

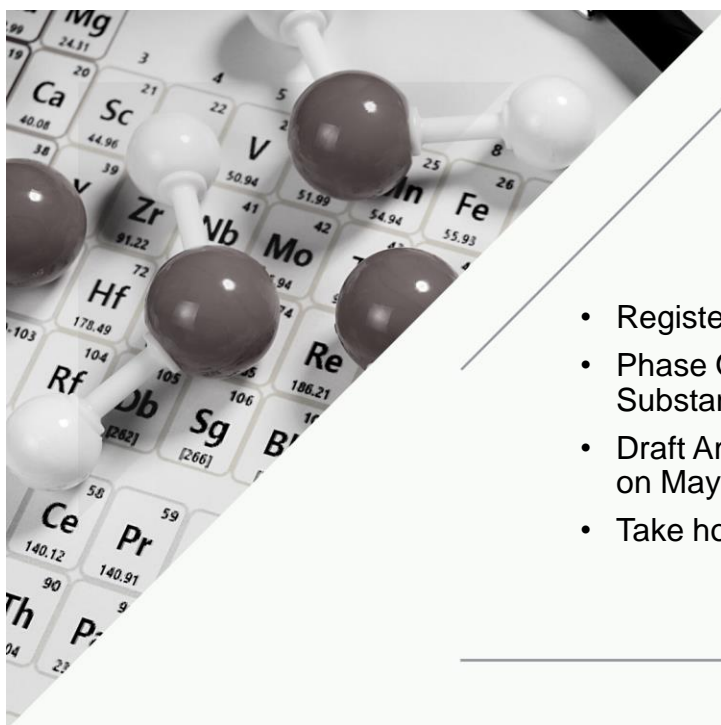
Draft Amendment to Taiwan's New and Existing Chemical Substances Registration Regulation



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Summary of Topics

- Register Substances in Taiwan
- Phase One Registration and Priority Existing Substances (PECs) Registration
- Draft Amendment to Registration (published on May 27th)
- Take home message



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Chemical Regulations in Taiwan:

Chemicals at Workplace: The Ministry of Labor

Occupational
Safety and Health
Act(OSHA);



Hazard
Communication
(GHS)

Priority
Management
Chemicals

Controlled
Chemicals

Industrial Chemicals: Environmental Protection Administration (EPA)

Toxic and Concerned
Chemical Substance
Control Act
(TCCSCA)



Class 1,2,3, and 4 of
Toxic Substances

Concerned
Substances



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Toxic and Concerned Chemical Substance Control Act

- Toxic and Concerned Chemical Substance Control Act (TCCSCA),
 - enacted on 16 January 2019
 - amended, and renamed from Toxic Chemical Substance Control Act (TCSCA)
 - Regulation on New and Existing Chemical Substances Registration (March 2019)
 - enforced since 1st January 2020
- On May 27, 2021: Taiwan's EPA proposed an amendment to the Regulation on New and Existing Chemical Substances.
 - open for public consultation until July 26.



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After January 16th 2019

Toxic Chemicals Substances Control Act (TCSCA)

Chapter 1
General Principles

Chapter 2
Hazard Assessment and Prevention

Chapter 3
Management

Chapter 4
Panel Provisions

Chapter 5
Supplementary Provisions



Toxic and Concerned Chemicals Substances Control Act (TCCSCA)

Chapter 1 General Principles (§ 1-7)

Chapter 2 Assessment, Prevention and Management of Toxic Chemical Substances (§ 8-23)

Chapter 3 Assessment, Prevention and Management of Concerned Chemical Substances (§ 24-29)

Chapter 4 Registration and Reporting of Chemical Substances (§ 30-34)

Chapter 5 Accident Prevention and Emergency Response (§ 35-43)

Chapter 6 Audit, Inspection, and Financial Matters (§ 44-49)

Chapter 7 Penal Provisions (§ 50-67)

Chapter 8 Supplementary Provisions (§ 68-75)



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Registration: Exemption

- Substances which occur in nature.
- Chemical substances in machines or equipment for test run purposes.
- Inseparable intermediates from chemical reactions in the reaction vessel or production process.
- Chemical substances for national security or national defense purposes.
- Chemical substances under customs supervision.
- Chemical wastes produced or released from industrial process.
- By-products or impurities that are of no commercial application.
- **Mixtures**; but individual constituents of mixtures shall not be applied to the Article.
- Articles
- **Polymers that the 2% Rule is Applicable** and listed on the inventory of existing chemical substances.

- Agro-pesticides, as defined by the Agro-pesticides Management Act.
- Feeds and feed additives, as defined by the Feed Control Act.
- Fertilizers, as defined by the Fertilizer Management Act.
- Veterinary drugs, as defined by the Veterinary Drugs Control Act
- Medicaments, as defined by the Pharmaceutical Affairs Act.
- Controlled drugs, as defined by the Controlled Drugs Act.
- Cosmetic(s), as defined by the Statute for Control of Cosmetic Hygiene.
- Foods, food additives, food utensils, food containers or packaging, and food cleansers, as defined by the Act Governing Food Safety and Sanitation.
- Tobacco products, as defined by the Tobacco Hazards Prevention Act
- Tobacco and alcohol, as defined by the Tobacco and Alcohol Administration Act.
- Radioactive materials, as defined by the Atomic Energy Act and the Ionizing Radiation Protection Act.
- Industrial use explosive materials, as defined by the Industrial Explosives Administrative Act.
- Chemicals regulated by the Montreal Protocol under the Air Pollution Control Act.
- Environmental agents, as defined by the Environmental Agents Control Act.
- **Toxic chemical substances**, as defined by the Act.



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Regulation on New and Existing Chemical Substances Registration

- Taiwan Chemical Substances Inventory (TCSI) contains 100,000+ substances that were manufactured in or imported in Taiwan between 1993 and 2014
- Existing Chemical Substances: those listed in TCSI

Phase One Registration (100 kg/year)

106 PECs: Standard Registration – level 1- 4 (above 1 TPA)

- For New Chemical Substance (those not listed in TCSI):
Depending on tonnage: simplified, small quantity and standard registration



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Existing Chemicals: Phase One Registration



Information required:

1. Name of substance, CAS No.
2. Tonnage band in a calendar year (estimated)
3. Information on use
4. Use information of this chemical (Product type)



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Existing Chemicals: Standard Registration

Article 16 of the regulation:

- The central competent authority may, by stages, designate the lists of existing chemical substances subject to standard registration...
- The first batch of PECs: 106 PECs (Appendix 6)
- Above 1 TPA : 1- 4 levels
- Information requirement (Appendix 7)
- Registration starts from 1 January 2020

類別 Stage	序號 Serial No.	化學文摘誌 登記號碼* CAS No.	英文名稱 English Name	中文名稱 Chinese Name
1	1	79-10-7	Acrylic acid	丙烯酸
1	2	10043-61-3	Aluminium sulfate	硫酸鋁
1	3	5664-41-7	Ammonia, anhydrous	氨, 無水
1	4	1336-21-6	Ammonium hydroxide	氯化銨溶液
1	5	123-77-3	1,1,1-Trichloroethane	1,1,1-三氯乙烷(甲氯烷)
1	6	100-52-7	Benzaldehyde	苯甲醛
1	7	552-30-7	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride	苯-1,2,4-三甲酸 1,2-酐
1	8	119-61-9	Benzophenone	二苯基酮
1	9	25973-55-1	2-(2H-Benzotriazol-2-yl)-4,6-dimethylphenol	2-(2H-苯并三嗪-2-基)-4,6-二甲基苯基酚
1	10	90-43-7	Dibutyltin dilaurate	二丁基錫
1	11	103-23-1	Bis(2-ethylhexyl) sulfite	己二酸雙(2-乙基己基) 酯
1	12	106-94-5	1-Bromopropane	1-溴丙烷
1	13	111-76-2	D-Butoxyethanol	2-丁氧基乙醇
1	14	25013-16-5	Burylated hydroxystyrene	丁基化酚基基甲基醇
1	15	128-37-0	Burylated hydroxytoluene	丁基化酚基甲基
1	16	57693-14-8	K.I. Acid black 172	K.I. 酸性黑 172
1	17	105-40-2	1,4-Caprolactam	ε-己內酰胺
1	18	1333-86-4	Carbon black	碳黑
1	19	95-48-7	o-Cresol	鄰甲酚
1	20	100-77-0	Kymerite chloride	1-羰基氯苯
1	21	108-94-1	Cyclohexanone	環己酮
1	22	95-33-0	N-Cyclohexyl-2-benzothiazylsulfonamide	N-環己基-2-苯并噻唑
1	23	108-91-8	Cyclohexylamine	環己胺
1	24	1309-64-4	Diamtinony trioxide	三氯化二碲
1	25	1303-86-2	Diboron trioxide	三氧化二硼
1	26	80-43-3	Decamyl peroxide	過氧化癸基基基基
1	27	7173-51-5	Dibutyltinmethylammonium chloride	氯化二癸基二丁基錫

Examples of Priority Existing Chemicals (PECs): Acrylic acid, Ammonia, Diboron trioxide



PECs Standard Registration Dossier

* The highest number of data required for submission

Section	Level 1 (1-10 tons)	Level 2 (10-100 tons)	Level 3 (100-1000 tons)	Level 4 (1000+ tons)
1 Information of the registrant and basic identification of the substance	v	v	v	v
2 Information on manufacture, use and exposure of the substance	v	v	v	v
3 Hazards classification and labelling	v	v	v	v
4 Safe use information	v	v	v	v
5 Physical and chemical properties	v(13)*	v(13)	v(15)	v(15)
6 Toxicological information	v(5)	v(8)	v(8)	v(9)
7 Ecotoxicological information	v(3)	v(7)	v(9)	v(16)
8 Hazard assessment		v	v	v
9 Exposure assessment		v	v	v

Data sharing applicable to Section :3, 5, 6, 7, (8)
Guidance for Existing Chemical Substances Standard Registration (Version 1) – June 2020



New Chemical: Registration information requirement

Section		Small quantity Registration ≤100 kg	Simplified Registration 100 kg - 1 ton	Standard Registration above 1 ton
1	Information of the registrant and basic identification of the substance	v	v	v (Level 1)
2	Information on manufacture, use and exposure of the substance	v	v	v (Level 1)
3	Hazards classification and labelling		v	v (Level 1)
4	Safe use information		v	v (Level 1)
5	Physical and chemical properties		v	v (Level 1)
6	Toxicological information			v (Level 1)
7	Ecotoxicological information			v (Level 1)
8	Hazard assessment			v (Level 2-4)
9	Exposure assessment			v (Level 2-4)



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New Chemical: Registration

Item	≤100 kg	100 kg - 1 ton	1 ton -10 tons	10 tons -100 tons	100 tons – 1000 tons	1000 + tons
New Chemical Substance	Small quantity Registration	Simplified registration	Standard Registration (Level 1)	Standard Registration (Level 2)	Standard Registration (Level 3)	Standard Registration (Level 4)
Scientific Research and Development			Simplified registration		Standard Registration (Level 1)	
Process oriented Research and Development (PRORD) On-site isolated intermediates Polymer	Small quantity Registration		Simplified registration		Standard Registration (Level 1)	
Polymer of Low ¹ Concern	Small quantity Registration					
CMR Substance	Standard Registration (Level 1)		Standard Registration (Level 2)	Standard Registration (Level 3)	Standard Registration (Level 4)	

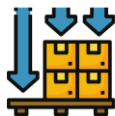


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Who can register?



Manufacturer



Importer



**Third Party
Representative (TPR)
with legal entity in Taiwan**

How can TPR help you and your company?

- Supply Chain Communication – communicate directly with your Taiwanese buyers to proceed TPR appointment and submit information to [Toxic and Chemical Substances Bureau, EPA](#)
- Phase One Registration/Standard Registration (include Dossier Preparation)



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Annual Reporting

The first Annual Reporting for Registered Chemical Substances took place during April 1st to September 30th 2020.

Manufacturers, importers and authorized TPR with valid Registration Number are eligible for Annual Reporting

Information to be included in Annual Reporting:

- Substance name
- CAS Number
- Registration number for each substance
- Volume in the previous year
- Information on importer or manufacturer



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Join Registration

- Joint Registration is not mandatory.
- Communication with the agency: it may take longer time for dossier review from the authority, and back-and forth conversations.
- Prepare your dossier to meet the deadline



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Background to the Amendment Draft

- To review the registration process and the actual registration situation
 - By June 1, 2021: Cases of Standard Reg. 51 (1-10 TPA), 5 (10-100 TPA), 2 (100+ TPA), 14 polymer (10+TPA),
- To include opinions from stakeholders and industries
- Delayed preparation for registration due to COVID 19
- The draft is announced on May 25 and open for public comments until July 26, 2021



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Key Change (1/5)

- Newly Added Exempted Substances
 - Controlled chemicals defined by Occupational Safety and Health Act, Regulations Governing Designation and Handling Permission of controlled Chemicals
 - Concerned Chemical Substances defined by TCCSCA, risk to environment and human health
- Valid Period of Registration and Confidentiality are extended to 5 years

Type of registration	Valid Period of Confidentiality
New Chemical Substance - Standard Registration PLC Small quantity registration	5 years
New Chemical Substance – simplified registration and small quantity registration	≥ 5 years
Existing chemical substance – Phase One Registration, Standard Registration	5 years

Max. confidential period is ~~40~~ 15 years

Max. confidential period is 15 years



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Key Change (2/5): Review period

	Current Regulation	Draft Amendment
Phase One Reg.	7	10
Small Quantity Reg. (New Substances)	7	10
Simplified Reg. (New Substances)	14	20
Standard Reg. (New Substances)	45	60
Standard Reg. (Existing Sub.)	90	90
Application for CBI extension	7	10
Application for inclusion to TSCI	14	20

Estimated Application process

2-4 weeks

2.5 months

5-6 months

11 to 13 months

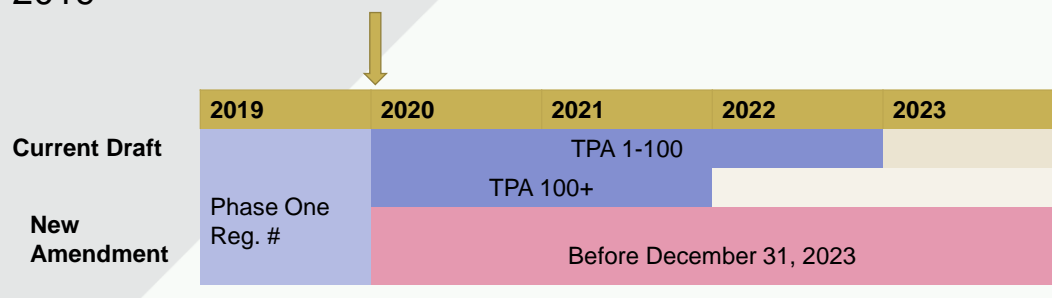
1 to 1.5 year



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Key Change (3/5)

Phase One Registration Number obtained before December 31, 2019

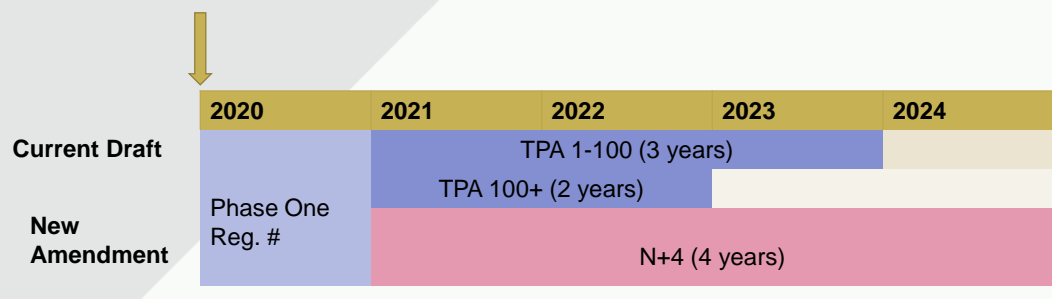


Deadline for Standard Registration extended to 4 years



Key Change (4/5)

Phase One Registration Number obtained after January 1, 2020



Deadline for Standard Registration extended to 4 years



Key Change (5/5): Standard Reg.

Section	
1	Information of the registrant and basic identification of the substance
2	Information on manufacture, use and exposure of the substance
3	Hazards classification and labelling
4	Safe use information
5	Physical and chemical properties
6	Toxicological information
7	Ecotoxicological information
8	Hazard assessment
9	Exposure assessment

Current Draft: Registration No. can be obtained if all required information approved by the authority

Draft Amendment: Registration No. can be obtained if 1-7 information approved by the authority. The rest can be submitted within suggested time.



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Take Home Message (1/2)

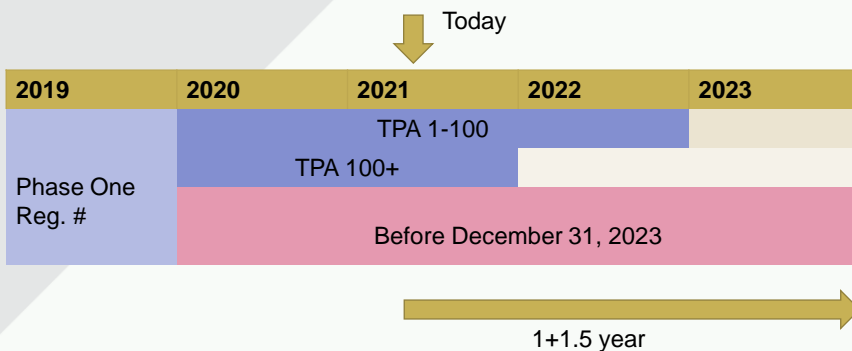
- Understand your registration obligation and start to prepare your dossiers as soon as possible.
- Joint registration is not mandatory.
- Expecting inquiries from your downstream buyers for compliance check
- Contact TPR to have professional support from experienced team



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Take Home Message (2/2)

- **Phase One Registration Number** obtained before December 31, 2019
- Expect 1.5 year submission period



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Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



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