Regulation of New and Existing Chemical Substances Registration

Thirty-three articles promulgated by Environmental Protection Administration Order Huan-Shu-Tu-Tzu No. 1030101706 on December 4, 2014.

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Chapter 1 General Provision

Article 1

These Regulations (hereinafter the Regulations) are stipulated according to Article 7-1 Paragraph 6 of the Toxic Chemical Substances Control Act (hereinafter the Act).

Article 2

The term “registrant” as used herein means a natural person, a juristic person, an unincorporated body having a representative or manager, an administrative authority, or a person who may be the subject of rights and obligations under other laws, that are subject to chemical substances registration pursuant to Article 7-1 of the Act.

A registrant may appoint a representative to apply for chemical substances registration. The representative should be a natural person possessing the nationality of the Republic of China, or a juristic person, an institute or an organization that is constituted or registered by laws.

Applying for chemical substance registration according to the Regulations, a registrant shall attach a copy of National Identification Card, a copy of company registration, business registration, factory registration, or other documents verifying its establishment. A representative shall supply a notarized appointment letter.

Article 3

The terms used in the Regulations are defined as follows:

I. Chemical Substance refers to a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any unintended constituent deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

II. Substance which Occur in Nature refers to substance that is unprocessed, processed only by manual, gravitational, or mechanical means, by dissolution in water, by water extraction, by vapor distillation, by flotation, by heating solely to remove water, are extracted from air by any means, without chemical change in the substance; or large molecules from organisms, or polymers occurring in nature and not chemically processed.

III. Mixture refers to a mixture or a solution composed of two or more substances in which they do not react.

IV. Article refers to a manufactured item formed to a specific shape or design during manufacture.

V. Polymer refers to a chemical substance that fits the following criteria:
   A. A macro-molecular chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units.
   B. A molecule contains at least three monomer units covalently bound; such molecules take over 50% of the weight of that substance, and the amount of the said molecules presenting the same molecular weight must be less than 50% of the weight of that substance.
   C. Differences in the molecular weight are primarily attributable to differences in the number of monomer units.

VI. Polymers for which the 2% Rule is Applicable refers to the monomer-based representation of polymers which may include or may not include monomers and other reactants used at 2 weight percent or less. A monomer-based representation means naming of polymers is based on constituent monomers.

VII. Polymer of Low Concern (PLC) refers to a substance that is evaluated by the central competent authority, and fulfills any one of the following conditions:
   A. A polymer with an average molecular weight in a range of 1,000 to 10,000 Daltons, contains oligomers of molecular weights below 500 Daltons in amount of less than 10%; oligomers below 1,000 Daltons in amount of less than 25%.
   B. A polymer with an average molecular weight over 10,000 Daltons, contains oligomers of molecular weights below 500 Daltons in amount of less than 2%; oligomers below 1,000 Daltons in amount of less than 5%.
   C. Polyester polymers.
   D. Insoluble polymers.

VIII. Intermediate refers to a chemical substance produced and consumed in the course of the manufacture of another chemical substance.

IX. On-site Isolated Intermediates refers to intermediates that are produced and consumed on the same site.

X. Incidental Reaction Products refers to chemical substances produced when a substance undergoes a chemical reaction that is consequent to the use of the substance, the result of storage or the change of environmental factors.

XI. Impurity refers to an unintended constituent present in a substance as produced. It originates from the starting materials or is the result of secondary or incomplete reactions during the production process. While it is present along with the final substance it was not intentionally added, nor does it enhance the commercial value of that substance. The concentration of an individual impurity is no more than 10% (w/w). All impurities presented are no more than 20% (w/w).

XII. Scientific Research and Development refers to any scientific experimentation, education, analysis, or chemical research carried out under strictly controlled conditions.

XIII. Product and Process Orientated Research and Development (PPORD) refers to any scientific development related to product development or the further development of a substance, in the course of which pilot plant or production trials are used to develop the production process or to test the fields of application of the substance.

XIV. Substance of Carcinogenic, Mutagenic or Toxic for Reproduction (CMR) refers to a substance that meets any criteria of carcinogenicity category 1; mutagenicity category 1; reproductive toxicity category 1, based on R.O.C. National Standards (CNS) 15030.

XV. Substances under Customs Supervision refers to chemical substances under customs supervision, which are in temporary storage or placed in a harbor's designated area or warehouse, container freight station, bonded warehouse, logistics center or free trade zone, with a provision for re-exportation or transit.

Article 4

The Regulations shall not apply to any of the following conditions:

I. Substances which occur in nature

II. Chemical substances in machines or equipment for test-run purposes

III. Inseparable intermediates from chemical reactions in the reaction vessel or production process

IV. Chemical substances for national defense purposes

V. Chemical substances under customs supervision

VI. Waste

VII. By-product or impurity that is of no commercial application

VIII. Mixtures; Exemption is not applicable to the individual chemical constituents of the mixtures

IX. Articles

X. A polymer for which the 2% rule is applicable and listed on the inventory of existing chemical substances, or that is a new chemical substance meeting the 2% rule

XI. Matters governed by the following respective laws:

A. Agro-pesticides, as defined by the Agro-pesticides Management Act

B. Feeds and feed additives, as defined by the Feed Control Act

C. Fertilizers, as defined by the Fertilizer Management Act

D. Veterinary drugs, as defined by the Veterinary Drugs Control Act

E. Medicaments, as defined by the Pharmaceutical Affairs Act

F. Controlled drugs, as defined by the Controlled Drugs Act

G. Cosmetic(s), as defined by the Statute for Control of Cosmetic Hygiene

H. Foods and food additives, as defined by the Act Governing Food Safety and Sanitation

I. Tobacco products, as defined by the Tobacco Hazards Prevention Act

J. Tobacco and alcohol, as defined by the Tobacco and Alcohol Administration Act

K. Radioactive Materials, as defined by the Atomic Energy Act and the Ionizing Radiation Protection Act

L. Chemicals regulated by the Montreal Protocol under the Air Pollution Control Act

M. Environmental agents, as defined by the Environmental Agents Control Act

Chapter 2 New Chemical Registration

Article 5

For a new chemical substance to be manufactured or imported in estimated annual volumes of one ton or more; or for a new chemical substance to be manufactured or imported for the purposes of scientific research and development, and product and process orientated research and development, in estimated annual volumes of ten tons or more, the registrant shall apply for the standard registration and submit data as specified in Appendix 1.

For a new chemical substance to be manufactured or imported in estimated annual volumes of 100 kilograms or more, but less than one ton; or for a new chemical substance to be manufactured or imported for the purposes of scientific research and development, and product and process orientated research and development, in estimated annual volumes of one ton or more, but less than ten tons, the registrant shall apply for the simplified registration and submit data as specified in Appendix 2.

For a new chemical substance to be manufactured or imported in estimated annual volumes of less than 100 kilograms; or for a new chemical substance manufactured or imported for the purposes of product and process orientated research and development, in estimated annual volumes of less than one ton, the registrant shall apply for the small quantity registration and submit data as specified in Appendix 3.

Article 6

For a new chemical substance in compliance with the definition of an on-site isolated

intermediate or polymer, which is to be manufactured or imported in estimated annual volumes of ten tons or more, the registrant shall apply for the standard registration and submit data as specified in Appendix 1.

For a new chemical substance in compliance with the definition of an on-site isolated intermediate or polymer, which is to be manufactured or imported in estimated annual volumes of one ton or more, but less than ten tons, the registrant shall apply for the simplified registration and submit data as specified in Appendix 2.

For a new chemical substance in compliance with the definition of an on-site isolated intermediate or polymer, which is to be manufactured or imported in estimated annual volumes of less than one ton, the registrant shall apply for the small quantity registration and submit data as specified in Appendix 3.

Article 7

For a new chemical substance in compliance with the definition of polymers of low concern, which is to be manufactured or imported in estimated annual volumes of less than one ton, the registrant shall be exempted from registration; if it is annually manufactured or imported volumes is estimated to be of one ton or more, the registrant shall apply for the small quantity registration and submit data as specified in Appendix 3.

A new chemical substance that is to be manufactured or imported after being evaluated as a polymer of low concern by the central competent authority, may be applicable for exemption pursuant to the previous paragraph.

Article 8

The central competent authority may demand a new chemical substance to the standard registration as specified in Appendix 1 if it is identified as a substance of carcinogenic, mutagenic, or toxic to reproduction; regardless if it is entitled to simplified registration as specified in Appendix 2 or small quantity registration as specified in Appendix 3.

Article 9

For a new chemical substance fulfilling the criteria of the substances used for the purposes of scientific research and development, or for product and process orientated research and development; or having other special forms, its chemical substance information, as specified by the Regulations, shall be filed by the correspondent registrant. Additional forms designated by the central competent authority shall be filled out and submitted as well.

Article 10

Upon reviewing new chemical substance information submitted by a registrant, the central competent authority shall approve the registration by attaching conditions to prohibit or restrict handling, and require submission of periodic report of handling status, updates of relevant registration reports, or hazard communication, if the central competent authority

determines that there is a concern over the toxicological characteristics of new chemical substances conforming to definitions of Class 1, Class 2, or Class 3 of toxic chemical substances.

Upon reviewing new chemical substance information submitted by a registrant, the central competent authority shall approve the registration along with conditions to restrict its handling, and require submission of information on exposure assessment and risk assessment, updates of relevant registration reports, or hazard communication, if the central competent authority determines that there is a concern of environmental pollution or endangerment to human health.

Article 11

Co-registrants, or the early and late registrants of the same new chemical substance, may apply for joint registration under agreement and share substance information required for registration among co-registrants.

The overall quantity of new chemical substances in the joint registration pursuant to the previous paragraph shall be the summation of individual quantity from each co-registrant. The new chemical substance subjected to joint registration is then registered according to the Regulations.

Taking into account the overall manufactured or imported quantity of new chemical substances granted under registration, the central competent authority may require registrants to re-register under designated registration type, or apply for joint registration.

For joint registration that is agreed by co-registrants, but has no agreement reached on the cost sharing of registration information, the co-registrants may submit an equal-cost-sharing request application to the central competent authority. Then utilization of registered chemical substance information shall be accepted after the shared cost has been paid according to the decision made by the central competent authority.

Article 12

The central competent authority issues registration documents for new chemical substances granted under registration. The contents of registration documents shall include items as specified in Appendix 4.

The chemical substances information approved under registration shall be provided for government authorities in charge of the subject industry to manage chemicals used in the subject industry.

A manufacturer or importer selling or transferring a new chemical substance shall take the initiative to present registration documents or identifiable labels as granted under registration, and provide information on safe use.

Article 13

The valid periods of the documents of the new chemical substance registration are as

follows:

I. The document of standard registration in accordance with Appendix 1 is valid for five years.

II. The documents of simplified registration and small quantity registration in accordance with Appendix 2 and 3, respectively, are valid for two years.

III. The document of PLC small quantity registration in accordance with Article 7 Paragraph 1 and Appendix 3 is valid for five years.

Article 14

Application of registration document extension pursuant to Subparagraph 2 of the previous article shall be made by registrants three months before the expiration of a registration document. Information on quantity of new chemical substances manufactured or imported shall be submitted to the central competent authority.

The central competent authority shall issue a new registration document after the extension application pursuant to the previous paragraph is approved.

If a type of registration intended for extension is inconsistent with the original registration document, a new application of registration shall be made.

Article 15

A new chemical substance granted under registration in any one of following circumstances shall be included in the inventory of existing chemical substances by the central competent authority.

I. It shall be at least five years after registration process is filed and completed in accordance with the standard registration as specified in Appendix 1.

II. It shall be at least five years after PLC registration process is filed and completed in accordance with the small quantity registration as specified in Appendix 3.

III. Toxic chemical substances announced by the central competent authority.

A registrant may apply for inclusion in the inventory of existing chemical substances, when a new chemical substance granted under registration meets any of the following situations:

I. Standard registration that has been filed and completed through submission of information on hazard assessment and exposure assessment, as specified in Appendix 1.

II. PLC registration that has been filed and completed in accordance with the small quantity registration, as specified in Appendix 3.

Article 16

For a chemical substance that is manufactured or imported before the Regulations take effect and is not included on the inventory of existing chemical substances, before March 31st, 2015, the registrant may attach documents evidencing that the chemical substance has been manufactured or imported. After evaluation by the central competent authority, the registrant

may apply chemical substance registration pursuant to the provisions of Chapter 3 of the Regulations.

Registrants, who fail to apply before the designated deadline pursuant to the previous paragraph, are to be denied by the central competent authority.

Article 17

A new chemical substance manufactured or imported during the period from the effective date of the Regulations to December 31st, 2015, shall undergo application for small quantity registration through submission of chemical information as specified in Appendix 3. With registration approval and registration documents granted by the central competent authority, the new chemical substance shall not be subjected to the restriction of Article 5 or Article 6.

The aforementioned registration document is valid for one year, which shall not be extended upon expiration.

Chapter 3 Existing Chemical Registration

Article 18

An existing chemical substance manufactured or imported shall apply for phase 1 registration and attach chemical information, as specified in Appendix 5, from September 1st, 2015, to March 31st, 2016, where annual average volume over the past three consecutive years prior to registration application exceeds 100 kilograms, or at least one highest annual volume during the three consecutive year period prior to registration application exceeds 100 kilograms.

The central competent authority is to issue phase 1 registration number to a registrant whose registration application is approved.

A manufacturer or importer selling or transferring an existing chemical substance shall take the initiative to present phase 1 registration number, registration document or other identifiable labels as granted under registration.

Article 19

After April 1st, 2016, an existing chemical substance first manufactured or imported in annual volume of 100 kilograms or more, shall apply for phase 1 registration and attach chemical information, as specified in Appendix 5, within the deadline determined by the central competent authority.

The central competent authority is to issue a phase 1 registration number to a registrant whose registration application is approved.

A manufacturer or importer selling or transferring an existing chemical substance shall take the initiative to present a phase 1 registration number, registration document or other identifiable labels as granted under registration.

Article 20

The central competent authority may announce designated lists of existing chemical substances subject to standard registration in stages, including quantity threshold and the deadline for registration, based on the conditions of Phase 1 registration of existing chemical substances.

For existing chemical substances listed on the said lists pursuant to previous paragraph, the registrant shall file for standard registration of existing chemical substances and submit content items as specified in Appendix 6 within the deadline announced.

Article 21

Different registrants of the same existing chemical substance, which is pursuant to Paragraph 1 of the previous article, may apply for joint registration under agreement.

Joint registration pursuant to the previous paragraph shall be filed according to Paragraph 2 of the previous article.

For joint registration that is agreed by co-registrants, but for which no agreement is reached on the cost sharing of registration information, the central competent authority may determine the cost to be equally shared at the request of the later co-registrants. Then utilization of registered information shall be accepted after the shared cost has been paid.

Article 22

The central competent authority issues registration documents to those who apply and complete chemical substance registration pursuant to the provisions of the previous two articles. Registration documents shall contain the following particulars as specified in Appendix 7.

Existing chemical substances information approved under registration shall be provided for government authorities in charge of the subject industry to manage chemicals used in the subject industry.

A manufacturer or importer selling or transferring an existing chemical substance shall take the initiative to present a registration number, registration document or identifiable labels as granted under registration, and provide information on safe use.

Chapter 4 Information Dissemination and Business Secret Protection

Article 23

Chemical substance information granted under registration by the central competent authority shall be made public. The information contents disclosed is as follows:

I. Identification of Registrant
II. Chemical substance name
III. Manufacture or import conditions
IV. Hazard classification and labelling
V. Safe use information
VI. Physical and chemical properties
VII. Toxicological and ecotoxicological information
VIII. Hazard assessment
IX. Exposure assessment.

The content that shall be disclosed pursuant to the previous paragraph shall be made public through the Internet.

Article 24

Chemical information registered, which concerns confidential matters on national security or business secrets, shall be kept secret. The aforementioned business secret shall conform to the following conditions:

I. It is not known to persons generally involved in the information of this type;
II. It has economic value, actual or potential, due to its secretive nature; and
III. Its owner has taken reasonable measures to maintain its secrecy.

For those registered information determined to be business secret, the following shall be protected and kept secret.

I. Identification of registrant
II. Identification of chemical substance
III. Information on manufacture or import
IV. Use of chemical substance

A registrant may apply for secret information protection with proof documents conforming to Paragraph 2 of this article, when filing for new chemical substance registration, or existing chemical substance registration, or three to six months prior to the application of inclusion in inventory of existing chemical substances pursuant to Article 15.

As the application of secret information protection pursuant to the previous paragraph is approved, the periods of confidentiality are as follows:

I. Standard registration: confidentiality is to be valid for five years from the date of approval.
II. Simplified registration or small quantity registration: confidentiality is to be valid for two years from the date of approval.

A registrant may apply for an extension when it is three months prior to the expiry of the confidentiality period. Extension of period of confidentiality is as follows:

I. Standard registration: five years
II. Simplified registration or small quantity registration: two years

A maximum duration of confidentiality protection for chemical registration information is

15 years.

Article 25

When the central competent authority publicly disseminates chemical substance information that is approved as confidential and protected pursuant to the previous article, in accordance with Article 41 Paragraph 2 of the Act, the registrant shall be notified.

Chapter 5 Supplementary Provisions

Article 26

Review periods of all the applications accepted by the central competent authority are as follows:

I. Prior evaluation of polymers of low concern, small quantity registration of new chemical substances, and phase 1 registration of existing chemical substances: seven working days from the date of receipt of the application.
II. Simplified registration of new chemical substances: 14 working days from the date of receipt of the application.
III. Standard registration of new chemical substances and business secret protection: 45 working days from the date of receipt of the application.

Where appropriate, the review periods pursuant to the previous paragraph may be extended. Registrants shall be notified of the extension. Extension is limited to one time only.

Article 27

The central competent authority shall review application documents for all applications accepted; should the review procedure find documents inadequate, mistaken, or unspecific, the central competent authority shall require the registrant to provide supplementation or correction within 30 working days commencing from the next day after receipt of the notice. The said notification of supplementation and correction shall be given only twice.

The application shall be rejected if the registrant fails to make supplementation or correction within the time limited, or fails to make the supplementation or correction within a given time period more than two times.

The duration for supplementation or correction shall be excluded from calculation of the review period pursuant to any subparagraph of the previous article.

Article 28

A registrant shall apply for modification of a registration document with related material under any one of following circumstances:

I. Changes to basic information related to a registrant;
II. Changes to use of the chemical substance

A modification application pursuant to subparagraph 1 shall be made within 30 working days upon receipt of documentary proof of company registration, business registration, factory registration, as well as other documentary proof issued by government authorities in charge of the subject industry; a modification application pursuant to subparagraph 2 of the previous paragraph shall be made within 30 working days of changes to the information.

If registration type for which modification is applied differs from the original registration document, a new registration application shall be submitted pursuant to the Regulations.

Article 29

If registrants who obtained chemical substance registration approval are found with any of the following circumstances, the central competent authority may void or revoke approval of the registration, and cancel their registration document and registration number.

I. Furnishing incorrect chemical substance registration information
II. Obtaining approval of chemical substance registration by fraud, coercion, or other improper means
III. Manufacturing or importing chemical substances by using or forging registration document or registration number that belongs to others
IV. Improper use of chemical substances reported by government authorities in charge of subject industry
V. Documentary proof of company registration, business registration, factory registration or other equivalent permission of business establishment has been voided or revoked by their competent authorities
VI. Dissolution or suspension of business
VII. Failing to make registration document modification pursuant to the previous article

Article 30

For chemical substances granted under registration having any of the following circumstances, the registrant shall provide supplementary information proactively or as prescribed by the central competent authority.

I. New scientific evidence on chemical substances
II. New information on toxicology and ecotoxicology of chemical substances
III. New information hazard assessment of chemical substances
IV. Other information designated by the central competent authority

Article 31

Registrants submitting all of the application pursuant to the Regulations shall pay a corresponding fee according to the fee standard set in the Act; the registrant shall submit the chemical substance information through the Internet transmission systems, registration tools, or forms designated by the central competent authority.

Information submitted through Internet transmission systems, registration tools, or forms

pursuant to previous paragraphs shall be written in Chinese. All foreign material shall have attached along with it a Chinese translation.

The central competent authority shall not accept any application if registrants fail to process registration pursuant to the previous 2 paragraphs. However, this requirement shall not apply to registrants who report to the central competent authority for its agreement.

Article 32

Registrants shall keep copies of all the information submitted and relevant verifying documents in written or electronic form for five years for recordkeeping and reference.

Information where business secrets are involved and information protection is applied for and approved by the central competent authority shall be kept in written or electronic form for 15 years for record and reference.

Article 33

The Regulations shall take effect on December 11th, 2014.

Appendix- Information Requirements of New Chemical Substances and Existing Chemical Substances Registration

Appendix 1- Standard Registration of New Chemical Substances-- Information Requirements *[1, 2, 3, 4, 5]

Section	Items
1. Basic identification of the registrant and substances	1.1 Information of the registrant 1.2 Substance identification
2. Substances manufacture, use and exposure information	2.1 Manufacture and importation 2.2 Use information 2.3 Exposure information
3. Hazards classification and labelling	3.1 Physical hazards 3.2 Health hazards 3.3 Environmental hazards 3.4 Labelling
4. Safe use information	4.1 First aid measures 4.2 Firefighting measures 4.3 Accidental release measures 4.4 Handling and storage 4.5 Transport information 4.6 Exposure controls / personal protection 4.7 Stability and reactivity 4.8 Disposal considerations
5. Physical and chemical properties	5.1 Physical state 5.2 Melting / freezing point 5.3 Boiling point 5.4 Density 5.5 Octanol/water partition coefficient 5.6 Water solubility 5.7 Vapor pressure 5.8 Flash point 5.9 Flammability 5.10 Explosive properties 5.11 Oxidation properties 5.12 pH value 5.13 Auto-ignition temperature

	5.14 Viscosity 5.15 Corrosive to metals
6. Toxicological information	6.1 Acute toxicity: oral, dermal, inhalation 6.2 Skin corrosion/irritation 6.3 Eye irritation 6.4 Skin sensitization 6.5 Genetic toxicity 6.6 Basic toxicokinetics 6.7 Repeat dose toxicity: oral, inhalation, dermal 6.8 Reproductive/Developmental toxicity 6.9 Carcinogenicity
7. Ecotoxicological information	7.1 Short-term toxicity testing on invertebrates (daphnia) 7.2 Toxicity to aquatic algae and cyanobacteria 7.3 Biodegradation in water: screening tests 7.4 Short-term toxicity testing on fish 7.5 Hydrolysis 7.6 Toxicity to microorganisms 7.7 Adsorption / desorption 7.8 Long-term toxicity testing on invertebrates (daphnia) 7.9 Long-term toxicity testing on fish 7.10 Toxicity to soil macroorganisms except arthropods 7.11 Toxicity to terrestrial organisms 7.12 Toxicity to soil microorganisms 7.13 Biodegradation in water and sediment: simulation test 7.14 Biodegradation in soil 7.15 Bioaccumulation: aquatic / sediment 7.16 Toxicity to sediment
8. Hazard assessment	8.1 Physicochemical-property-to-human-health hazard assessment 8.2 Health hazard assessment 8.3 Environmental hazard assessment 8.4 PBT and vPvB assessment
9. Exposure assessment	9.1 Exposure scenarios description 9.2 Exposure estimation 9.3 Risk characterization

Note:

1. Detailed information requirements shall refer to the content of the registration tool announced by the central competent authority.
2. Chemical substances annually manufactured or imported in volumes of one ton or more, but less than 1,000 tons, and do not meet definition of substance of carcinogenic, mutagenic or toxic for reproduction (CMR) Category 1 may be exempted from submission of Section 8-Hazard assessment and Section 9-Exposure assessment.
3. Chemical substances annually manufactured or imported in volumes of 1,000 tons or more and do not meet any of following conditions, may be exempted from submission of Section 9-Exposure assessment.
   (1) Human health hazardous physicochemical properties
   (2) Health hazardous
   (3) Environmental hazardous
   (4) Persistent, bioaccumulative and toxic (PBT)
   (5) Very persistent and very bioaccumulative (vPvB)
4. Chemical substances falling within definition of on-site isolated intermediates, polymers, scientific research and development, or product and process orientated research and development (PPORD) may be exempted from submission of Section 8-Hazard assessment and Section 9-Exposure assessment.
5. Submission of the aforesaid Section 5, 6, 7, 8, 9, physical and chemical properties, toxicological, eco-toxicological, hazard assessment, and exposure assessment information shall refer to respective registration information requirements of four levels, which is tabulated in the supplementary appendix below. In each level of registration information requirements, items marked with "V" should be submitted.

Supplementary Appendix * [a, b, c, d]

Section 5				
Physical and chemical properties	**I**	**II**	**III**	**IV**
Physical state	V	V	V	V
Melting / freezing point	V	V	V	V
Boiling point	V	V	V	V
Density	V	V	V	V
Octanol / water partition coefficient	V	V	V	V
Water solubility	V	V	V	V
Vapor pressure	V	V	V	V
Flash point	V	V	V	V
Flammability	V	V	V	V
Explosive properties	V	V	V	V
Oxidation properties	V	V	V	V

pH value	V	V	V	V
Auto-ignition temperature	V	V	V	V
Viscosity			V	V
Corrosive to metals			V	V
Section 6				
Toxicological Information	**I**	**II**	**III**	**IV**
Acute toxicity: oral, dermal, inhalation	V	V	V	V
Skin corrosion / irritation	V	V	V	V
Eye irritation	V	V	V	V
Skin sensitization	V	V	V	V
Genetic toxicity	V	V	V	V
Basic toxicokinetics		V	V	V
Repeat dose toxicity: oral, inhalation, dermal		V	V	V
Reproductive / Developmental toxicity		V	V	V
Carcinogenicity				V
Section 7				
Ecotoxicological Information	**I**	**II**	**III**	**IV**
Short-term toxicity testing on invertebrates (daphnia)	V	V	V	V
Toxicity to aquatic algae and cyanobacteria	V	V	V	V
Biodegradation in water: screening tests	V	V	V	V
Short-term toxicity testing on fish		V	V	V
Hydrolysis		V	V	V
Toxicity to microorganisms		V	V	V
Adsorption / desorption		V	V	V
Long-term toxicity testing on invertebrates (daphnia)			V	V
Long-term toxicity testing on fish			V	V
Toxicity to soil macroorganisms except arthropods				V
Toxicity to terrestrial organisms				V
Toxicity to soil microorganisms				V
Biodegradation in water and sediment: simulation test				V
Biodegradation in soil				V
Bioaccumulation: aquatic / sediment				V
Toxicity to sediment				V

Section 8				
Hazard assessment	**I**	**II**	**III**	**IV**
Physicochemical-property-to-human-health hazard assessment				V
Health hazard assessment				V
Environmental hazard assessment				V
PBT and vPvB assessment				V
Section 9				
Exposure Assessment	**I**	**II**	**III**	**IV**
Exposure scenarios description				V
Exposure estimation				V
Risk characterization				V

Note

a. Minimum information on physical and chemical properties, toxicology, and ecotoxicology shall be submitted for new chemical substances annually manufactured or imported based on annual tonnage manufactured/imported:

   i. Level I testing data shall be submitted for substances at tonnages of one ton or more, but less than ten tons per year;

   ii. Level II testing data shall be submitted for substances at tonnages of ten tons or more, but less than 100 tons per year;

   iii. Level III testing data shall be submitted for substances at tonnages of 100 tons or more, but less than 1,000 tons per year;

   iv. Level IV testing data shall be submitted for substances at tonnages of 1,000 tons or more.

b. For new chemical substances which meet the definition of on-site isolated intermediates, polymers, substances used for scientific research, or for product and process orientated research and development (PPORD) and in annual manufactured or imported volume of ten tons or more, the minimum information on physical/chemical properties and toxicological information may be requested referred to Level I testing data.

c. For new chemical substances that meet definition of carcinogenic, mutagenic or toxic to reproduction (CMR) Category 1, minimum information on physical and chemical properties, toxicological, and eco-toxicological shall be submitted:

   i. Level I testing data shall be submitted for substances in annual manufactured or imported volume of less than one ton;

ii. Level II testing data along with Section 8-Hazard assessment and Section 9-Exposure assessment shall be submitted for substances in annual manufactured or imported volume of one ton or more, but less than ten tons;

iii. Level III testing data along with Section 8-Hazard assessment and Section 9-Exposure assessment shall be submitted for substances in annual manufactured or imported volume of ten tons or more, but less than 100 tons;

iv. Level IV testing data along with Section 8-Hazard assessment and Section 9-Exposure assessment shall be submitted for substances in annual manufactured or imported volume of 100 tons or more.

d. Testing items in level I, II, III, IV testing data set of physical/chemical properties toxicological and eco-toxicological information shall be conducted according to registration tools and forms issued by the central competent authority.

Appendix 2- Simplified Registration of New Chemical Substances-- Information Requirements

Section	Items
1. Basic identification of the registrant and substances	1.1 Information of the registrant 1.2 Substance identification
2. Substances' manufacture, use and exposure information	2.1 Manufacture and importation 2.2 Use information 2.3 Exposure information
3. Hazards classification and labelling	3.1 Physical hazards 3.2 Health hazard 3.3 Environmental hazards 3.4 Labelling
4. Safe use information	4.1 First aid measures 4.2 Firefighting measures 4.3 Accidental release measures 4.4 Handling and storage 4.5 Transport information 4.6 Exposure controls / personal protection 4.7 Stability and reactivity 4.8 Disposal considerations
5. Physical and chemical properties	5.1 Physical state 5.2 Melting / freezing point 5.3 Boiling point 5.4 Density 5.5 Octanol / water partition coefficient 5.6 Water solubility

Note:

Detailed information requirements shall refer to the content of the registration tool announced by the central competent authority.

Appendix 3- Small Quantity Registration of New Chemical Substances--Information Requirements

Section	Items
1. Basic identification of the registrant and substances	1.1 Information of the registrant 1.2 Substance identification
2. Manufacture and use information	2.1 Manufacture and importation 2.2 Use information

Note:

Detailed information requirements shall refer to the content of the registration tool announced by the central competent authority.

Appendix 4- Information Indicated on the Registration Document for the New Chemical Substances

Information Items
1. Basic identification of the registrant
2. Name or a serial number of a new chemical substance
3. Registered uses
4. Type of registration
5. Date of registration and valid period of the registration document
6. Type of attached conditions

Appendix 5- Information Requirements of Phase 1 registration of the Existing Chemical Substances*[5]

Section	Items
1. Basic identification of the registrant	1.1 Type of the registrant 1.2 Full name of the company / organization 1.3 Company address 1.4 Telephone number, extension 1.5 Fax number 1.6 Industrial / commercial registration 1.7 Business Administration Number (BAN) 1.8 Name of the person responsible 1.9 Name of contact person 1.10 Telephone number of contact person 1.11 Email address of contact person 1.12 Consignor company*[1] 1.13 EMS administration number*[2]
2. Basic identification of the substance	2.1 CAS NO. or serial numbers*[3]
3. Substances manufacture and use information	3.1 Manufactured and imported quantities*[4] 3.2 Use information

Note:

1. If the registrant is an appointed notarized representative, company full name, country and address of the consignor company shall be provided.
2. If there is the EMS (Environmental Management System) administration number, it should be provided.
3. A serial number shall refer to a code assigned for an existing chemical substance listed in the national inventory of existing chemical substances established by the Ministry of Labor, where information confidentiality request has been approved, or the chemical substance has no CAS number.
4. The average annual volume in past three years right before an application, or the highest annual quantity right before an application (for manufacture or importation has been interrupted before an application).
5. Detailed information requirements shall refer to the content of the registration tool announced by the central competent authority.

Appendix 6- Phase-in Designated Standard Registration for the Existing Chemical Substances - Information Requirements*[1, 2, 3, 4, 5, 6]

Section	Items
1. Basic identification of the registrant and substances	1.1 Information of the registrant 1.2 Substance identification
2. Substances manufacture, use and exposure information	2.1 Manufacture and importation 2.2 Use information 2.3 Exposure information
3. Hazards classification and labelling	3.1 Physical hazards 3.2 Health hazards 3.3 Environmental hazards 3.4 Labelling
4. Safe use information	4.1 First aid measures 4.2 Firefighting measures 4.3 Accidental release measures 4.4 Handling and storage 4.5 Transport information 4.6 Exposure controls / personal protection 4.7 Stability and reactivity 4.8 Disposal considerations
5. Physical and chemical properties	5.1 Physical state 5.2 Melting / freezing point 5.3 Boiling point 5.4 Density 5.5 Octanol / water partition coefficient 5.6 Water solubility 5.7 Vapor pressure 5.8 Flash point 5.9 Flammability 5.10 Explosive properties 5.11 Oxidation properties 5.12 pH value 5.13 Auto-ignition temperature 5.14 Viscosity 5.15 Corrosive to metals
6. Toxicological information	6.1 Acute toxicity: oral, dermal, inhalation 6.2 Skin corrosion/irritation 6.3 Eye irritation

	6.4 Skin sensitization 6.5 Genetic toxicity 6.6 Basic toxicokinetics 6.7 Repeat dose toxicity : oral, inhalation, dermal 6.8 Reproductive / Developmental toxicity 6.9 Carcinogenicity
7. Ecotoxicological information	7.1 Short-term toxicity testing on invertebrates (daphnia) 7.2 Toxicity to aquatic algae and cyanobacteria 7.3 Biodegradation in water: screening tests 7.4 Short-term toxicity testing on fish 7.5 Hydrolysis 7.6 Toxicity to microorganisms 7.7 Adsorption / desorption 7.8 Long-term toxicity testing on invertebrates (daphnia) 7.9 Long-term toxicity testing on fish 7.10 Toxicity to soil macroorganisms except arthropods 7.11 Toxicity to terrestrial organisms 7.12 Toxicity to soil microorganisms 7.13 Biodegradation in water and sediment: simulation test 7.14 Biodegradation in soil 7.15 Bioaccumulation: aquatic / sediment 7.16 Toxicity to sediment
8. Hazard assessment	8.1 Physicochemical-property-to-human-health hazard assessment summary 8.2 Health hazard assessment summary 8.3 Environmental hazard assessment summary 8.4 PBT and vPvB assessment
9. Exposure assessment	9.1 Exposure scenarios description 9.2 Exposure estimation 9.3 Risk characterization

Note:

1. Detailed information requirements shall refer to the content of the registration tool announced by the central competent authority.
2. Chemical substances that do not meet definition of carcinogenic, mutagenic or toxic to reproduction (CMR) Category 1 and in annual manufactured or imported volumes of one ton or more, but less than 1,000 tons, may be exempted from submission of Section 8-Hazard

assessment and Section 9-Exposure assessment.

3. Chemical substances annually manufactured or imported in volumes of 1,000 tons or more and do not meet any of following conditions, may be exempted from submission of Section 9-Exposure assessment.
   (1) Human health hazardous physicochemical properties
   (2) Health hazardous
   (3) Environmental hazardous
   (4) Persistent, bioaccumulative, and toxic (PBT)
   (5) Very persistent and very bioaccumulative (vPvB)
4. Submission of the aforesaid Section 5, 6, 7, 8, 9, physical and chemical properties, toxicological, eco-toxicological, hazard assessment, and exposure assessment information shall refer to respective registration information requirements of four levels, which is tabulated in the supplementary appendix below. In each level of registration information requirements, items marked with "V" should be submitted.
5. The central competent authority may designate registration information to be submitted based on information collected from Phase 1 registration of existing chemical substances and international chemicals registration. Other requirements to be met shall refer to the registration tools announced by the central competent authority.
6. All of the co-registrants among joint registration pursuant to Article 21 of the Regulations shall submit information according to the registration tools announced by the central competent authority.

Supplementary Appendix*[a, b, c]

Section 5				
Physical and chemical properties	**I**	**II**	**III**	**IV**
Physical state	V	V	V	V
Melting / freezing point	V	V	V	V
Boiling point	V	V	V	V
Density	V	V	V	V
Octanol / water partition coefficient	V	V	V	V
Water solubility	V	V	V	V
Vapor pressure	V	V	V	V
Flash point	V	V	V	V
Flammability	V	V	V	V
Explosive properties	V	V	V	V
Oxidation properties	V	V	V	V
pH value	V	V	V	V
Auto-ignition temperature	V	V	V	V
Viscosity			V	V

Corrosive to metals			V	V
Section 6				
Toxicological Information	**I**	**II**	**III**	**IV**
Acute toxicity: oral, dermal, inhalation	V	V	V	V
Skin corrosion/irritation	V	V	V	V
Eye irritation	V	V	V	V
Skin sensitization	V	V	V	V
Genetic toxicity	V	V	V	V
Basic toxicokinetics		V	V	V
Repeat dose toxicity : oral, inhalation, dermal		V	V	V
Reproductive / Developmental toxicity		V	V	V
Carcinogenicity				V
Section 7				
Ecotoxicological Information	**I**	**II**	**III**	**IV**
Short-term toxicity testing on invertebrates (daphnia)	V	V	V	V
Toxicity to aquatic algae and cyanobacteria	V	V	V	V
Biodegradation in water: screening tests	V	V	V	V
Short-term toxicity testing on fish		V	V	V
Hydrolysis		V	V	V
Toxicity to microorganisms		V	V	V
Adsorption / desorption		V	V	V
Long-term toxicity testing on invertebrates (daphnia)			V	V
Long-term toxicity testing on fish			V	V
Toxicity to soil macroorganisms except arthropods				V
Toxicity to terrestrial organisms				V
Toxicity to soil microorganisms				V
Biodegradation in water and sediment: simulation test				V
Biodegradation in soil				V
Bioaccumulation: aquatic / sediment				V
Toxicity to sediment				V
Section 8				
Hazard assessment	**I**	**II**	**III**	**IV**
Physicochemical-property-to-human-health				V

hazard assessment				
Health hazard assessment				V
Environmental hazard assessment				V
PBT and vPvB assessment				V
Section 9				
Exposure Assessment	**I**	**II**	**III**	**IV**
Exposure scenarios description				V
Exposure estimation				V
Risk characterization				V

Note:

a. Minimum information on physical and chemical properties, toxicology, and ecotoxicology shall be submitted for existing chemical substances manufactured or imported per year based on annual tonnage manufactured/imported:
   i. Level I testing data shall be submitted for substances at tonnages of one ton or more, but less than ten tons per year;
   ii. Level II testing data shall be submitted for substances at tonnages of ten tons or more, but less than 100 tons per year;
   iii. Level III testing data shall be submitted for substances at tonnages of 100 tons or more, but less than 1,000 tons per year;
   iv. Level IV testing data shall be submitted for substances at tonnages of 1,000 tons or more.

b. For existing chemical substances that meet definition of carcinogenic, mutagenic or toxic to reproduction (CMR) Category 1, minimum information on physical and chemical properties, toxicological, and eco-toxicological shall be submitted:
   i. Level I testing data shall be submitted for substances in annual manufactured or imported volume of less than one ton;
   ii. Level II testing data along with Section 8-Hazard assessment and Section 9-Exposure assessment shall be submitted for substances in annual manufactured or imported volume of one ton or more, but less than ten tons;
   iii. Level III testing data along with Section 8-Hazard assessment and Section 9-Exposure assessment shall be submitted for substances in annual manufactured or imported volume of ten tons or more, but less than 100 tons;
   iv. Level IV testing data along with Section 8-Hazard assessment and Section 9-Exposure assessment shall be submitted for substances in annual manufactured or imported volume of 100 tons or more.

c. Testing items in level I, II, III, IV testing data set of physical/chemical properties toxicological and eco-toxicological information shall be conducted according to registration tools and forms issued by the central competent authority.

Appendix 7- Information Indicated on the Registration Document for Designated Standard Registration of the Existing Chemical Substances

Section	
1.	Basic identification of the registrant
2.	Name or serial number of existing chemical substances
3.	Designated phase for the existing chemical substance
4.	Registered use
5.	Date of registration