Amendments of Regulation of New and Existing Chemical Substances Registration (draft)

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 is 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 a National Identification Card, a copy of company registration, business registration, factory registration, or other documents verifying its establishment. A representative shall provide a notarized or certified 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 Occurs in Nature refers to a 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, or is extracted from air by any means, without chemical change in the substance; or for 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 that 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 percent weight or less. A monomer-based means of naming 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 or consumed in the course of the manufacture of another chemical substance.

IX. On-site Isolated Intermediates refers to intermediates that are produced or 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 for scientific or academic research.

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 substances or articles:

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; but constituents of mixtures shall be subject to the Regulations.

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

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

XIII. Fertilizers, as defined by the Fertilizer Management Act

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

XV. Medicaments, as defined by the Pharmaceutical Affairs Act

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

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

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

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

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

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

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

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

Raw materials as substances manufactured or imported in accordance with item XI to item XXIII as the above list shall be subject to in the Regulations.

Chapter 2 New Chemical Registration

Article 5

Manufacturers or importers, to apply for the new chemical registration approval, shall refer to the following registration type based on estimated annual manufactured or imported amount:

1. Small quantity registration: less than 100 kilograms.
2. Simplified registration: 100 kilograms or more, but less than 1 ton.
3. Standard registration: 1 ton or more.

If a new chemical substance to be manufactured or imported, falls under any of the following circumstances, its registration type shall be selected by referring to the estimated annual manufactured or imported quantity as specified in Appendix 1.

1. A substance used for Scientific Research and Development.
2. A substance used for Product and Process Orientated Research and Development, PPORD.
3. On-site Isolated Intermediates.
4. Polymers.
5. Polymer of Low Concern(PLC).

A registrant, to apply for the registration of Polymer of Low Concern pursuant to subparagraph 5 of the preceding paragraph, shall first submit a prior verification application to the central competent authority. Once the application is reviewed and verified, the registrant may select the registration type in accordance with the preceding paragraph.

Article 6

The registration types and the corresponding registration information items, specified as follows:

1. Standard registration as specified in Appendix 2.

2. Simplified registration as specified in Appendix 3.

3. Small quantity registration as specified in Appendix 4.

Article 7

The central competent authority may demand a manufactured or imported new chemical substance be subject to the standard registration if it is identified as a substance that is carcinogenic, mutagenic, or toxic to reproduction; regardless if it is entitled to the simplified registration or the small quantity pursuant to the preceding 2 articles.

Article 8

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, a registrant shall register this new chemical substance by submitting the information items in accordance with the Regulations. The following documents shall be submitted to the central competent authority:

1. Registration form for scientific research and development (SRD), product and process orientated research and development (PPORD).
2. Nanoscale chemical substances registration form.

Article 9

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 to 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 possibility that toxicological characteristics of the new chemical substances conform to the definitions of Class 1, Class 2, or Class 3 of toxic chemical substances, according to the Act.

Upon reviewing the new chemical substance information submitted by a registrant, the central competent authority shall approve the registration along with conditions to restrict its handling, and to 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 10

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

The new chemical substance, subjected to the joint registration pursuant to the preceding paragraph, is to be registered according to the Regulations, which the overall quantity of the joint registration shall be the summation of the individual quantities from each co-registrant.

By taking into account the overall manufactured or imported quantity of the new chemical substances registered and approved, the central competent authority may require registrants to apply for the new registration under the designated registration type, or apply for the joint registration.

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

Article 11

The central competent authority approves and issues the registration number for a new chemical substance registered.

Article 12

The valid periods of the new chemical substance registration approval are as follows:

I. The standard registration is valid for 5 years.

II. The simplified registration and small quantity registration are valid for 2 years.

III. The PLC small quantity registration in accordance with Article 5 Paragraph 2 is valid for 5 years.

Article 13

A registrant, to extend the valid period of the registration approval, shall make an application three months before its expiration. Information on estimated quantity of new chemical substances manufactured or imported for next year shall be submitted to the central competent authority. The aforementioned

extension application requires approval by the competent authority.

If the registration type intended for extension is inconsistent with the originally approved registration, a new application of registration shall be made according to the Regulations.

Article 14

A new chemical substance registered and approved in any one of following circumstances may 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 5.

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 registered and approved, meets any of the following situations:

I. Standard registration that has been completed and filed through submission of information on hazard assessment and exposure assessment.

II. PLC registration that has been completed and filed.

A new chemical substance registered and approved, which has been included in the inventory of existing chemical substances pursuant to the provisions of the preceding two paragraphs, is subject to the related rules of registered and approved existing chemical substance.

Chapter 3 Existing Chemical Registration

Article 15

An existing chemical substance manufactured or imported shall be applied for the phase 1 registration by attaching chemical information, as specified in Appendix 5, from September 1st, 2015, to March 31st, 2016, if its annual average volume over the past three consecutive years prior to the 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 the phase 1 registration number to a registrant whose registration application is approved.

Article 16

After April 1st, 2016, for an existing chemical substance first manufactured or imported in annual volume of 100 kilograms or more, a registrant shall, within 6 months from the date of occurrence of the fact, apply for the phase 1 registration and attach chemical information, as specified in Appendix 6. No existing chemical substance shall be manufactured or imported, unless the registration approval is obtained within the specified time period.

The central competent authority is to issue a phase 1 registration number to a registrant whose registration application is approved, pursuant to the preceding paragraph.

A registration may be made for existing chemical substances, which are manufactured or imported in annual volume less than 100 kilograms, in accordance with the preceding paragraph 1. After the registration application is approved, the above mentioned existing chemical substances are subject to the Regulation.

Article 17

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

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

Appendix 7 within the deadline announced.

Article 18

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

The registrant, to apply for the joint registration pursuant to the previous paragraph, shall register the chemical substance by submitting information 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 co-registrants. Then the registered information can be used after the shared cost has been paid.

Article 19

The central competent authority issues registration number to those who apply and complete chemical substance registration pursuant to the provisions of the previous two articles.

Chapter 4 Information Dissemination and Business Secret Protection

Article 20

Chemical substance information registered and approved 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 21

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, in any of the following conditions:

I. Application of the new chemical substance registration.

II. Application of the existing chemical substance phase 1 registration.

III. Application of the existing chemical substance standard registration.

IV. Three to six months prior to the application of inclusion in inventory of existing chemical substances pursuant to Article 14.

A registrant, who does not apply for secret information protection for a chemical substance registered and approved pursuant to the previous paragraph, may state the reasons, with proof documents conforming to Paragraph 2, and apply to the central competent authority for information protection after submitting the registration application.

Article 22

A chemical substance that has been registered and approved has the confidentiality periods specified as follows:

I. Existing chemical substance phase 1 registration, standard registration, and PLC small quantity registration: confidentiality is to be valid for 5 years from the date of registration approval.

II. Simplified registration or small quantity registration: confidentiality is to be valid for 2 years from the date of registration approval.

III. New chemical substances, which are included in the inventory of existing chemical substances in accordance with Article 14: confidentiality is to be valid for 5 years from the date of registration approval.

Except for the existing chemical substance registered under the phase 1 registration, pursuant to subparagraph 1 of the previous paragraph, the duration of confidentiality is the same as the validity period for the corresponding registration types.

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

A maximum duration of information protection for a chemical substance registered, pursuant to the previous paragraph, is 15 years; but for the new chemical substances, which are included in the inventory of existing chemical substances pursuant to Article 14, the maximum duration of the protection on the chemical identification is 10 years.

Article 23

The central competent authority shall notify the registrant when chemical substance information is publicly disseminated in accordance with Article 41 Paragraph 2 of the Act.

Chapter 5 Supplementary Provisions

Article 24

The central competent authority may provide the information of the registered new chemical substances and existing chemical substances to the government authorities in charge of the subject industry to manage chemical substances used in the subject industry.

A registrant selling or transferring new or existing chemical substances shall provide the information on safe use and other identifiable labels as granted under the Registrations.

Article 25

For the registered new and existing chemical substances, the registrant shall, starting from 2019 January 1st, during the period from March 1st to June 31st of each year, submit a report on the manufactured or imported quantity of the previous year for the new chemical substance, or the existing chemical substance, in accordance with Appendix 8.

The report, pursuant to the previous paragraph, shall be submitted via the internet transmission systems, designated by the central competent authority. However, a report in writing may be submitted with the consent of the central competent authority.

Article 26

The review periods of all the applications accepted by the central competent authority in the Regulations are as follows:

I. New chemical substances small quantity registration, PCL prior verification, PCL small quantity registration, existing chemical substance phase 1 registration, chemical information protection and corresponding extension: 7 working days from the date of receipt of the application.

II. New chemical substances simplified registration: 14 working days from the date of receipt of the application.

III. New chemical substances standard registration: 45 working days from the date of receipt of the application.

IV. Existing chemical substances standard registration: 90 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 under the Regulations; 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. However, if the failure to provide supplementation or correction within this limited period is caused by scientific or technical factors, this requirement shall not apply to registrants who report to the central competent authority for its consent.

The review periods, pursuant to any of the subparagraphs in the previous Article, shall be calculated anew from the date that the central competent authority accepts the supplementation or correction provided by the registrant pursuant to the previous paragraph.

The application pursuant to the previous paragraph 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.

Article 28

A registrant shall apply for modification when adding additional information to the application for chemical substance registration within 30 working days of changes to the information.

If the additional information pursuant to the previous paragraph involves the basic information related to a registrant, a modification application shall be made within 30 working days of changes 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.

If the registration type for which modification is applied differs from the original registration approved, 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 numbers.

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 numbers 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.

Article 30

For chemical substances registered and approved 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

If a registrant has any concerns regarding the result of registration review, a written appeal with stated reasons may be submitted within 30 working days from the next day the notice of the review result is received.

The appeal pursuant to the previous paragraph shall be made once only.

Article 32

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 consent.

Article 33

Registrants shall keep copies of all the information submitted and relevant verifying documents in written or electronic form for 5 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 34

The Regulations shall come into force upon the date of promulgation.

Amendments Appendixes of Regulation of New and Existing Chemical Substances Registration (draft)

Appendix 1-Registration Application Type for Chemical Substance by Estimated Annual Manufactured or Imported Quantity and Chemical Characteristics

Annual Manufactured or Imported Volume	**Scientific Research and Development**	**Process Orientated Research and Development, PPORD**	**On-site Isolated Intermediates**	**Polymer**	**Polymer of Low Concern (Prior Verification needed)**
Less than 1 ton	Exemption[*a]	Small Quantity Registration	Small Quantity Registration	Small Quantity Registration	Exemption
1 ton or more, but less than 10 tons	Simplified Registration	Simplified Registration	Simplified Registration	Simplified Registration	Small Quantity Registration
10 tons or more	Standard Registration	Standard Registration	Standard Registration	Standard Registration	

Note:

An academic organization is not required to submit documentation to the central competent authority for record and reference, if the new substance is used for any scientific experimentation, education, analysis, or chemical research carried out under strictly controlled conditions. However, as a chemical used in business premises, for the purpose of research and development, (including for research, analysis, sampling, or testing, etc.), submission of documentation to the central competent authority must be made for record and reference.

Appendix 2- Standard Registration of New Chemical Substances—Information Items *[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 1 ton or more, but less than 10 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 10 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 to Section 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	V	V

Health hazard assessment		V	V	V
Environmental hazard assessment		V	V	V
PBT and vPvB assessment		V	V	V
Section 9				
Exposure Assessment	**I**	**II**	**III**	**IV**
Exposure scenarios description		V	V	V
Exposure estimation		V	V	V
Risk characterization		V	V	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 1 ton or more, but less than 10 tons per year;

ii. Level II testing data shall be submitted for substances at tonnages of 10 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 10 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 1 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 1 ton or more, but less than 10 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 10 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 3- Simplified Registration of New Chemical Substances--Information Items

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 4- Small Quantity Registration of New Chemical Substances-- Information Items

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 5- Phase 1 Registration of the Existing Chemical Substances -Information Items *[5] -1

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 3 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 1 Registration of the Existing Chemical Substances -Information Items*[5] -2

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 manufacture and import volume at the time of application.
5. Detailed information requirements shall refer to the content of the registration tool announced by the central competent authority.

Appendix 7- Standard Registration for the Existing Chemical Substances - Information Items*[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 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 1 ton or more, but less than 10 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 10 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 to Section 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 18 of the Regulations shall submit information according to the registration tools announced by the central competent authority.

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	V	V
Health hazard assessment		V	V	V
Environmental hazard assessment		V	V	V
PBT and vPvB assessment		V	V	V
Section 9				
Exposure Assessment	**I**	**II**	**III**	**IV**
Exposure scenarios description		V	V	V
Exposure estimation		V	V	V
Risk characterization		V	V	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 1 ton or more, but less than ten tons per year;

   ii. Level II testing data shall be submitted for substances at tonnages of 10 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 as follows:

   i. Level I testing data shall be submitted for substances in annual manufactured or imported volume of less than 1 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 1 ton or more, but less than 10 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 10 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 8- New Chemical Substances and Existing Chemical Substances Reporting Requirement

Section	Items
1. Registrant and registration number	1.1 Information of the registrant 1.2 Approved registration number
2. Quantity of Substances Manufactured and imported	2.1 Manufactured quantity 2.2 Imported quantity

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