1.1.5	<i>Bacillus licheniformis</i>	<i>Bacillus brevis</i>	Alpha-acetolactate decarboxylase
Aqualysin	3.4.21.111	<i>Bacillus subtilis</i>	<i>Thermus aquaticus</i>	Aqualysin 1
Beta-amylase	3.2.1.2	<i>Bacillus licheniformis</i>	<i>Bacillus flexus</i>	Beta-amylase
Beta-galactosidase (or lactase)	3.2.1.23	<i>Bacillus licheniformis</i>	<i>Bifidobacterium bifidum</i>	Beta-galactosidase (or lactase)
Endo-1,4-beta-xylanase	3.2.1.8	<i>Bacillus subtilis</i>	<i>Pseudoalteromonas haloplanktis</i>	Endo-1,4-beta-xylanase

Enzyme	EC Number	Production organism	Donor organism	Donor gene
Alpha-acetolactate decarboxylase	4.1.1.5	<i>Bacillus licheniformis</i>	<i>Bacillus brevis</i>	Alpha-acetolactate decarboxylase
Glucoamylase (or amyloglucosidase)	3.2.1.3	<i>Aspergillus niger</i>	<i>Gloeophyllum trabeum</i>	Glucoamylase (or amyloglucosidase)
Phosphatidylinositol phospholipase C	3.1.4.11	<i>Pseudomonas fluorescens</i>	<i>Isolated from soil</i>	Phosphatidylinositol phospholipase C

4. 10 new food additives (listed below) will be permitted for use in food under good manufacturing practice. With the exception of potassium caseinate, the safety of these additives has been established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and all have been assigned Acceptable Daily Intakes (ADIs) of “Not specified” or “Not limited”. The Codex Alimentarius Commission has adopted provisions for the use of eight of these additives in food under good manufacturing practice. Tamarind seed polysaccharide is currently being considered at Step 3 of the Codex process for inclusion in Table 3 of the Codex General Standard for Food Additives, while potassium caseinate is regarded to be an edible caseinate in the Codex Standard for Edible Casein Products (CODEX STAN 290-1995).

To be permitted as Emulsifiers/Stabilisers (Sixth Schedule)	To be permitted as General Purpose Food Additives (Eighth Schedule)
<ol style="list-style-type: none"> Sodium carboxymethyl cellulose, enzymatically hydrolysed (Cellulose gum, enzymatically hydrolysed) (INS 469) Ethyl hydroxyethyl cellulose (INS 467) Potassium caseinate Tamarind seed gum (INS 437) 	<ol style="list-style-type: none"> Sodium fumarate (INS 365) Polyvinylpyrrolidone, insoluble (polyvinylpolypyrrolidone) (INS 1202) Triammonium citrate (INS 380) Cyclotetraglucose (INS 1504(i)) Cyclotetraglucose syrup (INS 1504(ii)) Magnesium hydroxide carbonate (INS 504(ii))

5. Paprika extract (INS 160c(ii)) (obtained by solvent extraction of the dried ground fruit pods of paprika) will be listed as a permitted colouring matter under Part II of the Fifth Schedule. JECFA has published the purity criteria for paprika extract and established an ADI of 0 – 1.5 mg/kg bw for paprika extract. Paprika extract is also a permitted colouring matter in major developed countries such as Australia, New Zealand, the European Union and Japan.
6. Monk fruit extract (containing 20% to 90% w/w mogroside V) will be permitted for use as a sweetening agent in food under good manufacturing practice. The additive has been permitted for use as a sweetener in Japan, the United States and China.

(B) TO EXTEND THE USE OF CURRENTLY APPROVED FOOD ADDITIVES IN ADDITIONAL FOOD CATEGORIES

- Propionic acid and its sodium and calcium salts are currently classified as Class II chemical preservatives and permitted for use only in a few categories listed in the Fourth Schedule, up to the maximum levels specified therein. Potassium

propionate, however, is not a permitted food additive under the Food Regulations. With the proposed amendments, propionic acid and its sodium, calcium and potassium salts (INS 280, 281, 282, 283) will be allowed for use in food as Class I chemical preservatives under good manufacturing practice. JECFA has established an ADI “Not limited” for propionic acid and its sodium, calcium and potassium salts, while the Codex Alimentarius Commission has adopted provisions for the use of propionic acid and its sodium, calcium and potassium salts in food under good manufacturing practice.

2. Dimethyl polysiloxane (INS 900a), a permitted anti-foaming agent, will be allowed for use in four new food categories “Lactobacillus milk drinks or cultured milk drinks”, “Flavoured milk”, “Ready-to-drink coffee” and “Ready-to-drink tea”, at levels up to 10 ppm. Internationally, the use of dimethyl polysiloxane in one or more of these categories has been endorsed by the Codex Alimentarius Commission, and permitted in Australia, New Zealand, Canada, the European Union and the United States.
3. Butylated hydroxyanisole (INS 320) and butylated hydroxytoluene (INS 321), will be allowed in a new food category “Breakfast cereals”, at levels up to 200 ppm and 100 ppm respectively, calculated on the fat or oil basis. Internationally, the use of butylated hydroxyanisole and butylated hydroxytoluene in breakfast cereals has been endorsed by the Codex Alimentarius Commission, and is also permitted in Canada and the United States.
4. Nisin (INS 234) will be allowed for use under good manufacturing practice in “liquid egg analogues” as a preservative to control the growth of toxin-producing food pathogens such as *Bacillus cereus* and *Clostridium botulinum*. “Liquid egg analogues” are products comprised of plant-based proteins with various food additives, and are intended for use as substitutes to liquid egg products.
5. Benzoic acid (and its sodium and potassium salts) (INS 210, 211 and 212) and sorbic acid (and its sodium, potassium and calcium salts) (INS 200, 201, 202 and 203) will be allowed in two new food categories “Custard fillings and toppings (egg-based)” and “Fillings and toppings based on fat emulsion”, at levels up to 1000 ppm, when used singly. Internationally, the use of benzoates and sorbates in these two categories has been endorsed by the Codex Alimentarius Commission and permitted in Canada and the United States.
6. Steviol glycosides (INS 960a) will be allowed for use in 19 new food categories, up to maximum permitted levels ranging from 40 to 360 ppm, in line with the maximum levels adopted by the Codex Alimentarius Commission for similar food categories.

Food categories	Maximum permitted levels (ppm)
Edible ices (including sherbet and sorbet)	270
Dairy-based desserts and dessert mixes	330
Fat-based desserts and dessert mixes, excluding dairy-based dessert products	330
Fruit-based desserts and dessert mixes, including fruit flavoured water-based desserts	350
Cereal-based and starch-based desserts and dessert mixes	165

Food categories	Maximum permitted levels (ppm)
Egg-based desserts and dessert mixes	330
Snacks: ready-to-eat, prepacked, dry, savoury starch products and coated nuts	170
Decorations, toppings (non-fruit) and sweet sauces	330
Candied fruit	40
Vegetables and seaweeds in vinegar, oil, brine, or soybean sauce	330
Canned or bottled (pasteurised) fruit	330
Fruit preparations (including pulp, purees and fruit toppings)	330
Fermented fruit products	115
Fruit fillings for pastries	330
Canned or bottled (pasteurised) or retort pouch vegetables and seaweeds	70
Fermented vegetable and seaweed products, excluding fermented soybean products	200
Jams, jellies and marmalades	360
Fruit-based spreads, excluding jams, jellies and marmalades	330
Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	200

(C) MAXIMUM LIMITS FOR INCIDENTAL CONSTITUENTS IN FOOD

1. The maximum limits for copper in food categories listed under the Tenth Schedule will be deleted as copper will no longer be regulated as an incidental constituent in food. Internationally, copper is not regarded as a food safety contaminant by the Codex Alimentarius Commission. Copper is also not regulated as a contaminant in food in the major developed countries such as Australia, Canada, Japan, the European Union, New Zealand and the United States.

On the other hand, copper is regarded as a food quality contaminant in edible fats and oils by the Codex Alimentarius Commission, which has adopted maximum limits for copper for this food category. Therefore, the maximum limit of 0.1 ppm for copper in edible fats and oils (currently stipulated under the Tenth Schedule) will be retained and moved to Regulation 78 on edible fats and oils. Two additional limits for copper in different types of edible fats and oils will be included in the Food Regulations, to be in line with the maximum limits adopted by the Codex Alimentarius Commission for different types of edible fats and oils.

In summary, the limits for copper in edible fats and oils are:

- 0.1 ppm, for refined fats and oils
 - 0.4 ppm, for virgin fats and oils; and cold pressed fats and oils
 - 0.4 ppm, for lard, rendered pork fat, premier jus (oleo stock) and dripping (edible tallow)
2. A maximum limit of 0.35 ppm for inorganic arsenic in husked rice will be included in the Food Regulations, so as to better protect consumer health. This is in line with the limit adopted by the Codex Alimentarius Commission in 2016. The food industry (in particular the rice traders and retailers) have been consulted during a public consultation exercise from 31 July to 29 September 2017. Based on the feedback received, AVA noted that the food industry had no objection to the proposed maximum limit for inorganic arsenic in husked rice.

3. The maximum limit of 5 ppm of formaldehyde in smoked meat, smoked sausage and smoked fish (Regulations 63, 67 and 74 respectively) will be removed. Formaldehyde is ubiquitous in the environment and occurs naturally in many plant and animal species. It can also be introduced to smoked foods, as a component of smoke. Neither the Codex Alimentarius Commission nor food safety authorities in major developed countries such as Australia, Canada, Japan, the European Union, New Zealand and the United States have established maximum limits for formaldehyde in smoked foods. The removal of the maximum limit of 5 ppm for formaldehyde incidentally absorbed in smoked foods must not be interpreted to mean that AVA allows the direct addition of formaldehyde to food. Formaldehyde is not a permitted food additive and the use of formaldehyde in or on food is not permitted under the Food Regulations.

(D) REMOVAL OF LABELLING REQUIREMENT FOR SHELL EGGS TREATED WITH MINERAL HYDROCARBONS

The requirement for eggs treated with mineral hydrocarbons to be marked with the word “SEALED” on the shell will be removed. Internationally, the application of mineral oils to eggs is recognised as a common practice by the regulatory authorities in Australia, New Zealand, Canada and the United States, without a need for additional labelling requirement.

(E) EXTENSION OF PERMITTED HEALTH CLAIM

AVA has received an application from the industry to extend the health claim on blood cholesterol lowering effect (listed under Regulation 9A(3)), currently approved for barley beta-glucan, to oat beta-glucan. AVA’s Advisory Committee on Evaluation of Health Claims has assessed the information provided and concluded that the cause and effect of the health benefits through consumption of oat beta-glucan can be established. The criteria under which the health claim for oat beta-glucan can be made will be the same as for barley beta-glucan. The proposed amendments (highlighted in yellow) are as follows:

“**9A(3)** Barley beta-glucans / Oat beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.”