ACT ON REGISTRATION AND EVALUATION, ETC. OF CHEMICAL SUBSTANCE

CHAPTER 1
GENERAL PROVISION

Article 1. Purpose
The purpose of this Act is to prescribe the matters for chemical registration, evaluation and assessment of hazard, risks of chemical substance and product containing hazardous chemical substance, designation of hazardous chemical substance, and to protect public health and environment by producing and utilizing the information of chemical substance.

Article 2. Definition
The terms used in this Act shall be defined as follows:

1. “Chemical substance” means a substance obtained by artificial reactions on elements and compounds and those obtained by modifying or extracting or refining substances existed in nature.

2. “Mixture” means a material or solution consisted of two or more of substances.

3. "Existing chemical substance“ means a chemical substance falls under one of followings:
   A. Chemical substances published by the Minister of Environment through the consultation with the Minister of Employment & Labor as chemical substances distributed for commercial uses in the country prior to February 2, 1991.
   B. Chemical substances published by the Minister of Environment as the substances cleared of the new chemical notification under the previous Toxic Chemicals Control Act after February 2, 1991.

4. “New chemical substance” means all other chemical substances which are not existing chemicals.

5. “Existing chemicals subject to registration” means the substances published by the Minister of Environment among existing chemical substances as necessary to register for Hazard Examination pursuant to Article 18 or Risk Assessment pursuant to Article 24 through the deliberation of Chemical Substance Evaluation Committee pursuant to Article 7.

6. “Toxic chemical substance” means the substances published by the Minister of Environment as being hazardous substances according to the criteria prescribed by the Presidential Decree.

7. “Authorization substance” means the substances published by the Minister of Environment as being concerned of its risks through the consultation with the heads of relevant central administrative agency pursuant to Article 25 and deliberation of chemical substance evaluation committee pursuant to Article 7 to manufacture, import and use after obtaining an authorization of the Minister of
8. “Restricted substance” means the substances published by the Minister of Environment as being recognized for its high risks in using of specific application and published by the Minister of Environment through the consultation with the head of relevant central administrative agency pursuant to Article 27 and deliberation of chemical substance evaluation committee pursuant to Article 7 to prohibit from manufacturing, import, sale, warehouse storage, transportation or use for such application.

9. “Prohibited substance” means the substances published by the Minister of Environment as being recognized for its high risks through the consultation with the head of relevant central administrative agency pursuant to Article 27 and deliberation of chemical substance evaluation committee pursuant to Article 7 to prohibit from manufacturing, import, sale, warehouse storage, transportation or use for all application.

10. “Hazardous substance” means toxic chemicals, authorization substances, restricted substances, prohibited substances and other substances of hazards or risks or concerned of such hazards or risks.

11. “Hazard” means the intrinsic properties of chemicals that affect adversely to human health or environment such as toxicity of chemicals, etc.

12. “Risk” means the degree of damage that may cause to human health or environment when exposed to hazardous substances.

13. “Generic name” means a name used in place of an actual name of chemical substance for the purpose of data protection.


15. “Product” means each of following that are likely to result in the exposure of chemicals to consumers as final consumer goods or parts thereof and accessories.

   A. Product consisting of a mixture.

   B. Product of which the chemicals are not released during the course of uses and perform a certain function in a particular solid form.

16. “Risk concerned product” means the ones published by the Ministry of Environment in consultation with the head of relevant central administrative agency as it is concerned to pose risks to public health or environment among followings:

   A. Product used mainly as household items by general consumers, such as Cleaner, Perfumery, Adhesives, Polish, Deodorizing agent, Synthetic detergents, Bleaching agent, Fabric softener, etc.

   B. Products used to kill the harmful creatures, except human and animals, such as insect repellents, disinfectants, preservatives, or inhibit interfere with the biological activity.

17. “Downstream user” means a person (in the case of a corporation, it shall limit to a corporation founded in Korea) who uses chemical substance or mixtures in the course of business activities; provided, however, that a person who manufactures, imports, sells chemical substance or mixture or consumers are excluded.
18. “Sale” means an act to put chemical substances, mixtures or products on the market.

**Article 3. Scope of Application**

The Act shall not apply to chemical substance falls under one of the following items:

1. Radioactive substances pursuant to Article 2 Paragraph 5 of the Atomic Energy Act;
2. Pharmaceutical products and quasi-drugs pursuant to Article 2 Paragraph 4 & 7 of the Pharmaceutical Affairs Act;
3. Narcotics pursuant to Article 2 Paragraph 1 of the Narcotics Control Act;
4. Cosmetics and raw materials for cosmetics pursuant to Article 2 Paragraph 1 of the Cosmetics Act;
5. Pesticides and active ingredients for pesticides pursuant to Article 2 Paragraph 1 & 3 of the Pesticides Control Act;
6. Fertilizers pursuant to Article 2 Paragraph 1 of the Fertilizers Control Act;
7. Food, food additives and device & container-packaging pursuant to Article 2 Paragraph 1, 2, 4 & 5 of the Food Sanitation Act;
8. Feeds pursuant to Article 2 Paragraph 1 of the Feeds Control Act;
9. Gunpowder pursuant to Article 2 Paragraph 3 of the Firearms, Swords and Gunpowder Control Act;
10. Military supplies pursuant to Article 2 of the Military Supplies Control Act and Article 3 Paragraph 2 of the Defense Acquisition Program Act (Routine items pursuant to Article 3 of the Military Supplies Control Act are excluded.);
11. Health functional foods pursuant to Article 3 Paragraph 1 of the Functional Foods for Health Act;
12. Medical devices pursuant to Article 2 Paragraph 1 of the Medical Devices Act.

**Article 4. Duties of State**

① The state shall identify hazard and risks of chemical substance, and shall establish and implement necessary measures in order to prevent the damages caused to it.

② The state shall provide technical - administrative - financial supports to produce - secure the information on hazard - risks of chemical substance and manage them systemically and have them pass the information concerned in the process of transfer - receipt the chemical substances.

③ The state shall establish - implement measures for safe management of products to protect public health and environment from chemical substances contained in products.

④ The state shall provide supports of investigation - research - training - promotion to small and medium size industries related to registration - evaluation, etc of chemical substances as prescribed by the Presidential Decree.

**Article 5. Duties of Business Entity**

① A business entity shall take necessary measures to reduce the use of hazardous substances or develop substances or technologies to replace hazardous substances, etc.
② A business entity shall actively produce • exchange • utilize information on hazard and risks of manufacturing • import substances, and shall participate and cooperate with the state's policies related to registration and hazard examination • risk assessment of chemical substance.

③ A business entity shall make an effort to protect public health and environment such as producing the information of use • safety of chemical substance and how to respond when exposed to chemical substance, etc.

④ A business entity who produces • imports products shall avoid damage to people's life • body or property due to the hazardous substance contained in the product.

**Article 6. Basic Plan for Evaluation of Chemical Substance, etc**

① The Minister of Environment shall establish a basic plan every 5 years for registration and evaluation of chemical substance, notification of product containing hazardous substance, safety management of risk concerned product, etc.

② The Minister of Environment shall deliberate with the Chemical Evaluation Committee pursuant to Article 7 after the consultation with the head of central administrative agency in advance, when establishing a basic plan. It applies the same when revising the basic plan.

③ The Basic Plan shall include each of followings:

   1. Method and plan to conduct registration • hazard examination • risk assessment of chemical substance, notification of product containing hazardous substance and risk assessment of risk concerned product, etc
   2. Matters related to development of technologies, etc. required for registration of chemical substance, notification of product containing hazardous substance and evaluation • assessment of hazard • risks
   3. Matters related to investigation • research on hazards. risks of chemical substance and product containing hazardous chemical substance, safety management of risk concerned product and international cooperation
   4. Matters related to activities of industries to prevent damages of public health or environment caused by chemical substance or risk concerned product, safety support and training for workers and consumers;
   5. Other matters necessary for the promotion of chemical registration and hazard examination • risk assessment, etc.

④ The Minister shall inform to the head of central administrative agency and the head of local government agency without delay once the basic plan is established.

⑤ The heads of central administrative agency and local government agency shall establish • implement relevant policies of concerned matters according to the basic plan.

**Article 7. Chemical Substance Evaluation Committee**

① The Chemical Substance Evaluation Committee (hereinafter referred to as the “Evaluation Committee”) shall be established under the Minister of Environment to deliberate following matters relating to chemical registration, notification of product
containing hazardous substance, evaluation · assessment of hazard · risks, etc.

1. Matters related to establishment of the basic plan
2. Matters related to designation of existing chemical substance subject to registration
3. Matters related to designation of chemical substance subject to authorization, restricted or prohibited substance;
4. Matters related to registration of chemical substance manufactured · imported less than one ton per year pursuant to Article 10 Paragraph 1 proviso
5. Matters related to the standard of safety labeling of risk concerned product
6. Other matters prescribed by Presidential Decree related to chemical registration and evaluation · assessment of hazard · risks and safety management of risk concerned product, etc.

② The Evaluation Committee shall consist of no more than 30 members including one chairperson and one vice chairperson.

③ The position of chairperson shall be assigned to the Vice-Minister of Environment, and the vice chairperson shall be elected by the committee from its members.

④ The members of the Evaluation Committee shall be appointed or commissioned by the Minister of Environment among following persons.

1. A person recommended by the head of the agency among public officials in charge of chemicals related works who belong to relevant central administrative agency
2. An expert with knowledge and experience in the related fields such as chemistry, environment and hygiene, etc, and persons from chemical-related companies and private organizations
3. A person recommended by the head of relevant central administrative agency among the persons in above 2.

⑤ The meeting of the Evaluation Committee shall be held when a majority of registered members are present, and pass resolutions by the affirmative vote of a majority of members present.

⑥ It may have a specialized committee for each sector such as Risk Assessment Committee, Management Committee of Risk Concerned Product, etc which is composed of the members of Evaluation Committee and experts in related field, if necessary for specialized research · review for the deliberation of the Examination Committee

⑦ Matters necessary for the formulation. operation, ,etc of the Evaluation Committee and the Specialized committee other than prescribed in Article 1 to Article 6 shall be stipulated by the Presidential Decree.

CHAPTER 2
REGISTRATION OF CHEMICAL SUBSTANCE

Article 8. Report of Manufacturing of Chemical Substance, etc

① Any person who manufacture · import · sell a new chemical substance or an existing
chemical substance 1 ton or more per year shall report the use of the substance and the volume, etc every year to the Minister of Environment as prescribed by the Ministerial Decree.

② Paragraph 1 shall not apply to the chemical substance falling under any of following subparagraphs:
1. Chemical substance imported as already equipped in machinery;
2. Chemical substance imported together with relevant machineries or equipments for the purpose of trial operation;
3. Chemical substance contained in a product performing specific function in particular sold form, which is not to be released during the process of use
4. Other chemical substance manufactured · imported for investigation · research, etc as prescribed by the Presidential Decree.

③ In the case that the changes prescribed by the Presidential Decree occur such as changes in use, etc among the data reported pursuant to Paragraph 1, it shall report the items changed as prescribed by the Ministerial Decree.

④ Other matters necessary for the reporting than those prescribed in Paragraph 1 to 3 shall be stipulated by the Ministerial Decree.

Article 9. Designation of Existing Chemicals subject to Registration
The Minister of Environment shall designate · publish existing chemicals subject to registration as prescribed by the Presidential Decree through the deliberation with the Evaluation Committee with the consideration of followings:
1. Domestic distribution volume of chemical substance concerned
2. Information related to hazard or risks of relevant chemical substance concerned

Article 10. Registration of Chemical Substance
① Any person who intends to manufacture · import a new chemical substance or an existing chemical subject to registration at 1 ton or more per year shall register such chemical substances prior to manufacturing · importation; Provided, however, that chemical substances designated. published as recognized to cause serious damage to public health and environment by the Minister of Environment through the deliberation of the Evaluation Committee shall be registered even if manufacturing · importing volume is less than 1 ton per year.

② Notwithstanding the Paragraph 1, any person who intends to manufacture · import an existing chemical subject to registration may manufacture · import without registration during the given grace period (hereinafter referred to as the “Grace Period”) as prescribed by the Presidential Decree.

③ Any person who intends to register pursuant to Paragraph 1 shall apply for registration to the Minister of Environment as prescribed by the Ministerial Decree.

④ The Minister of Environment shall decide and notify whether it is registered to an applicant within the period prescribed by the Ministerial Decree from the receipt of registration application pursuant to Paragraph 3.
5 Other matters necessary for the registration of chemical substance than prescribed in Paragraph 1 to 4 shall be stipulated by the Ministerial Decree.

Article 11. Exemption from Registration of Chemical Substance

1 Any person who intends to manufacture · import a new chemical substance or an existing chemicals subject to registration that fall under any of the following subparagraphs may manufacture · import without registration pursuant to Article 10:

1. Chemical substances that fall under Article 8 Paragraph 2 Item 1 to Item 3
2. Other chemical substances which have been confirmed of exemption from registration by the Minister of Environment (hereinafter referred to as the “Confirmation of Registration Exemption”) as chemical substances prescribed by the Presidential Decree such as chemical substances manufactured or imported in a quantity 10 tons or less per annum for the purposes of exporting the whole quantity.

2 Any person who intends to obtain a Confirmation of Registration Exemption pursuant to Paragraph 1 Item 2 shall apply for the Confirmation of Registration Exemption to the Minister of Environment. In this case, the Minister of Environment shall review whether it can be exempted or not and notify to an applicant as prescribed by the Ministerial Decree.

3 Besides the matters prescribed in Paragraph 1 to 2, matters necessary for the Confirmation of Registration Exemption such as criteria for confirmation of registration exemption, etc shall be determined by the Ministerial Decree.

Article 12. Amendment of Registration · Notification, etc.

1 Any person who had registered pursuant to Article 10 shall amend the registration, in the case that the changes fall under one of following subparagraphs occur as prescribed by the Ministerial Decree:

1. In case where the annual manufacturing · importing volume of registered chemical substance is changed at above the range prescribed by the Ministerial Decree.
2. In case where the uses, hazard and risks etc. of registered chemical substance is changed as prescribed by the Ministerial Decree.

2 Any person who had registered pursuant to Article 10 shall make a notification of the change as prescribed by the Ministerial Decree, in the case that name · location or company representative of registrant is changed.

3 Matters necessary for the registration or notification of amendment other than Paragraph 1 and 2 shall be stipulated by the Ministerial Decree.

Article 13. Measures for Non-Compliance with Registration Obligation, etc

1 Any person who intends to manufacture · import chemical substance shall not manufacture · import the chemical substance concerned before he/she receive a notice whether it’s registered pursuant to Article 10 Paragraph 4 or a notice of exemption pursuant to Article 11 Paragraph 2.

2 The Minister of Environment may order for necessary measures prescribed by the
Presidential Decree to a person who manufactured · imported chemical substance without the registration pursuant to Article 10 to discontinue the manufacturing · import · use · sale of chemical substance or withdraw chemical substance concerned, etc.

**Article 14. Submission Data for Registration of Chemical Substance**

① Any person who intends to apply for a registration pursuant to Article 10 Paragraph 3 shall submit following data (hereinafter referred to as the “Registration Dossier”) as prescribed by the Ministerial Decree; provided, however, that some part of data may not be submitted as prescribed by the Ministerial Decree, in case of new chemical substance or priority existing chemicals prescribed by the Presidential Decree:

1. Name, location and company representative who intends to manufacture · import
2. Chemical identity information; chemical name, molecular formula · structure, etc.
3. Use information of chemical substance
4. Classification and Labeling of chemical substance
5. Physico-chemical properties of chemical substance
6. Hazard information of chemical substance
7. Risks information including exposure scenario describing handling measures, exposure control-management process through the lifecycle of chemical substance (This shall apply only to chemical substance to be manufactured · imported 10 ton or more per year).
8. Guidance data for safe use (protective equipment, emergency measures for explosion, fire, release, etc.
9. Other data prescribed by the Ministerial Decree

② Among the Registration Dossier of Paragraph 1 Item 5 and Item 6, it shall submit the data specified by the Ministerial Decree conducted by one of following laboratories in the form of documents containing the test results.

1. Domestic testing laboratories pursuant to Article 21 Paragraph 1
2. Foreign testing laboratories which are confirmed to comply with OECD Good Laboratory Practice according to the Ministerial Decree.

③ Any person who intends to apply for a registration pursuant to Article 10 Paragraph 3 may submit a plan which includes the contents of tests and schedules, etc (hereinafter referred to as the “Test Plan’) in lieu of some parts of application dossier related to Paragraph 1 Item 5 and Item 6 as prescribed by the Ministerial Decree. In this case, the Minister of Environment shall review appropriateness of the content and schedule as prescribed by the Ministerial Decree, and shall notify the details of test and due date of data submission, etc to manufacturer · importer.

④ The details of data pursuant to Paragraph 1, Test methods to produce registration dossiers pursuant to Paragraph 1 Item 5 and Item 6, preparation methods of risk pursuant to Paragraph 1 Item 7, preparation method of test plan, etc shall be prescribed by the Ministerial Decree.
Article 15. Data Submission for Registration of Existing Chemical Substance Subject to Registration

① Any person who intends to apply for the registration of existing chemical substance subject to registration within the grace period shall individually apply for registration in accordance with the Article 10 Paragraph 3, but the registration data as prescribed by the Ministerial Decree shall be submitted jointly by lead registrant; provided, however, that it may submit individually after being confirmed by the Minister of Environment (hereinafter referred to as “Individual Submission Confirmation) in case it falls under one of following subparagraphs.

1. In case that it is anticipated to cause significant commercial damages due to the disclosure of company business information
2. In case that it costs more if submitted jointly than individually
3. Others prescribed by the President Decree

② The method and procedure for joint submission of registration data and individual submission confirmation, etc shall be prescribed by the Ministerial Decree.

Article 16. Joint Use of Existing Registration Data

① Any person who intends to apply for a registration pursuant to Article 10 Paragraph 3 may use the registration data prescribed by the Ministerial Decree for the purpose of their own registration among the existing data submitted by other registrant in accordance with Article 14 Paragraph 1 with an approval of data owner; provided, however, that in the case of the registration data registered more than 15 years ago, it may use without an approval from data owner.

② Any person who intends to apply for a registration in accordance with Article 10 Paragraph 3 may make an inquiry to the Minister of Environment if the same chemical substance has been registered, etc in order to use the existing registration dossier pursuant to Paragraph 1. In this case, the Minister of Environment shall inform of the result as prescribed by the Ministerial Decree.

③ Matters for the joint use of existing data other than specified in Paragraph 1 and 2 shall be prescribed by the Ministerial Decree.

Article 17. Exceptions for Vertebrate Animal Test Data

① In the case where vertebrate animal test data conducted by one of the test laboratories in Article 14 Paragraph 2 (hereinafter referred to as Vertebrate Animal Test Data) are already existed, any person who intends to apply for registration pursuant to Article 10 Paragraph 3 shall use the vertebrate animal test data for the purpose of his own registration after obtaining an approval from data owner to minimize animal test; provided, however, that in the case of the vertebrate animal test data have been more than 15 years since submitted as registration data, it may use the data without an approval from data owner.

② Notwithstanding the Paragraph 1, any person who intends to apply for registration may not submit the existing data after obtaining a confirmation by the Minister of Environment, in the case that the owner of vertebrate animal test data does not consent of using the data; Provided, however, that the Minister of Environment may order to
produce and submit relevant data within the period as prescribed by the Ministerial Decree in the event that it is recognized the vertebrate animal test data is necessary such as the case that it is difficult to judge the hazard of substance without the vertebrate animal test, etc.

③ Any person who receives a request for the consent to use vertebrate animal test data pursuant to Paragraph 1, it shall follow the request if not having a justifiable reason prescribed by the Presidential Decree.

④ Any person who refuses for the consent to use vertebrate animal test data without a justifiable reason pursuant to Paragraph 3 may not submit the same vertebrate animal test data for the purpose of registration.

⑤ Matters necessary for the consent of using vertebrate animal test data other than specified in Paragraph 1 to Paragraph 4 shall be prescribed by the Ministerial Decree.

CHAPTER 3
HAZARD EXAMINATION & RISK ASSESSMENT OF CHEMICAL SUBSTANCE

Article 18. Hazard Examination
① The Minister of Environment shall conduct a hazard examination for the chemical substance registered pursuant to Article 10, and shall notify the result to registrant.

② The Minister of Environment may order a registrant to submit necessary data for hazard examination if necessary for the hazard examination.

③ Matters necessary for the hazard examination and notification of the result pursuant to Paragraph 1 and the order of data submission pursuant to Paragraph 2 shall be prescribed by the Ministerial Decree.

Article 19. Hazard Evaluation, etc
① The Minister of Environment shall conduct hazard evaluation as prescribed by the Ministerial Decree for the chemical substances specified by the Presidential Decree as deemed necessary for hazard evaluation such as the chemical substances as the country to evaluate among the chemical substances being evaluated by international organizations.

② Any person who intends to use the result of hazard evaluation pursuant to Paragraph ① for the purpose of registration or hazard examination of chemical substance in other countries shall obtain an approval from the Minister of Environment.

③ Matters on how to obtain an approval to use the result of hazard evaluation, etc shall be prescribed by the Ministerial Decree.

Article 20. Designation of Toxic Chemical Substance
The Minister of Environment shall designate as toxic chemical substance according to the criteria prescribed by the Presidential Decree for the chemical substance as having hazards from the results of hazard examination, and make a public announcement.
Article 21. Publication of Hazard Examination Result

① The Minister of Environment, when the hazard examination is completed, shall publish the chemical name, hazard, whether it is toxic chemical substance or not pursuant to Article 20 and other matters prescribed by the Ministerial Decree.

② In case where the name of the chemical substance to be published pursuant to Paragraph 1 is subject to the confidentiality protection under Article 37 Paragraph 1, it shall publish in its generic name until the confidentiality protection period is expired; Provided, however, that in case the substance is designated as toxic chemical substance pursuant to Article 20, it shall publish a chemical name of the substance.

③ The details necessary for the publication pursuant to Paragraph 1 and 2 shall be prescribed by the Ministerial Decree.

Article 22. Designation of Testing Laboratories, etc

① Among the research institutes prescribed by the Presidential Decree, the Minister of Environment shall designate the testing laboratories capable of conducting the tests for physic-chemical properties and hazards of chemical substances. In this case the Minister of Environment shall also designate the field or type of testing allowed to be conducted for the testing laboratories concerned.

② The head of the research institute who wishes to be designated as a testing laboratory pursuant to Paragraph 1 shall apply for the designation to the Minister of Environment. In order to change the important matters prescribed by the Ministerial Decree among the designated matters, it shall apply for the amendment.

③ The Minister of Environment shall conduct periodic evaluation on whether the designated testing laboratories pursuant to Paragraph 1 are being properly operated as prescribed by the Ministerial Decree.

④ Matters other than those prescribed in Paragraph 1 to Paragraph 3 which is necessary for the designation of testing laboratories, standard procedures of amendment and management standard, etc shall be prescribed by the Ministerial Decree.

Article 23. Revocation of Designated Testing Laboratories

① In case where the designated testing laboratory pursuant to Article 22 falls under any of the following subparagraphs, the Minister of Environment shall revoke the designation of testing laboratory:
  1. Received the designation through false or other dishonourable means
  2. Conducted testing during the period of suspension
  3. Written the test results differently to the willful or gross negligence

② In case where the designated testing laboratory according to Article 22 falls under one of following subparagraphs, the Minister of Environment may revoke the designation of testing laboratory or the designation of field or type of testing allowed, or may order to suspend certain fields or types of tests up to a six-months period:
  1. In case that it fails to meet the standard of designation according to Article 22
Paragraph 4 from the evaluation result pursuant to Paragraph 3 thereof, or violate the management standard

2. In case that it fails to start conducting the designated fields or types of tests within two years from the date of designation without justifiable reason, or does not have work performance for at least two consecutive years

3. In case that it conducts the tests of field which are not designated or issued test report of such tests.

3. If less than 2 years after the date of revocation of designation pursuant to Paragraph 1 or Paragraph, the designation pursuant to Article 22 shall not be granted.

4. If less than 6 months after the date of revocation of the designation of fields or types of tests allowed to be conducted pursuant to Paragraph 2, the same fields or types of tests cannot be re-designated for the fields of types of tests pursuant to Article 22.

5. Administrative penalties in accordance with Paragraph 1 and Paragraph 2 shall be prescribed by the Ministerial Decree.

**Article 24. Risk Assessment**

1. The Minister of Environment shall conduct Risk Assessment as prescribed by the Ministerial Decree, based on the result of Hazard Examination, for the chemical substance which falls under any of followings among the chemical substances registered pursuant to Article 10, and shall notify the result of Risk Assessment to a registrant:
   1. Chemical substance which is manufactured or imported in quantity of 10 tons or more per annum
   2. Chemical substance which deems necessary for Risk Assessment from the result of Hazard Examination.

2. The Minister of Environment may order a registrant to submit necessary data for Risk Assessment as prescribed by the Ministerial Decree if necessary for Risk Assessment.

3. The Minister of Environment may take necessary measures as prescribed by the Presidential Decree to minimize the risks based on the result of Risk Assessment.

**CHAPTER 4**

**DESIGNATION & AMENDMENT OF AUTHORIZATION SUBSTANCE, ETC.**

**Article 25. Designation of Authorization Substance**

1. The Minister of Environment may designate and publish the authorization substances which are subject to obtain an approval of the Minister of Environment prior to manufacturing • import • use for the substances which show the concerns of risks from the hazard evaluation and risk assessment and for the substances fall under one of followings, after the consultation with the heads of relevant central administrative agency and the deliberation of Evaluation Committee. In this case, the Minister of Environment may grant for a period which can be manufactured • imported • used without obtaining the authorization (hereinafter referred to as the “Authorization Grace Period”) as prescribed by the Presidential Decree.
1. Substance causes or concerned to cause cancer, mutation, adverse fertility, disruption in endocrine system

2. Substance with high accumulation in human body and animal-plant, and remain for long-term period in environment

3. Substance may cause significant risks equal to or more of Item No 1 and No 2

② In case that the Minister of Environment designates publishes the substances pursuant to Article 1, name of authorization substance, use subject to authorization and authorization grace period, etc shall be included.

③ Matters necessary other than specified in Paragraph 1 and 2 for the designation and publication of authorization substance shall be prescribed by the Presidential Decree.

Article 26. Revocation for Designation of Authorization Substance, etc

The Minister of Environment may revoke the designation of authorization substance after the deliberation of the Evaluation Committee, or may change the contents wholly or in part published pursuant to Article 15 Paragraph 1, in case it falls under one of followings. In such case, it shall publish the revocation of designation or the amendment.

1. In case that the authorization substance is no longer be used as a substance or new technology is developed that may substitute the authorization substance

2. In case that there is no longer risk in using the authorization substance with the commercialization of new technology

3. In case that a new scientific evidence is found as to no risk of authorization substance

Article 27. Designation of Restricted Substance or Prohibited Substance, etc

① In case a substance falls under one of following subparagraphs, the Minister of Environment shall designate and publish the substance as Restricted substance or Prohibited substance after the consultation with the head of relevant central administrative agency and the deliberation with the Evaluation Committee as prescribed by the Presidential Enforcement Decree.

1. In case it is confirmed that the substance poses risks from the result of Hazard Examination and Risks Assessment.

2. In case it is recognized as having risks by international organization, etc

3. In case it is prohibited or restricted from manufacturing · import under the international treaty, etc.

4. In case it falls under the authorization substance revoked from the designation due to the reason of Article 26 Item 1.

② In case that the Minister of Environment intends to designate a Restricted substance or Prohibited substance, it shall issue a notice in advance in government gazette or internet homepage the name of chemical substance and the scheduled time of designation, etc; provided, however, that this does not apply in case it requires for an emergency response as it is determined the chemical substance causes or concerned to cause significant risk to human health or the environment.

③ In case that the Minister of Environment designate · publish the Restricted substance or
the Prohibited substance, the name of restricted substance or prohibited substance, the contents of restrictions depending on uses, etc shall be included.

④ Matters necessary for the designation and publication of the Restricted substance or Prohibited substance other than specified in Paragraph 1 and 2 shall be stipulated in the Presidential Enforcement Decree.

Article 28. Revocation for Designation of Restricted Substance or Prohibited Substance, etc.
The Minister of Environment may revoke the designation of Restricted substance or Prohibited substance or may amend wholly or in part the contents of publication made pursuant to Article 27 Paragraph 1, in case it falls under one of followings. In such case, it shall publish the revocation of designation or amendment:

1. No longer risks in using the Restricted substance or Prohibited substance with the commercialization of new technology
2. New scientific evidence is found as to the risk of Restricted substance or Prohibited substance

CHAPTER 5
PROVISON OF INFORMATION ON CHEMICAL SUBSTANCE

Article 29. Provision of Information relating to Chemical Substance

① Any person who transfers the substance registered in accordance with Article 10 or mixtures containing such substances shall prepare and provide the transferee with the information of the registration number of chemical substance, name, information regarding hazard and risk, and safe use, etc as prescribed by the Ministerial Decree of the Ministry of Environment; Provided, however, that in case where Material Safety Data Sheet pursuant to Article 41 of Industrial Safety Health Act needs to be prepared, it shall provide such information in the MSDS.

② In case where a transferor pursuant to Paragraph 1 transfers the same chemical substance or a mixture which contains such chemical substances repeatedly to the same person, it may provide the information pursuant to Paragraph 1 only at the first time of transfer.

③ In case that the changes prescribed by the Ministerial Decree occurs, a transferor or transferee of the information pursuant to Paragraph 1 and Paragraph 2 shall inform the changes to the other party within one month from the date known of such changes as prescribed by the Ministerial Decree.

④ The provision of information pursuant to Paragraph 1 through Paragraph 3 shall apply only when the transferred or received substance is used or consumed as raw materials of product at business place.

⑤ Matters necessary for the information provision other than specified in Paragraph 1 to 4 shall be stipulated in the Ministerial Decree.
Article 30. Information Provision to Downstream Users

1. Downstream user or seller of chemical substance or mixtures shall provide the use of chemical substance, exposure information, use • sales volume, safe use, etc to manufacturer • importer of the chemical substance or mixture in case they request such information for the compliance of the reporting requirement pursuant to Article 8 Paragraph 1 and the registration pursuant to Article 10.

2. Manufacturer or importer of chemical substance or mixtures shall inform of the information on the property of chemical substance, use, manufacturing • import volume, safe use information, etc to downstream users or sellers in case they request such information.

3. Matters necessary for the information provision pursuant Paragraph 1 and Paragraph 2 shall be stipulated in the Ministerial Decree.

Article 31. Notice for Provision of Information relating to Chemical Substance etc.

In order to provide smoothly the information of chemical substance pursuant to Article 29, Article 30 and Article 35, when the changes occur in the information subject to providing pursuant to Article 29 • Article 30 and Article 35, the Minister of Environment shall take necessary measures to notify promptly, etc. to registrant pursuant to Article 10 and notifier pursuant to Article 32.

CHAPTER 6
MANAGEMENT OF RISK-CONCERNED PRODUCT, ETC

Article 32. Notification of Product Containing Hazardous Substance

1. Any person who manufactures or imports products containing hazardous substances shall notify to the Minister of Environment in advance in case it exceeds 1 ton per year in total of each substances contained in products for the name of chemical substance, content, hazard information, use of hazardous substance in the product; Provided, however, that the substance which are not released during the course of use and performs specific function in particular solid form shall not apply.

2. In case it obtains an exemption confirmation (hereinafter refers to as “Exemption Confirmation of Notification”) as it falls under one of followings, it may manufacture • import a product without the notification pursuant to Paragraph 1.

   1. A substance which can block the exposure to human or environment when the product is used in normal usage.

   2. A substance already registered for the use of product concerned pursuant to Article 10

3. Any person who intends to obtain an Exemption Confirmation of Notification pursuant to Paragraph 2 shall make an application of Exemption Confirmation. In such case, the Minister of Environment shall notify to the applicant if it qualifies for an exemption as prescribed by the Ministerial Decree.

4. Matters necessary for the notification of product containing hazardous substances other
than specified in Paragraph 1 to 3 shall be stipulated by the Ministerial Decree.

**Article 33  Risk Assessment of Product, etc**

① The Minister of Environment shall conduct risk assessment for risk-concerned product by each item as prescribed by the Ministerial Decree in order to prevent the risks to the human health and environment which may occur due to the chemical substance contained in products.

② The Minister of Environment shall urgently conduct risk assessment to determine as for the risks in case of the risk-concerned products to human health and environment known to contain hazardous substance at home or abroad.

③ The Minister of Environment may entrust the risk assessment to the institute designated by the Minister of Environment as professional organization related to risk assessment, if necessary in conducting the risk assessment pursuant to Paragraph 1 and Paragraph 2.

④ The Ministry of Environment may inform the result of risk assessment pursuant to Paragraph 1 and 2 to relevant head of central administrative agency as prescribed by the Ministerial Decree.

⑤ The Minister of Environment may order to a person who manufacturers • imports, sell and distribute products to submit necessary data for risk assessment pursuant to Paragraph 1 and Paragraph 2 or have relevant public officials visit to collect minimum free samples necessary for risk assessment.

⑥ Public officials who visit the business entity, etc pursuant Paragraph 5 shall present an evidence showing such authorities to a person concerned.

⑦ Matters necessary for target of risk assessment, standard • method and time, etc other than specified in Paragraph 1 to 6 shall be stipulated by the Ministerial Decree.

**Article 34  Product Safety Labeling, etc**

① The Minister of Environment shall decide and publish the standards of product safety labeling relating to risks, etc for each item of risk-concerned product manufactured or imported, when the risk assessment is completed pursuant to Article 33.

② In the standards of product safety labeling pursuant to Paragraph 1, it shall specify the hazardous substances which are prohibited to use or publish necessary standards of the contents of hazardous chemicals in product, amount of effluent or evaporation, etc.

③ In determining the standards of product safety labeling pursuant to Paragraph 1, the Ministry of Environment may include the safety standard of container or package in the event that it is concerned of the risks caused by the container or package.

④ In case that the Minister of Environment determines the product safety labeling pursuant to Paragraph 1, it shall consult with relevant heads of central administrative agencies and deliberate with the Evaluation Committee in advance.

**Article 35  Information Provision on Chemical Substance Contained in Product**

① A transferor of product which contains hazardous substances notified pursuant to Article 32 shall prepare and provide the information stipulated by the Ministerial Decree about
name, use, conditions, etc of the substances contained as prescribed by the Ministerial Decree.

② A transferor of product pursuant to Article 1 shall provide the information related to safe use when it is requested by consumers of product as prescribed by the Ministerial Decree.

③ Relating to the method of information provision of chemical substances containing the product, etc shall apply the same as Article 29 Paragraph 2 to Paragraph 4 or Article 30.

④ Matters necessary for the information provision of chemicals containing the product other than the specified in Paragraph 1 to 3 shall be stipulated by the Ministerial Decree.

Article 36 Prohibition from Sales, etc

① Any person shall not sell • give or import • display • store • warehouse for the purpose of sales. giving the products which are not suitable for the safety labeling of risk-concerned product published pursuant to Article 34.

② Any person who intends to manufacture • Import the risk-concerned products for which safety labeling standards are not published shall obtain an approvals from the Minister of Environment by submitting the data of Article 14 Paragraph 1 on chemical substance containing the product as prescribed by the Ministerial Decree.

Article 37 Order of Withdrawal, etc

① The Minister of Environment may order of necessary measures to collect, prohibit sales, dispose, etc. of products as prescribed by the Ministerial Decree in case that it is not suitable for safety labeling standard pursuant to Article 34 or when deems to cause damages to human health or environment by selling • giving the risk concerned product for which the safety labeling standards are not published.

CHAPTER 7
SUPPLEMENTARY PROVISIONS

Article 38 Registration by the appointed person of foreign manufacturer, etc.

① Any person who manufactures or intends to manufacture chemical substance or product imported into Korea from overseas (hereinafter referred to as the “Foreign Manufacturer”) may appoint a person who fulfills the requirement specified by the Ministerial Decree and may have him perform following tasks in lieu of a person who imports or intends to import chemical substance or product:

1. Reporting of import volume and use, etc. pursuant to Article 8
2. Registration pursuant to Article 10 Paragraph 3
3. Notification pursuant to Article 32
4. Other tasks specified by the Presidential Decree

② A person who is appointed pursuant to Paragraph 1 shall report to the Minister of
Environment the fact appointed or dismissed by foreign manufacturer as prescribed by the Ministerial Decree.

**Article 39. Establishment·Operation of Chemical Substance Data Processing System**

1. The Minister of Environment shall establish·operate Chemical Substances Data Processing System so that any person who manufactures·imports or intends to manufacture·import chemical substance or product may process the tasks prescribed by the Presidential Decree electronically such as reporting pursuant to Article 8, registration pursuant to Article 10 Paragraph 3 or notification pursuant to Article 32, etc.

2. Matters related to establishment·operation of Chemical Substances Data Processing System pursuant to Paragraph 1 shall be stipulated by the Enforcement Decree.

**Article 40. Designation · Operation of Green Chemical Center**

1. The Minister of Environment, for the purposes of performing technology development etc. to prevent the damages from hazard and risks of chemical substance, may designate and operate the institutions prescribed by the Ministerial Decree as Green Chemical Center with the consultation of the heads of relevant central administrative agency.

2. The Green Chemical Center pursuant to Paragraph 1 (hereinafter referred to as the “Green Chemical Center”) may perform the duties set out below.
   1. Training and education of professional human resources for the production of chemical information, hazard examination and risks assessment
   2. Development of technology for the production of chemical information, hazard examination and risks assessment, reduction and prevention of risk of chemical substance, etc.
   3. Support of industry’s activities to reduce the risk of chemical substance and to prevent damage from chemical substance in public health and environment
   4. Other duties necessary for the prevention of damage from hazard and risk of chemical substance.

3. The Minister of Environment or the head of relevant central administrative agency may support all or part of the expenses necessary for the business of the Green Chemical Center within the scope of budget.

4. Matters necessary for designation process, designation requirements and operation etc. of Green Chemical Center other than specified in Article 1 to Article 3 shall be stipulated by the Presidential Decree.

**Article 41. Revocation of Designated Green Chemical Center, etc**

1. The Minister of Environment may revoke the designation of the Green Chemical Center or suspend all or part of its business up to six months in case it falls under any of followings; Provided, however, that it shall revoke in the case of Items 1 and 2.
   1. In case that the designation was falsely or improperly received
   2. In case that it performed any item of Article 40 Paragraph 2 during the suspension
3. In case that it does not fulfill the requirement of designation pursuant to Article 40 Paragraph 4
4. Other matters prescribed by the Presidential Decree

Necessary matters for the revocation of designation and standard and procedures of suspension, etc shall be stipulated by the Presidential Decree.

Article 42. Disclosure of Information of Chemical Substance

The Minister of Environment shall disclose the information of chemical substance name, hazards, etc as prescribed by the Ministerial Decree so that general public may easily check and utilize the information of hazard and risk of chemical substance.

Article 43. Report and Inspection, etc.

The Minister of Environment may order to submit necessary report or data to person listed in following subparagraphs, or may have public officials to access the facilities or business place to collect chemical substance or inspect relevant document, facility and equipment, etc as prescribed by the Ministerial Decree:

1. Any person how manufacture or import chemical substance
2. Any person who have to apply for the registration of chemical substance pursuant to Article 10 Paragraph 3
3. Any person who applied for the exemption confirmation of chemical substance pursuant to Article 11 Paragraph 2
4. Any person who manufacture .import product containing hazardous chemical substance pursuant to Article 32 Paragraph 1
5. Any person who manufactures .imports a risk concerned product
6. Any person entrusted with the duties by the Minister of Environment pursuant to Article 48 Paragraph 2

A public official who access or inspect pursuant to Paragraph 1 shall keep and present an evidence of such authority to persons concerned.

Article 44. Recording and Keeping of Documents

Any person who falls under one of following subparagraphs shall record and maintain matters related to manufacturing .import .sales .use of chemicals substance as prescribed by the Ministerial Decree:

1. Any person who reported the manufacturing, etc of chemical substances pursuant to Article 8 Paragraph 1
2. Any person who applied for registration of chemical substances pursuant to Article 10 Paragraph 3
3. Any Person who applied for exemption confirmation of chemical substance pursuant to Article 11 Paragraph 2
4. Any person who made a notification of product containing hazardous substance pursuant to Article 32 Paragraph 1

5. Any person who applied for exemption confirmation of product containing hazardous substance pursuant to Article 32 Paragraph 3

6. Any person who submitted the data of chemical substance contained in risk concerned product for which the safety labeling standard has not published pursuant to Article 36 Paragraph 2

Article 45. Data Protection

① The Minister of Environment shall not disclose the data during the granted period of confidentiality prescribed by the Ministerial Decree in case that a person who submitted the data pursuant to Article 8 Paragraph 1, Article 11 Paragraph 2, Article 12 Paragraph 1, Article 14 Paragraph 1, Article 18 Paragraph 2, Article 24 Paragraph 2, Article 32 Paragraph 1 and Paragraph 3, Article 36 Paragraph 2 requests for the data protection of the components of chemical substance, etc to protect the confidentiality; Provided, however, that it may disclose in case the data requested for the protection have already been disclosed or others fall under the data prescribed by the Presidential Decree.

② The Minister of Environment shall, when the data requested for the protection pursuant to the main body of Paragraph 1 does not come under the protection according to the proviso to Paragraph 1, notify the fact to an applicant of data protection.

③ Matters necessary for the procedures of data protection request other than specified in Paragraph 1 and Paragraph 2 shall be stipulated by the Ministerial Decree.

Article 46. Fees

Any person who intends to register, notify or confirm, obtain an approval pursuant to any of following subparagraphs shall pay fees as prescribed by the Ministerial Decree:

1. Registration of chemical substances pursuant to Article 10

2. Exemption confirmation of registration pursuant to Article 11 Paragraph 2

3. Amendment to the registration of chemical substances pursuant to Article 12 Paragraph 1

4. Approval for the use of risk assessment result pursuant to Article 19

5. Notification of product containing hazardous substance pursuant to Article 32 Paragraph 1

6. Exemption confirmation of product containing hazardous substance pursuant to Article 32 Paragraph 3

Article 47. Hearings

The Ministry of Environment shall hold hearings in order to revoke the designation pursuant to Article 23 and Article 41.
Article 48. Delegation · Entrustment of Authority

① The Minister of Environment may delegate some of the authorities under this Act to the head of National Institute of Environmental Research or to the head of Basin Environmental Office and Regional Environmental Office as prescribed by the Presidential Decree.

② The Minister of Environment may entrust, as prescribed by the Presidential Decree, parts of the duties under this Act to the Korea Chemical Management Association established in accordance with the Chemicals Control Act.

CHAPTER 8
PENAL PROVISIONS

Article 49. Penal Provisions

Any person who falls under any of the following items shall be punished by imprisonment with prison labor for not more than 7 years or by a fine not exceeding 200 million won:

1. Any person who manufacture · give or import · display · store · warehouse a product for the purpose of sales or giving which are not suitable for the safety labeling standard in violation of Article 36 Paragraph 1.

2. Any person who manufactures · imports a product for which safety labeling standard is not published, without submitting the data or submitted by false means, in violation of Article 36 Paragraph 2;

3. Any person who do not execute an order of product collection, sales prohibition, disposal, etc pursuant to Article 37 Paragraph 1

4. Any person who do not execute an order of emergency measures pursuant to Article 37 Paragraph 2

Article 50. Penal Provisions

Any person who falls under any of the following items shall be punished by imprisonment with prison labor for not more than 5 years or by a fine not exceeding 100 million won:

1. Any person who manufacture · import new chemical substance or priority existing chemical substance without registration or falsely registered in violation of Article 10 Paragraph 1.

2. Any person who do not make registration of changes or falsely registered of changes for the chemical substance in violation of Article 12 Paragraph 12

3. Any person who violate the order of action pursuant to Article 13 Paragraph 2

4. Any person who manufacture · import a product containing hazardous substances without the notification of product containing hazardous substance or falsely notified in violation of Article 32 Paragraph 1

5. Any person who conduct duties of Article 38 Paragraph 2 and 3 falsely as an appointed person pursuant to Article 38 Paragraph 1
Any person who falls under any of the following items shall be punished by imprisonment with prison labor for not more than 3 years or by a fine not exceeding 50 million won:
1. Any person who do not make a report of manufacturing, etc. of chemical substance or falsely reported in violation of Article 8 (including for an appointed person pursuant to Article 38)
2. Any person who manufacture. Import new chemical substance or priority existing chemical substance without obtaining an exemption confirmation or falsely obtained of exemption confirmation in violation of Article 11
3. Any person who violate an order of data submission pursuant to Article 18 Paragraph 2 and Article 24 Paragraph 2
4. Any person who manufacture · import a product containing hazardous substances without obtaining an exemption confirmation or falsely obtained in violation of Article 32 Paragraph 3

Article 52. Penal Provisions
Any person who falls under any of the following items shall be punished by imprisonment with prison labor for not more than 1 year or by a fine not exceeding 30 million won:
1. Any person who do not provide an information of chemical substance or falsely provided in violation of Article 29 Paragraph 1 and Article 35 Paragraph 1
2. Any person who do not provide an information of chemical substance or falsely provided in violation of Article 30 Paragraph 1 and 2
3. Any person who do not provide an information related to safe use of product to consumer or falsely provided in violation of Article 35 Paragraph 2

Article 53. Dual Punishment Provision
In case where corporation’s representatives or deputy of corporation or person, users or other employee commits any of the violations contained from Article 49 to Article 52 in connection with the tasks of the corporation or person, it shall impose a fine to relevant corporation or person in addition to punishing those committed such violations; Provided, however, that such fines shall not be imposed in case where the relevant corporation or person conducted the tasks with due care and was not negligent in order to prevent such violations.

Article 54. Administrative Fines
① Any person who falls under any of the following items shall be imposed an administrative fine not exceeding 10 million won:
1. Any person who do not make a notification of changes or falsely changed pursuant to Article 12 Paragraph 2
2. Any person who do not make a joint data submission without obtaining the
confirmation of individual submission in violation of Article 15 Paragraph 1

3. Any person who do not inform of changes in information or falsely informed in violation of Article 29 Paragraph 3

4. Any person who do not report or submitted or falsely submitted and refuse, disturb or avoid the access or inspection of public officials pursuant to Article 43 Paragraph 1

5. Any person who violate the obligations of document recording and keeping pursuant to Article 44.

② The fines in the above Paragraph 1 shall be imposed and collected by the Minister of Environment as prescribed by the Ministerial Decree.

ADDENDUM

Article 1. Effective Date

This Act shall enter into force on January 1, 2015; Provided, that Article 14 Paragraph 1 Item 7 and Article 24 Paragraph 1 Item 1 shall be effective according to followings:

1. In case that chemical substances intends to manufacture, import are 100 ton or more per annum: January 1, 2015

2. In case that chemical substances intends to manufacture, import are 70 ton or more per annum: January 1, 2017

3. In case that chemical substances intends to manufacture, import are 50 ton or more per annum: January 1, 2018

4. In case that chemical substances intends to manufacture, import are 20 ton or more per annum: January 1, 2019

5. In case that chemical substances intends to manufacture, import are 10 ton or more per annum: January 1, 2020

Article 2. Transitional Measures concerning Designation · Publication of Toxic Chemicals, Restricted Chemicals · Prohibited Chemicals

Toxic chemicals and Restricted chemicals ·Prohibited chemicals designated·published in accordance with the Toxic Chemicals Control Act before the enforcement of this Act shall be deemed to have been designated·published as Toxic chemicals pursuant to Article 20 and Restricted chemicals or Prohibited chemicals pursuant to Article 27.

Article 3. Transitional Measures concerning Registration of Chemical Substances

① Any person who made new chemical notification pursuant to the Toxic Chemicals Control Act before the enforcement of this Act shall be deemed to have completed registration of chemical substances pursuant to Article 10 and hazard examination pursuant to Article 18. In this case, the person shall notify to the Minister of Environment by the procedure prescribed by the Ministerial Decree.

② Despite the latter part of Paragraph 1, the notifier shall apply for a registration of changes in case that it falls under any of Article 12 Paragraph 1.
Article 4. Transitional Measures concerning Exemption Confirmation of Chemical Substances

Any person who had received an exemption confirmation of hazard examination pursuant to the Toxic Chemical Control Act before the enforcement of this Act shall be deemed to have received an exemption confirmation of registration pursuant to Article 11.

Article 5. Transitional Measures concerning Designation of Testing Laboratories

Testing laboratories which have been designated in accordance with Article 14 of the Toxic Chemical Control Act before the enforcement of this Act shall be deemed to have designated as testing laboratories pursuant to Article 22.

Article 6. Transitional Measures concerning Administrative Disposition

① In case of designation revocation or business suspension against the acts committed before the enforcement of this Act, it shall follow the provisions of previous Toxic Chemical Control Act despite the provision of Article 23.

② The testing laboratories which have been revoked or suspended in accordance with Article 14-2 Paragraph 1 or 2 of the Toxic Chemical Control Act before the enforcement of this Act shall be deemed to have been revoked or suspended in accordance with Article 22 Paragraph 1 or 2.

Article 7. Transitional Measures concerning Penalties and Administrative Fines

When imposing penalties and fines against the acts committed before the enforcement of this Act, the penalties and fines shall follow the provision of the previous Toxic Chemical Control Act.