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**ADMINISTRATIVE ORDER**

No. \_\_\_\_\_

**SUBJECT : Guidelines on the Use of Cyclamates Repealing Administrative Order No. 122 series of 1970 entitled “General Regulation Governing the Prohibition of the Use of Cyclamic Acid and its Salts (B-6.3. Food Additives and Preservatives)”**

**I. RATIONALE**

On August 14, 1970, the then Secretary of Health issued Administrative Order (AO) No. 122 series of 1970, with Subject General Regulation Governing the Prohibition of the Use of Cyclamic Acid and Its Salts (B-6.3 Food Additives and Preservatives).

The Codex Alimentarius Commission was created by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to protect the health of consumers and ensure fair practices in international trade of food through the development of food standards, codes of practice, guidelines and other recommendations. From the 2012 amendment of CODEX STAN 192-1995 on the Additives Permitted for Use under Specified Conditions in Certain Food Categories or Individual Food Items, cyclamates consisting of cyclamic acid, sodium cyclamate, and calcium cyclamate are listed under the Codex General Standard for Food Additives (GSFA). Moreover, the 71<sup>st</sup> Report of the Joint FAO/WHO Expert Committee on Food additives (JECFA) on its Safety Evaluation of Certain Food Additives that included Cyclamic Acid and its Salts: dietary exposure assessment, WHO Technical Report Series 956, 2010 has already addressed the issues on its use.

Hence, with the current scientific information on cyclamic acid and its salts provided for use as food additives under specified maximum levels in certain food categories or individual food items (Annex A); emergence of product innovations; as well as access to global trade, the repeal of Administrative Order No. 122 s. 1970 becomes imperative.

**II. OBJECTIVES**

1. To allow the use of cyclamic acid and its salts as food additives by lifting the ban as provided by Administrative Order No. 122 s. 1970.
2. To provide regulatory guidelines to food processors, importers, traders, distributors, wholesalers, manufacturers, and other food business operators on the safe and proper use of cyclamates as food additives with the setting of maximum use levels in certain food categories or individual food item.
3. To ensure regulatory compliance from the industry and effective enforcement by providing regulatory agencies with technical and scientific reference standard of safety

of cyclamates with proper use.

### III. SCOPE

This Administrative Order covers all cyclamates listed under the latest Codex GSFA.

### IV. DEFINITION OF TERMS

1. **Acceptable Daily Intake or ADI** refers to an estimate by the JECFA of the amount of a food additive, expressed on a body weight basis (60 kg-man), that can be ingested daily over a lifetime without appreciable health risk.<sup>1</sup> (Codex Stan 192-1995 Rev. 2012, (WHO Environmental Health Criteria No. 70, 1987).
2. **Cyclamates** refer to cyclamic acids and its sodium and calcium salts.
3. **FAO** refers to the Food and Agriculture Organization.
4. **Food additive** refers to any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.
5. **JECFA** refers to the Joint FAO/WHO Experts Committee on Food Additives.
6. **Maximum Level** or **Maximum Use Level** of an additive refers to the highest concentration of the food additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.

The maximum use level will not usually correspond to the optimum recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, considering the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

7. **WHO** refers to the World Health Organization.

### V. GUIDELINES

To ensure safe and proper use of cyclamates as food additives, the following guidelines are hereby issued for compliance:

1. The Food and Drug Administration (FDA) adopts the Codex standard of use of cyclamates as shown in Annex A of this Administrative Order. Food business operators

should adhere to the Codex standard on the permissible maximum level under specified conditions in certain food categories.

2. Updated values and information adopted by the Codex Alimentarius Commission shall be automatically included or adopted as an addendum to the attached Annex A on Cyclamic Acids and its Sodium and Calcium Salts.
3. Food processors of pre-packaged food products that uses any of the cyclamates are directed to declare the use of such non-nutritive sweetener and to indicate the appropriate function as food additive, i.e. sodium cyclamate (sweetener).
4. Manufacturers, distributors, and traders of cyclamates are directed to secure FDA License to Operate (LTO) and Certificate of Product Registration (CPR) as food additives.
5. All food additives subject to the provisions of this Order shall be used under the conditions of good manufacturing practice, which include the following:
  - 5.1. The quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;
  - 5.2. The quantity of the food additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,
  - 5.3. The additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.
6. In case ambulant vendors or other food establishments opted to use cyclamates as a non-nutritive sweetener, only FDA registered cyclamates shall be used at levels prescribed in this Order.
7. The Department of Interior and Local Government (DILG) and the Local Government units (LGUs) shall be provided with this AO for proper implementation as provided by Section 15 of Republic Act No. 10611, otherwise known as the Food Safety Act of 2013.

## **VI. PENALTY CLAUSE**

Violations to any provisions of this Order shall be subject to the penalties/sanctions provided by Republic Act No. 10611, Food Safety Act of 2013 and other penalties provided by other applicable laws.

## **VII. SEPERABILITY CLAUSE**

If any provision of this Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

**VIII. REPEALING CLAUSE**

Administrative Order No. 122 s. 1970, with Subject: “General Regulation Governing the Prohibition of the use of Cyclamic Acid and its Salts (B-6.3. food Additives and Preservatives)”, all orders, rules, regulations, and other related issuances inconsistent with or contrary to this Order are hereby repealed, amended, or modified accordingly.

All provisions of existing issuances which are not affected by this Order shall remain valid and in effect.

**IX. EFFECTIVITY**

This Order shall take effect within fifteen (15) days after its publication in a newspaper of general circulation and upon filing at the Office of the National Administrative Register (ONAR), University of the Philippines Law Center, Diliman, Quezon City.

**FRANCISCO T. DUQUE, III, MD**  
Secretary of Health

DTN 20191128154017

Draft for comments

## Annex A

**Cyclamic Acid and its Sodium and Calcium Salts  
Permitted for Use Under Specified Conditions  
In Certain Food Categories or Individual Food Items<sup>1</sup>**

<b>Food Category No.</b>	<b>Food Category</b>	<b>Maximum Level (mg additive/kg of food)</b>	<b>Note Number (see last page for details)</b>
01.1.4	Flavored fluid milk drinks	250 mg/kg	17 & 477
01.7	Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt)	250 mg/kg	17 & 477
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	250 mg/kg	17 & 161
03.0	Edible Ices, including sherbet and sorbet	250 mg/kg	17 & 477
04.1.2.4	Canned or bottled (pasteurized) fruit	1,000 mg/kg	17, 161 & XS319
04.1.2.5	Jams, jellies, marmalades	1,000 mg/kg	17 & 477
04.1.2.6	Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5	2,000 mg/kg	17 & 477
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	250 mg/kg	17 & 477
04.1.2.9	Fruit-based desserts, including fruit-flavored water-based desserts	250 mg/kg	17 & 477
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	250 mg/kg	17 & 161
05.1.2	Cocoa mixes (syrups)	250 mg/kg	17, 127 & 161
05.1.3	Cocoa-based spreads, including fillings	500 mg/kg	17, 477 & XS86
05.1.4	Cocoa and chocolate products	500 mg/kg	17 & 477
05.1.5	Imitation chocolate, chocolate substitute products	500 mg/kg	17 & 161
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	500 mg/kg	17, 156, 477 & XS309R & 161
05.3	Chewing gum	3000 mg/kg	17 & 477

<sup>1</sup> CODEX STAN 192-1995, Rev 2019, Codex General Standard for Food Additives.

05.4	Decorations (e.g., for fine bakery wares), toppings (non- fruit) and sweet sauces	500 mg/kg	17 & 477
06.5	Cereal and starch-based desserts (e.g., rice pudding, tapioca pudding)	250 mg/kg	17 & 161
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	1600 mg/kg	17 & 165
10.4	Egg-based desserts (e.g., custard)	250 mg/kg	17 & 477
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	500 mg/kg	17 & 159
11.6	Table-top sweeteners, including those containing high intensity sweeteners	GMP	17
12.6.1	Emulsified sauces and dips (e.g., mayonnaise, salad dressing, onion dip)	500 mg/kg	17 & 161
12.7	Salads (e.g., macaroni salad, potatosalad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	500 mg/kg	17 & 161
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400 mg/kg	17
13.4	Dietetic formulae for slimming purposes and weight reduction	400 mg/kg	17
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	400 mg/kg	17
13.6	Food supplements	1250 mg/kg	17
14.1.3.1	Fruit nectar	400 mg/kg	17 & 122
14.1.3.2	Vegetable nectar	400 mg/kg	17 & 161
14.1.3.3	Concentrates for fruit nectar	400 mg/kg	17, 122 & 127
14.1.3.4	Concentrates for vegetable nectar	400 mg/kg	17, 127 & 161
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	350 mg/kg	17 & 127
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	250 /kg	17

**Notes to the Comments**

Note 17	As cyclamic acid
Note 122	Subject to national legislation of the importing country.
Note 127	As served to the consumer.
Note 156	For use in micro-sweets and breath freshening mints at 2 500 mg/kg.
Note 159	For use in pancake syrup and maple syrup only.
Note 161	Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.
Note 165	For use in products for special nutritional use only.
Note 477	Some Codex Members allow use of additives with sweetener function in all foods within this Food Category while others limit additives with sweetener function to those foods with significant energy reduction or no added sugars.
Note XS86	Excluding products conforming to the Standard for Cocoa Butter (CODEX STAN 86-1981).
Note XS309R	Excluding products conforming to the Codex Regional Standard for Halawa Tehenia (CODEX STAN 309R-211).
Note XS319	Excluding products conforming to the Standard for Certain Canned Fruits (CODEX STAN 319-2015).