

# ENFORCEMENT RULE OF THE ACT ON REGISTRATION, EVALUATION, ETC. OF CHEMICALS

Ordinance Of the Ministry of Ministry of Environment No. 582, Dec. 24,  
2014

## Article 1 (Purpose)

The purpose of these Rules is to prescribe matters delegated by the Act on Registration, Evaluation, etc., of Chemicals and its Enforcement Decree and other matters necessary for the implementation thereof.

## Article 2 (Support for Small and Medium Enterprises)

The Minister of Environment may, in accordance with Article 4 (4) of the Act on Registration, Evaluation, etc., of Chemicals (hereinafter referred to as “the Act”), provide administrative and financial support to the institutions designated by the said Minister, within budgetary limits, to conduct support projects for small and medium enterprises (referring to small and medium enterprises defined in Article 2 of the Framework Act on Small and Medium Enterprises; hereafter the same shall apply in this Article), such as investigation, research, education, publicity, etc. concerning the following matters related to the registration, evaluation, etc., of chemicals:

1. Schemes for utilizing the chemical information system referred to in Article 39 of the Act;
2. Current status of chemical information;
3. Promotion of the provision of chemical information;
4. Creation of the infrastructure for production and management of chemical information;
5. Creation of the infrastructure for registration of chemicals;
6. Development of human resources for the management of chemicals;
7. Risk management of products containing harmful chemicals;
8. Mutual cooperation among small and medium enterprises;
9. Development and distribution of the technologies for replacing harmful chemicals;
10. Evaluation of the marketability of alternative substances, and facilitation of their entry into the market;
11. Designation of exemplary small and medium enterprises, and exemplary cases;
12. Implementation of training programs for the executives and employees of small and medium enterprises.

## Article 3 (Method for Reporting Manufacturing, etc.)

(1) Each person, who manufactures, imports, or sells a non-phase-in chemical, or a phase-in chemical in an annual quantity exceeding one ton, pursuant to Article 8 (1) of the Act, shall report the uses of such chemical, the quantities of such chemical manufactured, imported, and sold for the previous year, and other related matters to the head of the relevant river basin environmental office or the head of the relevant regional environmental office (hereinafter referred to as "the head of a regional environmental agency") by June 30 each year.

(2) Report filed under paragraph (1) shall be in Attached Form 1, along with the following documents:

1. A certificate of reporting the appointment by an overseas manufacturer or producer (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files a report);

- 2 A written application for data protection (limited to requests for data protection pursuant to Article 45 (1) of the Act);

3. A document evidencing the outsourcing, such as a copy of a contract for outsourcing (limited to where a person who outsources the manufacture of a chemical files a report).

(3) Each person, who intends to report a changed matter pursuant to Article 8 (3) of the Act, shall submit a report of change in Attached Form 1, to the head of a regional environmental agency within the following periods:

1. In cases of a change referred to in subparagraph 1 of Article 9 of the Decree: One month after the change occurs;

2. In cases of a change referred to in subparagraph 2 of Article 9 of the Decree: One month after becoming aware of the change.

(4) The head of a regional environmental agency in receipt of a report under paragraphs (1) through (3) shall verify the business registration certificate through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the reporting person withholds consent to the verification of his/her business registration certificate, the head of a regional environmental agency shall require such person to attach the relevant certificate.

(5) Where it is necessary for a person who has submitted a report to modify and supplement those materials submitted pursuant to paragraphs (1) through (3), the head of a regional environmental agency shall request such person to do so. In such cases, the person in receipt of such request shall modify and supplement the materials without delay, and shall then submit them.

#### **Article 4 (Method for Designation and Public Notification of Chemicals Subject to Registration)**

(1) Every three years, the Minister of Environment shall designate and publicly notify the chemicals subject to registration, including the following matters, pursuant to Article 9 of the Act:

1. Names and unique identifier numbers of phase-in chemicals subject to registration;

2. Registration grace period under Article 10 (1) of the Decree.

(2) Where the Minister of Environment designates and publicly notifies phase-in chemicals subject to registration pursuant to paragraph (1), he/she shall do so based upon the following matters and data:

1. Matters to be reported, such as the manufacture of chemicals, under Article 8 of the Act;
  2. Findings of statistical surveys on chemicals under Article 10 (1) of the Act on the Management of Chemicals;
  3. Domestic and overseas research data concerning the properties, hazards, and risks of chemicals;
  4. Other matters the Minister of Environment deems necessary for the designation and public notification of phase-in chemicals subject to registration.
- (3) Where the Minister of Environment intends to designate and publicly notify the phase-in chemicals subject to registration pursuant to paragraph (1), he/she shall give prior notice on the names and other related matters of the relevant chemicals in the Official Gazette or on the Internet website of the Ministry of Environment.

#### **Article 5 (Methods of Applications for Registration of Chemicals)**

(1) Each person, who intends to apply for registration of a non-phase-in chemical, or a phase-in chemical in an annual quantity exceeding one ton, pursuant to Article 10 (3) of the Act, shall submit a written application for registration in Attached Form 2 (referring to Attached Form 3 in cases of any other person who intends to manufacture or import a non-phase-in chemical under subparagraph 1 of Article 13 of the Decree), to the President of the National Institute of Environmental Research, along with the following materials:

1. Materials concerning the physical and chemical properties and hazards of the relevant chemical: Materials submitted using the methods for submission in Attached Table 1: Provided, That in cases of the chemical referred to in the proviso to Article 10 (1) of the Act, the data publicly notified by the Minister of Environment, which the said Minister deems necessary as at the time he/she designates and publicly notifies the relevant chemical;
2. Materials concerning the risks of the relevant chemical: Materials compiled using the methods for compilation in Attached Table 2;
3. Materials concerning the instructions for the safe use of the relevant chemical: Materials prepared using the methods for preparation in Attached Table 3;
4. Information on exposure from the uses of the relevant chemical: Materials submitted under Article 12 (1);
5. Reasons for omitting materials for application for registration under the main body of Article 14 (1) of the Act (hereinafter referred to as "materials for application for registration"), and evidential materials supporting such reasons (limited to where it is permitted to omit some materials for application for registration pursuant to the proviso to the main body of Article 14 (1) of the Act, and Article 13 of the Decree);
6. A test plan under the former part of Article 14 (3) of the Act (limited to where it is permitted to submit a test plan in lieu of some materials for application for registration pursuant to the former part of Article 14 (3) of the Act;

7. A copy of the written verification of individual submission (limited to where having obtained the verification of individual submission under the proviso to the main body of Article 15 (1) of the Act);
8. A written opinion verifying a refusal to share vertebrate animal test data (limited to where having obtained verification under the main body of Article 17 (2) of the Act);
9. A certificate of reporting the appointment by an overseas manufacturer or producer) (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act applies for registration);
10. A written application for data protection (limited to requests for data protection pursuant to Article 45 (1) of the Act);
11. Documents evidencing the outsourcing, such as a copy of a contract for outsourcing (limited to where a person who outsources the manufacture of a chemical applies for registration).

(2) Notwithstanding paragraph (1), the following materials need not be submitted, in any of the following cases, pursuant to the proviso to the main body of Article 14 (1) of the Act:

1. In cases of a non-phase-in chemical referred to in subparagraph 1 of Article 13 of the Decree: Materials described in paragraph (1) 1 through 3 and 5 through 8: Provided, That it shall be permitted to submit any material in possession of the manufacturer or importer of the relevant chemical among those described in paragraph (1) 1 through 3;
2. In cases of a non-isolated intermediate referred to in subparagraph 2 of Article 13 of the Decree: Materials concerning hazards among those described in paragraph (1) 1, and materials described in paragraph (1) 2 through 5: Provided, That it shall be permitted to submit any material in possession of the manufacturer or importer of the relevant non-isolated intermediate;
3. In cases of a chemical referred to in subparagraphs 3 through 7 of Article 13 of the Decree: Materials related to the relevant chemical among those described in paragraph (1) 1;
4. In cases of a chemical referred to in subparagraph 8 of Article 13 of the Decree: Materials related to the relevant chemical, among test data under subparagraph 1 of Attached Table 4.

(3) Upon receipt of an application for registration pursuant to paragraphs (1) and (2), the President of the National Institute of Environmental Research shall verify the business registration certificate through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the applicant withholds consent to the verification of his/her business registration certificate, the President of the National Institute of Environmental Research shall require such person to attach the relevant certificate.

#### **Article 6 (Notification of Whether Registration is Granted or Refused, and Period of Notification)**

(1) The President of the National Institute of Environmental Research shall assign a registration number and date to a chemical and give written notice thereof in Attached Form 4, to the applicant, by not later than thirty days from the date of receipt of an application for registration pursuant to Article 10 (4) of the Act: Provided, That in any of the following cases, written notice shall be given within the following periods:

1. Where a person who intends to manufacture or import any phase-in chemical subject to registration applies for registration within two months before the registration grace period referred to in Article 10 (1) of the Decree expires: Three months from the date of receipt of the application for registration;
  2. Where a person who intends to manufacture or import any non-phase-in chemical in conformity with the standards described in subparagraph 1 of Article 13 of the Decree and Attached Table 3 thereof applies for registration: Three days from the date of receipt of the application for registration: Provided, That where it is necessary to examine in detail, materials for application for registration: Seven days from the date of receipt of the application for registration.
- (2) Where it is necessary to modify or supplement materials for application for registration, the President of the National Institute of Environmental Research shall give written notice of modification or supplement in Attached Form 5, specifying the matters to be modified or supplemented and the period for submission.
- (3) The applicant in receipt of notice under paragraph (2) shall submit the materials modified or supplemented to the President of the National Institute of Environmental Research within the period for submission.

#### **Article 7 (Application for Verification of Exemption from Registration)**

- (1) Each person, who intends to apply for verification of exemption from registration under Article 11 (2) of the Act, shall submit a written application for verification of registration exemption in Attached Form 6, to an association concerning chemicals management (hereinafter referred to as an "association") described in Article 53 of the Chemicals Management Act, along with the following documents:
1. Data compiled using the methods for compilation in Attached Table 5;
  2. A certificate of reporting the appointment by an overseas manufacturer or producer (limited to where a person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files an application);
  3. A written application for data protection (limited to requests for data protection pursuant to Article 45 (1) of the Act).
- (2) The head of the relevant association in receipt of an application for verification of registration exemption under paragraph (1) shall verify the business registration certificate through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the applicant withholds consent to the verification of his/her business registration certificate, the head of the association shall require such person to attach the relevant certificate.
- (3) The head of the relevant association may, with respect to the matter applied pursuant to paragraph (1), verify whether the relevant chemical is exempt from registration under Article 11 (1) 2 of the Act and Article 11 of the Decree in any such manner as the examination of the President of the National Institute of Environmental Research and the onsite verification.
- (4) Exemption from registration under paragraph (2) shall be verified at the following intervals:

1. Chemicals described in Article 11 (1) 1 through 3 of the Decree: Verification of exemption from registration on an annual basis;
2. Chemicals described in Article 11 (1) 4 of the Decree: Verification of exemption from registration by unit of research and development plan;
3. Chemicals described in Article 11 (1) 5 through 8 of the Decree: Only one initial verification of exemption from registration.

#### **Article 8 (Notification of Result of Application for Verification of Exemption from Registration)**

- (1) Within three days from the date of receipt of an application for exemption pursuant to Article 7 (1), the head of the relevant association shall give written notice of the result of application in Attached Form 7, to the applicant: Provided, That where it is necessary to verify whether the relevant chemical is exempt from registration, the head of such association shall give written notice within ten days from the date of receipt of an application for exemption.
- (2) The head of the relevant association shall notify, on a quarterly basis, the President of the National Institute of Environmental Research of both the current status of applications for exemption from registration under Article 7 (1) and the performance of notification under paragraph (1). In such cases, the President of the National Institute of Environmental Research shall inform such data to the Minister of Employment and Labor.
- (3) The head of the relevant association shall report on the records of the previous year concerning both applications for exemption from registration and the performance of notification to the Minister of Environment by March, 31 each year.

#### **Article 9 (Methods for Registration of Change)**

- (1) Each person, who intends to apply for registration of change pursuant to Article 12 (1) of the Act, shall submit a written application for registration of change in Attached Form 8, to the President of the National Institute of Environmental Research, along with the following documents:
  1. Documents evidencing the change;
  2. Materials related to the change of registration described in Article 5 (1) 1 through 8;
  3. A copy of written notice of registration of the relevant chemical described in Article 6 (1);
  4. A certificate of reporting the appointment by an overseas manufacturer or producer) (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files an application);
  5. A written application for data protection (limited to requests for data protection pursuant to Article 45 (1) of the Act).
- (2) An application for registration of change under paragraph (1) shall be filed within the following periods:
  1. In cases of a change referred to in Article 10 (1): One month from the date on which the change occurs;

2. In cases of a change referred to in Article 10 (2) 1: One month from the date of becoming aware of the change;
  3. In cases of a change referred to in Article 10 (2) 2: Six months from the date of becoming aware of the change: Provided, That where the applicant requests the extension of the period, the period may, after the confirmation of the President of the National Institute of Environmental Research, be extended only once by six months.
- (3) Within thirty days from the date of receipt of an application for registration of change pursuant to paragraph (1), the President of the National Institute of Environmental Research shall give written notice of registration of change in Attached Form 9, to the applicant: Provided, That in any of the following cases, written notice shall be given within the following periods:
1. Where a person who manufactures or imports any phase-in chemical subject to registration applies for registration of change within two months before the registration grace period under Article 10 (1) of the Decree expires: Three months from the date of receipt of an application for registration of change;
  2. Where a person who manufactures or imports a non-phase-in chemical in conformity with the standards described in subparagraph 1 of Article 13 of the Decree and Attached Table 3 thereof applies for registration of change: Three days from the date of receipt of an application for registration of change: Provided, That where it is necessary to examine in detail, materials for application for registration, written notice shall be given within seven days from the date of receipt of an application for registration.

#### **Article 10 (Grounds for Registration of Change)**

- (1) The phrase "where ..... changed beyond the range prescribed by Ordinance of the Ministry of Environment" in Article 12 (1) 1 of the Act refers to where the annual quantity of a chemical manufactured or imported is changed from a level falling within the total tonnage band of the quantities of the chemical manufactured or imported under Attached Table 6 to a level over that band.
- (2) The phrase "where matters prescribed by Ordinance of the Ministry of Environment ..... are changed" in Article 12 (1) 2 of the Act refers to any of the following cases:
1. A case in which the uses of a registered chemical are changed and which falls under any of the following;
    - (a) Where the chemical use classification system described in subparagraph 2 of Article 9 of the Decree and Attached Table 2 thereof is changed;
    - (b) Where the detailed uses of a chemical are changed or the new use thereof is verified;
  2. A case in which the hazards, risks etc. of a registered chemical are changed and which falls under any of the following:
    - (a) Where new information on properties and hazards of the chemical, which does not exist at the time of registration and causes the change to the classification and labelling of such chemical under Article 14 (1) 4 of the Act, becomes available;

(b) Where new information on risks of the chemical, which does not exist at the time of registration and affects human health or the environment, becomes available.

(3) Details for classification and labelling under paragraph (2) 2 (a) shall be as listed in Attached Table 7.

#### **Article 11 (Methods, etc. for Report on Change)**

(1) Within one month from the date the name, location or representative of the registered person is changed, each person who intends to report on change pursuant to Article 12 (2) of the Act shall submit a report on change in Attached Form 8, to the President of the National Institute of Environmental Research, along with the documents described in Article 9 (1) 1 and 3 through 5.

(2) Within three days from the date of receipt of the report pursuant to paragraph (1), the President of the National Institute of Environmental Research shall give written notice of reporting a change in Attached Form 9, to the applicant.

#### **Article 12 (Materials for Application for Registration)**

(1) The phrase "materials determined by Ordinance of the Ministry of Environment" in Article 14 (1) 9 of the Act refers to materials concerning information on exposure from the uses of the relevant chemical prepared by the methods for preparation under Attached Table 8.

(2) The phrase "materials determined by Ordinance of the Ministry of Environment" in the main body of Article 14 (2) of the Act refers to materials described in subparagraph 2 of Attached Table 4.

#### **Article 13 (Verification by Foreign Testing Institution)**

(1) When submitting documents stating the result of a test conducted by a foreign testing institution pursuant to Article 14 (2) 2 of the Act, either of the following materials shall also be submitted:

1. Written authentication issued by a member state of the Organization for Economic Co-operation and Development;
2. A written statement that the result of a test conducted by the foreign testing institution conforms to OECD principles of Good Laboratory Practice (GLP).

(2) Upon receipt of materials falling under paragraph (1), the President of the National Institute of Environmental Research shall verify whether the relevant foreign testing institution complies with OECD principles of Good Laboratory Practice (GLP).

#### **Article 14 (Alternative Submission of Test Plan)**

(1) Each person, who intends to apply for registration pursuant to the former part of Article 14 (3) of the Act, may submit a test plan in lieu of materials described in subparagraph 3 of Attached Table 4 related to the matters referred to in Article 14 (1) 5 and 6 of the Act.

(2) A test plan shall be formulated, containing the following matters:

1. The name of the test;
2. A testing institution described in Article 14 (2) of the Act, expected to conduct the test;
3. Reasons for submitting the test plan;
4. Detailed methods for the test;



5. Detailed schedules for the test;
6. The date the test data can be submitted.

#### **Article 15 (Examination of Test Plan, and Notification thereof)**

(1) The President of the National Institute of Environmental Research shall examine the propriety of the test descriptions and test schedules stated in a test plan pursuant to the latter part of Article 14 (3) of the Act, and shall notify the person who has submitted the test plan of the result of examination and the deadline for submission of the test data.

(2) Where it is necessary to modify or supplement a test plan as a result of examination under paragraph (1), the President of the National Institute of Environmental Research shall notify the person who has submitted the relevant test plan of the following matters:

1. Conditions and methods of the test;
2. Deadline for submission of the test data;
3. Other matters to be modified or supplemented.

(3) Each person notified of the result of examination of a testing plan pursuant to paragraph (1), shall submit test data to the President of the National Institute of Environmental Research by the deadline for submission: Provided, That where the President of the National Institute of Environmental Research deems, as a result of onsite verification, that the testing institution referred to in Article 14 (2) of the Act cannot submit test data by the deadline for submission due to extenuating circumstances, he/she may extend such deadline for submission.

#### **Article 16 (Materials for Application for Registration to be Jointly Submitted)**

(1) The phrase “materials for application for registration prescribed by Ordinance of the Ministry of Environment” in the main body of Article 15 (1) of the Act refers to the following materials:

1. Materials concerning classification and labelling of chemicals referred to in Article 14 (1) 4 of the Act;
2. Materials concerning physical and chemical properties of chemicals referred to in Article 14 (1) 5 of the Act;
3. Materials concerning hazards of chemicals referred to in Article 14 (1) 6 of the Act;
4. A test plan referred to in the former part of Article 14 (3) of the Act.

(2) Notwithstanding paragraph (1), where all applicants for registration pursuant to Article 10 (3) of the Act reach agreement on the joint submission of the following materials, they may jointly submit such materials:

1. Materials concerning risks of chemicals referred to in Article 14 (1) 7 of the Act;
2. Materials concerning the instructions for safe use referred to in Article 14 (1) 8 of the Act.

#### **Article 17 (Methods and Procedures for Joint Submission of Materials for Application for Registration)**

(1) The parties to the joint submission of materials for application for registration pursuant to Article 16 shall elect their representative by mutual agreement: Provided, That in the absence of any agreement, such

representative shall be elected by a majority of votes.

(2) The representative elected under paragraph (1) shall perform the following affairs after consultation with the parties to the joint submission of materials for application for registration:

1. Affairs concerning the selection and production of materials to be jointly submitted;
2. Affairs concerning the apportionment of expenses incurred in the joint submission;
3. Other affairs concerning the joint preparation and submission of materials for application for registration.

(3) Where agreement on the apportionment of expenses referred to in paragraph (2) 2 fails to be reached among the parties, they shall share the expenses, taking into account the quantities of phase-in chemicals subject to registration the respective parties have manufactured or imported.

(4) The representative elected under paragraph (1) shall submit the materials for application for registration described in Article 16 before each party to the joint submission of materials for application for registration files a separate application for registration.

#### **Article 18 (Verification of Separate Submission of Materials for Application for Registration)**

(1) Each person, who intends to individually submit materials for application for registration pursuant to the proviso to the main body of Article 15 (1) of the Act, shall obtain verification from the head of the relevant association with respect to such separate submission.

(2) Each person, who intends to obtain verification under paragraph (1), shall submit a written application for verification concerning separate submission in Attached Form 10, to the head of the relevant association, along with the following documents:

1. A document evidencing that the person has any ground for separate submission under Article 15 (1) of the Act and Article 14 of the Decree;
2. A certificate of reporting the appointment by an overseas manufacturer or producer (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files an application).

(3) The head of the relevant association in receipt of an application under paragraph (2), shall examine the details for the application after interviews with the applicant, on-site inspections, etc. and shall give written notice of verification of separate submission in Attached Form 11, within 14 days from the date of application.

#### **Article 19 (Shared Use of Existing Materials for Application for Registration, etc.)**

(1) The phrase “materials for application for registration prescribed by Ordinance of the Ministry of Environment” in the main body of Article 16 (1) of the Act refers to the following materials.:

1. Materials concerning physical and chemical properties of chemicals referred to in Article 14 (1) 5 of the Act;
2. Materials concerning hazards of chemicals referred to in Article 14 (1) 6 of the Act.

(2) Where a person uses materials referred to in paragraph (1) to apply for registration after obtaining consent to such use from the owner pursuant to Article 16 (1) of the Act, he/she shall also submit a written

consent of the owner to the President of the National Institute of Environmental Research when applying for registration under Article 10 (3) of the Act.

**Article 20 (Inquiry of Whether Chemical has been Registered, etc.)**

(1) Each person, who intends to make an inquiry under Article 16 (2) of the Act, shall submit a written inquiry in Attached Form 12, to the President of the National Institute of Environmental Research, along with the certificate of reporting the appointment by an overseas manufacturer or producer (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act makes an inquiry).

(2) Within fourteen days from the date of receipt of the written inquiry under paragraph (1), the President of the National Institute of Environmental Research shall notify whether the relevant chemical is registered by giving written notice of verification in Attached Form 13. In such cases, the President of the National Institute of Environmental Research shall notify the information on the person who submits a written inquiry under paragraph (1) to the person who has submitted existing materials for application for registration.

**Article 21 (Consent to Use Vertebrate Animal Test Data, etc.)**

(1) Each person, who intends to obtain verification that the owner of vertebrate test data refuses to give consent under the main body of Article 17 (2) of the Act, shall submit a written application for verification in Attached Form 14, to the head of the relevant association, along with the following documents:

1. A document evidencing the owner's refusal to share his/her vertebrate test data;
2. A certificate of reporting the appointment by an overseas manufacturer or producer (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files an application)

(2) Within fourteen days from the date of receipt of an application under paragraph (1), the head of the relevant association shall give a written opinion concerning verification in Attached Form 15, to the applicant.

**Article 22 (Period for Submission of Vertebrate Animal Test Data)**

The phrase “period prescribed by Ordinance of the Ministry of Environment” in the proviso to Article 17 (2) of the Act, refers to such period required to produce the relevant vertebrate animal test data as is notified by the President of the National Institute of Environmental Research, when ordering the submission of the relevant vertebrate animal test data.

**Article 23 (Method, etc. for Hazard Analysis)**

(1) The President of the National Institute of Environmental Research shall conduct a hazard analysis pursuant to Article 18 of the Act from the date of giving written notice of registration under Article 6 (1) or written notice of registration of change under Article 9 (3), to the applicant.

(2) A period for hazard analysis referred to in paragraph (1) shall exceed any of the following periods. In such cases, the period from the date of an order issued under Article 25 to the date of submission shall not be included therein:

1. A non-phase-in chemical: Six months: Provided, That in cases of a non-phase-in chemical described in subparagraph 1 of Article 13 of the Decree, a period for hazard analysis of such chemical may be extended once or twice by six months;

2. A phase-in chemical subject to registration: One year.

(3) Methods of hazard analysis shall be as listed in Attached Table 9.

#### **Article 24 (Notification of Findings of Hazard Analysis, and Other Matters)**

When completing a hazard analysis under Article 23, the President of the National Institute of Environmental Research shall notify the findings thereof to the person who has applied for registration under Article 10 (3) of the Act or registration of change under Article 12 of the Act, by giving written notice of findings in Attached Form 16, and shall also give written notice of results in Attached Form 17, to the Minister of Employment and Labor.

#### **Article 25 (Order to Submit Data Necessary for Hazard Analysis)**

(1) In any of the following cases, the President of the National Institute of Environmental Research may, pursuant to Article 18 (2) of the Act, order a person who has made registration or registration of change to submit data necessary for a hazard analysis by a fixed deadline, by giving a written order for submission of materials in Attached Form 18. In such cases, the deadline for submission of such data shall be deemed appropriate by the President of the National Institute of Environmental Research, based on the period required to produce such data:

1. Where, as a result of examining materials submitted to apply for either registration under Article 10 (3) of the Act or registration of change under Article 12 of the Act, it is necessary to add other materials or supplement the initial materials;

2. Where, as a result of examining the use of, and information on exposure to, a chemical registered pursuant to Article 10 of the Act, it is necessary to identify the hazards thereof on the ground of likelihood of exposure therefrom to human health and the environment;

3. Where a chemical registered pursuant to Article 10 of the Act is likely to be designated as a hazardous chemical;

4. Where a chemical registered pursuant to Article 10 of the Act is contained in any product of risk concern;

5. Where a chemical registered pursuant to Article 10 of the Act is used for killing hazardous creatures other than human and animals, or obstructing and suppressing the activities thereof;

6. Where the accumulated quantities of a non-phase-in chemical manufactured or imported under subparagraph 1 of Article 13 of the Decree exceed one ton;

7. Where it is necessary to submit the whole text of the test data which describes the test result without manipulating the progress, procedures, etc. conducted to produce data concerning the physical and chemical properties, and hazards of a chemical referred to in Article 5 (1) 1.

(2) Data, the submission of which may be ordered pursuant to paragraph (1) shall be as follows:

1. Data concerning the physical and chemical properties of the relevant chemical;
2. Data concerning the hazards of the relevant chemical.

#### **Article 26 (Methods for Hazard Assessment)**

(1) The President of the National Institute of Environmental Research shall conduct a hazard assessment of chemicals listed in Article 16 of the Decree after determining the priority order thereof, based upon the following matters: Provided, That the chemicals which urgently require a hazard assessment shall be assessed with priority:

1. The quantities of the relevant chemical domestically manufactured, imported, and exported;
  2. Severity of the hazards of the relevant chemical;
  3. Whether the relevant chemical damages human health or the environment, and other related matters.
- (2) Domestic and foreign relevant laws and systems regarding the registration, hazard analysis, etc. of chemicals shall be considered in conducting a hazard assessment under paragraph (1).
- (3) Attached Table 9 shall apply mutatis mutandis to the method for hazard assessment under paragraph (1).

#### **Article 27 (Method, etc. of Approval for use)**

(1) Each person, who intends to obtain approval for the use of the findings of a hazard assessment pursuant to Article 19 (2) of the Act, shall submit a written application for approval for use in Attached Form 19, to the President of the National Institute of Environmental Research.

(2) Where deemed appropriate in consideration of the purpose of approval for use, the President of the National Institute of Environmental Research in receipt of a written application under paragraph (1) shall issue a written approval for use in Attached Form 20.

(3) Where necessary under laws and regulations of a foreign country for the registration of a chemical, the application for a hazard analysis, or any other purpose, a person in receipt of a written approval for use pursuant to paragraph (2) may submit such written approval for use or a copy thereof to the authority of such foreign country.

(4) Where a person in receipt of a written approval for use pursuant to paragraph (2) falls under any of the following cases, the President of the National Institute of Environmental Research may cancel the approval for use. In such cases, the President of the National Institute of Environmental Research shall immediately notify the fact to the person in receipt of such written approval:

1. Where having obtained the approval for use by fraud or other wrongful means;
  2. Where having allowed any other person who has not obtained the approval for use of the findings of a hazard assessment;
  3. Where having used the findings of a hazard assessment for other than the original purpose of the approval for use.
- (5) Except as otherwise expressly provided for in paragraphs (1) through (4), matters necessary for the methods of granting approval for the use of the findings of a hazard assessment, and other related matters shall be determined and publicly notified by the President of the National Institute of Environmental

Research.

#### **Article 28 (Public Notification of Findings of Hazard Analysis)**

The phrase “matters prescribed by Ordinance of the Ministry of Environment” in Article 21 (1) of the Act refers to the following matters:

1. Unique identifier number of the relevant chemical;
2. Classification and labelling of the relevant chemical;
3. Other matters necessary for the safety management of the relevant chemical.

#### **Article 29 (Procedures for Designation of Testing Institutions, and other Related Matters)**

(1) The head of a research institute who intends to apply for designation of a testing institution pursuant to the former part of Article 22 (2) of the Act shall submit a written application for designation in Attached Form 21, to the Minister of Environment, along with the following documents:

1. A detailed statement of the current status of facilities;
2. A detailed statement of the current status of operation;
3. Materials proving testing capability.

(2) The Minister of Environment shall examine a written application for designation and documents submitted under paragraph (1), and shall then issue a written designation in Attached Form 22 to the applicant if such written application and documents satisfy the standards for designation under paragraph (5).

(3) The phrase “important matters prescribed by Ordinance of the Ministry of Environment” in the latter part of Article 22 (2) of the Act refers to the following matters:

1. Name and representative of a testing institution;
2. Location of a testing institution or facility;
3. Detailed matters subject to a test or detailed test items.

(4) The head of a research institute who intends to apply for modified designation pursuant to the latter part of Article 22 (2) of the Act shall submit a written application for modified designation in Attached Form 23 to the Minister of Environment, along with the following documents. In such cases, the Minister of Environment shall modify a written designation in Attached Form 22 and issue it to the applicant, if such written application and documents satisfy the standards for modified designation under paragraph (5):

1. The original copy of a written designation under paragraph (2);
2. Documents evidencing the modified matters.

(5) The head of a research institute who intends to be designated as a testing institution or intends to modify such designation pursuant to Article 22 of the Act shall satisfy the standards publicly notified by the Minister of Environment, such as the organization and staff members in full charge and research facilities and equipment necessary for performing the tasks of a testing institution.

#### **Article 30 (Evaluation, etc. concerning of Testing Institutions)**

(1) The President of the National Institute of Environmental Research shall evaluate, on a regular basis, the business performance and follow-up management of a testing institution biannually from the date of designation pursuant to Article 22 (3) of the Act.

(2) The President of the National Institute of Environmental Research shall evaluate, on an occasional basis, a testing institution to verify the propriety and creditability of the details and result of tests performed by the testing institution.

(3) The President of the National Institute of Environmental Research may establish and operate an investigative team comprised of the relevant public officials and experts in order to efficiently conduct the evaluation under paragraphs (1) and (2).

(4) Necessary matters concerning standards of the evaluation concerning a testing institution under paragraphs (1) and (2), the details for the establishment and operation of an investigative team under paragraph (3), the management of a testing institution, etc. shall be determined and publicly notified by the Minister of Environment.

#### **Article 31 (Standards for Administrative Dispositions)**

The standards for making administrative dispositions under Article 23 (5) of the Act shall be as listed in Attached Table 10.

#### **Article 32 (Methods, etc. for Risk Assessment)**

(1) The President of the National Institute of Environmental Research shall conduct risk assessments of chemicals listed in Article 24 (1) of the Act, after determining the priority order thereof, based on the following matters:

1. The quantities of the relevant chemical domestically manufactured and imported;
2. Hazards of the relevant chemical;
3. Uses of, and ways of using, the relevant chemical;
4. Likelihood to damage human health or the environment;
5. Other available materials concerning the risks of the relevant chemical.

(2) A risk assessment referred to in paragraph (1) shall be conducted based on the following materials:

1. Materials submitted to apply for registration under Article 10 (3) of the Act and registration of change under Article 12 of the Act;
2. Other domestic and overseas well-known information concerning the relevant chemical.

(3) Where the President of the National Institute of Environmental Research conducts a risk assessment under paragraph (1), he/she shall prepare a report on risk assessment, including the following matters:

1. Name of the chemical subject to the risk assessment;
2. Period of the risk assessment;
3. Assessment of the physical and chemical properties of the relevant chemical with respect to human health;
4. Risk assessment of the relevant chemical with respect to human health and the environment;

5. Dose-response assessment of the relevant chemical;
  6. Exposure assessment of the relevant chemical;
  7. Severity of risks of the relevant chemical.
- (4) Except as otherwise expressly provided for in paragraphs (1) through (3), other necessary matters concerning detailed methods for risk assessments, such as selection of chemicals subject to a risk assessment, shall be determined and publicly notified by the President of the National Institute of Environmental Research.

#### **Article 33 (Notification, etc. of Findings of Risk Assessment)**

When completing a risk assessment under Article 32, the President of the National Institute of Environmental Research shall notify the findings thereof to the person who has applied for registration under Article 10 (3) of the Act or registration of change under Article 12 of the Act. In such cases, if any measure under Article 18 (1) of the Decree has been taken in relation to the relevant chemical, such measure shall be notified.

#### **Article 34 (Order to Submit Materials Necessary for Risk Assessment)**

(1) In any of the following cases, the President of the National Institute of Environmental Research may order the person who has made registration or registration of change pursuant to Article 24 (2) of the Act to submit materials necessary for a risk assessment by a fixed deadline, by giving a written order for submission of materials in Attached Form 24. In such cases, the deadline for submission of materials shall be deemed appropriate by the President of the National Institute of Environmental Research, based on the period required to produce the relevant materials:

1. Where, as a result of examining materials submitted to apply for either registration under Article 10 (3) of the Act or registration of change under Article 12 of the Act, it is necessary to add other materials or supplement the initial materials;
2. Where a chemical registered pursuant to Article 10 of the Act is likely to be designated as a hazardous chemical.

(2) Materials, the submission of which may be ordered shall be as follows:

1. Materials concerning the uses of the relevant chemical under Article 14 (1) 3 of the Act;
2. Materials concerning the risks of the relevant chemical under Article 14 (1) 7 of the Act;
3. Materials concerning the instructions for safe use under Article 14 (1) 8 of the Act;
4. Materials under Article 12 (1);
5. Materials concerning downstream users of the relevant chemical.

#### **Article 35 (Provision of Information on Chemicals)**

(1) The phrase "information prescribed by Ordinance of the Ministry of Environment, such as the registration number, name, information on hazards and risks, instructions for safe use of the relevant chemical" in the main body of Article 29 (1) of the Act refers to the following information (hereinafter referred to as "chemical safety information"):



1. Name or trade name, location, and contact information of the provider of safety information on the relevant chemical;
2. Name of product, and name or genetic name, of the relevant chemical;
3. Registration number (omittable in case of a non-phase-in chemical) and unique identifier number of the relevant chemical;
4. Classification and labelling of the relevant chemical;
5. Permissible uses or restricted uses of the relevant chemical;
6. Information concerning the physical and chemical properties and health and environmental hazards of the relevant chemical;
7. Information concerning risks, such as summarized information of an exposure scenario, measures to reduce risks, etc.;
8. Information on the content, etc, of any hazardous chemical, if any;
9. Information concerning the safe use of the relevant chemical, including handling methods, emergency response guidelines for a fire, etc., leakage control methods, protective equipment, and disposal methods;
10. Information concerning regulation of the relevant chemical.

(2) Notwithstanding paragraph (1), business proprietary information defined in subparagraph 2 of Article 2 of the Unfair Competition Prevention and Trade Secret Protection Act, such as ingredients and contents of the relevant chemical shall be excluded from chemical safety information described in paragraph (1): Provided, That this shall not apply where the relevant chemical is hazardous.

(3) Details for chemical safety information described in paragraph (1) shall be consistent with those of materials for application for registration referred to in Article 14 of the Act.

#### **Article 36 (Methods for Providing Information on Chemicals, and Other Related Matters)**

(1) A chemical safety information data sheet shall be prepared, based on information included in a data sheet in Attached Form 25: Provided, That where a material safety and health data sheet referred to in Article 41 of the Occupational Safety and Health Act is required to be prepared and provided pursuant to the proviso to Article 29 (1) of the Act, such data sheet shall be provided, along with the chemical safety information (on risks) data sheet prepared in Attached Form 26.

(2) A chemical safety information data sheet prepared under paragraph (1) shall be provided before or simultaneous with the transfer of either any chemical registered pursuant to Article 10 of the Act or any mixture containing such chemical.

(3) Necessary matters concerning methods for preparing a chemical safety information data sheet shall be determined and publicly notified by the President of the National Institute of Environmental Research.

#### **Article 37 (Methods for Providing Changed Information, and Other Related Matters)**

The phrase "any change determined by Ordinance of the Ministry of Environment" in Article 29 (3) of the Act refers to the following:

1. Where new information on physical and chemical properties, and hazards, of the relevant chemical is notified through written notice of findings of a hazard analysis under Article 18 (1) of the Act;
2. Where new information on risks of the relevant chemical is notified through written notice of findings of a risk assessment under Article 24 (1) of the Act;
3. Where new uses of the relevant chemical transferred pursuant to Article 29 (1) of the Act or of a mixture containing such chemical become available;
4. Where information on new regulation of the relevant chemical becomes available.

**Article 38 (Provision of Information by Downstream Users, etc.)**

(1) Chemical safety information to be provided by the downstream user and seller of a chemical, or a mixture thereof, pursuant to Article 30 (1) of the Act shall be as follows:

1. Names or trade names of the downstream user and seller;
2. Name or generic name of the relevant chemical, and the product name thereof;
3. Quantities of the relevant chemical used and sold;
4. Detailed uses of the relevant chemical;
5. Information on the exposure from the use of the relevant chemical;
6. Details for any measure taken for the safe use of the relevant chemical.

(2) Chemical safety information to be provided by the manufacturer and importer of a chemical, or a mixture thereof, pursuant to Article 30 (2) of the Act shall be as follows:

1. Names or trade names of the manufacturer and importer;
2. Name or generic name of the relevant chemical, and the product name thereof;
3. Quantities of the relevant chemical manufactured and imported;
4. Permissible uses or restricted uses of the relevant chemical;
5. Information concerning the safe use of the relevant chemical, including handling methods, emergency response guidelines for a fire, etc., leakage control methods, protective equipment, and disposal methods;
6. Information on physical and chemical properties, and hazards, of the relevant chemical;
7. Information on regulation of the relevant chemical.

(3) Notwithstanding paragraphs (1) and (2), business proprietary information defined in subparagraph 2 of Article 2 of the Unfair Competition Prevention and Trade Secret Protection Act, such as ingredients and contents of the relevant chemical shall be excluded from chemical safety information described in paragraphs (1) and (2): Provided, That this shall not apply where the relevant chemical, or a mixture thereof, is hazardous.

(4) Necessary matters concerning the methods for preparing a chemical safety information data sheet referred to in paragraphs (1) and (2) shall be determined and publicly notified by the President of the National Institute of Environmental Research.

**Article 39 (Methods for Providing Information by Downstream Users, etc.)**

(1) Chemical safety information described in Article 30 (1) and (2) of the Act shall be provided by submitting a chemical safety information data sheet in Attached Form 27.

(2) Each person in receipt of a request for the provision of chemical safety information pursuant to Article 30 (1) and (2), shall submit a chemical safety information data sheet to the other party to the request within one month from the date of such request.

#### **Article 40 (Methods and Procedures for Notification to Provide Information)**

(1) In any of the following cases, the President of the National Institute of Environmental Research shall, pursuant to Article 31 of the Act, notify the person registered under Article 10 of the Act and the person who has submitted a report pursuant to Article 32 of the Act:

1. Where new information becomes available as a result of a hazard analysis under Article 18 (1) of the Act;
2. Where new information becomes available as a result of a risk assessment under Article 24 (1) of the Act;
3. Where the relevant chemical is designated, or is designated after modification, as a hazardous chemical.

(2) Notwithstanding paragraph (1), where any of the following action has been taken, the President of the National Institute of Environmental shall be deemed to have notified pursuant to paragraph (1):

1. Notification of the findings of a hazard analysis under Article 18 (1) of the Act or a risk assessment under Article 24 (1) of the Act;
2. Designation and public notification of a toxic substance, permissible substance, restricted substance, or prohibited substance under Article 20, 25 (1) or 27 (1) of the Act;
3. Disclosure of the findings of a hazard analysis under Article 21 of the Act;
4. Cancellation of the designation of a permissible substance, restricted substance, or prohibited substance under Article 26 or 28 of the Act.

#### **Article 41 (Methods for Reporting Products Containing Hazardous Chemicals, and Other Related Matters)**

(1) Each producer or importer of a product containing hazardous chemicals, shall submit a written report on a product containing hazardous chemicals in Attached Form 28 for each hazardous chemical, to the head of a regional environmental office, along with the following documents, before such product is produced or imported from the date immediately after it is confirmed that the total quantities of respective chemicals contained (referring to where the weight ratio of a hazardous chemical to the relevant product exceeds 0.1 percent) therein exceed one ton per year:

1. A manual of the relevant product;
2. A photograph of the relevant product;
3. A certificate of reporting the appointment by an overseas manufacturer or producer (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act submits a report);

4. A written application for data protection (limited to request for the data protection pursuant to Article 45 (1) of the Act);
  5. A document evidencing the outsourcing, such as a copy of a contract for outsourcing (limited to where the person who outsources the manufacture of a chemical submits a report).
- (2) Notwithstanding paragraph (1), where a person has an extenuating circumstance preventing confirmation of the total quantities of respective chemicals contained in a product and it is estimated that such total quantities exceed one ton per year, he/she shall declare his/her personal identification information and the reasons for such circumstance to the head of a regional environmental agency before producing or importing the relevant product, and shall submit a written report and documents under paragraph (1) by April 30 of the next year.
- (3) The head of a regional environmental agency in receipt of a report under paragraphs (1) and (2) shall verify the business registration certificate through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the reporting person withholds consent to the verification of his/her business registration certificate, the head of the regional environmental agency shall require such person to attach the relevant certificate.
- (4) Where it is necessary modify or supplement any material submitted pursuant to paragraph (1), the head of a regional environmental agency shall request the modification or supplement. In such cases, the person in receipt of such request shall immediately modify and supplement such material, and shall then submit it.
- (5) Within seven days from the date of receipt of a written report on a product containing hazardous chemicals pursuant to paragraph (1), the head of a regional environmental agency shall issue a report certificate in Attached Form 29. In such cases, the period from the date of requesting the modification or supplement pursuant to paragraph (2) to the date of submission of materials modified or supplemented shall be excluded from the seven days.
- (6) Matters necessary for the methods of declaration, etc. under paragraph (2), shall be prescribed by the Minister of Environment.

#### **Article 42 (Verification of Exemption from Declaring Product Containing Hazardous Chemicals)**

(1) Each person, who intends to apply for the verification of exemption from declaration pursuant to Article 32 (3) of the Act, shall submit a written application for the verification of exemption form declaration in Attached Form 30, to the head of the relevant association, along with the following documents:

1. A detailed statement of ingredients of the relevant product;
2. A document evidencing that the relevant product is eligible for the verification of exemption from declaration;
3. A certificate of reporting the appointment by an overseas manufacturer or producer (limited to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files an application);

4. A written application for data protection (limited to request for data protection pursuant to Article 45 (1) of the Act).
- (2) The head of the relevant association in receipt of an application for the verification of exemption from declaration under paragraph (1) shall verify the business registration certificate through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the reporting person withholds consent to the verification of his/her business registration certificate, the head of the association shall require such person to attach the relevant certificate.
- (3) Within seven days from the date of receipt of an application under paragraph (1), the head of the relevant association shall notify the results of the application by issuing a written verification of exemption from declaration in Attached Form 31, to the applicant: Provided, That where the examination of the relevant specialized institution is necessary to verify whether the product in question is exempt from declaration, the head of the relevant association shall notify the result within ten days from such date.
- (4) The head of the relevant association shall, on a quarterly basis, notify the President of the National Institute of Environmental Research of both the current status concerning applications for the verification of exemption from declaration, and the performance of notification, so as to use them for risk assessments, etc. under Article 33 of the Act.
- (5) The head of the relevant association shall report on the records of the previous year concerning both applications for the verification of exemption from declaration, and the performance of notification, to the Minister of Environment by March, 31 each year.

**Article 43 (Methods for Risk Assessment, etc.)**

- (1) A risk assessment under Article 33 (1) shall be conducted in the following order: Provided, That this shall not apply where the President of the National Institute of Environmental Research deems it necessary to conduct the risk assessment differently from such order, based on the current technology level, the characteristics of risk elements, etc.:
1. Identification of hazards of chemicals contained in a product of risk concern;
  2. Calculation of permissible exposure limits for chemicals contained in a product of risk concern to human health and the environment;
  3. Assessment of the amount and severity of exposure to chemicals contained in a product of risk concern to human health and the environment and the degree of their exposure thereto;
  4. Risk level of a product of risk concern;
  5. Direction-setting for formulation of the safety standards and labelling standards under Article 34 of the Act with respect to a product of risk concern.
- (2) When conducting a risk assessment under paragraph (1), the President of the National Institute of Environmental Research shall refer to the following matters:
1. Information on registration, and registration of change, under Articles 10 and 12 of the Act;
  2. Information on hazardous chemicals obtained through a declaration of products containing hazardous chemicals under Article 32 of the Act;

3. Outcomes of domestic and overseas research concerning the risks of both products of risk concern and chemicals contained therein.

(3) The President of the National Institute of Environmental Research may preferentially conduct a risk assessment for each of the following products, among products of risk concern, pursuant to Article 33 (2) of the Act:

1. A product containing hazardous chemicals, the production, importation, use, etc. of which is controlled by an international organization or a foreign government on the ground of likelihood of risks to human health or the environment;

2. A product in which a chemical likely to damage human health or the environment is detected by a research or inspection institution;

3. A product, the risk assessment of which is requested by any of the following institutions and deemed likely to damage human health or the environment:

(a) A consumer organization defined in subparagraph 3 of Article 2 of the Framework Act on Consumers;

(b) A non-profit, non-governmental organization defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act;

4. A product, the safety standards and labelling standards under Article 34 of the Act of which are not publicly notified;

5. Except as otherwise expressly provided for in subparagraphs 1 through 4, a product deemed by the Minister of Environment to be required to undergo the urgent risk assessment due to likelihood of risks to human health or the environment.

(4) A risk assessment under Article 33 (2) of the Act may be conducted by the following methods:

1. Adaptation, or citation, of the results of decisions on the risks assessed by an international organization and a reliable domestic or overseas institution;

2. Estimation of the severity of the risk, only based on the danger identification or exposure assessment of a hazardous chemical, where it is impracticable to determine the dangers thereof;

3. Estimation of the severity of the risk, only based on the danger identification of a hazardous chemical, where a person has died of exposure to a product containing such hazardous chemical or other risks have occurred;

4. Conduct of an exposure assessment by using available scientific models, where data for exposure assessment are insufficient or absent;

5. Conduct of a risk assessment targeting a specific civilian group, such as children or pregnant women, where such group is highly likely to be exposed.

(5) Except as otherwise expressly provided for in paragraphs (1) through (4), other necessary matters concerning the targets, methods, etc. of risk assessments shall be determined and publicly notified by the President of the National Institute of Environmental Research.

#### **Article 44 (Timing of and Procedures for Risk Assessment, and Other Related Matters)**

- (1) The President of the National Institute of Environmental Research shall, with respect to products of risk concern, formulate plans for risk assessments for each item thereof biannually.
- (2) When formulating plans for risk assessments under paragraph (1), the order of priority in risk assessments may be determined, based on the degree, urgency, etc. of subject products.
- (3) When conducting a risk assessment pursuant to Article 43, the President of the National Institute of Environmental Research shall prepare a report on the findings after deliberation by the Committee on Management of Products of Risk Concern referred to in Article 7 (6) of the Act, and shall then submit such report to the Minister of Environment.
- (4) The Minister of Environment shall notify the relevant central administrative agencies of the report on the findings submitted under paragraph (3).

#### **Article 45 (Provision of Information on Chemicals Contained in Products)**

- (1) The phrase “information prescribed by Ordinance of the Ministry of Environment, such as the name, uses, and conditions of any chemical” in Article 35 (1) of the Act refers to the following information:
  1. Trade name of the relevant product;
  2. Names and contents of hazardous chemicals contained in the relevant product;
  3. Permissible uses or restricted uses of the relevant product;
  4. Methods for proper use of the relevant product, and using conditions thereof;
  5. Matters requiring precautions in handling the relevant product, such as exposure response guidelines.
- (2) Where the customer of a product requests the provision of information thereon, the person who transfers such product pursuant to Article 35 (2) of the Act shall provide the information described in paragraph (1).
- (3) Notwithstanding paragraph (1), business proprietary information defined in subparagraph 1 of Article 2 of the Unfair Competition Prevention and Trade Secret Protection Act, such as ingredients and contents of chemicals contained in the relevant product shall be excluded from the information described in paragraph (1): Provided, That this shall not apply to those products of risk concern, the safety standards and labelling standards regarding risks, etc. for which are publicly notified pursuant to Article 34 of the Act.
- (4) Details for information described in paragraph (1) shall be consistent with those reported or verified pursuant to Article 32 of the Act.

#### **Article 46 (Methods for Providing Information on Chemicals Contained in Product, and Other Related Matters)**

- (1) Information described in Article 45 (1) and (2) shall be provided by issuing a data sheet in Attached Form 32.
- (2) A data sheet compiled pursuant to paragraph (1) shall be issued before or simultaneous with the transfer of a product containing hazardous chemicals reported pursuant to Article 32 (1) of the Act: Provided, That where the customer of the product requests the provision of information pursuant to Article

35 (2) of the Act, such information shall be provided free of charge within 45 days from the date of receipt of such request.

(3) Necessary matters concerning the methods of compiling data sheets under paragraph (1) shall be determined and publicly notified by the President of the National Institute of Environmental Research.

**Article 47 (Submission of Materials concerning Substances Contained in Products of Risk Concern Not Publicly Notified)**

(1) Each person, who intends to produce or import, pursuant to Article 36 (2) of the Act, any product, the safety standards and labelling standards for which are not publicly notified among products of risk concern, shall submit materials described in Article 14 (1) of the Act concerning chemicals contained in the relevant product to the President of the National Institute of Environmental Research before producing or importing such product, and shall then obtain approval therefor.

(2) Where a person subject to approval under Article 36 (2) of the Act requests the President of the National Institute of Environmental Research to inform him/her of the names of chemicals subject to approval, the kinds, period for submission, etc. of materials to be submitted, the President of the National Institute of Environmental Research may determine whether to inform such matters, and notify the person thereof.

(3) Articles 5 and 6 shall apply mutatis mutandis to the methods for approval of materials submitted pursuant to paragraph (1), determination as to whether to grant approval, and other related matters.

**Article 48 (Order to Take Measures, such as Recall, and Other Related Matters)**

(1) Where the head of a regional environmental agency intends to issue an order to take necessary measures, such as collection, recall, sale prohibition, disposal, improvement, correction, etc. of any product of risk concern (hereinafter referred to as an "order to take measures, such as recall") pursuant to Article 37 (1) of the Act, he/she shall receive a plan for taking measures, such as recall, which contains the following matters, from a producer or importer of the relevant product of risk concern:

1. Name of the relevant product, trade name of a transacting entity, quantities of the relevant product produced, imported and sold;
2. Planed quantities of the relevant product to be collected, recalled, sale-prohibited, disposed of, improved, corrected, etc. (such quantities shall be calculated, based on the quantity of the relevant product of risk concern supplied to customers as at the time the plan for taking measures, such as recall, is submitted);
3. Grounds for collection, recall, sale prohibition, disposal, improvement, correction, etc.;
4. Methods for collection, recall, sale prohibition, disposal, improvement, correction, etc.;
5. Periods for collection, recall, sale prohibition, disposal, improvement, correction, etc., and estimated period required for completion thereof;
6. Places and detailed methods for collection, recall, sale prohibition, disposal, improvement, correction, etc.;



7. Methods for informing Korean Citizens of collection, recall, sale prohibition, disposal, improvement, correction, etc.

(2) The head of a regional environmental agency in receipt of a plan for taking measures under paragraph (1), shall issue an order to take measures, such as recall, specifying the degree of injuries caused to human health or the environment, details for the order, the matters to be considered in implementing the order, the period for implementing the order, and other related matters.

(3) Each person who receives an order to take measures, such as recall pursuant to paragraph (2) shall, after implementing the order, prepare a written result of the measures, such as recall, which contains the following matters, and shall then submit it to the head of a regional environmental agency:

1. Records of measures, such as recall, which contains the quantities of the relevant product produced, imported, sold, recalled, unrecalled, etc.;
2. Details for the quantity of the relevant product unrecalled, etc., and a plan for future measures;
3. Countermeasures for prevention of recurrence.

#### **Article 49 (Qualification for Persons Appointed by Overseas Manufacturer or Producer)**

(1) The phrase "person qualified as prescribed by Ordinance of the Ministry of Environment" in the main body of Article 38 (1) of the Act refers to a person qualified as follows:

1. A citizen of the Republic of Korea;
2. A person domiciled (referring a place of business in cases of a corporation) in the Republic of Korea.

(2) Each person, who intends to report appointment or dismissal pursuant to Article 38 (2) of the Act, shall submit a written appointment or written dismissal in Attached Form 33, to the head of the relevant regional environmental agency, the President of the National Institute of Environmental Research, or the head of the relevant association, along with the following documents:

1. A document evidencing the qualification described in paragraph (1);
2. A document evidencing the appointment or dismissal, such as a copy of an agreement on appointment.

(3) Upon receipt of a report pursuant to paragraph (2), the head of a regional environmental agency, the President of the National Institute of Environmental Research or the head of the relevant association shall verify the business registration certificate through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the reporting person withholds consent to the verification of his/her business registration certificate, he/she shall require such person to attach the relevant certificate.

(4) Within seven days from the date of receipt of a report under paragraph (2), the head of the relevant regional environmental agency, the President of the National Institute of Environmental Research or the head of the relevant association shall issue a report certificate in Attached Form 34.

(5) An overseas manufacturer or producer under paragraph (2) or the person appointed by him/her shall send a copy of the report certificate under paragraph (4) and the records of the performance of the affairs under Article 38 (1) of the Act to the importer of the relevant chemical or product.

## **Article 50 (Request for Designation of Green Chemical Center)**

(1) Each institution, which intends to apply for designation pursuant to Article 26 (2) of the Decree, shall submit a written application for designation in Attached Form 35, to the Minister of Environment, along with the documents listed in Article 26 (2) of the Decree.

(2) The Minister of Environment in receipt of a written application for designation under paragraph (1) shall verify the certificate of incorporation or business registration certificate of the applicant through administrative data matching under Article 36 (1) of the Electronic Government Act: Provided, That where the reporting person withholds consent to the verification of his/her certificate of incorporation or business registration certificate, he/she shall require such person to attach the relevant certificate.

(3) A written designation of a green chemical center under Article 26 (3) of the Decree shall be in Attached Form 36.

## **Article 51 (Disclosure of Information on Chemicals, and Other Related Matters)**

The President of the National Institute of Environmental Research shall disclose the following information via its website, etc. pursuant to Article 42 of the Act: Provided, That where the name of a chemical is subject to the protection of data under Article 45 (1) of the Act, the generic name of such chemical shall be disclosed in lieu of the name thereof until the period for protection of such data expires:

1. Name and unique identifier number of the relevant chemical;
2. Uses of the relevant chemical according to the use classification system of chemicals;
3. Classification and Labelling of the relevant chemical;
4. Whether the chemical constitutes a toxic substance, permissible substance, restricted substance or prohibited substance;
5. Physical and chemical properties of the relevant chemical;
6. Hazards and risks of the relevant chemical;
7. Details for safe use of the relevant chemical, such as precautions in handling.

## **Article 52 (Access for Inspection)**

(1) Access for inspection under Article 43 of the Act shall be conducted where any of the following grounds exists:

1. Where access for inspection is conducted according to any such plan for regular guidance and inspection as formulated by the head of a regional environmental agency to ensure the proper management of chemicals and products containing chemicals;
2. Where risks of chemicals and products containing chemicals have caused, or are likely to cause, harm to public health or the environment;
3. Where any other agency requests access for inspection with a legitimate authority, or a civil petition therefor is filed;
4. Where access for inspection is necessary to verify whether to fulfill any duty under the Act, such as a duty to report or register a chemical, the verification of exemption from registration, a duty to report a product containing hazardous chemicals, a duty to comply with safety standards and labelling standards,

and other duties;

5. Where it is necessary to verify whether any data to be protected under Article 45 (1) of the Act is so appropriately managed to a level that the protection thereof may be requested.

(2) Where the Minister of Environment, the President of the National Institute of Environmental Research or the head of the relevant regional environmental agency accesses to a place of business, etc. for inspections pursuant to Article 43 of the Act, he/she shall collectively conduct the access for inspection, if the facilities or places of business subject to the following access are identical: Provided, That the same shall not apply where such integrated access for inspection is deemed impracticable due to civil petitions, environmental pollution, wide-area monitoring activities, or operation of human resources:

1. Access for inspection under Article 41 (1) or (2) of the Act on the Management and Use of Livestock Excreta;
2. Access for inspection under Article 82 (1) of the Clean Air Conservation Act;
3. Access for inspection under Article 47 (1) of the Noise and Vibration Control Act;
4. Access for inspection under Article 68 (1) of the Water Quality and Aquatic Ecosystem Conservation Act;
5. Access for inspection under Article 39 (1) of the Wastes Control Act;
6. Access for inspection under Article 69 (1) or (2) of the Sewerage Act;
7. Access for inspection under Article 49 (1) of the Chemicals Control Act.

#### **Article 53 (Inspection Institutions)**

When sampling chemicals pursuant to Article 43 (1) of the Act, the head of a regional environmental agency may request any of the following entities to verify, test or inspect such chemicals or products containing such chemicals:

1. The National Institute of Environmental Research;
2. The Korea Environment Corporation incorporated under the Korea Environment Corporation Act;
3. Public health and environment research institutes established in the Special Metropolitan City, other Metropolitan Cities, Dos and the Special Self-Governing Province pursuant to the Public Health and Environment Research Institute Act;
4. The Korea Environmental Industry and Technology Institute incorporated under the Environmental Technology and Industry Support Act;
5. Testing and inspection institutions recognized under Article 23 (2) of the Framework Act on National Standards.

#### **Article 54 (Documentation and Retention of Materials)**

(1) Each person required to document and retain the relevant materials pursuant to Article 44 of the Act, shall document and retain the following materials related to the manufacturing, import, sale, and use of the relevant chemicals for five years. In such cases, the materials referred to in subparagraph 8 shall be documented and retained for five years from the date the period for protection of data under Article 30 of the Decree expires:

1. Materials related to the report of manufacturing a chemical under Article 8 of the Act;
  2. Materials related to registration, and registration of change, of a chemical under Articles 10 and 12 of the Act;
  3. Materials related to verification of exemption from registration of a chemical under Article 11 of the Act;
  4. Materials related to the report on a product containing hazardous chemicals under Article 32 (1) of the Act;
  5. Materials related to verification of exemption from reporting a product containing hazardous chemicals under Article 32 (3) of the Act;
  6. Materials submitted with respect to chemicals contained in a product of risk concern, the safety standards and safety standards for which are not publicly notified pursuant to Article 36 (2) of the Act;
  7. Materials concerning information provided under Articles 29, 30 and 35 of the Act;
  8. Materials subject to protection of data pursuant to Article 45 (1) of the Act.
- (2) Materials concerning business affairs referred to in Article 22 of the Decree, among materials to be documented and retained pursuant to paragraph (1), may be electronically stored.

#### **Article 55 (Application for Protection of Data)**

(1) Each person, who intends to apply for protection of data pursuant to the main body of Article 45 (1) of the Act, shall submit a written application for data protection in Attached Form 37, to the President of the National Institute of Environmental Research, the head of the relevant regional environmental agency, or the head of the relevant association, along with the following documents. The same shall apply to the application for the extension of the period for data protection under the proviso to Article 30 (1) of the Decree:

1. A copy of written notice of the receipt and result of processing an application for data protection (applicable only to application for the extension of the period for data protection);
2. A certificate of reporting the appointment by an overseas manufacturer or producer (applicable only to where the person appointed by the overseas manufacturer or producer pursuant to Article 38 of the Act files an application).

(2) Upon receipt of a written application for data protection under paragraph (1), the President of the National Institute of Environmental Research, the head of the relevant regional environmental agency, or the head of the relevant association shall, after examining whether the relevant data is subject to protection, notify the applicant of the result by giving written notice on the receipt and results of processing an application in Attached Form 38.

(3) Necessary matters concerning methods for preparing a written application for protection of data under paragraph (1), methods for managing protected materials and other related matters shall be determined and publicly notified by the Minister of Environment.

#### **Article 56 (Fees)**

(1) Fees provided for in Article 46 of the Act shall be as listed in Attached Table 11.

(2) Fees referred to in paragraph (1) shall be payable either by means of revenue stamps or by means of electronic currencies, electronic settlement, etc. through an information and communication network.

## ADDENDA

### **Article 1 (Enforcement Date)**

These Rules shall enter into force on January 1, 2015.

### **Article 2 (Documents to be Submitted by Persons who have Completed Hazard Analysis at Time of Reporting)**

(1) The phrase "written report prescribed by Ordinance of the Ministry of Environment" in Article 3 (1) of Addenda of the Decree refers to a written report in Attached Form 39.

(2) The phrase "materials prescribed by Ordinance of the Ministry of Environment" in Article 3 (1) of Addenda of the Decree refers to the following materials:

1. A written notice of the findings of a hazard analysis under Article 12 of the former Toxic Chemicals Control Act;

2. Information concerning manufacturers or importers who have given notice under subparagraph 1 (referring to information concerning the initial owner in cases where written notice is given);

3. Materials evidencing the quantities of the relevant chemical manufactured and imported for the preceding three years including the relevant year.

(3) The President of the National Institute of Environmental Research shall, after examining the propriety of the materials provided pursuant to paragraphs (1) and (2), give written notice of report in Attached Form 40, to the reporting person.

### **Article 3 (Special Exception to Registration of Change of Non-Phase-In Chemical in Small Quantity)**

Where a person in receipt of written notice of registration with respect to a non-phase-in chemical under subparagraph 1 of Article 13 of the Decree pursuant to Article 6 (1) after these Rules enter into force is required to register the change pursuant to Article 10 (1), he/she shall, notwithstanding Article 9 (2), complete registration of change by December 31, 2021.

### **Article 4 (Transitional Measures concerning Non-Phase-In Chemicals for which Exemption from Hazard Analysis has been Verified)**

Notwithstanding Article 5 (1), each person, who intends to manufacture or import a non-phase-in chemical for which verification of exemption from a hazard analysis is notified under Article 12 of the former Toxic Chemicals Control Act and Article 8 (1) of the Rules of the same Act, shall apply for registration by the following dates:

1. A non-phase-in chemical referred to in Article 10 (1) 3 of the former Toxic Chemicals Control Act and subparagraph 1 of Article 9 of the former Enforcement Decree of the Toxic Chemicals Control Act: December 31, 2015;

2. A non-phase-in chemical referred to in Article 10 (1) 3 of the former Toxic Chemicals Control Act and subparagraph 5 of Article 9 of the former Enforcement Decree of the Toxic Chemicals Control Act: December 31, 2017.

