

General Explanation of Draft Version of paragraph 15 and paragraph 1 Table1 and paragraph 4 Table 4 of the Guidelines on Regulated Toxic Chemical Substances and the Management of Their Handling

The Toxic Chemical Substances Control Act was revised and promulgated on December 11, 2013. In accordance with Article 7 of this Act, the central competent authority shall officially announce toxic chemical substances as Class 1, Class 2, Class 3 or Class 4 toxic chemical substances when the toxicological characteristics of chemical substances conform to the toxic chemical substance classification definitions prescribed in Article 3 of this Act. Furthermore, according to Article 11, Paragraph 1 of the Toxic Chemical Substances Control Act, unless other regulations apply, the handling of toxic chemical substances shall be conducted in compliance with methods announced or approved by the central competent authority, which may also authorize the announcement of toxic chemical substance control concentration standards and large-scale handling standards in accordance with management needs.

In view of the recent occurrence of food safety incidences and the introduction of illegal chemical substances into the food supply that affect people's health, this announcement has added regulations for strengthened controls for the eight major handling activities of manufacturing, importing, exporting, selling, transporting, using, storing, and disposing and for strengthening the package labeling for 13 types of toxic chemical substances, including malachite green, that present food safety risks, for which there is concern of endangerment to human health, and that are Class 4 toxic chemical substances as announced pursuant to the Toxic Chemical Substances Control Act. Furthermore, the Chinese substance name for chromium carbonyl has been changed from and the control standard has been amended to chromium concentration 1% or more. The summary of amendments is as follows:

1. Added Paragraph 15: Apart from requiring relevant markings in accordance with the "Toxic Chemical Substances Labeling and Materials Safety Data Sheets Regulations" and other relevant regulations, "Not for use in foods" must be marked on container packaging when handling malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin.
2. Revision of Paragraph 1 Table 1:
 - (1) Addition of malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin as Class 4 toxic chemical substances with control concentration standards of 1% or more.
 - (2) The Chinese substance name for chromium carbonyl has been changed and the chromium content control concentration standard has been amended to chromium concentration 1% or more.
3. Revision of Paragraph 4 Table 4: Addition of summary table of improvement deadlines for malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin.

Announcement										Explanation
15. Apart from requiring relevant markings to adhere to the "Toxic Chemical Substances Labeling and Materials Safety Data Sheets Regulations" and other relevant regulations, "Not for use in foods" must be marked on container packaging when handling malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin. The characters of such markings must be clearly rendered on a visible area of the largest external surface area of containers, and the markings shall be primarily in Chinese. The area of the markings may not be smaller than 35% of the surface area, and the color of the markings must contrast with the background color.										Addition of official announcement concerning 13 toxic chemical substances, including malachite green, that pose a food safety risk and are suspected of being hazardous to human health. Apart from being announced as Class 4 toxic chemical substances subject to increased control in accordance with these Guidelines, also strengthens packaging marking requirements and adds a warning that the substances may not be used in foods.
Table 1 Summary table of announced toxic chemical substances and their control concentration standards and large-scale handling standards										1. The Chinese substance name for chromium carbonyl has been changed and the chromium content control concentration standard has been amended to chromium concentration 1% or more. 2. Addition of the 13 chemical substances malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin, which are suspected of posing a food safety risk and may be hazardous to human health, and are therefore listed as Class 4 toxic chemical substances.
Listed No.	Series No.	Chinese Name	English Name	Chemical Formula	CAS. Number	control concentration standard w/w %	large-scale handling standard (Kg)	Toxicity Classify	Announced Date	
055	24	六羧鉻	Chromium carbonyl	Cr(CO) ₆	13007-92-6	chromium concentration 1% or more	500	2	85.05.31 88.07.19 88.12.24 89.10.25 106.○.○	
175	01	孔雀綠	Malachite green	C ₂₃ H ₂₅ ClN ₂	569-64-2	1	—	4	106.○.○	
176	01	順丁烯二酸	Maleic acid	C ₄ H ₄ O ₄	110-16-7	1	—	4	106.○.○	
176	02	順丁烯二酸酐	Maleic anhydride	C ₄ H ₂ O ₃	108-31-6	1	—	4	106.○.○	
177	01	對位乙氧基苯脲	(4-Ethoxyphenyl)urea、Dulcin	C ₉ H ₁₂ N ₂ O ₂	150-69-6	1	—	4	106.○.○	
178	01	溴酸鉀	Potassium bromate	KBrO ₃	7758-01-2	1	—	4	106.○.○	
179	01	富馬酸二甲酯	Dimethyl fumarate (DMF)	C ₆ H ₈ O ₄	624-49-7	1	—	4	106.○.○	
180	01	苳基紫	Benzyl violet 4B	C ₃₉ H ₄₀ N ₃ NaO ₆ S ₂	1694-09-3	1	—	4	106.○.○	
181	01	皂黃	Metanil yellow	C ₁₈ H ₁₄ N ₃ NaO ₃ S	587-98-4	1	—	4	106.○.○	
182	01	玫瑰紅 B	Rhodamine B	C ₂₈ H ₃₁ ClN ₂ O ₃	81-88-9	1	—	4	106.○.○	
183	01	二甲基黃	Butter yellow	C ₁₄ H ₁₅ N ₃	60-11-7	1	—	4	106.○.○	
184	01	甲醛次硫酸氫鈉	Sodium F	CH ₇ NaO ₅ S	6035-47-8	1	—	4	106.○.○	
185	01	三聚氰胺	Melamine	C ₃ H ₆ N ₆	108-78-1	1	—	4	106.○.○	
186	01	α-苳並吡喃酮	Coumarin	C ₉ H ₆ O ₂	91-64-5	1	—	4	106.○.○	
Table 4 Summary table of improvement deadlines for handling of announced toxic chemical substances										Addition of a summary table of improvement deadlines for Class 4 toxic chemical substances malachite green, maleic acid and maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin.
Summary table of improvement deadlines for malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin										
Toxic chemical substance		Improvement deadlines for malachite green, maleic acid, maleic anhydride, dulcin, potassium bromate, dimethyl fumarate, benzyl viologen 4B, metanil yellow, rhodamine B, butter yellow, sodium F, melamine, and coumarin								
Item										
Production of handling records, release quantity records, and regular reports in accordance with regulations.		Begin recording and reporting in accordance with regulations starting on February 15, 2018.								
Completion of containers, packaging, and handling premise and facility markings and preparation of material safety data sheets.		Complete improvements before July 15, 2018.								
Acquisition of manufacture, import, sale, use, storage, and export approval documents in accordance with regulations.		Obtain before January 15, 2019.								
Other matters not listed in this table.		Handle in accordance with relevant regulations starting from February 15, 2018.								