

PRESIDENTIAL DECREE ON THE TOXIC CHEMICALS CONTROL ACT

Established by Presidential Decree No. 13,257, January 28, 1991

Amended by Presidential Decree No. 13,681, June 30, 1992

Amended by Presidential Decree No. 14,247, May 4, 1994

Amended by Presidential Decree No. 14,255, May 4, 1994

Amended by Presidential Decree No. 14,544, March 2, 1995

Wholly amended by Presidential Decree No. 15,413, June 26, 1997

Article 1. (Purpose)

The purpose of this Presidential Decree is to define matters delegated by the Toxic Chemicals Control Act and matters necessary for the enforcement thereof.

Article 2. (Criteria for the Designation of Toxic Chemicals and Observational Chemicals)

The criteria for the designation of toxic chemicals and observational chemicals set forth in Article 2, Items 3 and 5 of the Toxic Chemicals Control Act (hereinafter referred to as the "Act") shall be as prescribed in Annex 1.

Article 3. (Consultation on Major Plans and Measures)

The phrase, "plans or measures designated by Presidential Decree" set forth in Article 5 of the Act shall refer to any of the following plans or measures:

1. National plans for establishing systems for the prevention and handling of hazardous chemicals accidents;
2. Plans for establishing and amending test guidelines and hazard evaluations of chemicals;
3. Plans regarding alternatives to hazardous chemicals; and
4. Policies or measures regarding the safe transportation and warehousing of dangerous substances set forth in Article 23 of the Traffic Safety Act and Article 16, Paragraph (2) of the Vessel Safety Act.

Article 4. (Exemption from Hazard Evaluation)

The phrase, "other substances designated by Presidential Decree" set forth in Article 7, Paragraph (1), Item 4 of the Act shall refer to any of the following substances:

1. Any chemicals whose annual import amount does not exceed 100kg (Unless the importer provides data or materials indicating the presence of new chemicals in the product, it shall be determined based on the weight of the product itself.);
2. Any chemical reagents in small packages to be directly used for tests, research or examinations;
3. Any chemicals imported as already contained in machines or equipment, or chemicals imported together with the relevant machinery or equipment to be used for preliminary testing or operation;
4. Any solid chemicals imported in a finished form that consumers can directly use without additional processing (including chemicals used for stationery or painting); and
5. Any chemicals that have been designated as chemicals that do not require hazard evaluations in a Public Notice made by the head of the National Institute of Environmental Research (hereinafter referred to as the "NIER") after consultation with the Minister of Labor, or chemicals acknowledged by the head of the NIER as not requiring hazard evaluations.

Article 5. (Issuance of Chemical Certificate)

(1) If an importer of any chemicals applies for the issuance of a chemical certificate, in order to confirm whether the relevant chemicals require hazard evaluations under the provisions of Article 7, Paragraph (1) of the Act, the Minister of Environment may issue such a certificate by reviewing the relevant documents submitted by the importer in accordance with the guidelines for application and issuance for the certificate as prescribed by the Minister of Environment. If the issuance of a certificate concerns a new chemical, the Minister of Labor shall be notified of the details of the issuance.

(2) An applicant pursuant to Paragraph (1) above shall pay a fee as prescribed by Ministerial Ordinance of the Ministry of Environment.

Article 6. (Designation of Testing and Research Institutes for Issuance of Test Reports)

(1) The phrase, "testing and research institutes designated by Presidential Decree" set forth in Article 7, Paragraph (2) of the Act shall refer to any of the following Items:

1. Any institutes among the following, which are designated in a Public Notice by the head of the NIER:
 - a. National or public test and research institutes or evaluation institutes;
 - b. Universities or colleges established under the Education Act;
 - c. Research institutes under the Specialized Research Institutes Promotion Act; and
 - d. Research institutes attached to any enterprises under the Technology Development and Promotion Act.

2. Any institutes acknowledged by the head of the NIER among institutes which correspond to the designation and management standards pursuant to Paragraph (2) below and whose test reports are internationally recognized.

(2) The designation of testing and research institutes pursuant to Paragraph (1), Item 1 above shall be made upon the institutes' application, in accordance with the designation and management standards for hazard evaluation institutes established and announced in advance in a Public Notice by the head of the NIER.

Article 7. (Test Guideline)

The head of the NIER shall establish and make a Public Notice of the test guidelines for toxicity and degradability of chemicals as stipulated by Article 7, Paragraph (2) of the Act.

Article 8. (Constitution of Chemical Substance Evaluation Committee)

(1) The Chemical Substance Evaluation Committee (hereinafter referred to as the "CSEC") pursuant to Article 9, Paragraph (1) of the Act shall consist of at most twenty (20) members including one Chairman, and at most ten (10) of the twenty shall be full-time members.

(2) The head of the NIER shall appoint or entrust the members from among relevant government officials or experts with ample knowledge and experience in such fields as chemistry, environmental science, health science, etc.

(3) The head of the NIER shall designate the Chairman from among those members who are government officials. The Chairman shall supervise the general duties of the CSEC.

(4) The term of entrusted members who are experts in relevant fields in accordance with Paragraph (2) above shall be two (2) years; however, such members may be reentrusted.

Article 9. (Duties of the CSEC)

The CSEC shall perform the following duties:

1. Technologically review the data or materials for evaluating and determining the toxicity of chemicals in accordance with the hazard evaluation method pursuant to Article 8, Paragraph (3) of the Act;
2. Verify relevant submitted data or materials, such as test reports, and review domestic and foreign data and materials;
3. Review and research domestic and foreign data or materials that relate to hazard evaluations of chemicals; and
4. Perform other duties which the head of the NIER deems necessary for hazard evaluations.

Article 10. (Compensation for Members of the CSEC)

(1) Members may receive, within the range of the budget, the allowances, travel expenses and other actual expenses necessary to perform their duties.

(2) Matters which pertain to the CSEC's operation, other than those stipulated in this Presidential Decree, shall be determined by the Chairman of the CSEC through resolutions made by the CSEC.

Article 11. (Exemption from Importation Reports on Toxic Chemicals)

The phrase, "toxic chemicals designated by Presidential Decree" set forth in Article 12, Paragraph (1) of the Act shall refer to any of the following:

1. Chemicals other than chemical reagents used for testing, research or examination (including standard gases used for calibrating and operating measuring equipment), whose annual import amount does not exceed 100 kg (Unless the importer provides data or materials indicating the presence of toxic chemicals in the product, it shall be determined based on the weight of the product itself.); and
2. Restricted toxic chemicals.

Article 12. (Exemption from the Registration of a Toxic Chemicals Business)

The phrase, "business designated by Presidential Decree" set forth in Article 15, Paragraph (1) of the Act shall refer to any of the following:

1. Any person or business who opens a pharmacy or who sells those pharmaceutical products considered under the Pharmaceutical Affairs Act to be toxic chemicals, such as sterilizers, insecticides or rodenticides for household uses;
2. Any person or business who sells, stores, transports or uses chemical reagents for the purpose of testing, research or examination;
3. Any person or business who sells, stores, transports or uses toxic chemicals contained in machines or equipment;
4. Any person or business who falls under any of the following sub-Items, other than a person or business who uses toxic chemicals in a place of business within the water supply source protection areas under Article 5 of the Water Supply Act;
 - A. A person or business who uses sixty (60) tons of toxic chemicals or less per year in a place of business within an area subject to special measures for the preservation of the environment under Article 22 of the Basic Environmental Policy Act;
 - B. A person or business who uses one hundred and twenty (120) tons of toxic chemicals or less in a place of business within a designated residential district of a quasi-urban area under Article 7 of the Presidential Decree of the National Land Utilization Act or within areas designated by Article 17 of the Urban Planning Act (excluding districts exclusively used for industrial purposes); and
 - C. A person or business who uses two hundred forty (240) tons of toxic chemicals or less per year in places other than those prescribed in A or B.
5. Any person or business who loads, unloads or transports toxic chemicals within a confined area such as a harbor or a train station;
6. Any person or business who transports one (1) ton of toxic chemicals or less at one time;
7. Any person or business who has obtained a permission to manufacture or to use toxic chemicals in

accordance with Article 38, Paragraph (1) of the Industrial Safety and Health Act; and

8. Any other person or business designated by the Minister of Environment as being exempt from the registration requirements.

Article 13. (Exemption from Permission for a Restricted Toxic Chemicals Business)

The phrase, "a business designated by Presidential Decree" set forth in Article 20, Paragraph (1) of the Act shall refer to any of the following:

1. Any person or business who uses sixty (60) tons of restricted toxic chemicals or less per year (excluding use in a place of business within an area subject to special measures for preservation of the environment under Article 22 of the Basic Environmental Policy Act or within water supply source protection areas under Article 5 of the Water Supply Act);
2. Any person or business who is subject to Article 12, Items 2, 3 or 7; and
3. Any other person or business who is designated by the Minister of Environment as exempt from the permission requirements.

Article 14. (Types of Violations Subject to the Imposition of an Administrative Surcharge and the Criteria for Determining the Amount of the Surcharges)

Types of violations subject to the imposition of administrative surcharges and the amount of such surcharges under Article 21, Paragraph (2) of the Act shall be as prescribed in Annex 2.

Article 15. (Payment of Administrative Surcharges)

(1) When the Minister of Environment intends to impose administrative surcharges in accordance with Article 21, Paragraph (1) of the Act, the Minister shall give a writ of payment which specifies necessary matters, including the type of violation, the amount of the surcharges and the place of payment.

(2) Any person who receives a writ of payment in accordance with Paragraph (1) above shall pay administrative surcharges to the institution designated by the Minister of Environment within twenty (20) days of receipt of the writ. However, if any person who receives a writ of payment fails to pay the administrative surcharges within the fixed period of time due to natural disaster, payment shall be made within seven (7) days after such cause ceases to exist.

(3) An institution that receives payment of administrative surcharges in accordance with Paragraph (2) above shall issue a receipt to the payer.

Article 16. (Grants of Collection Costs and Expenses)

(1) When the Minister of Environment delegates authority to collect administrative surcharges to mayors of Seoul Metropolitan City or other metropolitan cities or to provincial governors (hereinafter referred to as "mayors or governors") in accordance with Article 21, Paragraph (5) of the Act, the Minister may grant an amount equal to ten hundredths (10/100) of the collected administrative surcharges to mayors or governors as costs and expenses of collection.

(2) On a monthly basis, the Minister of Environment shall accurately identify and calculate such costs and expenses, as prescribed in Paragraph (1) above, which have been incurred in collecting administrative surcharges and depositing them in the Environmental Improvement Special Account under the Environmental Improvement Special Account Act, and shall pay such costs and expenses to the mayors and governors by the end of the following month.

Article 17. (Circumstances Resulting in Relocation Orders)

The phrase, "circumstances prescribed by Presidential Decree" in Article 23 of the Act shall refer to any of the following:

1. When, in the course of manufacturing, selling, transporting, storing, warehousing, or using toxic chemicals at a place of business within a designated residential district of a quasi-urban area prescribed in Article 7 of the National Land Utilization Act or at a place of business within a designated area prescribed in Article 17 of the Urban Planning Act (excluding districts exclusively used for industrial purposes), an explosion or a leak of toxic chemicals that, considering the quantity of toxic chemicals, the population density of neighboring areas and the distribution of public facilities, is likely to cause egregious harm to people and properties;
2. When, with justifiable reason, it is impossible to carry out an improvement order under Article 22 of the Act that is supposed to prevent explosion, burning or leakage of toxic chemicals at an existing place of business, and it is recognized that failure to carry out the improvement order may cause egregious harm to people and properties of the neighboring areas;
3. When, in the course of manufacturing, selling, transporting, storing, warehousing or handling toxic chemicals at a place of business in an area subject to special measures for environmental improvement under Article 22 of the Basic Environmental Policy Act or within a water supply source protection area under Article 5 of the Water Supply Act or their neighboring areas, leakage occurs that is likely to cause egregious harm to water supply sources; and
4. When, in consultation with the heads of the relevant central administrative bodies, the Minister of Environment recognizes and determines that a relocation order is necessary due to a cause similar to Items 1 through 3.

Article 18. (Exemption from Submittal of Safety Management Rules)

The phrase, "the categories prescribed by Presidential Decree" under Article 31, Paragraph (1) of the Act shall refer to any of the following:

1. Any business entity whose facilities for manufacture, warehousing or transportation are smaller than the capacity set forth in Annex 3;
2. Any business entity which has submitted a safety process report in accordance with Article 49-2, Paragraph (1) of the Industrial Safety and Health Act with respect to the facilities for manufacturing, warehousing or transporting toxic chemicals; and
3. Any other business entity designated and announced in a Public Notice by the Minister of Environment.

Article 19. (Special Institution for Gas Safety Management)

Special institutions for gas safety management in Article 31, Items 1 and 2 and Article 32, Item 3 of the Act shall refer to any of the following:

1. The Korean Industrial Safety Corporation prescribed in Article 47 of the Industrial Safety and Health Act; and
2. Special institutions prescribed by Ministerial Ordinance of the Ministry of Environment.

Article 20. (Establishment of On-site Pollution Prevention Plan)

The phrase, "a toxic chemicals or restricted toxic chemicals business entity designated by Presidential Decree" set forth in Article 33, Paragraph (1) of the Act shall refer to any of the following:

1. Any business entity set forth in Article 15, Paragraph (1) of the Act which manufactures, sells, stores, warehouses or uses two thousand (2,000) tons or more of toxic chemicals per year; and
2. Any business entity which has obtained permission for a restricted toxic chemicals business in accordance with Article 20, Paragraph (1) of the Act.

The same shall not apply to a business entity which has submitted a safety process report in accordance with Article 49-2, Paragraph (1) of the Industrial Safety and Health Act.

Article 21. (Business Entities Subject to Submitting On-site Pollution Prevention Plan Reports)

The phrase, "business entity which has its place of business within an area designated by Presidential Decree" set forth in Article 33, Paragraph (3) of the Act shall refer to any of the following:

1. Any business entity which operates its business within a national industrial complex or regional industrial complex designated by Articles 6 and 7 of the Act concerning the Industrial Location and Development thereof;
2. Any business entity which operates its business within a free export zone designated by Article 3 of the Free Export Zone Establishment Act; and
3. Any business entity which operates its business within areas recognized and announced in a Public Notice by the Minister of Environment, in consultation with the heads of relevant central administrative bodies, as likely to cause harm to human health or the environment in the course of handling toxic chemicals.

The same shall not apply to a business entity which is not likely to cause a fire or an explosion because toxic chemicals are stored underground.

Article 22. (Hallucinogenic Substances)

The phrase, "hazardous chemicals which may be used for hallucination, etc. as prescribed by Presidential Decree" set forth in Article 35, Paragraph (1) of the Act shall refer to any of the following:

1. Toluene, Ethyl acetate, or Methyl alcohol;

2. Thinner (organic solvents used for reducing the viscosity of paints), adhesives and paints containing substances in Item 1; and

3. Butane Gas

Article 23. (Test Guideline for Hazardous Chemicals)

The Minister of Environment shall determine and make a Public Notice of the test guidelines for hazardous chemicals to attain precise and consistent results determining whether the chemicals in question should be classified as toxic chemicals or observational chemicals under Article 37, Paragraph (1) of the Act.

Article 24. (Cooperation with Relevant Institutions)

The phrase, "matters designated by Presidential Decree" set forth in Article 38, Item 3 of the Act shall refer to any of the following:

1. Matters regarding the improvement of storage and warehousing methods for hazardous chemicals;
2. Matters regarding the improvement of transportation or usage methods for hazardous chemicals; and
3. Matters regarding the manufacture or handling methods for products containing hazardous chemicals.

Article 25. (Delegation and Entrustment of Authority)

(1) The Minister of Environment shall delegate authority to perform any of the following duties to mayors or governors in accordance with Article 44, Paragraph (1) of the Act, with the exception of the duties concerning the place of business as prescribed in Annex 4:

1. Survey the amount in circulation or release amount of chemicals as set forth in Article 14, Paragraphs (1) or (2) of the Act (including protection of submitted materials in accordance with Article 39, Paragraph (1) of the Act);
2. Impose necessary conditions for the registration of a business entity and for changes thereof in accordance with Article 15, Paragraphs (1) and (2) of the Act;
3. Accept reports of business closures in accordance with Article 17 of the Act (including closures of restricted toxic chemicals business prescribed in Article 20, Paragraph (3) of the Act);
4. Suspend businesses or cancel registrations in accordance with Article 18 of the Act (including cases suspending or cancelling restricted toxic chemicals entities as prescribed in Article 20, Paragraph (3) of the Act);
5. Accept reports of successions of rights and obligations in accordance with Article 19, Paragraph (2) of the Act (including cases applied mutatis mutandis as prescribed in Article 20, Paragraph (3) of the Act);
6. Permit, permission changes and impose necessary conditions for restricted toxic chemicals business

entities in accordance with Article 20, Paragraphs (1) and (2) of the Act;

7. Impose and collect administrative surcharges in accordance with Article 21, Paragraphs (1) and (3) of the Act;

8. Issue improvement orders in accordance with Article 22, Paragraph (1) of the Act;

9. Issue relocation orders of places of business in accordance with Article 23 of the Act;.

10. Accept reports of appointments of managers of toxic chemicals or changes thereof in accordance with Article 25, Paragraph (1) of the Act;

11. Approve the joint use of managers, facilities or equipment and accept reports of changes thereof in accordance with Article 26 Paragraphs (1) and (2) of the Act;

12. Issue replacement orders for managers of toxic chemicals in accordance with Article 27 of the Act;

13. Issue submittance orders for materials or reports and inspect them in accordance with Article 37, Paragraph (1), Items (4) and (5) of the Act;

14. Conduct hearings in respect to duties delegated to mayors or governors in accordance with Article 42 of the Act; and

15. Impose and collect administrative surcharges with respect to matters delegated to mayors or governors in accordance with Article 49 of the Act.

(2) With respect to a place of business prescribed in Attachment 4 in accordance with Article 44, Paragraph (1) of the Act, the Minister of Environment shall delegate the duties to the head of the Environmental Management Office or the head of the Regional Environmental Management Office.

(3) The Minister of Environment shall delegate authority to perform any of the following duties to the head of the NIER in accordance with Article 44, Paragraph (1) of the Act:

1. Accept applications for hazard evaluations in accordance with Article 7, Paragraphs (1) and (2) of the Act (including the protection of submitted materials in accordance with Article 39 of the Act)

2. Execute hazard evaluations or request the submittance of documents and materials necessary for hazard evaluations in accordance with Article 8, Paragraphs (1) and (2) of the Act;

3. Make Public Notices and inform applicants of evaluation results in accordance with Article 10 of the Act; and

4. Request submittance of documents or materials necessary for hazard evaluations in accordance with Article 13, Paragraph (2) of the Act.

(4) The Minister of Environment shall, in accordance with Article 44, Paragraph (2) of the Act, entrust the performance of any of the following duties to the head of the Korea Toxic Chemicals Management Association (hereinafter referred to as the "Association") established in accordance with Article 40, Paragraph (1) of the Act.

1. Issue certificates in accordance with Article 5, Paragraph (1) of this Decree;

2. Accept import and export of toxic chemicals reports in accordance with Article 12, Paragraphs (1)

and (2) of the Act;

3. Accept manufacture or import of observational chemicals reports in accordance with Article 13, Paragraph (1) of the Act; and

4. Educate managers of toxic chemicals in accordance with Article 36 of the Act.

Article 26. (Supervision of Activities Related to the Delegation of Duties)

(1) The Minister of Environment may, with respect to places of business other than those prescribed in Attachment 4, check or confirm, or order the head of the Environmental Management Office or the head of Regional Environmental Management Office to check or confirm, any violation of relevant acts, decrees or regulations including violations of the toxic chemicals management standards when such checks and confirmations are deemed necessary for broader management of air and water pollution.

(2) The Minister of Environment, the head of the Environmental Management Office or the head of the Regional Environmental Management Office shall inform the mayors or governors of the particulars of any violations or suggested measures which are discovered as a result of checks or confirmations in accordance with Paragraph (1) above.

(3) If mayors or governors, the head of the Environmental Management Office or the head of the Regional Environmental Management Office intend to issue a relocation order in accordance with Article 23 of the Act, they shall take into account the Minister of Environment's opinion. In such a case, the Minister of Environment may consult with the heads of the relevant central administrative bodies.

(4) When intending to execute delegated authority or to make relevant Public Notices in accordance with Article 25, Paragraph (3) of this Decree (including Public Notices prescribed in Articles 6 and 7 of this Decree), the head of the NIER shall take into account the Minister of Environment's opinion.

Article 27. (Reports)

When mayors or governors, the head of the Environmental Management Office, the head of the Regional Environmental Management Office or the head of the NIER or the head of the Association performs any delegated or entrusted duties in accordance with Article 25, Paragraph (1) of this Decree, they shall report the details thereof to the Minister of Environment as set forth in Ministerial Ordinance of the Ministry of Environment.

Article 28. (Imposition of Administrative Surcharges)

(1) When the Minister of Environment, mayors or governors, the head of the Environmental Management Office, or the head of the Regional Environmental Management Office (hereinafter referred to as the "Authorities"), after investigating and confirming a violation, impose an administrative surcharge in accordance with Article 49, Paragraph (3) of the Act, they shall issue a writ of payment which specifies the violation, the method and the period for raising an objection, to the person subject to an administrative surcharge.

(2) When the Minister of Environment intends to impose an administrative surcharge in accordance with Paragraph (1) above, the Minister shall provide the person subject to an administrative surcharge

with an opportunity to state an opinion orally or in writing within a period of ten (10) days or more. In this case, if the person does not state an opinion until a designated date, it shall be taken for granted that there is no objection.

(3) The Authorities shall take into consideration the motivation for and the results of a violation in determining the amount of an administrative surcharge.

(4) The procedure of collecting an administrative surcharge shall be prescribed by Ministerial Ordinance of the Ministry of Environment. When the Minister of Environment delegates any authority to mayors or governors in accordance with Article 25, Paragraph (1) of this Decree, the procedures for collecting administrative surcharges shall be prescribed by ordinances of relevant, local, autonomous entities.

Addenda

Article 1. (Date of Enforcement)

This Presidential Decree shall be effective as of July 1, 1997; however, Articles 6 and 7 shall be effective as of January 1, 1998.

Article 2. (Interim Measures for Exemption from Hazard Evaluation)

Any chemicals, which the Minister of Environment has acknowledged and announced in a Public Notice as having been manufactured in or imported to Korea in accordance with the previous provisions at the time of the enforcement of this Presidential Decree, shall be deemed to be chemicals acknowledged and announced in a Public Notice by the head of the NIER as having been manufactured or imported in accordance with the amended provisions of Article 4, Item 6 of this Decree.

Article 3. (Interim Measures for Business Enterprises Using Toxic Chemicals)

Any business entity which is currently engaged in toxic chemicals business at the time of the enforcement of this Presidential Decree and which should re-register as a toxic chemicals business entity in accordance with the amended provisions of Article 12, Item 4 of this Decree, shall satisfy the requirements for facilities, equipment, technical manpower, etc., as prescribed in Article 15, Paragraph (1) of the Act and apply for registration of its business within six (6) months of the enforcement of this Presidential Decree.

Article 4. (Interim Measures for Restricted Toxic Chemicals Business Entities)

Any business enterprise which is currently engaged in restricted toxic chemicals business at the time of enforcement of this Presidential Decree and which should obtain a new permission for restricted toxic chemicals business in accordance with the amended provisions of Article 13, Item 1 of the Act, shall satisfy the requirements for facilities, equipment, technical manpower, etc., as prescribed in Article 20, Item 1 of the Act and apply for permission within six (6) months of the enforcement of this Presidential Decree.

- (6) Chemicals of which the concentration (LC50, 96hr) that kills half the number of test fish in acute fish toxicity test for fish is 1.0mg/l or less
- (7) Chemicals that have a bioconcentration factor of 500 or more, of which the NOEL(No Effect Level) has been confirmed to be 10mg/kg/day or less as a result of a toxicity test of repeated dose (28days) or that causes specific damage to the liver or kidney in prolonged tests
- (8) Chemicals that have not been tested for carcinogenicity and of which test results in *in vivo* tests, gene mutation test using bacteria, or *in vitro* tests or the same or higher level, among gene toxicity tests are positive
- (9) Chemicals that show evidence of causing cancer in more than 2 types of carcinogenic tests, or Class 1 and Class 2A chemicals that have been classified by specialized international institutions such as International Agency for Research on Cancer (IARC), as chemicals that cause cancer to humans or that have been concluded as having a risk of causing cancer
- (10) Chemicals that have been known to cause adverse effects to the next generation in one or two generation test for reproductive toxicity or in a developmental toxicity in animals, or cause similar effects in human

B. Observational Chemicals

- (1) Nondegradable chemicals that have a logarithm of the octanol/water partition coefficients (logPow) of 4~7, or a bioconcentration factor of 500 or more for fish
- (2) Chemicals of which test results in a gene mutation test using bacteria and in a chromosomal-aberration test using mammalian cell (*in vitro*) or in tests of the same level or higher are all positive, or that cause genetic damages in *in vivo* mutation tests using test animals
- (3) Chemicals that show carcinogenic evidence in more than one test animal, or that are classified by international organizations, e.g. IARC as class 2B, a possible carcinogen to humans
- (4) Chemicals with insufficient evidence in causing no effects to the next generation in one or two generation test for reproductive toxicity or in a developmental toxicity test

Reference : (1). As a rule, the unit of inhalation toxicity should be ppm in the case of exposure to gas or

(2). In the evaluation of fish toxicity, in cases where test data obtained from tests conducted with regard to the actual environment instead of that obtained from tests conducted by the methods in accordance with Article 7 of this Decree are available, the prior may preferentially be considered. That is, in special cases with reasons, such as cases where the chemical in question is easily absorbed or decomposed in the waters, the chemicals may be designated toxic chemicals based on test reports obtained from tests conducted in aforementioned special cases or situation. Moreover, when the fish toxicity test data is from tests based on 48 hours instead of 96 hours, a coefficient factor of 2 may tentatively be used. In cases where data on various fish types are available, domestic fish shall preferentially be considered.

(3). When data on various items in evaluating the octanol-water partition coefficient (logPow) and bioaccumulation is available, priority shall be based on known scientific facts. That is, a chemical may not be designated as an observational chemical based only on the high logPow despite its low bioconcentration. Moreover, chemicals that do not dissolve in the biomembrane nor pass through the biomembrane due to its properties, may not be designated as an observational chemical.

(4). The evaluation of fish toxicity, bioaccumulation, genetic toxicity, nondegradation, logPow, and etc, may be based on data obtained from Prediction Programs of Structure-Activity Relationships generally used by OECD countries.

(5). The evaluation of nondegradable chemicals should be based on the OECD biodegradability test guidelines. However, rapid abiotic degradation such as photolysis, hydrolysis, etc., may have priority over biodegradation.

2. In spite of the Criteria in Item 1, a chemical may not be designated as a toxic chemical or an observational chemical after considering its physico-chemical properties, purpose of use, predicted exposure amount, and frequency of use.

3. The Designation Criteria for toxic chemicals and observational chemicals for compounds or mixtures that include chemicals that apply to the Criteria in Item 1 above, shall be determined and announced in a Public Notice by the head of the National Institute of Environmental Research.

[Annex 2]

The Criteria for Administrative Surcharges According to the Degree and

[illegible]

Types of Violations (In relation to Article 14)

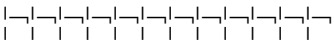
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Violations	Annual Amount of Manufacture or Use of Toxic Chemicals (ton)		
	less than 1,000	1,000 or more - less than 5,000	5,000 or more
	1,000	2,000	5,000
(1) When a person manufactures or uses a toxic chemical whose manufacture, etc., are prohibited or restricted, violating the provisions of Article 11, Paragraph (1) of the Act	500	1,000	3,000
(2) when a person fails to register for changes pursuant to Article 14, Paragraph (1) of the Act	500	1,000	3,000
(3) When requirements regarding facilities, equipment, technical manpower, etc., pursuant to Article 15, Paragraph (1) of the Act, do not meet the registration standards	200	500	1,000
(4) When a person fails to meet the conditions needed for appropriate management of toxic chemical items pursuant to Article 15, Paragraph (2) of the Act	1,000	2,000	5,000
(5) When a person fails to acquire permission regarding the changes pursuant to Article 20, Paragraph (1) of the Act	500	1,000	3,000
(6) When requirements regarding facilities, equipment, technical manpower, etc., pursuant to Article 20, Paragraph (1) of the Act, do not meet the permission standards			

	200	500	1,000
	1,000	2,000	5,000
	500	1,000	3,000
	1,000	2,000	5,000
(7) When a person fails to meet the conditions needed for appropriate management of restricted toxic chemicals pursuant to Article 15, Paragraph (2) of the Act	200	500	1,000
(8) When a person fails to carry out an improvement order pursuant to Article 22, Paragraph (1) of the Act			
(9) When a person violates the management standards of toxic chemicals pursuant to Article 24 of the Act			
(10) When a person fails to appoint a toxic chemical manager pursuant to Article 25 of the Act or reports the toxic chemical manager by methods of perjury or illegality	500	1,000	3,000
(11) When a business manager disturbs the work proficiency of the toxic chemical manager pursuant to Article 25, Paragraph (4) of the Act, or refuses a request required for the accomplishments without justifiable reason			
(12) When a person sells or give away a toxic chemical that lacks a toxic chemical labelling pursuant to Article 30, Paragraph 2 of the Act, or stores or displays the toxic chemical with a purpose to sell			

Reference : The 'Annual Amount of Manufacture or Use of Toxic Chemicals' refers to the amount manufactured or the amount used during the year immediately preceding the particular year in which the violation has been discovered. However, when the period of opening the business is less than one (1) year, the amount manufactured or used shall be accumulated until the violation is checked and confirmed.

Safety-Management Rule



(In relation to Article 18, Item 1)

Threshold Limit Level (ppm)	Regulated Amount (kg or m ³)	Applicable Gas
1 or less	2.5 or 0.25	Gaseous toxic chemicals such as phosgene, phosphines, aligins, and formaldehyde
more than 1;10	25 or 2.5	Gaseous toxic chemicals such as hydrogen cyanide, hydrogen iodide, hydrogen fluoride, and hydrogen bromide
more than 10;100	250 or 25	Gaseous toxic chemicals such as ammonia
more than 100;200	500 or 50	Gaseous toxic chemicals in gaseous state such as methyl chloride

Reference : 1. Threshold limit level refers to the concentration of the concerned gaseous toxic chemical present in the air which does not affect the health of an average person.

2. Gaseous toxic chemicals of which the threshold limit level exceeds 200ppm, are exempt from the requirement to submit safety management rules.

3. The Regulated Amount refers to the maximum amount that is manufactured, stored (including the amount stored in the manufacturing process), or transported in one day, calculated at 25°C and atmospheric pressure.

4. The threshold limit level for mixtures of gaseous toxic chemicals shall be calculated by the following equation.

Threshold limit level of A(%) x Threshold limit value of B(%)

_____ x 100

[(Threshold limit level of A (%) x (Threshold limit level of B

