

## **GUIDELINES ON REGULATED TOXIC CHEMICAL SUBSTANCES AND THE MANAGEMENT OF THEIR HANDLING**

### **General information on the revision draft of Paragraph 4, Paragraph 16, Paragraph 1 Table 1, Paragraph 2 Table 2, Paragraph 3 Table 3 and Paragraph 4 Table 4**

The Guidelines on Regulated Toxic Chemical Substances and the Management of Their Handling was announced and implemented in 2007. The Official Announcement has gone through 10 revisions throughout the past 10 years. Based on Article 7 and Article 11 of the Toxic Chemical Substances Control Act, the central competent authority has been authorized, based on its management requirements, to release a list of toxic chemical substance control concentration standards and large-scale handling standards.

Fourteen toxic chemical substances, including Sudan dyes, have been classified as Class 4 toxic chemical substances under the specifications of this Official Announcement. These classifications were made in light of a number of food safety incidents in recent years, in response to illegal chemical substances entering the food supply chain and being mixed in with food products or animal feed, and in consideration of food safety risks that endanger the public health. Furthermore, in response to international regulatory trends, pentachlorophenyl laurate has been classified as a Class 1 and a Class 3 toxic chemical substance, and perfluorooctanoic acid as a class 4 toxic chemical substance. The controlled concentration level of perfluorooctane sulfonic acid has also been revised. Based on the revision draft of the Official Announcement, the key revisions are as follows:

- I. Corrected the wording in order to return to the original purpose of the legislation. (Revised of Paragraph 4)
- II. Added Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan Red 7B, Diethyl yellow/Solvent

yellow 56, Basic Orange 2, Auramine, Red No. 2, Azorubine, and Orange 2 as Class 4 toxic chemical substances; in addition, the containers of these substances must have a label stating "Not for use in foods and animal feed" and "The area of the markings may not be smaller than 35% of the surface area." (Revised of Paragraph 16)

- III. Added pentachlorophenyl laurate as a Class 1 and Class 3 toxic chemical substance; Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan Red 7B, Diethyl yellow/Solvent yellow 56, Basic Orange 2, Auramine, Red No. 2, Azorubine and Orange 2 and perfluorooctanoic acid as Class 4 toxic chemical substances. With the exception of pentachlorophenyl laurate and perfluorooctanoic acid which have the controlled concentration standards of 0.01% or more, and perfluorooctane sulfonic acid which has corrected the controlled concentration standards more rigorous of 0.01% or more, all others on the list have a controlled concentration standards of 1% or more. (Revised of Paragraph 1 Table 1)
- IV. Added the prohibited handling of pentachlorophenyl laurate. (Revised of Paragraph 2 Table 2)
- V. Added the intended use of pentachlorophenyl laurate. (Revised of Paragraph 3 Table 3)
- VI. Added the pentachlorophenyl laurate and perfluorooctane sulfonic acid with the controlled concentration standards of 0.01% or more, Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan Red 7B, Diethyl yellow/Solvent yellow 56, Basic Orange 2, Auramine, Red No. 2, Azorubine, Orange 2 and perfluorooctanoic acid to the summary table of improvement deadlines. (Revised of Paragraph 4 Table 4 item (II) and (III))

**Revision draft comparison table for Paragraph 4 and Paragraph 16 of the Guidelines on Regulated Toxic Chemical Substances and the Management of Their Handling**

Proposed Revision	Current Measure	Explanation
<p>Announcement details: 4. Handlers who have already used these substances prior to the official announcement made by the central competent authority declaring them as toxic chemical substances must complete all <u>relevant items specified in Table 4 within the established deadline.</u></p>	<p>Announcement details: 4. Handlers who have already used these substances prior to the official announcement made by the central competent authority declaring them as toxic chemical substances must complete all improvement measures specified in Table 4 within the established deadline.</p>	<p>The use of "improvement deadlines" is inconsistent with the use of "deadlines for making improvements" in Chapter IV of the Toxic Chemical Substances Control Act. To avoid confusion, the wording has been modified to "must complete all relevant items within the established deadline" in order to return to the original purpose of the legislation.</p>
<p>16. Apart from requiring relevant markings to adhere to the "Toxic Chemical Substances Labeling and Materials Safety Data Sheets Regulations" and other relevant regulations, it must be marked on container packaging when handling Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan Red 7B, Diethyl yellow/Solvent yellow 56, Basic Orange 2, Auramine, Red No. 2, Azorubine and Orange 2. The characters of such markings must be clearly rendered on a visible area of the largest external surface area of containers:</p> <p>(I) "Not for use in foods and animal feed ", and the markings shall be primarily in Chinese.</p> <p>(II) The area of the markings may not be smaller than 35% of the surface area.</p> <p>(III) The color of the markings must contrast with the background color.</p>		<p>I. <u>Added this item.</u></p> <p>II. The 14 toxic chemical substances, including the Sudan dyes, are substances which impact food safety and can be harmful to the public health. Therefore, in order to tighten controls over these substances, they have been listed as Class 4 toxic chemical substances under the specifications of this Official Announcement.</p> <p>III. As a result of multiple cases involving Sudan dyes being mixed in illegally with animal feed, specifications related to package labels have been revised and reinforced by adding " Not for use in foods and animal feed" and the wording has been modified accordingly.</p> <p>IV. The definition of the labeling area has been modified to the " surface of area of the main display."</p>

## Paragraph 1 Table 1 revision draft comparison table

Proposed Revision										Current Measure										Explanation
Table 1 Summary table of announced toxic chemical substances and their control concentration standards and large-scale handling standards										Table 1 Summary table of announced toxic chemical substances and their control concentration standards and large-scale handling standards										<p>I. In conjunction with the addition of pentachlorophenyl laurate into Annex A (Elimination) of the Stockholm Convention on Persistent Organic Pollutants and the management of international controlled substance list, as well as to conform with the Class 1 and Class 3 toxic chemical properties of the Toxic Chemical Substances Control Act, pentachlorophenyl laurate has been listed as a Class 1 and Class 3 toxic chemical substance with a controlled concentration standard of 0.01%.</p> <p>II. Currently, the controlled concentration standard of perfluorooctane sulfonic acid (Listed No. 169, Series No. 01) is 1%. In order to strengthen the control over toxic substances, the controlled concentration standard has been revised to 0.01%.</p> <p>III. Current deliberations of the Stockholm Convention on Persistent Organic Pollutants have included perfluorooctanoic acid as a controlled substance. Although the deliberations have not concluded, in consideration of the fact that the Convention has already completed its yearly deliberation procedures related to perfluorooctanoic acid, which will most likely be included in the Convention in the near future, we are making an advanced announcement to classify perfluorooctanoic acid as a Class 4 toxic chemical substance.</p> <p>IV. Added 14 chemical substances, including the Sudan dyes (Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan Red 7B), Diethyl yellow/Solvent yellow 56, Basic Orange 2, Auramine, red No. 2, Azorubine, and orange No. 2.</p> <p>V. Sudan dyes have been listed as Class 4 toxic chemical substances</p>
Listed No.	Series No.	Chinese Name	English Name	Chemical Formula	CAS No.	Controlled Concentration standard (w/w %)	Large-scale Handling Standard (Kg)	Toxicity Classify	Announced Date	Listed No.	Series No.	Chinese Name	English Name	Chemical Formula	CAS No.	Controlled Concentration standard (w/w %)	Large-scale Handling Standard (Kg)	Toxicity Classify	Announced Date	
007	02	月桂酸五氯苯酯	Pentachlorophenyl laurate	$C_{18}H_{23}Cl_5O_2$	3772-94-9	0.01	50	1.3	107.00.00	169	01	全氟辛烷磺酸	Perfluorooctane sulfonic acid	$C_8HF_{17}O_3S$	1763-23-1	1	50	1.2	99.12.24	
169	01	全氟辛烷磺酸	Perfluorooctane sulfonic acid (PFOS)	$C_8HF_{17}O_3S$	1763-23-1	0.01	50	1.2	99.12.24 107.00.00											
169	04	全氟辛酸	Perfluorooctanoic acid (PFOA)	$C_8HF_{15}O_2$	335-67-1	0.01	50	4	107.00.00											
187	01	蘇丹 1 號	Sudan 1	$C_{16}H_{12}N_2O$	842-07-9	1%	—	4	107.00.00											
187	02	蘇丹 2 號	Sudan 2	$C_{18}H_{16}N_2O$	3118-97-6	1%	—	4	107.00.00											
187	03	蘇丹 3 號	Sudan 3	$C_{22}H_{16}N_4O$	85-86-9	1%	—	4	107.00.00											
187	04	蘇丹 4 號	Sudan 4	$C_{24}H_{20}N_4O$	85-83-6	1%	—	4	107.00.00											
187	05	蘇丹紅 G	Sudan Red G	$C_{17}H_{14}N_2O_2$	1229-55-6	1%	—	4	107.00.00											
187	06	蘇丹橙 G	Sudan Orange G	$C_{12}H_{10}N_2O_2$	2051-85-6	1%	—	4	107.00.00											
187	07	蘇丹黑 B	Sudan Black B	$C_{29}H_{24}N_6$	4197-25-5	1%	—	4	107.00.00											
187	08	蘇丹紅 7B	Sudan Red 7B	$C_{24}H_{21}N_5$	6368-72-5	1%	—	4	107.00.00											
188	01	二乙基黃	Diethyl yellow/Solvent yellow 56	$C_{16}H_{19}N_3$	2481-94-9	1%	—	4	107.00.00											
189	01	王金黃(塊黃)	Basic orange 2	$C_{12}H_{13}ClN_4$	532-82-1	1%	—	4	107.00.00											
190	01	鹽基性芥黃	Auramine	$C_{17}H_{22}ClN_3$	2465-27-2	1%	—	4	107.00.00											
191	01	紅色 2 號	Red No.2	$C_{20}H_{11}N_2Na_3O_{10}S_3$	915-67-3	1%	—	4	107.00.00											
192	01	氮紅	Azorubine	$C_{20}H_{12}N_2Na_2O_7S_2$	3567-69-9	1%	—	4	107.00.00											
193	01	橘色 2 號	Orange2	$C_{16}H_{11}N_2NaO_4S$	633-96-5	1%	—	4	107.00.00											

		due to food safety concerns which may endanger public health and due to the fact that certain metabolites of Sudan dyes have been classified as group 2B carcinogens by the IARC, which meets the screening and identification standards of Class 4 toxic chemical substances specified within the “Screening and Identification Principles of Toxic Chemicals Established by the Environmental Protection Administration, Executive Yuan.”
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## Paragraph 2 Table 2 revision draft comparison table

Proposed Revision				Current Measure				Explanation
Table 2 Summary table of the prohibited use of controlled toxic chemical substances				Table 2 Summary table of the prohibited use of controlled toxic chemical substances				By referencing Annex A (Elimination) of the Stockholm Convention on Persistent Organic Pollutants as well as the management practices of international regulations, prohibited handling details for pentachlorophenyl laurate were added.
Listed No.	Series No.	Chinese Name of the Chemical	Prohibited Handling Details	Listed No.	Series No.	Chinese Name of the Chemical	Prohibited Handling Details	
007	02	月桂酸五氯苯酯	<u>Manufacturing, importing, selling, and using are strictly prohibited. However, for research, testing, and educational purposes, these restrictions do not apply.</u>					

### Paragraph 3 Table 3 revision draft comparison table

Proposed Revision				Current Measure				Explanation
Table 3 Summary table of intended uses for controlled toxic chemical substances				Table 3 Summary table of intended uses for controlled toxic chemical substances				Pentachlorophenyl laurate may be used for research, testing, and education.
Listed No.	Series No.	Chinese Name of the Chemical	Intended Use	Listed No.	Series No.	Chinese Name of the Chemical	Intended Use	
007	02	月桂酸五氯苯酯	1. Research, testing, and education.					

## Paragraph 4 Table 4 revision draft comparison table

Proposed Revision	Current Measure	Explanation																																																				
<p>Table 4 Summary table of improvement deadlines for handling of announced toxic chemical substances</p> <p>(I) Summary table of improvement deadlines for malachite green, maleic acid, maleic anhydride, 4-Ethoxyphenyl urea, potassium bromate, dimethyl fumarate (DMF), benzyl violet, methyl yellow, rhodamine B, dimethyl yellow, sodium hydroxymethanesulfinate, melamine, and coumarin</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Item</th> <th style="width: 80%;">Toxic Chemical Substances</th> </tr> </thead> <tbody> <tr> <td>Production of handling records, release quantity records, and regular reports in accordance with regulations.</td> <td>Improvement deadlines for malachite green, maleic acid, maleic anhydride, 4-Ethoxyphenyl urea, potassium bromate, dimethyl fumarate (DMF), benzyl violet, methyl yellow, rhodamine B, dimethyl yellow, sodium hydroxymethanesulfinate, melamine, and coumarin</td> </tr> <tr> <td>Completion of containers, packaging, and handling premise and facility markings and preparation of material safety data sheets.</td> <td>Begin recording and reporting in accordance with regulations starting on February 15, 2018.</td> </tr> <tr> <td>Acquisition of manufacture, import, sale, use, storage, and export approval documents in accordance with regulations.</td> <td>Complete improvements before July 15, 2018.</td> </tr> <tr> <td>Other matters not listed in this table.</td> <td>Obtain before January 15, 2019.</td> </tr> <tr> <td></td> <td>Handle in accordance with relevant regulations starting from February 15, 2018.</td> </tr> </tbody> </table> <p>(II) Summary table of improvement deadlines for pentachlorophenyl laurate and perfluorooctane sulfonic acid (with a concentration standard greater than 0.01% and less than 1%)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Item</th> <th style="width: 80%;">Toxic Chemical Substances</th> </tr> </thead> <tbody> <tr> <td>Production of handling records, release quantity records, and regular reports in accordance with regulations.</td> <td>Improvement deadlines for pentachlorophenyl laurate and perfluorooctane sulfonic acid (with a concentration standard greater than 0.01% and less than 1%)</td> </tr> <tr> <td>As specified under the regulations, hazard prevention and response plans are to be submitted.</td> <td>Begin recording and reporting in accordance with regulations starting on January 1, 2018.</td> </tr> <tr> <td>Completion of containers, packaging, and handling premise and facility markings and preparation of material safety data sheets.</td> <td>Reports are to be filed before January 1, 2019.</td> </tr> <tr> <td>Transporting toxic chemical substances.</td> <td>Complete improvements before January 1, 2019.</td> </tr> <tr> <td>The preparation of emergency response tools and equipment.</td> <td>To be processed according to the regulations before July 1, 2019.</td> </tr> <tr> <td>As specified under the regulations, reports on response equipment and the setup/operating plans of detection/alert systems shall be submitted.</td> <td>Improvement measures shall be completed by January 1, 2019.</td> </tr> <tr> <td>As specified under the regulations, a toxic chemical substance defense organization shall be established</td> <td>Reports are to be filed before April 1, 2019.</td> </tr> <tr> <td>Complete the setup of detection and alert systems.</td> <td>To be completed before April 1, 2019.</td> </tr> <tr> <td>Perform thorough investigations on the implementation of hazard prevention and response plans.</td> <td>Setup shall be completed before July 1, 2019.</td> </tr> <tr> <td>Deployment of professional technical management personnel.</td> <td>To become effective on July 1, 2019.</td> </tr> <tr> <td>Acquisition of manufacture, import, sale, use, storage, and export approval documents in accordance with regulations.</td> <td>Setup shall be completed before July 1, 2019.</td> </tr> <tr> <td>Other matters not listed in this table.</td> <td>Obtain before July 1, 2019.</td> </tr> <tr> <td></td> <td>Handle in accordance with relevant regulations starting from January 1, 2018.</td> </tr> </tbody> </table>	Item	Toxic Chemical Substances	Production of handling records, release quantity records, and regular reports in accordance with regulations.	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Handle in accordance with relevant regulations starting from January 1, 2018.	<p>Table 4 Summary table of improvement deadlines for handling of announced toxic chemical substances</p> <p>(I) Summary table of improvement deadlines for malachite green, maleic acid, maleic anhydride, 4-Ethoxyphenyl urea, potassium bromate, dimethyl fumarate (DMF), benzyl violet, methyl yellow, rhodamine B, dimethyl yellow, sodium hydroxymethanesulfinate, melamine, and coumarin</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Item</th> <th style="width: 80%;">Toxic Chemical Substances</th> </tr> </thead> <tbody> <tr> <td>Production of handling records, release quantity records, and regular reports in accordance with regulations.</td> <td>Improvement deadlines for malachite green, maleic acid, maleic anhydride, 4-Ethoxyphenyl urea, potassium bromate, dimethyl fumarate (DMF), benzyl violet, methyl yellow, rhodamine B, dimethyl yellow, sodium hydroxymethanesulfinate, melamine, and coumarin</td> </tr> <tr> <td>Completion of containers, packaging, and handling premise and facility markings and preparation of material safety data sheets.</td> <td>Begin recording and reporting in accordance with regulations starting on February 15, 2018.</td> </tr> <tr> <td>Acquisition of manufacture, import, sale, use, storage, and export approval documents in accordance with regulations.</td> <td>Complete improvements before July 15, 2018.</td> </tr> <tr> <td>Other matters not listed in this table.</td> <td>Obtain before January 15, 2019.</td> </tr> <tr> <td></td> <td>Handle in accordance with relevant regulations starting from February 15, 2018.</td> </tr> </tbody> </table>	Item	Toxic Chemical Substances	Production of handling records, release quantity records, and regular reports in accordance with regulations.	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Added a list of relevant items which shall be completed within the specified deadline for pentachlorophenyl laurate, perfluorooctanoic acid, and perfluorooctane sulfonic acid (with a concentration standard greater than 0.01% and less than 1%).</p> <p>II. The wording for improvement deadlines in the header is inconsistent with the deadline for making improvements specified within Chapter 4 on penalties. In order to avoid complications, the wording has been modified to "must complete all relevant items within the established deadline" in order to return to the original purpose of the legislation.</p> <p>III. Added Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan Red 7B, Diethyl yellow/Solvent yellow 56, Basic Orange 2, auramine, Red No. 2, Azorubine, and Orange No. 2 as Class 4 toxic chemical substances; a summary table for relevant items which shall be completed within the specified deadline; minor changes to the wording.</p>
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Item	Toxic Chemical Substances
Production of handling records, release quantity records, and regular reports in accordance with regulations.	Relevant items which shall be completed within the specified deadline for Sudan 1, Sudan 2, Sudan 3, Sudan 4, Sudan Red G, Sudan Orange G, Sudan Black B, Sudan 7B, Diethyl yellow/Solvent yellow 56, Basic Orange 2, Auramine, Red No. 2, Azorubine, and Orange No. 2. Begin recording and reporting in accordance with regulations starting on January 1, 2018.
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