

REGULATION OF THE FOOD AND DRUG CONTROL AGENCY

NUMBER YEAR

REGARDING

THE REQUIREMENT OF HEAVY METALS CONTAMINATION IN PROCESSED FOOD

BY THE GRACE OF THE ALMIGHTY GOD

HEAD OF THE FOOD AND DRUG CONTROL AGENCY

- Considers:
- a. that in order to protect the public from processed food containing heavy metals contamination exceeding the maximum threshold and to support increasing the competitiveness of Indonesian processed food, it is necessary to regulate requirements for heavy metals contamination in processed food;
 - b. that the regulation regarding the maximum limit of heavy metals contamination in processed food as stipulated in the Regulation of the Food and Drug Control Agency Number 5 Year 2018 regarding the Maximum Limit of Heavy Metals Contamination in Processed Food needs to be adjusted to the development of science and technology, so that it needs to be replaced;
 - c. that based on the considerations as referred to in letters a and b as well as to implement the provisions of Article 5 paragraph (2) of Government Regulation Number 86 of 2019 regarding Food Safety, it is necessary to stipulate a Regulation of the Food and Drug Control Agency regarding The Requirement of Heavy Metals Contamination in Processed Food;
- In view of:
1. Law Number 18 Year 2012 regarding Food (State Gazette of the Republic of Indonesia Year 2012 Number 226, Supplement to State Gazette of the Republic of Indonesia Number 5360);
 2. Government Regulation Number 86 Year 2019 regarding Food Safety (State Gazette of the Republic of Indonesia Year 2019 Number 248, Supplement to State Gazette of the Republic of Indonesia Number 6442);
 3. Presidential Regulation Number 80 Year 2017 regarding the Drug and Food Control Agency (State Gazette of the Republic of Indonesia Year 2017 Number 180);
 4. Regulation of the Food and Drug Control Agency Number 21 Year 2020 regarding the Organization and Working Procedures of the Food and Drug Control Agency (State Gazette of the Republic of Indonesia Year 2020 Number 1002);
 5. Regulation of the Food and Drug Control Agency Number 22 Year 2020 regarding the Organization and Working Procedures of the Technical Implementer Unit within the Food and Drug Control Agency (State Gazette of the Republic of Indonesia Year 2020 Number 1003) as amended by Regulation of the Food and Drug Control Agency Number 23 Year 2021 regarding the Amendment to Regulation of the Food and Drug Control Agency Number 22

Year 2020 regarding the Organization and Working Procedures of the Technical Implementer Unit within the Food and Drug Control Agency (State Gazette of the Republic of Indonesia Year 2021 Number 1151);

HAS DECIDED:

To stipulate: THE REGULATION OF FOOD AND DRUG CONTROL AGENCY REGARDING THE REQUIREMENT OF HEAVY METALS CONTAMINATION IN PROCESSED FOOD.

Article 1

In this Agency Regulation, these terms shall be construed as follow:

1. Food shall be Food is anything derived from biological sources of agricultural products, plantations, forestry, fisheries, livestock, territorial waters, and water, whether processed or unprocessed, intended as food or drinks for human consumption, including food additives, food raw material, and other ingredients used in the process of preparation, processing, and/or making of food or beverages.
2. Processed Food shall be processed food or beverage using a particular system or method, with or without additives.
3. Food Contamination, hereinafter referred to as Contamination, is a material that is accidentally and/or unwanted in Food originating from the environment or as a result of processes along the food chain, in the form of biological contaminants, chemical heavy metals contaminants, mycotoxins, radioactive substances, and other chemical contaminants, residues of veterinary drugs and pesticides as well as other objects that can interfere, harm, and endanger human health.
4. Heavy Metals shall be chemical elements of metallic and metalloids, have high atomic weights and density, which are toxic to living things.
5. Maximum Limit is the maximum permissible concentration of Heavy Metals Contaminants that can be accepted in Processed Food.
6. Every Person shall be an individual or corporation, whether legal entity or non-legal entity.
7. Head of the Agency shall be the Head of Food and Drug Control Agency.

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CHAPTER II THE REQUIREMENT

Article 2

- (1) Each Person that implementing the activity or process of production, storing, transporting, and/or distributing the Processed Food shall be obliged to fulfill the sanitation requirement.
- (2) Sanitation requirement as referred to in paragraph (1) that is regulated in this Agency Regulation shall be the fulfillment of the requirements for Heavy Metals Contamination in Processed Food.
- (3) The requirement of Heavy Metals Contamination in Processed Food as referred to in paragraph (2) includes type and Maximum Limit of Heavy Metals Contamination in Processed Food.

Article 3

- (1) Type of Heavy Metals Contamination in Processed Food as referred to in Article 2 paragraph (3) shall be in the form of:
 - a. Arsenic (As);
 - b. Lead (Pb);
 - c. Cadmium (Cd);
 - d. Mercury (Hg); and
 - e. Tin (Sn).
- (2) The Maximum Limit of Heavy Metals Contamination in Processed Food as referred to in Article 2 paragraph (3) shall be listed in the Appendix which is an integral part of this Agency Regulation.

Article 4

- (1) The fulfillment of the requirements for the Maximum Limit of Heavy Metals Contamination in Processed Food as referred to in Article 3 paragraph (2) is proven by the result of testing from accredited laboratories in accordance with the provisions of the legislation.
- (2) The testing as referred to in paragraph (1) is carried out using a validated or verified analytical method.
- (3) In the case of imported Processed Food, the results of laboratory testing as referred to in paragraph (1) can be issued by a laboratory at the country of origin, which already has a mutual recognition agreement with the authorized institution and/or accredited laboratory in Indonesia in accordance with the provisions of the legislation.

CHAPTER III SUPERVISION

Article 5

The supervision to the fulfillment of the requirements for Heavy Metals Contamination in Processed Food is carried out in accordance with the provisions of the legislation.

CHAPTER IV TRANSITIONAL PROVISION

Article 6

- (1) Processed Food that has obtained a distribution permit before this Agency Regulation comes into force, must comply with the provisions of this Agency Regulation no later than 12 (twelve) months from the promulgation of this Agency Regulation.
- (2) Processed Food that is in the process of applying for a distribution permit will continue to be processed in accordance with the provisions of the Agency Regulations which are the basis for the application and must comply with the provisions of this Agency Regulation no later than 12 (twelve) months from the promulgation of this Agency Regulation.

CHAPTER V CLOSING PROVISION

Article 7

At the time this Agency Regulation comes into force, the Regulation of the Food and Drug Control Agency Number 5 of 2018 regarding the Maximum Limit of Heavy Metals Contamination in Processed Food (State Gazette of the Republic of Indonesia of 2018 Number 673), is revoked and declared invalid.

Article 8

This Agency Regulation comes into force on the date of promulgation.

For public cognizance, ordering the promulgation of this Agency Regulation by placing it in the State Gazette of the Republic of Indonesia.

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Stipulated in Jakarta
On date

HEAD OF FOOD AND DRUG CONTROL
AGENCY

PENNY K. LUKITO

Promulgated in Jakarta
On dated

DIRECTOR GENERAL OF
THE LEGISLATION
THE MINISTRY OF LAW AND HUMAN RIGHTS
THE REPUBLIC OF INDONESIA,

BENNY RIYANTO

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR . . . NUMBER

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APPENDIX
 REGULATION OF FOOD AND DRUG
 CONTROL AGENCY
 NUMBER . . . YEAR
 REGARDING
 THE REQUIREMENT OF HEAVY
 METALS CONTAMINATION IN
 PROCESSED FOOD

THE MAXIMUM LIMIT OF HEAVY METALS CONTAMINATION IN PROCESSED FOOD

A. Arsenic (As), Lead (Pb), Mercury (Hg), and Cadmium (Cd)

No.	Type of Processed Food	Maximum Limit (mg/kg)			
		As*	Pb	Hg	Cd
1.	Dairy Processed Products	0.10**	0.02**	0.02**	0.05**
2.	Fat Processed Products	0.10	0.10	0.05	0.10
3.	Fat Emulsion, Especially Type of Water-in-Fat Emulsion	0.10	0.10	0.03	0.10
4.	Ice Processed Product to Eat, including Sherbet and Sorbet	0.20	0.15	0.03	0.01
5.	Vegetable Processed Products	0.15	0.20	0.03	0.05
6.	Seaweed	1.0 (as inorganic arsenic)	0.20	0.03	0.05
7.	Pure Jelly (from seaweed) Flour(Raw Material)	1.0	1.0	0.50	0.50
8.	Jelly (from seaweed) Flour	0.01**	0.01**	0.005**	0.005**
9.	Processed Fruit other than contains Cranberry, Currants, and Elderberry	0.15	0.10	0.03	0.05
10.	Processed Fruit that Contains Cranberry, Currants, and Elderberry	0.15	0.20	0.03	0.05
11.	Jam, Jelly, and Marmalade	1.0	0.40	0.03	0.20
12.	Confectionery/Candy***	1.0	1.0	0.05	0.50

Note:

* If not stated, otherwise calculated as a total arsenic

** calculated against ready-to-eat products

***Toppings (Non-Fruit), Decorations and Sweet Sauces

13.	Chocolate Products with Total of Cocoa Solids < 30% (based on dry weight)	1.0	1.0	0.05	0.30
14.	Chocolate Products with Total of Cocoa Solids >= 30% to < 50% (based on dry weight)	1.0	1.0	0.05	0.70
15.	Chocolate Products with Total of Cocoa Solids >= 50% to < 70% (based on dry weight)	1.0	1.0	0.05	0.80
16.	Chocolate Products with Total of Cocoa Solids >= 70% (based on dry weight)	1.0	1.0	0.05	0.90
17.	Cocoa mass & cocoa powder (which will be chocolate products)	1.0	1.0	0.03	1.0
18.	Processed products from cereal grains, roots and tubers, nuts and pith (excluding bakery products)	0.1 (except wheat flour as a food ingredient 0.50; and Flour for Dough (for example to coat the surface of fish or chicken meat 0.20))	0.25 (except wheat flour as a food ingredient 1.0)	0.03 (except for wheat flour as a food ingredient 0.05)	0.05 (except wheat flour as a food ingredient 0.1; and Flour for Dough (for example to coat the surface of fish or chicken meat 0.20))
19.	Bakery products	0.50	0.50	0.05	0.20
20.	Meat Processed Products	0.25	0.50	0.03	0.05
21.	Fish Processed Products	2.0	0.30 (except for processed fish that included in cephalopods or shellfish 1.0)	0.50 (except for predatory fish, such as: shark, tuna, marlin 1.0)	0.30 (except for processed fish that included in cephalopods or shellfish 1.0)
22.	Egg Processed Products	0.25	0.25	0.03	0.10

Note:

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***Toppings (Non-Fruit), Decorations and Sweet Sauces

23.	Sweeteners, except white crystal sugar and honey	1.0	0.25	0.03	0.20
24.	White Crystal Sugar	1.0	2.0	0.05	0.20
25.	Honey	1.0	1.0	0.03	0.20
26.	Salt	0.10	1.0 (except iodized salt 10.0)	0.05 (except iodized salt 10.0)	0.50
27.	Spice Processed Products, Herb Processed Products, Seasoning and Condiment	0.15 (except seasoning products made from seaweed 0.40 as inorganic arsenic; and seasoning products made from fish product 0.30)	1.0	0.05	0.50
28.	Soup, Sauce, Salad, Protein Products, including Yeast	0.15	1.0	0.05	0.5
29.	Processed Food for Special Nutrition Purposes (Besides that are mentioned on No. 30-36)	0.10	0.25	0.01	0.01
30.	Baby Formula, Advanced Formula, and Growth Formula	0.02**	0.01**	0.01**	0.01**
31.	Processed Food for Special Medical Purposes for Infants and Children	0.02**	0.01** for infants 0.02** for children	0.01**	0.01**
32.	Processed Food for Infants and Children in Growth Period	0.10 (except food for infants and children in growth period that made from fish products	0.10	0.01	0.05

Note:

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** calculated against ready-to-eat products

***Toppings (Non-Fruit), Decorations and Sweet Sauces

		0.08 as inorganic arsenic			
33.	Processed Food for Special Medical Purposes for Adult	0.02**	0.02**	0.01**	0.01**
34.	Processed Food for Weight Control	0.10	0.25	0.01	0.01
35.	Processed Food for Athlete	0.10	0.25	0.01	0.01
36.	Processed Food Specially for Pregnant Women and or Breast-Feeding Mothers	0.02**	0.02**	0.01**	0.01**
37.	Natural Mineral Water and Its Source	0.05	0.01	0.001	0.003
38.	Processed Drink Water	0.01	0.005	0.001	0.003
39.	Processed Vegetable Juice	0.10 (except for concentrates are counted as ready-to-drink products)	0.10 (except for concentrates are counted as ready-to-drink products)	0.02 (except for concentrates are counted as ready-to-drink products)	0.03 (except for concentrates are counted as ready-to-drink products)
40.	Processed Fruit Juice	0.10	0.03 For concentrates are counted as ready-to-drink products (except fruit juices that derived from berries or other type of berries 0.05 for concentrates are counted as ready-to-drink products and grape	0.02	0.03

Note:

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** calculated against ready-to-eat products

***Toppings (Non-Fruit), Decorations and Sweet Sauces

			juice 0.04 for concentrates are counted as ready-to- drink products)		
41.	Processed Fruit Nectar and Vegetable Nectar	0.10 (except for concentrates are counted as ready-to- drink)	0.20 (except for concentrates are counted as ready-to- drink)	0.03 (except for concentrates are counted as ready-to- drink)	0.05 (except for concentrates are counted as ready-to- drink)
42.	Beverages Flavored Water Based, Electrolyte Beverages, and Particulated Drinks	0.05 (except for liquid and solid concentrates are counted as ready-to- drink products)	0.05 (except for liquid and solid concentrates are counted as ready-to- drink products)	0.01 (except for liquid and solid concentrates are counted as ready-to- drink products)	0.05 (except for liquid and solid concentrates are counted as ready-to- drink products)
43.	Coffee, Substituted Coffee, Tea, Herbal Brewing, and Hot Grain and Cereal Drinks, except Chocolate	1.0	2.0	0.03	0.20
44.	Alcoholic Beverages, Including Similar Low Alcohol Beverages	0.10	0.20	0.03	0.20
45.	Ready to Eat Snacks	0.25	0.25	0.03	0.05

Note:

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** calculated against ready-to-eat products

***Toppings (Non-Fruit), Decorations and Sweet Sauces

B. Tin (Sn)

No.	Type of Processed Food	Maximum Limit (mg/kg)
1.	Infants Formula, Advanced Formula, Growth Formula and Processed Food for Special Medical Purposes for Infants and Children	10**
2.	Food for Infants and Children in Growth Period	40
3.	Canned Beverages	100**
4.	Other Processed Products Packaged in Cans	250
5.	Other Processed Products that are not Packaged in Cans	40

HEAD OF FOOD AND DRUGS CONTROL AGENCY

PENNY K. LUKITO

Note:

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** calculated against ready-to-eat products

***Toppings (Non-Fruit), Decorations and Sweet Sauces