



Regulations on Chemical Substances Management in Taiwan -Introduction and Updates-

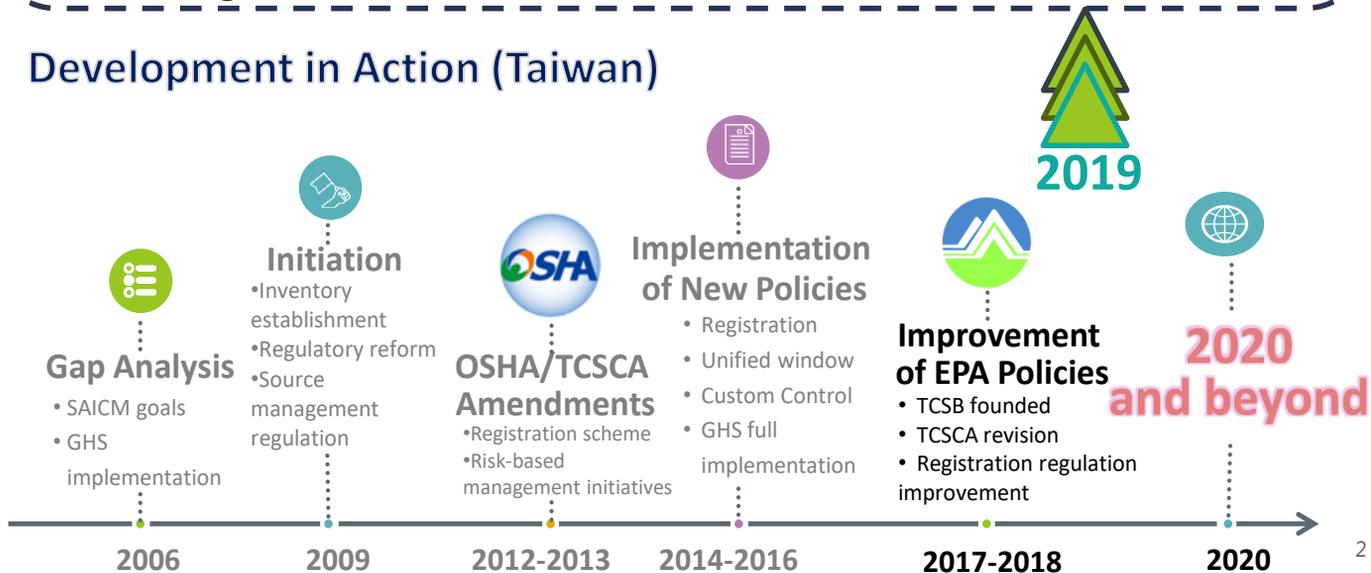


Outline

1. National Sound Chemical Management Program
2. EPA TCSCA Amendments: introduction of substances of concern, chemical funding, and whistleblower measures
3. EPA Registration Regulations Amendments (draft)
4. OSHA Regulations Update: GHS Labelling and Priority Management Chemicals

國家化學物質管理政策綱領

Development in Action (Taiwan)



National Sound Chemical Management Program

國家化學物質管理政策綱領 (2018.4.2)

行政院
Executive Yuan

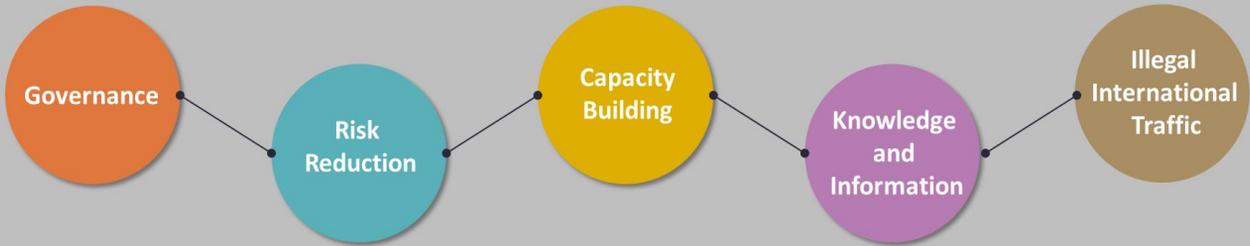
行政院環境保護署
Environmental Protection Administration
Executive Yuan, R.O.C. (Taiwan)

saicm

TCSB

NIEHS

Other agency logos



✓ Align with UN SAICM

✓ 17 Acting Legislations

✓ 13 Responsible Agencies

✓ Annual Development Progress and Implementation Report



Regulations under Environmental Protection Administration (EPA)

- Toxic Chemical Substances Control
Act (TCSCA)

**Toxic and Concerned Chemical
Substance Control Act**
(TCCSCA) 毒性及關注化學物質管理法

- Regulation of New and Existing
Chemical Substances Registration

新化學物質及既有化學物質資料登錄辦法

Structure of TCCSCA- Before and After (Jan. 2019 promulgated by President)



TCCSCA



**Toxic Chemicals and
Concerned Substances
Control Act (TCCSCA)**

NEW

Chapter 1 General Principles (§1-7)
Chapter 2 TCS Assessment, Prevention, and Management (§8-23)
Chapter 3 Assessment, Prevention, and Management of Concerned Substances (§24-29)
Chapter 4 Substance registration and reporting (§30-34)
Chapter 5 Accident prevention and emergency responses (§35-43)
Chapter 6 Inspection and finance (§44-49)
Chapter 7 Penal Provisions (§50-67)
Chapter 8 Supplementary Provisions (§68-75)

Chapter 1 General Principles (§1-6)
Chapter 2 Hazard Assessment and Prevention (§7-10)
Chapter 3 Management (§11-28)
Chapter 4 Penal Provisions (§29-37)
Chapter 5 Supplementary Provisions (§38-44)





TCCSCA at A Glance

- Add a new chapter for Concerned Substances
 - authorize their evaluation, prevention, and management
- New chapter for accident prevention and emergency response
- Strengthen inspection and standard analysis methods
- Expand self-sustained funding scheme
- National Chemical Management Board as a coordinating body
- Encourage compliances and public participations
 - Whistleblowers and rewards
 - Citizen litigations

EPA. TCCSCA Amendment. Available at:

<https://www.ey.gov.tw/Page/9277F759E41CCD91/542f9cf3-af49-4a71-87a4-52f1022017d4>

Amendment of Registration Regulation at A Glance

2019.3 promulgated



Harmonize domestic legislation



Information requirement harmonized between EPA and MoL regarding hazard assessment and exposure assessment

Harmonize valid periods between CBI and registration



Consistency ensured in the period of the information confidentiality and the validity of registration approval

Reduce administrative burden



Registration number issued without registration document after registration is completed

Clarify phase 1 existing registration



Trigger quantity clarified as existing chemical substances ≥ 100 kg/year shall be registered. A voluntary registration is allowed for those chemicals below trigger quantity

Clarify the scope of application



Toxic Chemical Substances in TCSCA and Industrial use explosive materials, as defined by the Industrial Explosives Administrative Act

Designate 106 existing chemical substances subject to standard registration



Specific information released including substances list, data requirements, registration periods and tonnage bands
**More details including draft registration guidance and tool will be communicated with stakeholders

Require annual reporting



Annual volume report enforced for all registered new and existing chemical substances during April-September every year from 2020

Increase flexibility of review/correction process



- Review period calculated anew during correction process
- The possibility of extending time period and the number of times for correction provided
- Written appeals allowed

EPA. Amendment of Regulation of New and Existing Chemical Substances Registration. 2019. Available at: <https://oaout.epa.gov.tw/law/LawContent.aspx?id=GL005417>



New Chemical Substance Registration

Based on annual manufacturing/import quantity

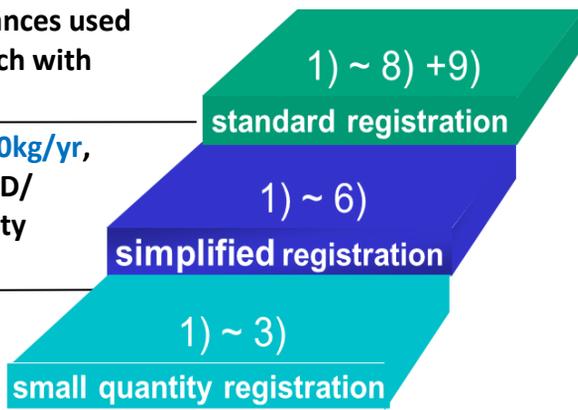
Types of Registration

Information Required

Quantity over 1 t/yr, or substances used for pilot R&D/scientific research with quantity over 10 ts/yr

Quantity between 100kg-1,000kg/yr, or chemicals used for pilot R&D/scientific research with quantity between 1t - 10 ts/yr

Chemicals less than 100kg, or Polymers of low concern with quantity over 1t/yr.



- 1) Basic identification of the registrant and substances
- 2) Substances manufacture, use and exposure information
- 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

In total, around **3,800** new chemical substance applications were received. (2015-2018)

- Small Quantity registration :~2,500
- Simplified registration:~120
- Standard registration:~40
- Polymer of low concern:~1,100

> 10 ton/yr after amendment



Existing Chemical Substance Registration

Sep. 2015~Mar. 2016



Article 18

**Phase 1
Registration**

> 100 kg/yr

Mar. 2016~



Article 19

**Post Phase 1
Registration**

> 100 kg/yr for the first
time after March, 2016

After 2019



Article 20

**Standard
Registration**

designated chemical
substances > 1 ton/yr



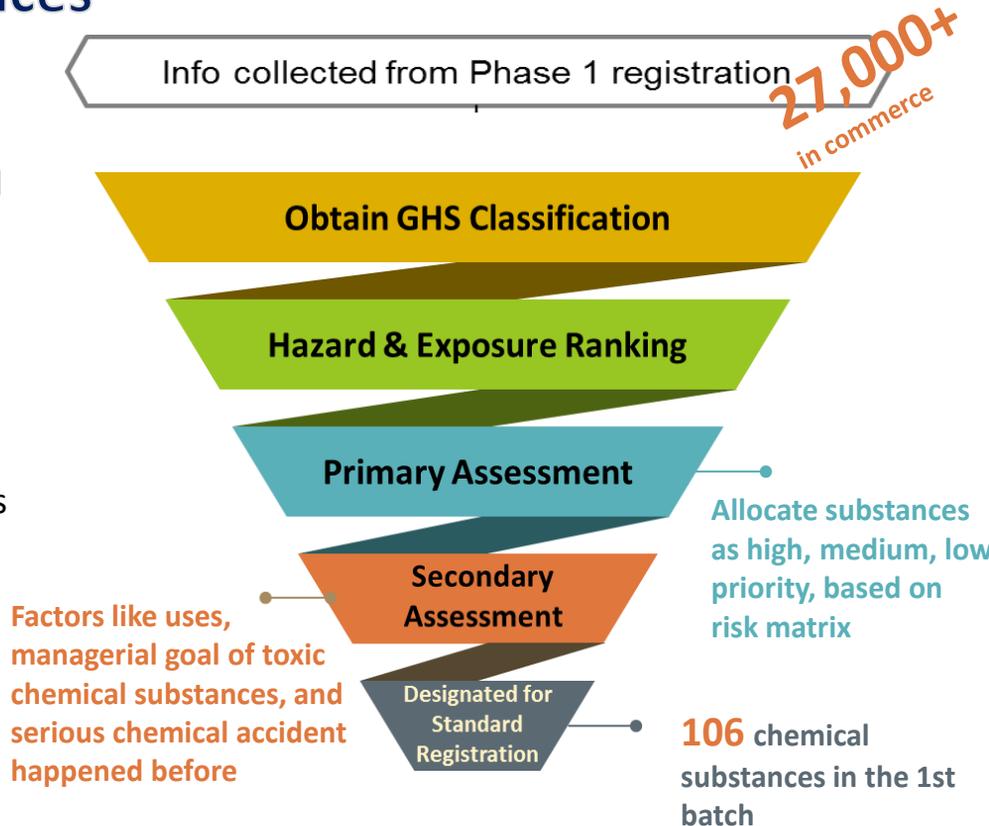
Prioritization Process

Around **27,000** existing chemical substances were received during phase 1 registration.



Existing Chemical Substance Registration - Prioritization for Designated Chemical Substances

- **Tier 0 Risk assessment**
 - Risk based prioritization
 - Hazard ranking allocated according to GHS classification
 - Exposure ranking allocated according to national wide tonnage band
 - List of the first batch was announced in mid-2018 with 106 substances





Existing Chemical Substance Registration - Risk-based Prioritization

Hazard Levels according to GHS

1. Environmental hazards level		
GHS Classification – Environmental hazards classification (use the most hazardous category)	Ranking	Hazards level
Acute Cat.1 or Chronic Cat.1	High	Level 5
Acute Cat.2 or Chronic Cat.2	Medium	Level 4
Acute Cat.3 or Chronic Cat.3/4	Low	Level 3
2. Human health risk level		
GHS Classification - Human Health (use the most hazardous category)	Ranking	Hazards level
<ul style="list-style-type: none"> ● Mutagen Cat. 1 ● Carcinogen Cat. 1 ● Reproductive toxicant Cat. 1, 2 ● Acute Cat.1 	High	Level 5
<ul style="list-style-type: none"> ● Mutagen Cat. 2 ● Carcinogen Cat. 2 ● Acute Cat.2 ● Specific target organ toxicity - repeated exposure Cat. 1 ● Respiratory sensitizer Cat. 1 	Medium-High	Level 4
<ul style="list-style-type: none"> ● Acute Cat.3 ● Specific target organ toxicity - repeated exposure Cat. 2 ● Specific target organ toxicity - single exposure Cat. 1 ● Specific target organ toxicity - single exposure Cat. 2 ● Skin corrosion/irritation Cat.1 ● Serious eye damage/eye irritation Cat. 1 ● Skin sensitizer Cat. 1 	Medium	Level 3
<ul style="list-style-type: none"> ● Acute Cat.4, 5 ● Specific target organ toxicity - single exposure Cat.3 ● Skin corrosion/irritation Cat. 2, 3 ● Serious eye damage/eye irritation Cat.2 ● Aspiration toxicity Cat. 1, 2 	Medium-Low	Level 2
Non-environmental and non-health hazardous classification	Low	Level 1
3. EDC risk level		
EDC classification	Ranking	Hazards level
Internationally known or presumably to be endocrine disruptors	High	Level 5
Internationally suspected to be endocrine disruptors	Medium	Level 4
Internationally potential endocrine disruptors	Low	Level 3

Exposure Levels

Exposure Levels	
Indicator to surrogate for national wide environmental emission (tons)	Exposure Levels
>=10,000	Level 5
>= 1,000 < 10,000	Level 4
>= 100 < 1,000	Level 3
>= 10 < 100	Level 2
< 10	Level 1

Risk Matrix

		Hazard level					
		High			Low		
		Level 5	Level 4	Level 3	Level 2	Level 1	
Exposure Level	High	Level 5	High	High	High	Medium	Medium
		Level 4	High	High	Medium	Medium	Low
		Level 3	High	Medium	Medium	Medium	Low
		Level 2	Medium	Medium	Medium	Low	Low
Low	Low	Level 1	Medium	Low	Low	Low	Low



Existing Chemical Substance Registration - Tentative Timeline

- Designated chemical substances subject to standard registration (1st batch)
- Annual Reporting





Existing Chemical Substance Registration - Information Requirement of Standard Registration

1-10 ton 10-100 ton 100-1000 ton >1000 ton

Designated chemical
substance > 1 ton/yr

Type of acceptable
registration data:

- 1) Full testing report, or
- 2) RSS with LOA, or
- 3) Systematic review, or
- 4) SAR report (OECD reporting format), or
- 5) Testing proposal (subject to testing items)

Sections

	Level I	Level II	Level III	Level IV
1 Basic information of substances identification and registrant	✓	✓	✓	✓
2 Substances manufacture & use information exposure information	✓	✓	✓	✓
3 GHS hazards classification	✓	✓	✓	✓
4 Safe use information	✓	✓	✓	✓
5 Physical and chemical properties	○ (13)	○ (13)	○ (15)	○ (15)
6 Toxicological Information	○ (5)	○ (8)	○ (8)	○ (9)
7 Ecotoxicological Information	○ (3)	○ (7)	○ (9)	○ (16)
8 Hazard assessment report		✓	✓	✓
9 Exposure assessment report		✓	✓	✓



Existing Chemical Substance Registration

- Key points of Designated Standard Registration

Schedule has been delayed :

proposed Registration Regulation is expected to be passed in 2019 Q1



Joint Registration is NOT mandatory

One registrant, one dossier



Registration information sharing



Using token-like scheme when using same data set with other registrants (information sharing), subject to prior successful submission



Regulations under Occupational Safety and Health Administration (OSHA), Ministry of Labor(MoL)

NEW

Regulations for the Labeling and Hazard Communication of Hazardous Chemicals

危害性化學品標示及通識規則

Amended Date: 2018-11-09

SDS Information Protection

effective date: November 9, 2018

- To add that hazardous substances listed in **Standards of Permissible Exposure Limits at Job Site** shall NOT apply for SDS information withholding.
- If documents are deficient, the applicant shall make corrections and supplements **within 30 days** after receiving the notification of corrections and supplements from the central competent authority. Corrections and supplements shall only be made **no more than twice**. In case corrections and supplements are not made in time, the application shall not be accepted.

SDS

The text for the SDS shall be primarily in **Chinese** characters, and if necessary, in foreign languages that workers understand as supplement.

SDS

Section 3 - Composition/information on ingredients

effective date: January 1, 2020

Mixture:

chemical properties		
Chinese and English names of the hazardous ingredients	Chemical Abstract Service number (CAS No.)	concentration or concentration ranges (ingredient percentage)

*If the hazardous ingredients do not have a CAS No., its item may be exempted.

SDS Information Protection

- 
- Prior to providing the hazardous chemicals to business entities or self-employed workers, the manufacturers, **importers**, or suppliers shall label them and provide safety data sheets; the same shall be applied for any change of information.
 - Application for SDS **information disclosure withheld** has been carried out in Sep., 2016.
 - For the necessity of national security or trade secret protection purposes to withhold the disclosure information, **importers** shall provide the related written documentation to MOL for approval. Information can be protected:
 - the name and concentration of hazardous chemical ingredients, manufacturer, importer or supplier's name
 - Hazardous chemical ingredients possessing the following hazards as specified in CNS15030 Classification (UN GHS) **shall NOT apply** for withholding from the aforementioned SDS disclosure:
 1. Acute toxicity category 1, category 2, or category 3;
 2. Skin corrosion/irritation category 1;
 3. Serious eye damage/eye irritation category 1;
 4. Respiratory or skin sensitization;
 5. Germ cells mutagenicity;
 6. Carcinogenicity;
 7. Reproductive toxicity;
 8. Specific target organ systemic toxicity -- single exposure category 1
 9. Specific target organ systemic toxicity -- repeated exposure category 1





Priority Management Chemicals Report

優先管理化學品之指定及運作管理辦法

NEW

Phase 0

From 2015/01/01

98 substances

①

+

Phase 1

From 2015/11/05

503 substances

②③

+

Phase 2

From 2019/04/01

572 substances

②③

- ① Chemicals particularly with high risk to the youth and pregnant women
- ② Chemicals classified as Category 1 Carcinogen, Category 1 Mutagen or Category 1 Reproductive Toxicant
- ③ Chemicals possessing physical hazards or health hazards



Workers \geq 100 :

filing the report within 6 months

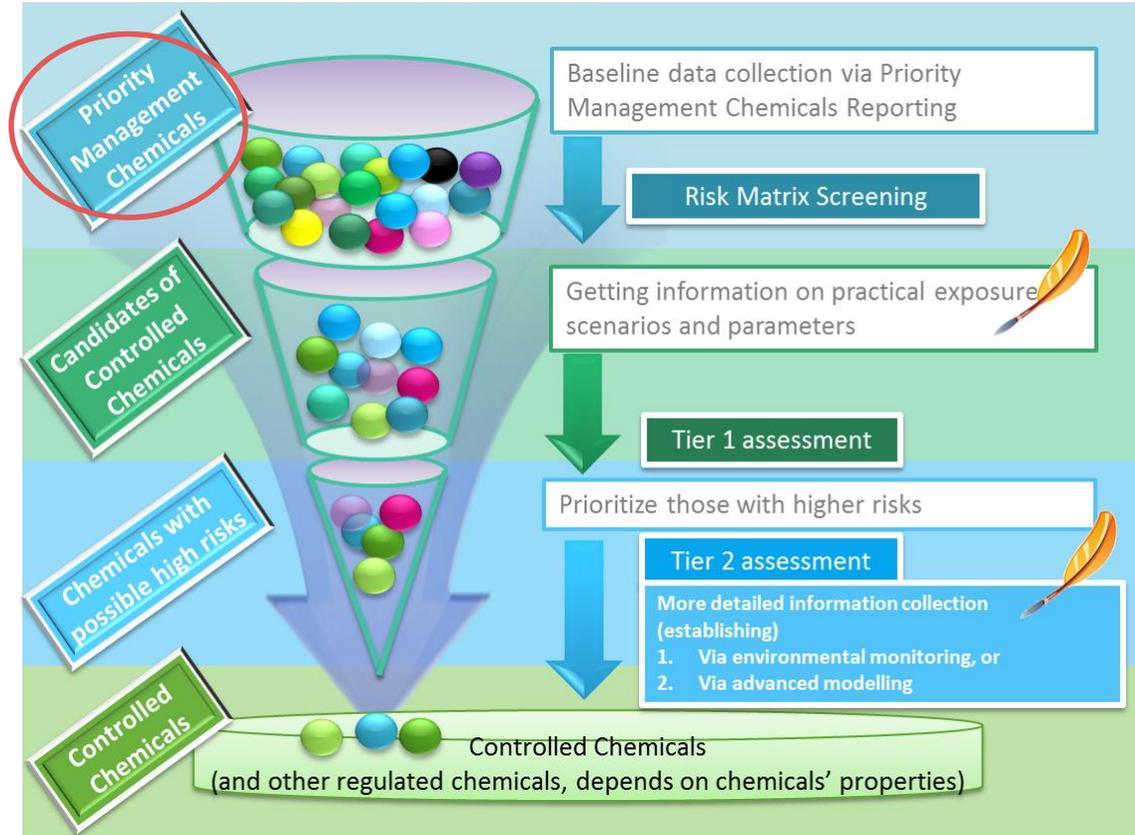


Workers < 100

Filing the report within 18 months



Chemical Risk Assessment Scheme under OSHA





Take-home Message

- ✚ **Stay Tuned:** Concerned Substances and their corresponding management measures will be announced under TCCSCA in the near future
- ✚ Keep eyes on the release of EPA's Registration Regulation Amendments
 - designated existing chemical standard registration
 - ▶ 1st batch: 106 Substances with tonnage \geq 1 ton/yr
 - ▶ Begin from 2020
 - Annual Reporting of Registered Chemical Substances
- ✚ Require providing **CAS No.** of chemical substances on SDS starting from 2020
- ✚ Require GHS compliance of SDS and labelling primarily in **Chinese**
- ✚ Consider applying information protection for SDS and registration if necessary
- ✚ File report of Priority Management Chemicals from Apr.-Sep. each year





References

- **National Sound Chemical Management Program**
http://yeric.yuntech.edu.tw/attachment/ppt/ppt_180507002.pdf
- **Environmental Protection Administration, Executive Yuan (Taiwan EPA)**
 - Toxic Chemical Substances Control Act (2019.1.16)
 - ▶ <https://law.moj.gov.tw/LawClass/LawAll.aspx?PCode=O0060012> (Chinese)
 - ▶ <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=O0060012> (English)
 - Regulation of New and Existing Chemical Substances Registration (2019.3.11)
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=O0060043>
- **Ministry of Labor- Occupational Safety and Health Act (2013.7.3)**
<http://law.moj.gov.tw/LawClass/LawAll.aspx?PCode=N0060001>
 - Regulations for the Labeling and Hazard Communication of Hazardous Chemicals (2018.11.9)
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=N0060054>
 - Regulations Governing Designating and Handling of Priority Management Chemicals (2014.12.30)
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=N0060064>
 - Standards of Permissible Exposure Limits at Job Site(2018.03.14)
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=N0060004>
 - Regulations for Hazardous Chemical Assessment and Control Banding (2014.12.31)
<http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=N0060070> (Chinese Only)
 - Standards of Permissible Exposure Limits at Job Site (2018.3.14)
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=N0060004>
- **CSNN TCSI searching engine and registration platform**
<https://csnn.osha.gov.tw/content/home/NewsEng.aspx>
- **Chemical Substances Registration Platform**
<http://tcscachemreg.epa.gov.tw/content/masterpage/index.aspx>



Thank you!