

ENFORCEMENT DECREE OF THE ACT ON REGISTRATION, EVALUATION, ETC. OF CHEMICALS

Presidential Decree No. 25835, Dec. 9, 2014

Article 1 (Purpose)

The purpose of this Decree is to prescribe matters delegated from the Act on Registration, Evaluation, etc. of Chemicals and matters necessary for the enforcement of such matters.

Article 2 (Definitions)

The definitions of terms used in this Decree shall be as follows:

1. The term "non-isolated intermediate" means a chemical substance produced in the process of manufacturing other chemical substance and the whole quantity of which is used in such chemical process, which is not intentionally removed or isolated from the manufacturing facility;
2. The term "isolated intermediate" means a chemical substance which is produced in the manufacturing process of other chemical substance and the whole quantity of which is used in such chemical process, which does not fall under non-isolated intermediate;
3. The term "high molecular compound" means a chemical substance meeting all the following requirements. In such cases, where a high molecular compound consisting of monomers excluding monomers whose weight ratio does not exceed two percent falls under existing chemicals, such high molecular compound shall be deemed an existing chemical:
 - (a) It shall be composed of molecules in which at least one kind of monomer unit is continuously repeated;
 - (b) It shall show the characteristic distribution of molecular weights in accordance with repetitive numbers of monomer units in each molecule;
 - (c) Its molecules that at least three monomer units form a covalent bond with at least one monomer unit or other reactants shall be at least 50 percent;
 - (d) Its molecules of the same molecular weight shall be not more than 50 percent of the weight ratio.
4. The term "monomer" means a chemical substance forming a high molecular compound by combining it with at least two other molecules and reactants participating in such chemical reaction;
5. The term "monomer unit" means structure that monomers are repeated in a high molecular compound where the reaction of monomers has formed the high molecular compound;
6. The term "number average molecular weight" means the value obtained by dividing the total molecular weight of all molecules consisting of a high molecular compound by the total number of

molecules.

Article 3 (Criteria for Designation of Toxic Substances)

"Criteria prescribed by Presidential Decree" in subparagraph 2 of Article 2 and Article 20 of the Act means criteria under attached Table 1.

Article 4 (Matters to be Discussed by Committee on Evaluation of Chemicals)

"Matters prescribed by Presidential Decree" in Article 7 (1) 6 of the Act on Registration, Evaluation, etc. of Chemicals (hereinafter referred to as the "Act") means the following:

1. Matters concerning the safety management, etc. of products likely to be hazardous;
2. Matters concerning the composition and operation of expert committees in each field (hereinafter referred to as "expert committee") under Article 7 (6) of the Act;
3. Matters concerning international cooperation related to the registration of chemicals, the examination or evaluation of the toxicity or hazard of chemicals, the safety management, etc. of products likely to be hazardous;
4. Other matters referred to discussion by the Minister of Environment in relation to the registration of chemicals, the examination or evaluation of the toxicity or hazard of chemicals, and the safety management, etc. of products likely to be hazardous.

Article 5 (Composition of Evaluation Committee)

(1) The term of office of members of the Committee on Evaluation of Chemicals (hereinafter referred to as the "Evaluation Committee") under Article 7 (1) shall be two years.

(2) The Minister of Environment shall commission experts who have extensive knowledge and experience in the related fields including chemistry, the environment and public health, and relevant persons of industrial circles or civic groups related to chemicals in equal ratios as members he/she commissions pursuant to Article 7 (4) of the Act, in consideration of gender.

(3) In addition to matters provided in paragraphs (1) and (2), matters necessary for the composition, etc. of the Evaluation Committee shall be prescribed by the Chairperson of the Evaluation Committee following the resolution made thereby.

Article 6 (Operation of Evaluation Committee)

(1) The Chairperson of the Evaluation Committee shall represent the Evaluation Committee and preside over its affairs: Provided, That where the Chairperson is unable to perform any of his/her duties due to unavoidable circumstances, the Vice Chairperson shall perform his/her duties on his/her behalf.

(2) Meetings of the Evaluation Committee shall be classified into regular meetings and extraordinary meetings, and shall be held in accordance with the following classification:

1. Regular meeting: Semi-annually;
2. Extraordinary meeting: When the Chairperson deems it necessary or at least one-fifth of the members demands it.

(3) The Chairperson of the Evaluation Committee shall convene a meeting by giving notice, specifying the following, to each member by not later than seven days prior to the date of the meeting:

1. Time and place of the meeting;
 2. Objectives and items on the agenda of the meeting;
 3. Other necessary matters in relation to the meeting.
- (4) Where necessary for deliberations or resolutions, the Chairperson of the Evaluation Committee may require persons related to the relevant items on the agenda or experts to attend its meetings to make inquiries thereof, or for them to make statements.
- (5) In addition to matters provided in paragraphs (1) through (4), matters necessary for the operation, etc. of the Evaluation Committee shall be prescribed by the Chairperson of the Evaluation Committee following the resolution made by the Evaluation Committee.

Article 7 (Composition and Operation of Expert Committees)

- (1) The following expert committees shall be established pursuant to Article 7 (6) of the Act:
1. The Hazard Evaluation Committee;
 2. The Committee on Management of Products likely to be hazardous;
 3. The Socioeconomics Analysis Committee.
- (2) Each expert committee shall be comprised of not exceeding ten members including one chairperson, in consideration of gender.
- (3) The Chairperson of the Evaluation Committee shall appoint or commission the chairperson of each expert committee from among those with extensive knowledge and experience in the relevant field.
- (4) The Minister of Environment shall commission members of each expert committee from among any of the following:
1. Experts who have knowledge and experience in the relevant fields, such as chemistry, the environment, public health, toxicity, economics or policy;
 2. Persons recommended by industrial circles or non-governmental organizations related to chemicals and chemical products;
 3. Persons recommended by members of the Evaluation Committee from among those under subparagraph 1.
- (5) The chairperson of each expert committee shall report matters discussed by the relevant expert committee, to the Evaluation Committee.
- (6) In addition to matters provided for in paragraphs (1) through (5), matters necessary for the composition, operation, etc. of expert committees shall be prescribed by the Chairperson of the Evaluation Committee following the resolution made by the Evaluation Committee.

Article 8 (Chemicals Subject to Exception to Reporting of Manufacture, etc. of Chemicals)

"Chemicals prescribed by Presidential Decree, such as chemicals manufactured or imported for the purpose of inspection or research" in Article 8 (2) 4 of the Act means any of the following chemicals:

1. Chemicals manufactured or imported for the purpose of scientific experiments, analysis or chemical research, such as reagents;

2. Chemicals falling under any of the following, which are manufactured or imported for the purpose of research and development:

- (a) Cases for the development of chemicals, products, etc.;
- (b) Cases for the improvement or development of manufacturing processes;
- (c) Cases for testing of the fields of application of chemicals at the place of business;
- (d) Cases for pilot manufacturing of chemicals or pilot production of products, etc.

3. Non-isolated intermediates.

4. Chemicals with a very low hazard announced by the Minister of Environment, much information on which is known, among the existing chemicals.

Article 9 (Reporting of Changes in Manufacture, etc. of Chemicals)

"Changed matters prescribed by Presidential Decree, such as changes to the uses of chemicals" in Article 8 (3) of the Act means matters falling under any of the following:

1. Changes of the trade name, location, contact details, etc. of a person who manufactures, imports or sells chemicals;
2. Changes to the chemicals purposes classification system under attached Table 2.

Article 10 (Grace Period for Registration, etc. of Existing Chemicals Subject to Registration)

(1) The grace period for registration (hereinafter referred to as "grace period for registration") under Article 10 (2) of the Act shall be three years from the date existing chemicals subject to registration are designated and announced pursuant to Article 9 of the Act.

(2) Notwithstanding paragraph (1), any person who intends to manufacture or import existing chemicals subject to registration files an application for registration within two months before the expiration date of the grace period for registration, the grace period for registration shall be extended to three months from the following date of the expiration date of the grace period for registration.

Article 11 (Exemption from Registration of Chemicals)

(1) "Chemicals prescribed by Presidential Decree, such as chemicals manufactured or imported not more than ten tons per year to export the whole quantity thereof overseas" in Article 11 (1) 2 of the Act means chemicals falling under any of the following:

1. Chemicals manufactured or imported not more than ten tons per annum to export the whole quantity thereof overseas;
2. Chemicals manufactured or imported not more than ten tons per year to manufacture other chemicals for the export of the whole quantity of such other chemicals overseas;
3. Chemicals for scientific experiments, analysis or chemical research, such as reagents;
4. Chemicals for the purpose of research and development falling under any of the following:
 - (a) Cases for developing chemicals, products, etc.;
 - (b) Cases for improving or developing manufacturing processes;
 - (c) Cases for testing the fields of application of chemicals at the place of business;

(d) Cases for pilot manufacturing of chemicals or pilot production of products, etc.

5. High molecular compounds falling under any of the following:

(a) A high molecular compound whose number average molecular weight is at least 10,000, in which the content of molecules whose weight is less than 1,000, is less than five percent and the content of molecules whose weight is less than 500 is less than two percent;

(b) A high molecular compound whose number average molecular weight is not less than 1,000 or less than 10,000, in which the content of molecules whose weight is less than 1,000, is less than 25 percent and the content of molecules whose weight is less than 500 is less than 10 percent

6. Chemicals formed by reacting functional groups on the surface of a substance subject to surface treatment with another substance that treats the surface of the substance where both the substance subject to surface treatment and another substance that treats the surface of the substance do not constitute new chemicals and existing chemicals subject to registration;

7. Non-isolated intermediates;

8. Isolated intermediates whose outflow or leakage is blocked by technical means.

(2) Notwithstanding paragraph (1) 5, high molecular compounds falling under any of the following shall not be included in those subject to confirmation of exemption from registration under Article 11 (1) 2 of the Act:

1. Cationic high molecular compounds (high molecular compounds which are used only in solid state, and not soluble or dissolved in water, shall be excluded);

2. High molecular compounds whose number average molecular weight is less than 10,000, in which monomers, which are new chemicals, hazardous chemicals, and chemicals announced by the Minister of Environment because such chemicals are or are likely to be toxic or hazardous, constitute more than two percent by the weight ratio.

Article 12 (Measures against Nonperformance of Duty to Register)

"Necessary measures prescribed by Presidential Decree, such as the withdrawal of the relevant chemicals" in Article 13 (2) of the Act means the following measures:

1. Withdrawal of the relevant chemicals;

2. Destruction of the relevant chemicals which cause or are likely to harm human health or the environment;

3. Reporting of a plan for implementation of the registration of chemicals under Article 10 of the Act.

Article 13 (Omission of Data to be Submitted When Applying for Registration of Chemicals)

"New chemicals or existing chemicals subject to registration prescribed by Presidential Decree" in the proviso to Article 14 (1) of the Act means substances falling under any of the following:

1. New chemicals manufactured or imported in compliance with standards under attached Table 3;

2. Isolated intermediates: Provided, That isolated intermediates under Article 11 (1) 8 shall be excluded;

3. Chemicals whose danger to human health or the environment may be judged through the results obtained from internationally recognized qualitative or quantitative structure activity relationship

models (QSAR models), the quantity of which intended to be manufactured or imported is less than ten tons per year;

4. Chemicals whose hazards to human health or the environment may be judged through the results obtained from internationally recognized in vitro testing methods;
5. Chemicals whose hazards to human health or the environment may be judged through the results obtained from chemicals with similar structure;
6. Chemicals whose hazards to human health or the environment may be judged through the reliable results on par with internationally recognized testing methods;
7. Chemicals the test of which is technically impossible;
8. Chemicals that may be judged through data for application for registration under Article 14 (1) 7 or 9 of the Act that they will not be exposed to humans or the environment.

Article 14 (Grounds for Individual Submission of Data When Applying for Registration of Existing Chemicals Subject to Registration)

"Cases that constitute grounds prescribed by Presidential Decree" in Article 15 (1) 3 of the Act means cases falling under any of the following:

1. Where the classification of chemicals disagrees with the labelling of chemicals on the same items to be tested;
2. Where a person's opinion disagrees with the representative's opinion in choosing test data for the same items to be tested.

Article 15 (Grounds for Refusal of Consent to Use Vertebrate Test Data)

"Justifiable grounds prescribed by Presidential Decree" in Article 17 (3) of the Act means where the price a person who has made a request for consent to use vertebrate test data intends to pay the owner of the relevant data, is not equivalent to the use of vertebrate test data.

Article 16 (Chemicals Whose Hazard Evaluation Is Deemed Necessary)

"Chemicals prescribed by Presidential Decree, whose hazard evaluation is deemed necessary, such as chemicals of which the Republic of Korea is supposed to conduct hazard evaluations among chemicals whose hazards are evaluated by international organizations" in Article 19 (1) of the Act means the following chemicals:

1. Chemicals of which the Republic of Korea is supposed to conduct hazard evaluations among chemicals whose hazards are evaluated by international organizations, such as the Organization for Economic Cooperation and Development (OECD);
2. Chemicals for the implementation of international conventions;
3. Chemicals manufactured or imported not more than ten tons per year to export the whole quantity thereof overseas;
4. Chemicals under subparagraphs 3 through 6 of Article 13;
5. Chemicals to develop test methods concerning physical and chemical properties and hazards of chemicals;

6. Chemicals that cause or are likely to cause damage to human health or the environment;
7. Chemicals manufactured by small and medium enterprises under the subparagraphs of Article 2 (1) of the Framework Act on Small and Medium Enterprises;
8. Nanomaterials.

Article 17 (Research Institutes)

"Research institutes prescribed by Presidential Decree" in the main body of Article 22 (1) of the Act means the following institutes:

1. National or public testing and research institutes or inspection agencies;
2. Schools under Article 2 of the Higher Education Act;
3. Specific research institutes under Article 2 of the Support of Specific Research Institutes Act;
4. Research institutes affiliated with enterprises under Article 14 (1) 2 of the Basic Research Promotion and Technology Development Support Act;
5. Government-funded research institutes under the Act on the Establishment, Operation and Fostering of Government-Funded Research Institutes or the Act on the Establishment, Operation and Fostering of Government-Funded Science and Technology Research Institutes;
6. Testing and research institutes designated or recognized by other Acts.

Article 18 (Measures Based on Results of Evaluation of Hazards)

(1) The Minister of Environment may take the following measures pursuant to Article 24 (3) of the Act:

1. Recommending related administrative agencies, public institutions, etc. to implement measures for the management of hazards (hereinafter referred to as "measures for the management of hazards") including measures that may prevent hazards in the process of handling the relevant chemicals;
2. Recommending manufacturers or importers and subordinate users of chemicals to implement measures for the management of hazards;
3. Other measures deemed necessary by the Minister of Environment to minimize hazards of chemicals.

(2) Where the Minister of Environment takes measures under paragraph (1), he/she shall formulate measures for the management of hazards in advance.

Article 19 (Designation and Announcement of Substances Requiring Permission)

(1) Where the Minister of Environment intends to designate a substance requiring permission pursuant to Article 25 (1) of the Act, he/she shall prepare a written analysis of socioeconomics (hereinafter referred to as "analysis paper of socioeconomics") that has analyzed socioeconomic effects generated from the purposes of the relevant chemical substance in advance. In such cases, where he/she has not conducted a hazard evaluation of the relevant chemical substance, he/she shall also conduct the hazard evaluation thereof.

(2) Criteria for designation of substances requiring permission under the former part of Article 25 (1) of the Act shall be as specified in attached Table 4.

(3) Where the Minister of Environment grants a grace period for permission (hereinafter referred to as "grace period for permission") under the latter part of Article 25 (1) of the Act, he/she shall take the

following matters into consideration:

1. Results of a hazard evaluation of the relevant chemical substance;
 2. Results of an analysis paper of socioeconomics of the relevant chemical substance;
 3. Measures for the management of hazards of the relevant chemical substance;
 4. Information on a substance or new technology that may replace the relevant chemical substance.
- (4) Where necessary before the Minister of Environment grants a grace period for permission pursuant to the latter part of Article 25 (1) of the Act, he/she may request the head of an association (hereinafter referred to the "Association") concerning the management of chemicals, established pursuant to Article 53 (1) of the Chemicals Control Act to prepare and submit a written review on the grace period for permission of the relevant chemical substance.
- (5) Where the Minister of Environment intends to designate a substance requiring permission pursuant to Article 25 (1) of the Act, he/she shall make a preliminary announcement of the name of the relevant chemical substance on the Official Gazette or the Internet homepage in advance.
- (6) Where the Minister of Environment intends to designate a substance requiring permission or grant a grace period for permission pursuant to Article 25 (1) of the Act, he/she shall undergo the procedure for gathering opinions from manufacturers, importers, users, etc. of the relevant chemical substance.
- (7) Where the Minister of Environment designates and announces a substance requiring permission pursuant to Article 25 (1) of the Act, he/she shall include the following:
1. Name and unique number of the relevant chemical substance;
 2. Purposes subject to permission: Provided, That cases for scientific experiments, analyses or chemical research, such as a reagent, shall be excluded;
 3. Grace period for permission.

Article 20 (Designation and Announcement of Restricted Substances or Prohibited Substances)

- (1) Where the Minister of Environment intends to designate a restricted substance or prohibited substance pursuant to Article 27 (1) of the Act, he/she shall take into consideration the possibility of replacement, such as a substance or new technology that may replace the relevant chemical substance, and socioeconomic effects generated from the purposes of the relevant chemical substance.
- (2) Where the Minister of Environment intends to designate a restricted substance or prohibited substance pursuant to Article 27 (1) of the Act, he/she shall undergo the procedure for gathering consensus from manufacturers, importers, users, etc. of the relevant chemical substance.
- (3) Where necessary to designate a restricted substance or prohibited substance pursuant to Article 27 (1) of the Act, the Minister of Environment shall prepare an analysis paper of socioeconomics in advance. In such cases, where he/she has not conducted a hazard evaluation of the relevant chemical substance, he/she shall also conduct the hazard evaluation thereof.
- (4) Where the Minister of Environment designates and announces a restricted substance or prohibited substance pursuant to Article 27 (1) of the Act, he/she shall include the following matters:

1. Name and identification number of the relevant chemical substance;
2. Purposes of restriction or prohibition and the details thereof.

Article 21 (Affairs of Persons Appointed by Overseas Manufacturers or Producers)

"Affairs prescribed by Presidential Decree" in Article 38 (1) 4 of the Act means the following affairs:

1. Affairs concerning applications for confirmation of exemption from registration under Article 11 (2) of the Act;
2. Affairs concerning the registration of changes or reporting of changes under Article 12 of the Act;
3. Affairs concerning individual submission of data for application for registration of existing chemicals subject to registration under the proviso to Article 15 (1) of the Act;
4. Affairs concerning inquiries about whether the registration of chemicals under the former part of Article 16 (2) of the Act has been obtained;
5. Affairs concerning confirmation of whether the owner of vertebrate test data under the main sentence of Article 17 (2) of the Act has consented to use the vertebrate test data;
6. Affairs concerning the provision of information on chemicals under Article 29 of the Act;
7. Affairs concerning the provision of information under Article 30 (2) of the Act;
8. Affairs concerning applications for confirmation of exemption from reporting under Article 32 (3) of the Act;
9. Affairs concerning the provision of information on chemicals contained in products under Article 35 of the Act;
10. Affairs concerning the submission of data for approval of the Minister of Environment under Article 36 (2) of the Act;
11. Affairs concerning requests for data protection under the main sentence of Article 45 (1) of the Act.

Article 22 (Affairs Processed by Chemical Information Processing System)

"Affairs prescribed by Presidential Decree" in Article 39 (1) of the Act means the following affairs:

1. Affairs concerning the reporting of the manufacture, etc. of chemicals under Article 8 of the Act;
2. Affairs concerning the registration of chemicals under Article 10 of the Act;
3. Affairs concerning exemption from registration under Article 11 of the Act;
4. Affairs concerning the registration of changes, the reporting of changes, etc. under Article 12 of the Act;
5. Affairs concerning the provision of information on chemicals under Article 29 of the Act;
6. Affairs concerning notification, etc. for the provision of information on chemicals under Article 31 of the Act;
7. Affairs concerning the reporting of products that contain hazardous chemicals and confirmation of exemption from reporting under Article 32 of the Act;
8. Affairs concerning applications, etc. for registration filed by persons appointed by overseas manufacturers or producers under Article 38 of the Act;

9. Affairs concerning the disclosure of information on chemicals under Article 42 of the Act;

10. Affairs concerning the protection of data under Article 45 of the Act.

Article 23 (Operation of Chemical Information Processing System)

(1) Where a chemical information processing system (hereinafter referred to as "chemical information processing system") under Article 39 (1) of the Act malfunctions, the Minister of Environment shall first handle affairs under Article 22 through other methods, and supplement such matters handled when the chemical information processing system operates normally.

(2) Where affairs under Article 22 are handled through a chemical information processing system, electronic documents or other methods may be used in lieu of documents to be attached. In such cases, an electronic signature may take the place of a signature and sealing or signature of a person who handles affairs through electronic documents.

Article 24 (Designation of Green Chemical Centers)

"Institutions prescribed by Presidential Decree" in Article 40 (1) of the Act means the following institutions:

1. Korea Environment Corporation established pursuant to the Korea Environment Corporation Act;
2. Korea Environmental Industry and Technology Institute under Article 5-3 of the Environmental Technology and Industry Support Act;
3. Korea Institute of Industrial Technology under Article 8 (1) and subparagraph 7 of attached Table of the Act on the Establishment, Operation, and Fostering of Government-Funded Science and Technology Research Institutes;
4. The Association;
5. Other institutions deemed by the Minister of Environment to have human resources, organization, budget and facilities enough to conduct affairs concerning the production of information on chemicals, reduction of hazards, research, development, dissemination, etc. of technology.

Article 25 (Requirements for Designation of Green Chemical Centers)

Any institution that intends to be designated as a green chemical center (hereinafter referred to as "green chemical center") under Article 40 (1) of the Act shall meet all the following requirements:

1. It shall have an organization exclusively in charge, equipment and tools for research, research facilities, equipment, etc. to conduct affairs under the subparagraphs of Article 40 (2) of the Act and prepare the regulations for operation;
2. It shall have at least eight professionals to conduct affairs under the subparagraphs of Article 40 (2) of the Act;
3. It shall have performance track records of affairs under the subparagraphs of Article 40 (2) of the Act it has conducted for the last two years.

Article 26 (Procedures for Designation of Green Chemical Centers)

(1) Where the Minister of Environment intends to designate green chemical centers pursuant to Article 40 (1) of the Act, he/she shall officially announce a designation plan, a schedule, requirements for

designation, requirements for qualification of professionals, etc. in the Official Gazette or the Internet homepage in advance for at least ten days.

(2) Any institution which intends to obtain designation as a green chemical center shall submit an application for designation of green chemical center to the Minister of Environment along with the following documents:

1. Specialized fields;
2. The current status of the organization exclusively in charge and professionals in the institution;
3. The current status of equipment and tools for research, research facilities, equipment, etc. secured;
4. Performance of affairs in the field of green chemicals for the last two years and evidential data;
5. A business plan and the rules for operation.

(3) Where the Minister of Environment designates a green chemical center pursuant to Article 40 (1) of the Act, he/she shall issue a written designation of the green chemical center prescribed by Ordinance of the Ministry of Environment, to the relevant institution, and post the designation thereof on the Internet homepage of the Ministry of Environment.

Article 27 (Operation, etc. of Green Chemical Centers)

(1) Each green chemical center shall report the operations of the relevant green chemical center to the Minister of Environment in accordance with the following classification:

1. A business plan for the relevant year: By the end of February every year;
2. Results of the performance of business and results of the execution of budget in the preceding year: By March 31 every year.

(2) The Minister of Environment shall conduct evaluations on a business plan, the results of the performance of business, and the results of the execution of budget of each green chemical center based on the results reported to him/her pursuant to paragraph (1). In such cases, he/she may request green chemical centers to submit data or make a report necessary for evaluation.

(3) The Minister of Environment or the head of a related central administrative agency may subsidize all or some of expenses incurred in conducting business of green chemical centers, such as the development of environmentally friendly chemicals or new chemicals, or the development of alternative technology to hazardous chemicals.

Article 28 (Grounds, etc. for Revocation of Designation of Green Chemical Centers)

"Cases prescribed by Presidential Decree" in Article 41 (1) 4 of the Act means where the performance of business is significantly poor as a result of the evaluation under Article 27 (2).

Article 29 (Criteria for Administrative Disposition)

Criteria for administrative disposition under Article 41 (2) of the Act shall be as specified in attached Table 5.

Article 30 (Protection of Data)

(1) The Minister of Environment shall not disclose data submitted to him/her pursuant to the main sentence of Article 45 (1) of the Act for five years: Provided, That where a person who has submitted data

applies for an extension of the period for data protection, as prescribed by Ordinance of the Ministry of Environment, the Minister of Environment may permit the extension thereof only twice by each five years.

(2) "Data prescribed by Presidential Decree" in the proviso to Article 45 (1) of the Act means data falling under any of the following, which are not trade secrets under subparagraph 2 of Article 2 of the Unfair Competition Prevention and Trade Secret Protection Act:

1. Data concerning the commercial names of chemicals or the names of products;
2. Data concerning the purposes of chemicals or products;
3. Data concerning the safe use, such as matters requiring attention when handling chemicals or products or methods of destruction;
4. Data concerning methods of responding to chemical accidents;
5. Data concerning physical and chemical properties of chemicals;
6. Summary data concerning the toxicity of chemicals;
7. Summary data concerning hazards of chemicals;
8. Other data announced because the Minister of Environment deems the disclosure of such data necessary to protect human health and the environment.

Article 31 (Delegation and Entrustment of Authority)

(1) The Minister of Environment shall delegate the following authority to the President of the National Institute of Environmental Research:

1. Receipt of applications for registration, determination as to whether to allow registration and notification under Article 10 (3) and (4) of the Act;
2. Receipt of applications for registration of changes or the reporting of changes, and notification of the result thereof under Article 12 (1) and (2) of the Act;
3. Receipt of data for application for registration and test plans under Article 14 (1) and (3) of the Act;
4. Receipt of questions about registration and notification of the result thereof under Article 16 (2) of the Act;
5. Orders to submit vertebrate test data under the proviso to Article 17 (2) of the Act;
6. Review of toxicity, notification of the result thereof, and orders to submit data under Article 18 (1) and (2) of the Act;
7. Evaluation of toxicity and approval for the use of the result of the evaluation of toxicity under Article 19 (1) and (2) of the Act;
8. Announcement of the results of reviews of toxicity under Article 21 (1) of the Act;
9. Evaluation of testing institutions under Article 22 (3) of the Act;
10. Hazard evaluation, notification of the result thereof, and orders to submit data under Article 24 (1) and (2) of the Act;
11. Notification, etc. for the provision of information under Article 31 of the Act;
12. Evaluation, etc. of hazards of products under Article 33 of the Act;

13. Receipt and approval of data on chemicals contained in products likely to be hazardous whose safety standards and labelling standards under Article 36 (2) of the Act have not been announced;
 14. Receipt of reports concerning the appointment or dismissal under Article 38 (2) of the Act (only applicable where reports have been made to the President of National Institute of Environmental Research);
 15. Operation of the chemical information processing system under Article 39 of the Act;
 16. Disclosure of information under Article 42 of the Act;
 17. Orders to reports or submit data, access, inspection, etc. under Article 43 (1) of the Act (only applicable to cases under Article 43 (1) 2 of the Act);
 18. Receipt of requests for data protection and notification of data ineligible for data protection under Article 45 (1) and (2) of the Act (only applicable to data submitted to the President of National Institute of Environmental Research);
 19. Receipt of reports and notification under the latter part of Article 3 (1) of Addenda of the Act on Registration, Evaluation, etc of Chemicals, Act No. 11789;
 20. Preparation of measures for the management of hazards under Article 18 (2);
 21. Preparation of a written analysis of socioeconomic effects under Article 19 (1) and conducting hazard evaluations under Article 20 (3).
- (2) The Minister of Environment shall delegate the following authority to the head of a river basin environmental protection office or the head of a regional environmental protection office (hereinafter referred to as "head of a regional environmental protection office") pursuant to Article 48 (1) of the Act:
1. Receipt of reports and reports on changed matters under Article 8 (1) and (3) of the Act;
 2. Measures against nonperformance of duty to obtain registration under Article 13 (2) of the Act;
 3. Receipt of reports on products containing hazardous chemicals under Article 32 (1) of the Act;
 4. Orders to take necessary measures, such as recall, prohibition of sale or destruction of products, and orders to take emergency measures under Article 37 (1) and (2) of the Act;
 5. Receipt of reports on the appointment or dismissal under Article 38 (2) of the Act (only applicable to cases reported to the head of a regional environmental protection office);
 6. Orders to make reports or to submit data, access, inspection, etc. under Article 43 (1) of the Act (only applicable to cases under Article 43 (1) 1, 4 and 5 of the Act);
 7. Receipt of requests for data protection and notification of data ineligible for data protection under Article 45 (1) and (2) of the Act (only applicable to data submitted to the head of a regional environmental protection office);
 8. Imposition and collection of fines for negligence under Article 54 of the Act (only applicable regarding matters delegated to the head of a regional environmental protection office);
- (3) The Minister of Environment shall entrust the following affairs to the Association pursuant to Article 48 (2) of the Act:

1. Receipt of applications for confirmation of exemption from registration and notification of the result thereof under Article 11 (2) of the Act;
2. Confirmation of grounds for individual submission under Article 15 (1) of the Act;
3. Confirmation of the fact that the owner of vertebrate test data has not given consent to use such data under Article 17 (2) of the Act;
4. Receipt of applications for confirmation of exemption from reporting products containing hazardous chemicals and notification of the results thereof under Article 32 (3) of the Act;
5. Receipt of reports on appointment or dismissal under Article 38 (2) of the Act (only applicable to cases reported to the Association);
6. Receipt of requests for data protection and notification of data ineligible for data protection under Article 45 (1) and (2) of the Act (only applicable to data submitted to the head of the Association)

Article 32 (Criteria for Imposition of Fines for Negligence)

Criteria for imposition of fines for negligence under Article 54 (1) of the Act shall be as specified in attached Table 6.

ADDENDA <Presidential Decree No. 25835, Dec. 9, 2014>

Article 1 (Enforcement Date)

This Decree shall enter into force on January 1, 2015.

Article 2 (Period of Validity of Entrustment to Association)

@Article 31 (3) 1, 4, 5 and 6 shall remain in force until December 31, 2017.

Article 3 (Procedures for Reporting of Persons Who Underwent Review of Toxicity)

(1) Any person that intends to report pursuant to the latter part of Article 3 (1) of Addenda of the Act on Registration, Evaluation, etc of Chemicals, Act No. 11789, shall submit a report prescribed by Ordinance of the Ministry of Environment to the Minister of Environment along with data prescribed by Ordinance of the Ministry of Environment by the deadline based on the following classification:

1. New chemicals: June 30, 2015;
2. Existing chemicals subject to registration: Six months from the date of designation and announcement of existing chemicals subject to registration.

(2) The Minister of Environment shall review data submitted pursuant to paragraph (1), as prescribed by Ordinance of the Ministry of Environment, and notify the result thereof within 30 days after the deadline based on the classification under the subparagraphs of paragraph (1).

Article 4 (Transitional Measures concerning Protection of Data)

Where any person that has submitted data pursuant to Articles 10 (2) through (4), 11 (2), and 18 (4) of the former Toxic Chemicals Control Act as at the time this Decree enters into force makes a request for the protection of data pursuant to Article 51 (1) of the Act, data being protected pursuant to Article 27 of the former Enforcement Decree of the Toxic Chemicals Control Act shall be deemed protected pursuant to Article 30 (1) of this Decree.

Article 5 Omitted.

