Regulation Concerning the Hazard Evaluation (Notification) of Chemical Substances

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Chapter 1. General Provisions

Article 1. (Purpose)

The purpose of this Regulation is to prescribe detailed matters concerning the method and procedures for hazard evaluations (notification) of chemical substances and labelling for toxic chemicals under Article 7, Article 8, Article 10, Paragraph (2) of Article 13 and Article 28 of the Toxic Chemicals Control Act (hereinafter referred to as the "Act"), Article 2 and Article 4 of the Presidential Decree on the Act (hereinafter referred to as the "Presidential Decree"), and Articles 2 through 6, Article 28 of the Ministerial Ordinance on the Act (hereinafter referred to as the "Ministerial Ordinance").

Article 2. (Definitions)

Terms used in this regulation shall be defined as follows:

1. "Chemical Name" shall mean a chemical name under IUPAC (International Union of Pure and Applied Chemistry) or CA (Chemical Abstracts) nomenclature, or a common name under ISO (International Standard Organization). In case of reaction products or polymers, the chemical name is made based on the chemicals or monomers used to initiate the reaction. In case of reaction mixtures which can not be isolated or can be used for commercial use without isolation, the chemical name shall be made in the form of the reaction mixture.

2. "Existing Chemicals Inventory" shall mean the list of chemicals that had been circulated domestically prior to the effective date (February 2, 1991) of the Act and published by the head of the National Institute of Environmental Research(hereinafter referred to as "the NIER") under Article 4, Paragraph (5) of the Ministerial Ordinance.

3. "Polymer" shall mean a chemical substance which consists of sequences consecutively built up from one or more types of monomer units, which shows a characteristic distribution of molecular weights primarily according to the number of monomer unit within each species. It also contains at least 3

monomer units covalently linked to at least one other monomer unit or another reaction component, and such polymeric species account for at least 50%. Furthermore, the weight percentage of the species with the same molecular weight does not exceed 50%.

4. "Block Polymer" shall mean any polymer, created as a result of a reaction of a polymer with another polymer or of a monomer with a polymer, in which monomer units are repeated in the form of a block.

5. "Graft polymer" shall mean a polymer with a different polymer attached to the main stem of the polymer in the form of a branch.

6. "Chemical substances subject to a simplified evaluation (notification)" shall mean a chemical substance pursuant to Paragraph (2) of Article 3 of the Ministerial Ordinance that is listed on the Existing Chemicals Inventory published before February 2, 1991 in two or more countries (the European Union is deemed as a single country) with laws and regulations equivalent to Article 8 of the Act.

7. "Evaluation at its own discretion" shall mean a hazard evaluation pursuant to Article 8 of the Act for a chemical which had been circulated domestically and commercially prior to the effective date (February 2, 1991) of the Act, or which had received a hazard evaluation (notification) and been announced in a Public Notice as a chemical not subject to the toxic chemical or designated as an observational chemical under the Act.

8. "Monomer" shall mean a chemical substance which has the capacity to form links between two (2) or more other molecules.

9. "Monomer unit" shall mean a repeated form of a monomer in a polymer.

10. "Number average molecular weight" shall mean a value derived from the total weight of molecules in a polymer divided by the number of moles.

11. "Stabilities in acid and alkali" shall mean the properties of which a polymer is resistant to hydrolysis or any change under acidic or alkaline conditions, by maintaining the inherent characteristics of a polymer, such as number average molecular weight, molecule weight distribution, etc..

12. "Acute toxicity" shall mean the toxic effects occurring within a short time (i.e., one or two weeks) after a chemical substance has been administered to test animals once or several times within 24 hours, or if capable of being inhaled, after it is exposed to test animals for a limited time within 24 hours.

13. "Irritation" shall mean the properties of which a chemical may cause inflammation or destruction of biological tissue through immediate, prolonged or repeated contact with the biological tissue including eye, skin or respiratory tract.

14. "Sensitization" shall mean the properties of which, when test animals are additionally exposed to a chemical after being inhaled or absorbed through the skin, a chemical elicits a reaction of hypersensitization such as characteristic adverse effects to the respiratory system or skin.

15. "Genetic toxicity" shall mean the property of inducing inheritable genetic defects to a living organism or accelerating their incidence.

16 "Octanol water partition coefficient" shall mean the equilibrium ratio of molar concentrations of a chemical in n-octanol and water, in dilute solution.

17. "Ecotoxicity" shall mean toxicity that adversely affects aquatic animals and plants in fresh water or sea water, such as fishes, algae, daphnia, etc., or plants when exposed to a chemical once or chronically.

18. "Degradability" shall mean the property of a chemical substance that decomposes its original structure under natural or artificial conditions by physical or chemical factors (abiotic degradation) or that is decomposed by a microorganism which obtains its energy from chemical substance (biotic degradation or biodegradation).

19. "Ready biodegradability test" shall mean the biodegradability test conducted under stringent conditions where more limited opportunity for biodegradation and acclimatization than in an actual natural environment is provided in order to assess whether a chemical substance has the intrinsic properties to be inherently biodegraded in the environment.

20. "Inherent biodegradability test" shall mean the biodegradability test conducted under more favorable conditions for degradation in order to examine whether a chemical substance has the intrinsic properties to be inherently biodegraded in the environment.

21. "Persistence" shall mean the property of the chemical substance persisting in the natural environment, such as in soil, water or crops, in a non-decomposed form or in a form not much different from the original chemical substance, structurally or toxicologically.

22. "Bioconcentration" shall mean the property of increasing concentration of a chemical substance in or on the tissues of animals, such as fish, etc., compared to those of the chemical substance in water, and the ratio of such concentration shall be named as the bioconcentration factor(BCF).

23. "Repeated dose toxicity" shall mean the toxic effects occurring in test animals as a result of repeated administration or exposure of a chemical substance for one (1) to three (3) months.

24. "Carcinogenicity" shall mean the properties of a chemical substance that induces cancer or increases its incidence.

25. "Reproductive toxicity" shall mean the properties of a chemical causing impairment of male or female reproductive function or capacity and the induction or non-inheritable adverse effects to offspring, such as death, growth retardation, or adverse effects on structure and function.

26. "Chronic toxicity" shall mean the general toxic effects occurring as a result of repeated administration or exposure of a chemical substance for a considerable part of the expected life span or full life span. In this definition, reproductive toxicity, genetic toxicity and carcinogenicity are excluded from the chronic toxicity in this regulation.

27. "No Observed Adverse Effect Level"(hereinafter referred to as the "NOAEL") shall mean the highest exposure level at which there are no statistical and biological increases of frequency or severity of adverse effects between the appropriate control group and the exposed group in dose response tests, including a chronic toxicity test. At such a level, certain effects may occur. However, it is not regarded as an adverse effect if it does not have direct relevance to specific adverse effects.

Article 3. (Scope of Application)

This Regulation shall be applied to matters falling under any of the following Items:

1. Preparation method of application for hazard evaluation (notification) and its attachment data or

materials pursuant to provisions of Article 7 of the Act and Article 2 of the Ministerial Ordinance;

2. Exemption from submitting the test reports pursuant to the provisions of Article 7, Paragraph (2) of the Act and Article 3 of the Ministerial Ordinance;

3. Request for submission of supplementary data or materials required for hazard evaluation (notification) pursuant to the provisions of Article 8, Paragraphs (1) and (2) of the Act and Article 5, Paragraphs (1) and (2) of the Ministerial Ordinance;

4. Method and procedures of hazard evaluation (notification) pursuant to the provisions of Article 8, Paragraph (3) of the Act and Article 4 of the Ministerial Ordinance;

5. Public announcement and notification of the evaluation results pursuant to the provisions of Article 10 of the Act and Article 6 of the Ministerial Ordinance;

6. Order of submitting data or materials required for the hazard evaluation (notification) of observational chemicals pursuant to the provisions of Article 13, Paragraph (2) of the Act;

7. Classification criteria for labelling and hazard symbols indicating the presence of toxic chemicals pursuant to the provisions of Article 28 of the Act and Article 28, Paragraph (2) of the Ministerial Ordinance;

8. Designation criteria for toxic chemicals and observational chemicals for compounds or mixtures pursuant to the provisions of Item 3 of Annex 1 of the Presidential Decree; and

9. Exemption from the hazard evaluation (notification) pursuant to the provisions of Article 4 of the Presidential Decree.

Article 4. (Supplementation of Data or Materials)

(1) Upon reviewing attachment data or materials, the applicant may be ordered to supplement necessary documents if they fall under any of the following Items:

1. If the attachment is omitted or substituted or if the attachment is not prepared in accordance with the preparation method pursuant to the provisions of Chapter 2 of this Regulation; or

2. If test reports submitted are not made pursuant to the provisions of Article 5.

(2) When there is an order intending to supplement necessary documents in accordance with the foregoing Paragraph (1) above, the reason, detailed contents and period for supplementation shall be clearly described.

Article 5. (Acceptability of Test Reports)

(1) Test reports to be submitted in accordance with Paragraph (2) of Article 7, Article 8, Article 26 and Article 27 shall be in the form of the one which is issued by Testing and Research Institute pursuant to the provisions of Article 7, Paragraph (2) of the Act (Institutes which are designated pursuant to the "Regulation on Designation of Testing and Research Institutes for Hazard Evaluation of Chemical Substances").

(2) Data or materials on polymers to be submitted for hazard evaluation (notification) pursuant to the provisions of Article 2, Item 3, chemical substances subject to a simplified evaluation (notification) prescribed by Item 6 of the same Article and chemical substances falling under Article 9, Paragraph (3)

may not be subject to the foregoing Paragraph (1) above in accordance with Article 3 of the Ministerial Ordinance.

(3) If it is not clear whether or not a test report falls under the foregoing Paragraph (1) above, the Head of the NIER may regard the test report as one falling under the foregoing Paragraph (1) in consideration of the properties of the relevant chemical substance, source of data or material, period of test, country of test, and test institution and method.

Article 6. (Designation Criteria for Toxic Chemicals and Observational Chemicals for Compounds and Mixtures)

(1) In accordance with Item 3 of Annex 1 of the Presidential Decree, compounds and mixtures falling under any of the following items may be designated as toxic chemicals or observational chemicals :

1. Compounds and mixtures with at least 1% of toxic chemicals falling under one or more of Item 1, A, (1) through (8) of Annex 1 of the Presidential Decree, or of observational chemicals falling under Item 1, B, (1) or (2) of Annex 1 of the Presidential Decree; and

2. Compounds and mixtures with at least 0.1% of toxic chemicals falling under Item 1, A, (9) or (10) of Annex 1 of the Presidential Decree, or of observational chemicals falling under Item 1, B, (3) or (4) of Annex 1 of the Presidential Decree (However, they shall be excluded if the toxic chemical or observational chemical is contained as an impurity).

(2) Notwithstanding the foregoing Paragraph (1), the Head of the NIER may not designate compounds or mixtures as toxic chemicals or observational chemicals in consideration of degree of toxicity, usage and restriction in other nations.

Chapter II. Preparation Method for Attachment Document for Hazard Evaluation (Notification)

Article 7. (Preparation Method for Attachment Document)

(1) Pursuant to the provisions of Article 2, Paragraph (1), Item 1, data or materials regarding the main purpose of use, the physico-chemical properties, such as melting point, boiling point, vapor pressure, solubility, octanol water partition coefficient, etc., shall include all of the following Items:

1. The main purpose of use which dictates the general use and specific examples of use, etc.;

2. The information necessary to carry out the evaluation of the physico-chemical properties, such as melting point, boiling point, vapor pressure, water solubility, solubilities in common solvents, etc.; and

3. The measured or calculated octanol water partition coefficient. The submission of this data for a chemical substance of which water solubility provided in Item 2 above is 100 mg/L or more, or a polymer may be exempt.

(2) The test reports for acute toxicity, genetic toxicity and degradability (hereinafter referred to as "basic data or materials") pursuant to the provisions of Article 2, Paragraph (1), Item 2 of the Ministerial Ordinance shall include all of the following Items:

1. The acute toxicity test report shall contain data on acute oral toxicity on rodents. However, acute dermal or inhalation toxicity data shall be submitted if it is deemed necessary from the physico-

chemical properties or use of the chemical substance that any exposure thereto will be mainly through skin or inhalation;

2. The genetic toxicity test report shall contain bacteriological mutation test data and chromosomal aberration test data using cultured mammalian cells; and

3. The degradability test report shall contain biodegradability test data. However, in case of a chemical showing rapid abiotic degradation, degradability test data proving such degradation shall be submitted.

(3) The test data provided in Paragraph (2) above shall include general test procedures and results, such as the testing institute, test method, results, etc. in accordance with the Regulation on the Designation of Testing and Research Institutes for Hazard Evaluation of Chemical Substances prescribed by Article 6, Paragraph (2) of the Presidential Decree.

(4) Data or materials regarding major route released to the environment and estimated amount of release as provided in Article 2, Paragraph (1), Item 3 of the Ministerial Ordinance shall include all of the following Items:

1. Release route to each environmental media during the production or use, in consideration of the use, physico-chemical properties, and production process; and

2. The estimated amount of release to each environmental media in accordance with Item 1 above.

(5) Data or materials regarding the number average molecular weight, composition of monomer, contents of residual monomer, and stabilities of polymer as provided in Article 2, Paragraph (1), Item 4 of the Ministerial Ordinance shall include all of the following Items:

1. Test data showing the number average molecular weight and molecular weight distribution;

2. Materials on the chemical name of monomers used in the production of the substance, their CAS (Chemical Abstracts Service) registry numbers, and typical composition (%). The compositions of each monomer can be counted on the basis of its constituent ratio in the final polymer;

3. Content data (%) on residual monomers;

4. Data on the content of species with molecular weight of 1,000 or less; and

5. Data or materials on stability in acidic and alkaline conditions.

(6) In cases where data or materials regarding Paragraphs (1) through (5) are made in foreign languages, a short translated paper shall be attached to the front of the data or materials. However, the short translated paper regarding Paragraph (2) above can be replaced by the Annexed Form of Summary of Test Report.

(7) In cases where attached data or materials, or Summary of Test Report include information to be protected, the relevant data shall be submitted with keeping that part unseen. An applicant shall indicate the contents to be protected by underlining them in red pen, and then collected the pages concerned only, make partial file, put them into an envelope, tightly seal it, and thereafter, list the confidential information concerned and write "information protected" in red pen on the front side of the envelope. That part of the data or materials shall be submitted with the application form for hazard evaluation (notification).

Article 8. (Request for Supplementary Data or Materials)

(1) "Chemical Substances whose properties are that : they are directly exposed to the environment during their use, or they pose concerns of chronic toxicity, carcinogenicity, persistence, bioaccumulation or ecotoxicity" in Article 5, Paragraph (1) of the Ministerial Ordinance shall mean these chemicals which fall under any of the following Items upon reviewing the data or materials submitted in accordance with Article 7, by Chapter IV, Sections 2 and 4:

1. Chemical substances (including polymers) which are directly exposed to the environment during their use, such as active ingredients in pesticides, water treatment agents, fungicides and insecticides (except for agricultural use), etc.;

2. Non-biodegradable neutral organic chemical substances with a water solubility of 100 mg/L or more and polymers which pose concerns about ecotoxicity;

3. Chemical substances which pose concerns about bioaccumulation and persistence upon considering degradability, octanol water partition coefficient, and permeability through biomembrane;

4. Chemical substances whose structures are similar to those chemicals known to be chronically toxic, or chemicals which are deemed to be necessary to extend the period of exposure or administration; and

5. Chemical substances whose structures are similar to those chemicals known to be carcinogens or suspected carcinogens to humans or animals and whose risk of causing cancer, and whose probability of exposure are high in the channels of exposure of chemicals known to be carcinogens.

(2) The Head of the NIER may require, within the scope of the following Items, submission of the necessary supplementary data for the chemicals prescribed in Paragraph (1) above in accordance with Article 5, Paragraph (1) of the Ministerial Ordinance

1. For a chemical substance pursuant to Paragraph (1), Items 1 or 2 above, an ecotoxicity test report such as a fish toxicity test;

2. For a chemical substance pursuant to paragraph (1) Items 1 or 3 above, a bioconcentration test report;

3. For a chemical substance pursuant to Paragraph (1) Items 3 or 4 above, a chronic toxicity test report; and

4. For a chemical substance pursuant to Paragraph (1), Item 5 above, a carcinogenicity test report.

(3) For a chemical substance showing positive results in one or more test reports upon reviewing, in accordance with the provisions of Article 13, test reports as provided in Article 7, Paragraph (2), Item 2, an applicant shall submit any of the following Sub-items:

a. If only the results of a bacteriological mutation(reverse mutation) test report is positive, a gene mutation test report; and

b. If other test reports and the test report provided in "a" above are positive, a genetic toxicity test report using test animals.

(4) The summary of the test report prepared in accordance with the Annexed Form shall be attached when submitting the supplementary data or materials under Paragraphs (1) through (3).

Chapter III. Exemption from the Submission of Test Reports

Article 9. (Exemption from the Submission of Test Report)

(1) A polymer stipulated in Article 3, Item 1 of the Ministerial Ordinance may be exempt from the requirement of the submission of test report as set forth in Article 7, Paragraph (2) above. In case of application for hazard evaluation (notification) of a polymer without complying with the provisions of Article 7, Paragraph (5) above, a test report pursuant to a simplified evaluation (notification) as stipulated in Paragraph (2) hereunder may be submitted.

(2) As to a chemical substance subject to a simplified evaluation (notification) as stipulated in Article 3, Paragraph (2) of the Ministerial Ordinance, the test report set forth in Article 7, Paragraph (2), Items 1 and 2 may be exempt. However, the submission of a test report pursuant to Article 7, Paragraph (2), Item 3 above may be replaced by the acute toxicity test report pursuant to Article 7, Paragraph (2), Item 1, and either a bacteriological mutation test report or an in vitro chromosomal aberration test report stipulated in Article 7, Paragraph (2), Item 2.

(3) The phrase "chemicals determined and made a Public Notice by the Head of the NIER that, in consideration of the physico-chemical properties of the chemicals concerned, the submission of test reports is not required" set forth in Article 3, Item 3 of the Ministerial Ordinance shall refer to any of the following Items :

1. A chemical substance with significant physical hazardous properties, such as explosiveness, oxidizing, corroding, etc.;

2. A chemical substance of which a substantial change in chemical structure or characteristics occur when exposed to a natural conditions, such as water, air or sunlight, etc., and under mechanical impact;

3. A chemical substance of which in place of its data or materials, sufficient data for any chemical substance with similar structure are submitted;

4. An intermediate used in a specific production process;

5. An inorganic chemical substance; and

6. A chemical substance of which in place of data or materials required for submission, other test reports submitted are acknowledged as those to be more toxicologically relevant.

Chapter IV. Hazard Evaluation Method

Section 1. Hazard Evaluation

Article 10. (Hazard Evaluation)

(1) For the hazard evaluation (notification) of a chemical substance in accordance with Article 4 of the Ministerial Ordinance, the Head of the NIER shall examine and determine all of the following matters:

1. Assessment of attached document submitted in accordance with Article 7;

2. Assessment of whether or not a chemical substance falls under Article 5, Paragraph (1) of the Ministerial Ordinance;

3. Assessment of additional data or materials submitted in accordance with Article 8 for a chemical substance which falls under Item 2;

4. Assessment of data or materials that are voluntarily submitted by the applicant;

5. Determination of whether a chemical substance falls under the designation criteria for observational chemicals or toxic chemicals;

6. Determination of whether there is a need for a chemical substance to be examined or designated as a restricted toxic chemical (including a banned chemical); and

7. Determination of matters necessary for classification and labelling.

(2) For the hazard evaluation of a chemical substance in accordance with Paragraph (1) above, the following matters shall be assessed:

1. Whether a chemical substance may cause risk to human health by ingestion or short term direct exposure when assessed for acute toxicity and irritation, etc.;

2. Whether a chemical substance may cause damage to or adverse effects on human organs through repeated ingestion or exposure when assessed for repeated dose toxicity, carcinogenicity, genetic toxicity or reproductive toxicity;

3. Whether a chemical substance may cause adverse effects on the ecosystem when assessed for fish toxicity, etc.;

4. Whether a chemical substance may cause adverse effects on humans through bioconcentration, etc. if released once or repeatedly to the environment when assessed for degradability, bioconcentration, or octanol-water partition coefficient;

5. Whether a chemical substance may cause risks or danger due to its physico-chemical properties, such as reactivity, flammability, etc.;

6. Whether the potential for release to the environment is high; and

7. Restrictions in foreign countries.

Article 11. (Assessment Report)

(1) The Chemical Substance Evaluation Committee (hereinafter referred to as the "CSEC") shall prepare an assessment report, which includes all of the following matters:

1. Matters related to Article 5, Paragraph (3) and Article 9, Paragraph (3);

2. Results of hazard evaluation (notification) set forth in Article 10;

3. Assessment results from the CSEC, in case a chemical is assessed as requiring designation as a restricted chemical (including banned chemicals);

4. Matters related to classification and labelling; and

5. Matters related to the protection of information as set forth in Articles 47 through 49 of the Ministerial Ordinance.

(2) The assessment report set forth in Paragraph (1) above shall contain assessment results with the following matters after comprehensively reviewing each test results:

1. Whether a chemical substance falls under the category of a toxic chemical, and the range of its compound and mixture for toxic chemicals;

2. Whether a chemical substance falls under the category of an observational chemical, and the range of its compound and mixture for observational chemicals;

3. Whether a chemical substance falls under the category of a restricted toxic or banned chemical, and its contents;

4. Matters related to classification and labelling in the case of toxic chemicals;

5. Measures to be taken when the specific caution on use and handling after reviewing the assessment result of appropriate items is necessary; and

6. Whether the application for protection of information should be accepted or not.

Section 2. Assessment of Basic Data or Materials

Article 12. (Assessment of Acute Toxicity)

(1) For the assessment of acute toxicity, the following Items shall be considered:

1. The capacity of a test chemical to kill test animals, such as 50% lethal dose (oral, dermal) or 50% lethal concentration (inhalation), etc.;

2. The difference in toxicity between females and males, duration of toxic effect and its severity;

3. The difference in toxicity among test animal species;

4. The exposure duration and method; and

5. The particle size and distribution in case of acute toxicity test for dusts or mists,

(2) If after assessing the data or materials stipulated in Paragraph (1), Item 2 above, a clinical abnormality or gross lesion in necropsy occurs during the test, the result shall be included in the assessment report provided in Article 11 above even though the degree of acute toxicity expressed by 50% lethal dose or 50% lethal concentration is low.

Article 13. (Assessment of Genetic Toxicity)

(1) The assessment of genetic toxicity shall be comprehensively performed considering the strength of evidence and weight of evidence through in vitro test, in vivo test and human evidence.

(2) If the result of the genetic toxicity test is not positive, the following Items shall be taken into account, but not limited to:

1. Whether the dose of the test chemical is high enough;

2. Whether the concentration of the test chemical during the test was maintained appropriately;

3. In case of in vivo test, whether the test chemical reaches the target tissue in sufficiently high concentrations; and

4. Whether the reactivity of the test chemical is not sufficiently high.

(3) The results of in vivo tests may take preference over that of in vitro tests. However, it shall not fully override in vitro test results. Even though the results of in vivo tests show negative, the applicant for hazard evaluation (notification) shall be notified of necessary cautions if the in vitro test results are very positive.

Article 14. (Assessment of Degradability)

(1) Unless a chemical falls under all of the Items of Article 15 hereunder, the evaluation of degradability shall be based on the degradability test using microorganisms considering the following matters:

1. The appropriateness of the test method;

2. The activities of microorganisms (including inhibition of activities by the chemical); and

3. The acclimation of microorganisms.

(2) In the biodegradability test method, solubility, volatility and absorption of the chemical shall be considered, and the ready biodegradability test guideline that falls under the test guidelines approved by the Organization for Economic Cooperation and Development (hereinafter referred to as the "OECD") shall be used for assessment. However, if the inherent biodegradability test was conducted through scientific evidence or prediction, this data can be used for an assessment.

Article 15. (Assessment of Abiotic Degradation Test)

A chemical substance with rapid abiotic degradation provided in Item 1, Reference 5 of Annex 1 of the Presidential Decree and Article 7, Paragraph (2), Item 3 above shall refer to any of the following:

1. In the hydrolysis test as a function of pH or the persistence test conducted in water, a chemical substance whose value of a half-life is less than 12 hours in neutral pH range and ambient temperature;

2. In the photolysis test in aqueous solution, a chemical substance whose value of a half-life is less than 12 hours in natural sun light or artificial light similar to natural sun light; and

3. In the persistence test in soils, a chemical whose value of a half-life is less than three (3) months in outdoor field conditions.

Article 16. (Assessment of Polymers)

(1) For the assessment of a polymer, the following Items shall be considered:

1. Molecular weight distribution, including the contents of a low molecular weight species;

2. Structure of an estimated monomer unit;

3. Contents of monomers concerned;

4. Degradability and depolymerization under normal temperature and pressure;

5. Reactivity with a biological tissue; and

6. Solubilities.

(2) In case of an unstable polymer of which presents an unreasonable risk to humans and the environment, the degree of repetition of the monomer units and the known hazard properties of the monomer or degradation products shall be assessed.

Section 3. Assessment of Additional Data or Materials

Article 17. (Assessment of Fish Toxicity)

For the assessment of fish toxicity, the following Items shall be considered:

1. 50% lethal concentration (LC 50) for test fishes;

2. Exposure duration and method;

3. Water solubility;

4. Species of test fish; and

5. Characteristic behaviors of the chemical substance in water.

Article 18. (Assessment of Bioconcentration)

For the assessment of bioconcentration, the following Items shall be considered:

1. Degradability (including abiotic degradation);

2. Octanol water partition coefficient;

3. Permeability through biological membranes;

4. Solubility; and

5. Aquatic toxicity.

Article 19. (Assessment of Chronic Toxicity, etc.)

(1) Chronic toxicity and repeated dose toxicity shall be assessed by NOAEL, and this value shall be determined by considering statistically significant differences between the test group and control group for general items to be observed in a chronic toxicity test, recovery, reproducibility, and dose response relationship. However, in case it is deemed appropriate not to base it on NOAEL, the evaluation may be made based on No Observed Effect Level (NOEL) or Lowest Observed Adverse Effect Level (LOAEL).

(2) Without other available data, the NOAEL shall be determined from 90 days toxicity test data.

However, in case of other test periods, it may be assessed through converting it into those for 90 days.

Article 20. (Assessment of Carcinogenicity)

(1) For the assessment of carcinogenicity, the following Items relating to test animals and humans shall be considered:

1. Casual relationship between human exposure and development of cancer;

2. Number of test animal species indicating a carcinogenic response;

3. Number of organs in a single species indicating a carcinogenic response;

4. Structural similarity to those of the chemicals classified as causing cancer by international organizations;

5. Coincidence between the real exposure route to humans and those to test animals;

6. Relevant hispathological findings observed in a repeated dose toxicity test; and

7. Difference in toxicokinetics and mode of action between humans and test animals.

(2) Chemical substances which have been already classified as human carcinogen or as suspected or possible human carcinogen by international or specialized institutions, such as the International Agency for Research on Cancer and the OECD may not be assessed for their carcinogenicity.

Section 4. Assessment of Other Data or Materials

Article 21. (Other Data or Materials)

In cases where data or materials are obtained through voluntarily submission by the applicant or sought during hazard evaluation (notification), including carcinogenicity test data, but do not fall under basic data or materials or additional data or materials to be submitted under this regulation, evaluation of toxicity of the chemical concerned shall also be based on such data or materials.

Article 22. (Assessment of Reproductive Toxicity)

(1) Assessment of reproductive toxicity shall be based on any adverse effects on reproductive function or capacity or on development of the offspring, seen in humans or observed in appropriate animal tests in one or multiple generation experiments. In addition, the followings shall be considered in assessment of reproductive toxicity, but not limited to:

1. Histopathological findings for gonads including endocrine, etc. in repeated dose toxicity tests;

2. Structural similarity to known reproductive toxic chemicals;

3. Major populations considered to be exposed;

4. Gross or microscopic findings, mating index, fertility index, gametogenesis, reproductive cycle, implantation, teratogenicity, parturition, lactation, weaning; and

5. Test methods.

(2) During the assessment of the contents stipulated in Paragraph (1), Item 4 above, the possibility of non-specific secondary effects in the presence of maternal toxicity induced by the reduction of the ingestion of food, etc. shall be fully considered.

(3) In case of adverse effects related to lactation during the assessment of reproductive toxicity, the concentration of the chemical in breast milk shall be considered.

Article 23. (Evaluation of Irritation)

During the evaluation of skin and eye irritation, the following Items shall be considered:

1. Human evidence;

2. Data or materials related to structure activity relationship or structure property relationship;

3. pH;

4. Number of animals with positive results; and

5. Severity and reversibility of damage.

Article 24. (Assessment of Sensitization)

During the assessment of sensitization to skin and respiratory system, the following Items shall be considered:

1. Human evidence;

2. Possibility of repeated exposure;

3. Proportion of animals with positive results;

4. Sensitizating rate and potency; and

5. Test methods.

Chapter V. Announcement and Notice

Article 25. (Announcement and Notice)

The announcement and notice of the results of a hazard evaluation (notification) shall be made pursuant to the provisions of Article 6, Paragraph (1) of the Ministerial Ordinance. If it is announced that the chemical does not fall under the toxic chemicals or observational chemicals categories and its name is subject to application for protection of confidential information and such application is accepted, the generic name for the chemical shall be publicly notified.

Chapter VI. Evaluation at Own Discretion

Article 26. (Request Manufacturer or Importer to Submit Data or Materials)

(1) Based on the data from the survey of amount in circulation pursuant to provisions of Article 14, Paragraph (1) of the Act, the Head of the NIER may request a manufacturer or importer of a chemical substance which one company manufactured or imported 500 tones or more in the previous year or the total quantity manufactured or imported by the top five companies in the previous year was 1,000 tones or more, to submit necessary data or materials, such as relevant data or test reports stipulated in Articles 7 and 8 above, in accordance with Article 8, Paragraph (2) of the Act.

(2) In case of a request for submission of data in accordance with the foregoing Paragraph (1) above, the deadline for the submission shall be determined in consideration of the test period necessary for the production of the data or materials and domestic or overseas test ability. However, the deadline for the submission of data other than the data regarding chronic toxicity test may be one (1) year or less.

(3) When making a request for the submission of data or materials in accordance with the foregoing Paragraphs (1) and (2) above, the Head of the NIER shall consult with the manufacturer or importer in accordance with Article 5, Paragraph (2) of the Ministerial Ordinance.

Article 27. (Submission of Data or Materials of Observational Chemicals)

(1) The phrase "documents necessary for the hazard evaluation of such observational chemicals" set forth in Article 13, Paragraph (2) of the Act shall refer to any of the following:

1. In case of a chemical substance which is designated as an observational chemical for causes provided in Item 1, B, (1) of Annex 1 of the Presidential Decree, a test report on bioconcentration or chronic toxicity;

2. In case of a chemical substance which is designated as an observational chemical for causes provided in Item 1, B, (2) or (3) of Annex 1 of the Presidential Decree, a test report on carcinogenicity; and

3. In case of a chemical substance which is designated as an observational chemical for causes provided in Item 1, B, (4) of Annex 1 of the Presidential Decree, a test report on reproductive toxicity using other test animals.

(2) Based on the report of the volume of observational chemicals to be manufactured or imported pursuant to the provisions of Article 13, Paragraph (1) of the Act, the Head of the NIER may order the manufacturer or importer of the observational chemical of which total quantity manufactured or imported by one company in the previous year exceeded 500 tones or of which the total quantity manufactured or imported by top five companies in the previous year exceeded 1,000 tones, to submit necessary data or materials in accordance with Article 13, Paragraph (2) of the Act.

Chapter VII. Exemption from Application for Hazard Evaluation (Notification)

Article 28. (Exemption from Hazard Evaluation)

(1) A chemical substance for which hazard evaluation is deemed not necessary in accordance with Article 4, Paragraph (2) of the Ministerial Ordinance shall be any of the following Items:

1. Chemical substances listed on the Existing Chemicals Inventory;

2. Chemical substances used for study or research; or

3. Polymers which fall under any of the following sub-Items:

a. Polymers which are composed of monomers or reactants listed on the Existing Chemicals Inventory, excluding monomers or reactants whose weight percentage contained in a polymer is 2% or less;

b. Block polymers of which all blocks are listed on the Existing Chemicals Inventory; and

c. Graft polymers whose stem and branches are listed on the Existing Chemicals Inventory.

Article 29. (Management of List)

The Head of the NIER may take necessary measures to reorganize the Existing Chemicals Inventory in order to harmonize with international practices or for everyone to have access to the Inventory through the National Administrative Computer Network or Public Information Network.

Chapter VIII. Labelling of Toxic Chemicals

Article 30. (Position for Labelling of Toxic Chemicals)

The position for labelling toxic chemicals pursuant to the provisions of Article 28, Paragraph (2) of the Ministerial Ordinance shall be as follows:

1. For places that warehouse, store or display toxic chemicals, labelling of the presence of toxic chemicals provided in Annex 4, Item 1 of the Ministerial Ordinance shall be attached on the entrance or a conspicuous position;

2. For vehicles used to transport toxic chemicals, labelling indicating the presence of toxic chemicals stipulated in Annex 4, Item 2 of the Ministerial Ordinance shall be attached or engraved on the center of the back side of the vehicles; and

3. For containers and packages of toxic chemicals, labelling indicating the presence of toxic chemicals stipulated in Annex 4, Item 3 of the Ministerial Ordinance shall be attached after printing or printed directly.

Article 31. (Classification of Chemical Substances)

Classification of chemical substances pursuant to the provisions of Article 28, Paragraph (2) of the Ministerial Ordinance shall be any of the following Items:

1. Health hazardous substances

a. Very toxic substances

b. Toxic substances

c. Harmful substances

d. Corrosive substances

e. Irritant substances

f. Sensitizing substances

g. Carcinogenic substances

h. Mutagenic substances

i. Substances toxic to reproduction

2. Substance hazardous to the environment

3. Physically hazardous substances

a. Explosive substances

b. Oxidizing substances

c. Extremely flammable substances

d. Highly flammable substances

e. Flammable substances

f. Water prohibiting substances

Article 32. (Classification Criteria and Graphic Hazard Warnings of Toxic Chemicals)

(1) Classification criteria and graphic hazard warnings (hazard symbols and indication of hazard in word) of toxic chemicals pursuant to the provisions of Article 31 shall be as prescribed in the Annex. However, in case of mixtures which have two (2) or more kinds of criterium for classification and graphic hazard warnings, labelling indicating the higher hazard or toxicity among the hazards shall be posted.

(2) Notwithstanding the foregoing Paragraph (1) above, if there is any additional information for the toxic chemicals or mixtures on physico-chemical properties and toxicities, etc., graphic hazard warnings may be appropriately chosen and posted in accordance with the criteria as provided in Annex hereunder.

Addenda(September 5, 1997)

Article 1. (Date of Enforcement)

This Regulation shall become effective as of the date of the Public Notice.

Article 2. (Interim Measures for Existing Chemicals Inventory)

The Existing Chemicals Inventory pursuant to the provisions of Ministry of Environment Public Notice No. 1996-170 (Public Notice on Chemicals Exempted from the Notification) and Ministry of Labor Public Notice No. 1996-44 shall be deemed as one announced in a Public Notice by the Head of the

NIER pursuant to the provisions of Article 2, Item 2 of this Regulation.

Addenda(June 27, 1998)

This regulation shall become effective as of the date of the Public Notice.

[Annex]

Classification Criteria of Substances and Graphic Hazard Warnings (Related to Article 32, Paragraph (1))

1. Classification, classification criteria and graphic hazard warnings for toxic chemicals shall be as follows:

Classification	Classification Criteria	Graphic Hazard Warnings
Highly Toxic Substances	Substances of which a very small amount causes death or acute or chronic damage when inhaled, ingested or absorbed through the skin and which fall within any of the following items: a. When administered orally, LD50¡Â25 mg/kg (rat); b. When applied dermally for 24 hours, LD50¡Â50 mg/kg (rat or rabbit); c. When continuously inhaled for 4 hours, gases or vapors: LC50¡Â0.5 mg/L (rat), dusts or mists: LC50¡Â0.25 mg/L/4hr (rat);	
Toxic Substances	Substances of which a small amount causes death or acute or chronic damage when inhaled, ingested or absorbed through the skin and which fall within any of the following items: a. When administered orally, 25< LD50¡Â200 mg/kg (rat); b. When applied dermally for 24 hours, 50<LD50¡Â400 mg/kg (rat or rabbit); c. When continuously inhaled for 4 hours, gases or vapors:	

	0.5 < LC 50¡Â2 mg/L/4hr (rat), dusts or mists : 0.25<LC50¡Â1mg/ L/4hr (rat);	

Classification	Classification Criteria	Graphic Hazard Warnings
Harmful Substances	Substances which are likely to cause acute or chronic damage when inhaled, ingested or absorbed through the skin and which fall within any of the following Items: 1. Acute toxicity a. When administered orally, 200 <LD50¡Â2000 mg/kg (rat); b. When applied dermally for 24 hours, 400<LD50¡Â2000 mg/kg (rat or rabbit); c. When continuously inhaled for 4 hours, gases or vapors: 2<LC50¡Â20 mg/L/4hr (rat), dusts or mists: 1<LC50¡Â5mg/L/4hr (rat); 2. Repeated Dose Toxicity (90 days) a. When administered orally, NOAEL¡Â50mg/kg/day (rat); b. When applied dermally, NOAEL¡Â100 mg/kg/day (rat); and c. When continuously inhaled for 6 hours, NOAEL¡Â0,5mg/L/6hr/day (rat).	

Corrosive Substances	Substances which produce destruction of the skin tissue in contact with animal or human skins (including reactions caused by strong acids less than pH 2 or alkaline substances above pH 11.5).	

Classification	Classification Criteria	Graphic Hazard Warnings
Irritant Substances	When inhaled, in contact with the skin or eye, substances which fall within any of the following items : a. respiratory irritant : substances which cause a serious irritation to respiratory tracts in humans; b. skin irritant: substances which cause skin inflammation, edema or any other adverse reaction being continued for 24 hours when exposed to skin for 4 hours in skin irritation tests or which cause serious dermatitis in human skin; and c. eye irritant: substances which cause corneal opacity, conjunctival redness, chemosmosis, or iritis within 72 hours after exposure and such reactions continue for more than 24 hours thereafter, as a result of eye irritant tests and substances which cause ocular lesions in human.	

Sensitizing Substances	When inhaled in contact with the skin, substances which fall within any of the following items: a. skin sensitizer : substances which induce sensitization to substantial persons upon skin contact or animals in skin sensitization test; b. respiratory sensitizer (*) : substances which induce a specific respiratory hypersensitivity at a great frequency than would be expected as a result of respiratory sensitization study on general populations.	

Classification	Classification Criteria	Graphic Hazard Warnings
Carcinogenic Substances	When inhaled, ingested or absorbed through skin, substances classified as known human carcinogen or suspected human carcinogen by international or specialized organizations including IARC or ACGIH.	
Mutagenic Substances	Substances which are likely to cause gene mutation or genetic defects or to increase their incidences.	
Substances Toxic to Reproduction	Substances which cause or may cause serious adverse effects on reproductive ability or capacity, or on development of the conceptus or the offspring.	
	Substances which fall within any of the following items: 1. Ecotoxicity	

Substances Hazardous to the Environment	a. LC50(96hr)¡Â1.0 mg/L (fish); b. EC50(48hr)¡Â1.0 mg/L (daphnia); c. IC50(72hr)¡Â1.0 mg/L (algae); 2. Substances which are not rapidly degradable or/and octanol water partition coefficient (log Pow)¡Ã3 (unless the experimentally determined BCF<100) a. 1.0 mg/L (LC50(96hr)¡Â10 mg/L (fish); b. 1.0 mg/L (EC50(48hr)¡Â10 mg/L (daphnia); c. 1.0 mg/L (IC50(72hr)¡Â10 mg/L (algae);	
Explosive Substances	Substances in the state of solid, liquid, paste, or gelatin, gas which can be exploded or can be explosively given off fumes or smokes, by a exothermic reaction while rapidly liberating gas in the absence of oxygen.	

Classification	Classification Criteria	Graphic Hazard Warnings
Oxidizing Substances	Substances which fall within any of the following items: a. which may cause fire by itself; and b. which cause fire or explosion when mixed or in contact with other substances, especially combustible substances.	
Extremely Flammable	Substances which fall within any of the following items: a. Liquid substances which have a flash point lower than 0℃ and a boiling point lower than or equal to 35℃; and	

Substances	b. Gaseous substances which are flammable in contact with air at ambient temperature and pressure (i.e., atmospheric temperature)	
Highly Flammable Substances	Substances which fall within any of the following items: a. Liquid substances which have an ignition point lower than 21℃; and b. Substances which may become hot and finally catch on fire in contact with air at the ambient temperature without any input of energy.	
Flammable Substances	Liquid substances having an flash point equal to or greater than 21℃ and less than or equal to 55℃.	
Water Prohibiting Substances	Substances which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities.	

(*) Remark

(1) Chronic toxic effect shall refer to any of the following Items:

a. Death or serious damage, when exposed to a chemical substance;

b. Significant functional impairment to central or peripheral nervous system including vidual, hearing and smelling sensation, when assessed accordingly the result of clinical observations or other appropriate methods;

c. Consistent clinical changes such as reduction of blood cell production in the bone marrow. etc.;

d. Damage to target organs such as liver, kidney, nerve system, lung, etc.;

e. Impairment of blood or hemopoietic system which result in deteriorating the function of hemoglobin, etc.; and

f. Functional impairment or irreversible change in any organs.

(2) If there is 28 days repeated dose toxicity test data, it converts into 90 days repeated dose toxicity by multiplying it by three(3).

(3) Serious inflammation shall mean redness, edema. etc., occurring, when in contact with skin.

2. Other necessary matters which are not provided in the criteria for classification prescribed in the foregoing Item 1 above may be rationally made in consideration of the evaluation results in accordance with Chapter IV of this regulation.