Content

Title：	Regulations of New and Existing Chemical Substances Registration Ch
Date：	2021.11.23
Legislative：	The original 33 articles were promulgated by Order of the Environmental Protection Administration, Executive Yuan on December 4, 2014 and took into force from December 11, 2014. The full 33 articles were amended and promulgated by Order of the Environmental Protection Administration, Executive Yuan on March 11, 2019. The full 32 articles were amended and promulgated by Order of the Environmental Protection Administration, Executive Yuan on November 23, 2021.

Content：

Chapter 1 General Principles

Article 1

These Regulations are stipulated pursuant to Article 30, paragraph 5 of the Toxic and Concerned Chemical Substances Control Act (hereinafter "this 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 body, who may be the subject of rights and obligations under other laws, that is subject to chemical substances registration pursuant to Article 30 of this Act.

A registrant may appoint a representative to process the application and/or reporting affairs covered in the Regulations. The representative should be a natural person possessing the nationality of the Republic of China (R.O.C.), or a juristic person, an institute or an organization that is constituted or registered by law.

When applying for chemical substances 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 the registrant's 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 additives necessary to preserve its stability and any unintended constituents deriving from the processes 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 naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means without any chemical changes, or a large molecule from living organisms or natural polymer obtained without chemical processing.

III. "Mixture" refers to a mix or solution composed of two or more substances which do not react.

IV. "Article" refers to an object which during production is given a specific shape or design.

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 containing at least three monomer units that are covalently bound to at least one other monomer unit; such molecules account for 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; and

C. Differences in the molecular weight are primarily attributable to differences in the number of monomer units.

VI. "Polymer to which the 2% Rule is applicable" refers to monomers or reactants of polymer that are not regarded as part of the polymer when the weight percentage of the monomers or reactants is less than 2%; if the naming of the polymer is a monomer-based representation, it may or may not include monomers and other reactants used at less than 2% weight. A monomer-based representation means the naming of polymer is based on constituent monomers.

VII. "Polymer of Low Concern" (PLC) refers to a chemical substance that is evaluated by the central competent authority and fulfills any one of the following conditions:

A. Polymer with an average molecular weight in a range of 1,000 to 10,000 Daltons, containing oligomers of molecular weights below 500 Daltons in an amount less than 10% and oligomers of molecular weights below 1,000 Daltons in an amount less than 25%;

B. Polymer with an average molecular weight over 10,000 Daltons, containing oligomers of molecular weights below 500 Daltons in an amount less than 2% and oligomers of molecular weights below 1,000 Daltons in an amount less than 5%;

C. Polyester; or

D. Insoluble polymer.

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

IX. "On-site Isolated Intermediate" refers to an intermediate that is produced and consumed on the same site.

X. "Incidental Reaction Product" refers to a chemical substance resulting from a chemical reaction induced by any change in environmental condition during the use and the storage of the original chemical substance.

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

XII. "Scientific Research and Development" (SRD) 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 plants or production trials are used to develop the production process or to test the fields of application of the substance.

XIV. "Substance classified as Carcinogenic, Mutagenic or Toxic for Reproduction (CMR)" refers to a substance that is classified as carcinogenicity category 1, mutagenicity category 1, or reproductive toxicity category 1, based on the R.O.C. National Standards (CNS) 15030.

XV. "Chemical Substance under Customs Supervision" refers to a chemical substance under customs supervision, which is temporarily

stored or placed in a harbor's designated area, 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 items:

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 security or national defense purposes

V. Chemical substances under customs supervision

VI. Chemical waste produced or released from industrial processes

VII. Incidental reaction products or impurities that are of no commercial application

VIII. Mixtures, but individual constituents of mixtures shall not be applied to this Article

IX. Articles

X. Polymer to which the 2% Rule is Applicable and is listed on the inventory of existing chemical substances

The Regulations shall not apply to the substances or items regulated under the following Acts promulgated by the government authorities:

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

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

III. Fertilizers, as defined by the Fertilizer Management Act

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

V. Medicaments, as defined by the Pharmaceutical Affairs Act

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

VII. Cosmetics, as defined by the Cosmetic Hygiene and Safety Act

VIII. Foods, food additives, food utensils, food containers or packaging, and food cleansers, as defined by the Act Governing Food Safety and Sanitation

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

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

XI. Radioactive materials, as defined by the Atomic Energy Act and the Ionizing Radiation Protection Act

XII. Industrial use explosive materials, as defined by the Industrial Explosives Administrative Act

XIII. Controlled chemicals as prescribed in the Occupational Safety and Health Act

XIV. Chemical substances regulated by the Montreal Protocol under the Air Pollution Control Act

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

XVI. Toxic and concerned chemical substances, as defined by this Act

For a chemical substance manufactured or imported as a raw material in the preceding paragraph, the chemical substance shall be subject to the provisions of the Regulations.

Chapter 2 New Chemical Substances Registration

Article 5

To apply for new chemical substances registration approval, manufacturers or importers shall refer to the following registration types based on estimated annual manufactured or imported quantity:

I. Standard registration: at 1 ton or more

II. Simplified registration: at 100 kilograms or more, but less

than 1 ton

III. Small quantity registration: less than 100 kilograms

If the uses or properties of a new chemical substance to be manufactured or imported meets 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.

I. A substance used for the purpose of SRD

II. A substance used for the purpose of PPORD

III. An On-site Isolated Intermediate

IV. Polymer

V. Prior verified Polymer of Low Concern, PLC

Article 6

The quantity thresholds for standard registration are specified in Appendix 2.

The registration information items of each registration type are specified as follows:

I. Standard registration: as specified in Appendixes 3 and 4

II. Simplified registration: as specified in Appendix 5

III. Small quantity registration: as specified in Appendix 6

Article 7

For a manufactured or imported new chemical substance undergoing application for simplified registration or small quantity registration pursuant to the previous two Articles, the central competent authority may demand the registrant to register data in accordance with the requirements of standard registration if the new chemical substance is identified as a CMR substance.

Article 8

For a new chemical substance meeting the circumstances of being a substance used for the purposes of SRD or PPORD; or having other special forms, in addition to registering the new chemical substance in accordance with the required information items of the Regulations, the registrant shall fill in and submit the following documents to the central competent authority:

I. Registration form for SRD and PPORD

II. Registration form for nanoscale chemical substances

Article 9

Upon reviewing information of a new chemical substance submitted by a registrant, the central competent authority shall approve the registration along with an incidental provision to prohibit or restrict handling, and shall require the registrant to regularly report handling conditions, update registration report data, or submit chemical substances hazard information, if the central competent authority determines that there is a concern over the toxicological characteristics of a new chemical substance conforming to the definitions of Class 1, Class 2, or Class 3 toxic chemical substances.

Upon reviewing information of a new chemical substance submitted by a registrant, the central competent authority shall approve the registration along with an incidental provision to restrict handling, and shall require the registrant to submit information on exposure assessment and risk assessment, update registration report data, or submit chemical substances hazard information, if the central competent authority determines that there is a concern of environmental pollution or any threat to human health.

Article 10

When different registrants apply to register the same new chemical substance jointly or sequentially, they may use common data needed for the registration through consultation.

The new chemical substance, subjected to the joint registration pursuant to the preceding paragraph, is to be registered according to the Regulations,

for which the overall quantity of the joint registration shall be the sum 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 to apply for joint registration.

For a joint registration that is agreed upon by co-registrants, but for which no agreement has been reached on the cost sharing of the registration data, the central competent authority may determine an average apportionment at the request of the application's registrants. The registration data can be used after the registrants have paid their respective shares of expenses according to the decision made by the central competent authority.

Article 11

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

Article 12

The valid period of the new chemical substances registration approval is 5 years.

Upon agreements for the joint registration for early and late registrants, the valid periods of such joint registration for the late registrants shall be consistent with those periods for the early registrants.

Article 13

A registrant, to extend the valid period of the registration approval, shall make an application to the central competent authority three to six months prior to its expiration. Information on estimated quantity of new chemical substances manufactured or imported for the following year shall be submitted to the central competent authority at the same time. Upon approval of the central competent authority, the extension shall be granted pursuant to the previous Article.

If the central competent authority is unable to make the rejection/approval decision for the extensions before the original approval registration expires, those who file the extension application pursuant to the preceding paragraph may continue to manufacture or import the new chemical substances, in compliance with the situation specified in the originally approved registration, until the review is completed.

If the central competent authority is unable to make the rejection/approval decision for the extensions before the original approval registration expires, those who fail to file the extension application pursuant to paragraph 1 shall stop manufacturing or importing the new chemical substances after the original approval registration expires. If a registrant does not apply for an extension before the original approval registration expires, the original approval registration becomes ineffective exactly on the following day of the expiration day specified in the original approval registration. A new application for registration shall be made in order to continue manufacturing or importing such chemical substances.

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

Article 14

A new chemical substance registered and approved under 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 5 years after the standard registration is filed and completed;

II. It shall be at least 5 years after the PLC registration is filed and completed in accordance with the small quantity registration; or

III. A new chemical substance becomes a toxic or concerned chemical

substance announced by the central competent authority.

A registrant may apply for inclusion in the inventory of existing chemical substances, when a new chemical substance has been registered and approved for any of the following registrations:

I. Standard registration filed and completed through submission of information on hazard assessment and exposure assessment, or

II. PLC registration in accordance with the small quantity registration.

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 substances.

Chapter 3 Existing Chemical Substances Registration

Article 15

For an existing chemical substance first manufactured or imported in annual quantity 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 information, as specified in Appendix 7. No existing chemical substance shall be manufactured or imported, unless the registration approval is obtained within the specified 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.

Registration for existing chemical substances, manufactured or imported in annual quantity less than 100 kilograms, may be made in accordance with paragraph 1. After the registration application is approved, the abovementioned existing chemical substances are subject to the Regulations.

Article 16

The central competent authority may, by stages, designate the lists of existing chemical substances subject to standard registration, including the names of the chemical substances, quantity thresholds and deadlines for registration, based on the circumstances of the phase 1 registration of existing chemical substances.

The quantity thresholds subject to the standard registration of existing chemical substances designated by stages pursuant to the previous paragraph are specified in Appendix 8, whereas the designated lists and deadlines are specified in Appendix 9.

Registrants manufacturing or importing any existing chemical substances listed in Appendix 9 shall apply for the standard registration of such existing chemical substances and attach information, as specified in Appendixes 3 and 4.

On-site isolated intermediates may be exempted from needing an application for the standard registration of existing chemical substances pursuant to the provisions of the preceding three paragraphs.

Registrants manufacturing or importing existing chemical substances, which are not any of the chemical substances listed in Appendix 9 or do not meet the quantity thresholds in Appendix 8, may apply for the registration of chemical substances pursuant to paragraph 3.

Article 17

When different registrants, pursuant to Article 16, paragraphs 2 or 5, apply to register the same existing chemical substance jointly or sequentially, they may use common data needed for the registration through consultation.

The existing chemical substance, subjected to the joint registration pursuant to the preceding paragraph, is to be registered according to Article 16, paragraph 3.

For a joint registration that is agreed upon by co-registrants, but for which no agreement has been reached on the cost sharing of the registration data, the central competent authority may determine an average apportionment at the request of the application’s registrants. The registration data can be used after the share of expenses has been paid.

Article 18

The central competent authority issues the completion number for the standard registration of an existing chemical substance to those who apply and complete information registration specified in Appendix 3 pursuant to the provisions of the previous two Articles.

Upon acquisition of the completion number as described in the previous paragraph, the registrant shall complete information registration specified in Appendix 4 proactively or before the due date decided by the central competent authority.

Chapter 4 Information Dissemination and Protection of Business Secrets

Article 19

Information on chemical substances registered and approved by the central competent authority shall be disseminated to the public. The information items which shall be disseminated are as follows:

I. Registrant information
II. Names of chemical substances
III. Manufacture or import conditions
IV. Classification and labelling
V. Guidance on safe use
VI. Physical and chemical properties
VII. Toxicological and ecotoxicological information
VIII. Hazard assessment
IX. Exposure assessment

The content pursuant to the previous paragraph shall be publicly disseminated through the Internet by the central competent authority.

Article 20

Information on chemical substances that is registered, which involves confidential matters on national defense or business secrets, shall be kept confidential.

The aforementioned business secrets shall conform to the following conditions:

I. They are not known to persons generally involved in information of this type;
II. They have economic value, actual or potential, due to their secretive nature; and
III. The owners have taken reasonable measures to maintain their secrecy.

For registered information determined to be business secrets pursuant to paragraph 1, the following shall be protected and kept confidential:

I. Registrant information
II. Substance identification
III. Information on manufacturing and importing
IV. Life cycle description

A registrant may apply for protection of confidential information with supporting documentation conforming to paragraph 2, on any of the following occasions:

I. Application for the registration of a new chemical substance,
II. Application for the phase 1 registration of an existing chemical substance,
III. Application for the standard registration of an existing chemical substance, or
IV. Application for the inclusion in the inventory of existing chemical substances pursuant to Article 14.

A registrant who does not apply for protection of confidential information regarding a chemical substance that is registered and approved pursuant to the previous paragraph may state the reasons for confidentiality, provide supporting documentation conforming to paragraph 2, and apply to the central competent authority for protection of confidential information when filing an extension application for a

registered new chemical substance, or after the registration is approved for an existing chemical substance.

Article 21

The confidential period of the information on chemical substances approved by the central competent authority is valid for 5 years.

Except for the existing chemical substances, the confidential period pursuant to Article 20, paragraph 5 expires as the valid period for the corresponding registration expires.

A registrant may apply for extension of a confidential period specified in paragraph 1 three to six months prior to expiry of the period.

The maximum confidential period for a new chemical substance is 15 years; for an existing chemical substance, the maximum confidential period is 10 years. For a new chemical substance that has been included in the inventory of existing chemical substances, the maximum confidential period is 15 years.

Article 22

The central competent authority shall notify the registrants when information on chemical substances is publicly disseminated in accordance with Article 69, paragraph 2 of this Act.

Chapter 5 Supplementary Provisions

Article 23

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

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

Article 24

For registered new and existing chemical substances, the registrant shall, starting from the following year after the registration is approved, submit a report annually on the manufactured or imported quantity in the previous year for the new or existing chemical substances, in accordance with Appendix 10, between April 1 and September 30.

Where the information reported by the registrant is incomplete as determined by the central competent authority, the central competent authority shall notify the registrant to make a correction within a prescribed period. Where the registrant fails to do so or the correction fails to meet the requirements, the central competent authority shall impose an administrative penalty in accordance with this Act.

The report and correction, pursuant to the previous two paragraphs, shall be submitted via the Internet transmission system designated by the central competent authority. However, a report or correction in writing may be submitted with the consent of the central competent authority.

Article 25

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, PLC prior verification, PLC small quantity registration, existing chemical substances phase 1 registration, protection of confidential information, and corresponding extension: 7 working days from the date of receipt of the application

II. New chemical substances simplified registration and the inclusion in the inventory of existing chemical substances: 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

The review periods for small quantity registration and simplified registration may be extended to 45 working days when the registration applications satisfy the conditions in Article 9.

The central competent authority shall notify the registrants if the review periods of the previous two paragraphs are extended. The number of extensions is limited to one.

Article 26

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 a correction within 30 working days from the date of receiving the notification from the central competent authority. The said corrections shall be given only twice. However, if the failure to provide a 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 and obtain 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 receives the correction submitted by the registrant pursuant to the previous paragraph.

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

Article 27

A registrant shall apply for changes to the registered information on chemical substances proactively or within 30 working days from the date of receiving the notification from the central competent authority.

If the change pursuant to the previous paragraph involves basic information related to a registrant, an application for change shall be made within 30 working days from receiving approval for change of company registration, business registration, factory registration, as well as other documentary proof issued by the industry competent authorities. An application for change of a designated responsible person to the registered information shall be made within 60 working days after the change in the designated responsible person approved by the industry competent authorities.

If the registration type for which a change is applied differs from the original registration type that has been approved, a new registration application shall be submitted.

Under any of the following circumstances, the registrant may file an application to the central competent authority for a revocation of an approval registration and a cancellation of the corresponding registration number:

I. A new registration has been submitted and approved pursuant to the preceding paragraph; or

II. A chemical substance with registration approval is no longer being manufactured or imported.

Article 28

If registrants who obtained chemical substances registration approval are found with any of the following circumstances, the central competent authority may withdraw or revoke approval of the registration and cancel their registration numbers:

I. False registration information;

II. Obtaining approval of chemical substances registration by fraud, coercion, or other improper means;

III. Manufacturing or importing chemical substances by using or forging registration numbers that belong to others;

IV. Improper use of chemical substances reported by the industry competent authorities;

V. Documentary proof of company registration, business

registration, factory registration, or other equivalent permission of business establishment that has been withdrawn or revoked by the industry competent authorities; or
VI. Dissolution or termination of business.

Article 29

For chemical substances registered and approved under any of the following circumstances, the registrant shall provide supplementary information proactively or before the due date decided by the central competent authority:
I. New scientific evidence on chemical substances,
II. New information on the uses of chemical substances,
III. New information on toxicology or ecotoxicology of chemical substances,
IV. New information on hazard assessment or exposure assessment of chemical substances, or
V. Other information designated by the central competent authority.

Article 30

If a registrant has any concerns regarding the result of registration review, written appeal with stated reasons may be submitted within 30 working days from receiving the notification of the review result.

The number of appeals pursuant to the previous paragraph shall be only one.

Article 31

Registrants submitting all of the applications pursuant to the Regulations shall pay a corresponding fee according to the fee-charging standards set for this Act; the registrants shall submit the information on chemical substances via the Internet transmission system designated by the central competent authority.

The information as prescribed in the previous paragraph shall be written in Chinese. All foreign materials shall be written in English or in other foreign languages with a Chinese or English edition attached.

The central competent authority shall not accept any application if registrants fail to process their registration pursuant to the previous two paragraphs. However, this requirement shall not apply to registrants who report to the central competent authority and obtain its consent.

Article 32

The Regulations take into force upon the date of promulgation.

Files： Regulations of New and Existing Chemical Substances Registration.pdf

Attachments： Appendix 1.pdf
Appendix 2.pdf
Appendix 3.pdf
Appendix 4.pdf
Appendix 5.pdf
Appendix 6.pdf
Appendix 7.pdf
Appendix 8.pdf
Appendix 9.pdf
Appendix 10.pdf