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REACH24H USA

September 29, 2015

Practical Interpretation of China & Taiwan Chemical Management and GHS

Part 1

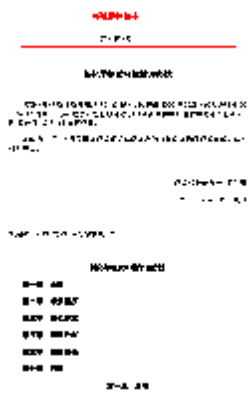
China New Chemical Substance Notification ---Updates and Developments

Background

- Official name: “Measures on the Environmental Management of New Chemical Substances” (MEP Order No. 7)
  - ü Came into effect Oct 15, 2010

- Other names:
  - ü New Chemical Substance Notification (NCSN)
  - ü Measures
  - ü “China REACH”?

中华人民共和国环境保护部
Ministry of Environmental Protection of the People's Republic of China



Order No.7

‘CHINA REACH’ ?

~~Existing chemicals~~

New chemicals

Registration

Evaluation

~~Restriction~~

~~Authorization~~

Inventory of Existing Chemical Substance in China (IECSC)

IECSC 2013 (pdf)
45,612 substances
Jan-24, 2013

3,270 confidential substances
8,486 substances without CAS number

Not found in the public inventory?

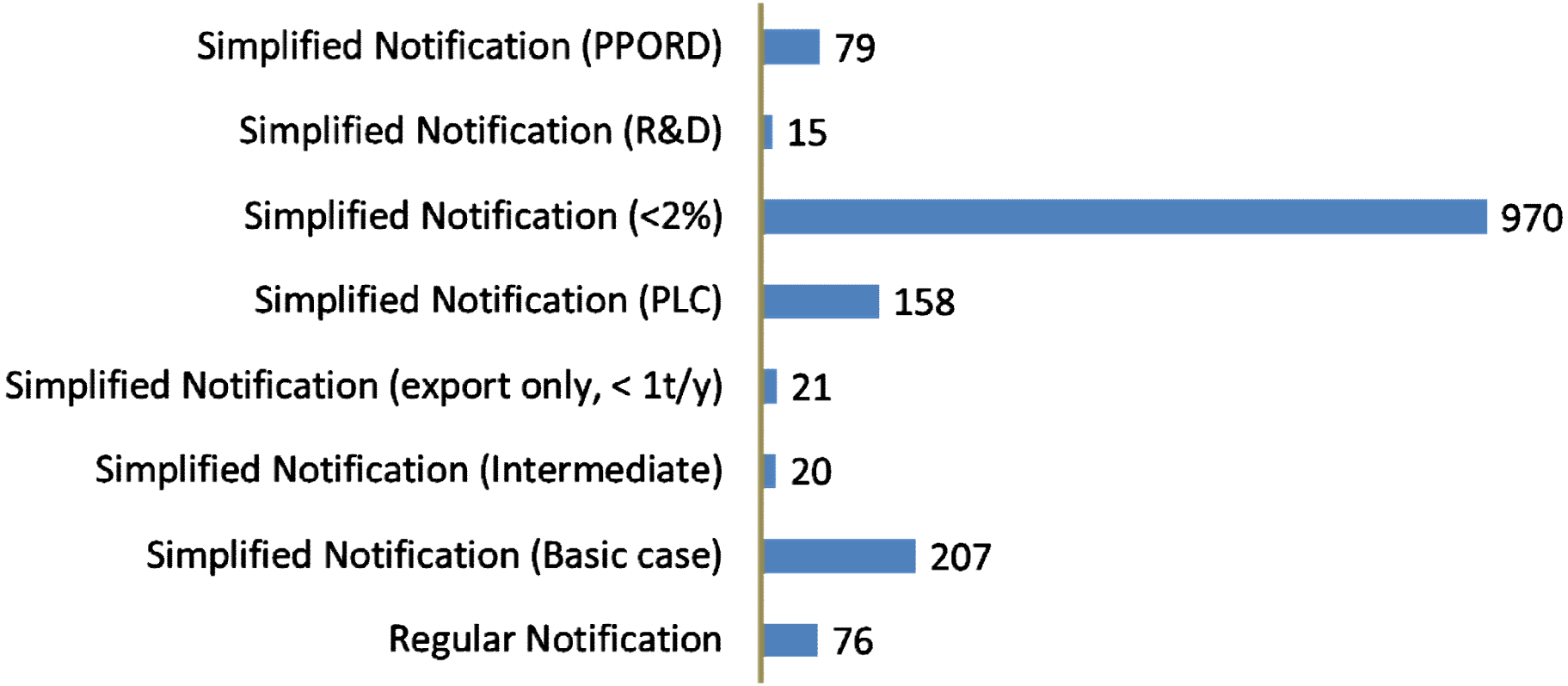
— formal inquiry to SCC-MEP is needed!

Download the Public IECSC (PDF version)
http://www.mep.gov.cn/gkml/hbb/bgg/201301/t20130131_245810.htm

On-going work:

- Listing in IECSC: For substances with regular notification certificate, if the substance is 5 years since the first actual activity, the registrant can apply for the IECSC listing.
- Revision of inaccurate information in IECSC is still ongoing review by the SCC-MEP.

Notification 2015 H1 Statistics



New Testing “Guidelines”

2nd version of Chinese **‘Guidelines for the Testing of Chemicals’** were published in Sep, 2013

Volume 1
- Physical-chemical properties and physical hazards

Volume 2
- Effects on biotic systems

Volume 3
- Degradations and accumulation

Volume 4
- Health effects

New Testing "Guidelines"

What's **NEW**

✓ Increasing methods

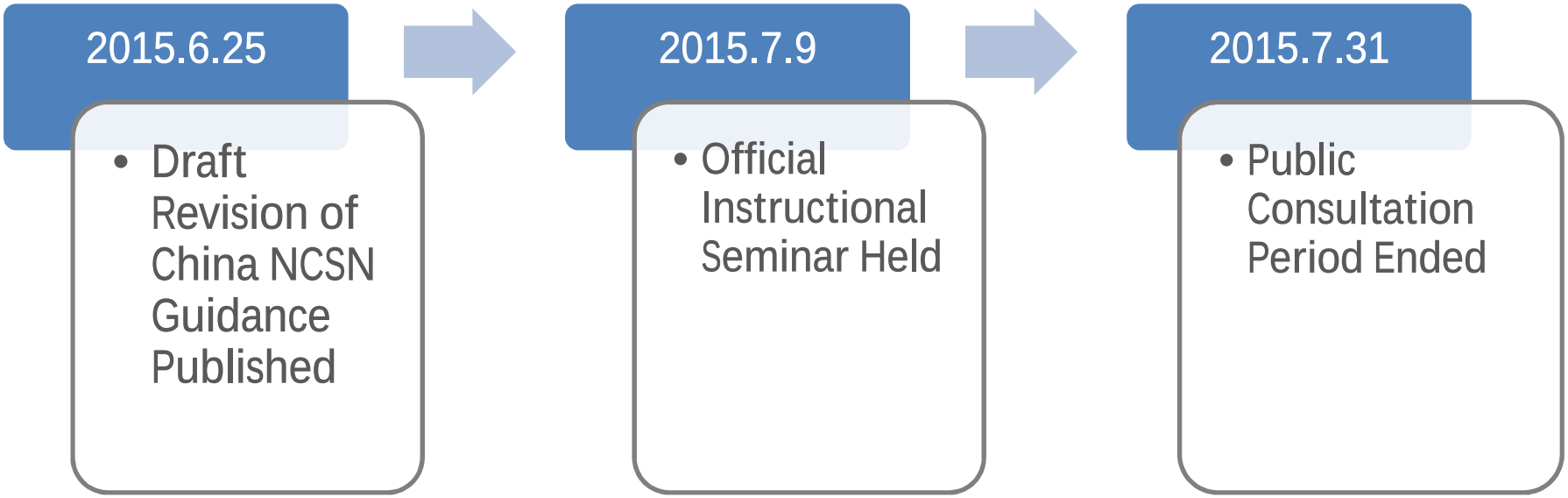
Methods	1st version	2nd version
Physical & Chemical	OECD101-OECD120	Add OECD121, 123, 191, Add 17 Physical hazards testing methods-GHS
Effects on biotic systems	18 OECD methods	36 OECD methods
Degradations and accumulation	17 OECD methods	37 OECD methods
Health effects	46 OECD methods	73 methods (including 66 OECD methods)

✓ Add alternative Tox methods

OECD 429(LLNA), OECD 430(TER), OECD 431(Human Skin Model Test),
OECD 432(3T3 NRU), OECD 435(Membrane Barrier Test), OECD 436(Acute Inhalation Class),
OECD 437(BCOP), OECD 438(ICE), OECD 439(Epidermis), OECD 442A,B(LLNA-DA, -BrdU),
OECD 487(In-vitro Micronucleus Test)

Revision work of China NCSN is on-going now

Key Timeline – NCSN Guidance Revision



NCSN Guidance – Amendments

Scope

Chemical substances subject to notification

Applicable Categories	Added exemptions: fertilizer, enzyme* Not exempt: new substance in article which may cause exposure (e.g., surface coating of an article)
Applicable Area	Added Free Trade Zone (FTZ) area, same requirement with bonded area
Simplified notification	“Export only” now includes both manufacture and import at <1 t/a

NCSN Guidance – Amendments

Policy

Key messages about general policy

Certificate holder	Overseas notifier becomes certificate holder (no longer OR); local representative agent is still necessary
Tonnage	Regular notification levels 1-3: either specific volume or tonnage band is accepted
Simplified notification	If not approved, applicant is not allowed to use the same notification type for the same substance in the future; instead higher notification type should be applied for
Certificate modification	Reduced workload for notifier and no exchange for new certificate needed; confirmation letter instead

NCSN Guidance – Amendments

Polymer

Key messages about polymer

Tonnage	Volume not recorded/specified on the certificate for Simplified Notification (Special) for polymer
Simplified notification (Special)	Not applicable: (1) unstable or degradable polymers, or (2) water-absorbing polymers with Mn≥10,000
2% Rule	If a monomer/reactant is new and more than 2%, but has been registered for regular notification, the “2% rule of polymer” of simplified notification (special) is applicable

NCSN Guidance – Amendments

Data

Key messages about the data requirements

Expiry date of study report	If a guideline of an existing study report has been updated more recently than 5 years before notification, the study should be repeated following the latest version of the guideline. The old study report can be submitted as reference.
Chinese test organism	Local organisms cultivated and bred in China that comply with the requirements for the designated tests including: *Gobiocypris rarus* (Rare minnow), activated sludge within Chinese territory. Zebra fish won't be applicable.

NCSN Guidance – Amendments

Data

Key messages about the data requirements

Acute toxicity	Acute toxicity by dermal and inhalation routes is optional according to corresponding exposure scenario and phys-chem properties (Regular notification level 1 only)
90 day repeated dose toxicity	Refer to the criteria of EU REACH Annex VIII (Regular notification level 2 only)
Fish, 14-day prolonged toxicity	Deleted endpoint (Regular notification level 2)

NCSN Guidance – Amendments

Data

Key messages about the data requirements

Mutagenicity	More flexible combination of mutagenicity tests will be adopted
Carcinogenicity	Study required when: 1) Wide dispersive use, long term exposure to human, and 2) Hyperplasia or pre-neoplastic lesions induced in repeated dose study, or known germ cell mutagenicity category 2; else, carcinogenicity assessment might be acceptable
Toxicokinetics	More specified requirements for toxicokinetics
Chronic toxicity	Original waiver criteria deleted but “combined study of chronic toxicity/carcinogenicity is available” added

China HazChem Registration and GHS

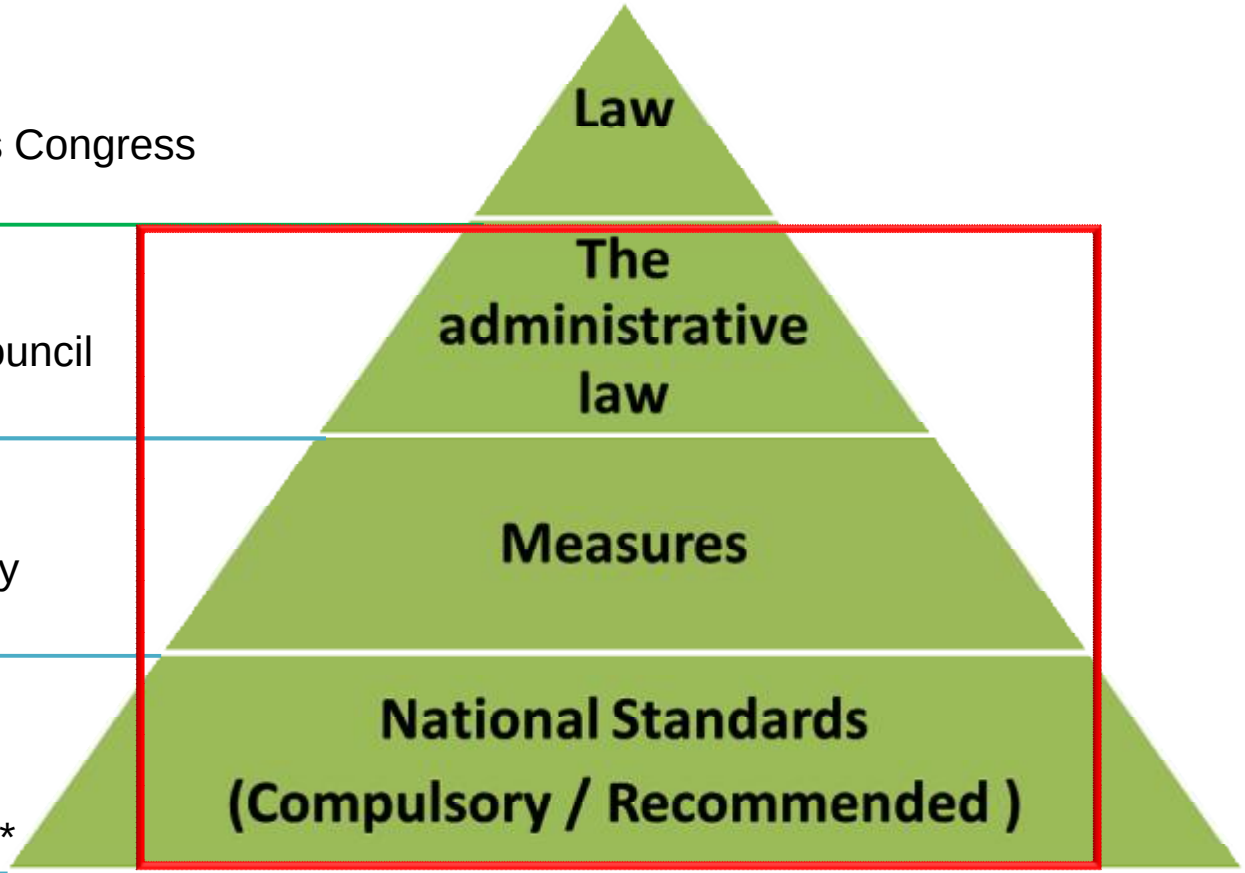
Legal Framework of China

Level 1
Legislated by the People's Congress
e.g. **Constitution**

Level 2
Legislated by the State Council
e.g. **Decree 591**

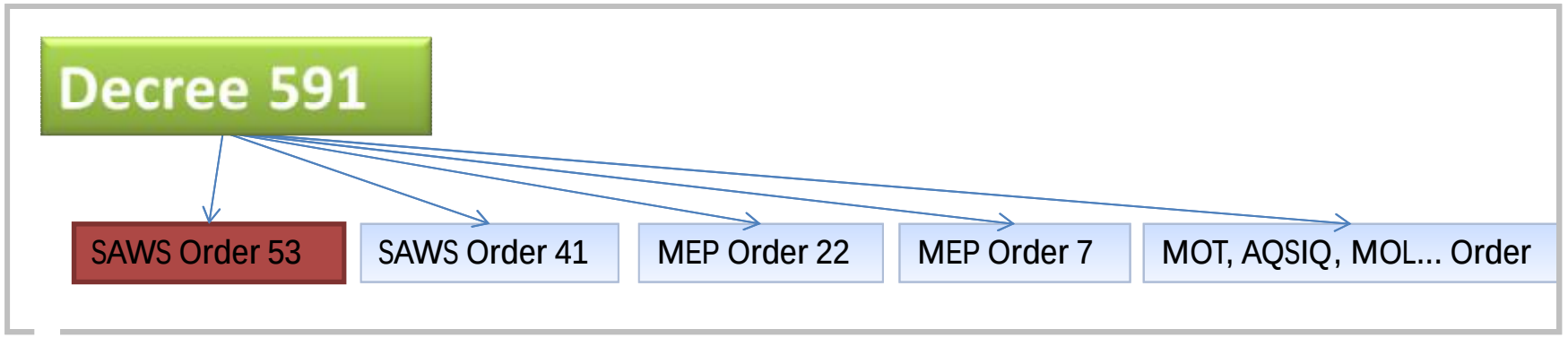
Level 3
Legislated by each Ministry
e.g. **SAWS Order 53**

Level 4
e.g. **GB xxx or GB/T xxx** *



Compulsory Standards = "**GB**";
Recommended Standards = "**GB/T**"

GHS-Related Regulations and GB standards



China

Fully implemented from *Dec 1, 2011*

Classification

Old (UN GHS rev 1)

26 Hazard Classes

GB 13690-2009

GB 20576~20599, 20601, 20602-2006

New (UN GHS rev 4)

28 Hazard Classes

GB 30000.1~ 30000.30-2013

From Nov. 1, 2014

SDS

SDS Standard

GB/T 16483-2008

SDS Guidance

GB/T 17519-2013

From Jan. 1, 2014

Label/ Packaging

Label: GB 15258-2009

Packaging: GB 190-2009

C&L Inventory

Inventory of Hazardous Chemicals (2015 new version, 2828 substances)

Guidance of the Inventory (C&L)

(Published in 02 SEP)

GHS-Related Regulations

	Chemicals on the C&L Inventory	Chemicals containing one or more constituents on the C&L Inventory	Chemicals not on the C&L Inventory
Hazard Identification and Classification	GHS Classification (GB 30000 series)	Physical Hazard Identification and Classification (SAWS Order 60)	Physical Hazard Identification and classification (SAWS Order 60)
Registration	HazChem Registration (SAWS Order 53); Environmental Management Registration (MEP Order 22)	Very likely to be subject to Hazchem Registration (SAWS Order 53) acc. to the identification and classification results	May be subject to HazChem Registration (SAWS Order 53) acc. to the identification and classification results
Administrative Licensing	Safe Manufacturing Permit (SAWS Order 41); Safe Operation Permit (SAWS Order 55); Safe Use Permit (SAWS Order 57)		
Entry-Exit Inspection and Quarantine	Declaration of conformity, inhibitor/ stabilizer info, GHS labels and SDSs in Chinese, etc. (AQSIQ Announcement 30 of 2012)		
GHS Compliance	Classification, Labeling and SDS (China GHS)	Classification; labels and SDSs are required if HazChem Registration is required, otherwise remain recommended	Classification; labels and SDSs are required if HazChem Registration is required, otherwise remain recommended

GB 30000 Standards

Standard No.	Standard Title (Safety rules for classification and labeling of chemicals -)	Replaced Standard
GB 30000.1-2013	General rules	GB 13690-2009
GB 30000.2-2013	Explosives	GB 20576-2006
GB 30000.3-2013	Flammable gases	GB 20577-2006
GB 30000.4-2013	Aerosols	GB 20578-2006
GB 30000.5-2013	Oxidizing gases	GB 20579-2006
GB 30000.6-2013	Gases under pressure	GB 20580-2006
GB 30000.7-2013	Flammable Liquids	GB 20581-2006
GB 30000.8-2013	Flammable Solids	GB 20582-2006
GB 30000.9-2013	Self-reactive substances and mixtures	GB 20583-2006
GB 30000.10-2013	Pyrophoric liquids	GB 20585-2006
GB 30000.11-2013	Pyrophoric solids	GB 20586-2006
GB 30000.12-2013	Self-heating substances and mixtures	GB 20584-2006
GB 30000.13-2013	Substances and mixtures, which in contact with water, emit flammable gases	GB 20587-2006
GB 30000.14-2013	Oxidizing liquids	GB 20589-2006
GB 30000.15-2013	Oxidizing solids	GB 20590-2006
GB 30000.16-2013	Organic peroxides	GB 20591-2006
GB 30000.17-2013	Corrosive to metals	GB 20588-2006
GB 30000.18-2013	Acute toxicity	GB 20592-2006
GB 30000.19-2013	Skin corrosion/irritation	GB 20593-2006
GB 30000.20-2013	Serious eye damage / eye irritation	GB 20594-2006
GB 30000.21-2013	Respiratory or skin sensitization	GB 20595-2006
GB 30000.22-2013	Germ cell mutagenicity	GB 20596-2006
GB 30000.23-2013	Carcinogenicity	GB 20597-2006
GB 30000.24-2013	Reproductive toxicity	GB 20598-2006
GB 30000.25-2013	Specific target organ toxicity - Single exposure	GB 20599-2006
GB 30000.26-2013	Specific target organ toxicity - Repeated exposure	GB 20601-2006
GB 30000.27-2013	Aspiration hazard	NEW
GB 30000.28-2013	Hazardous to the aquatic environment	GB 20602-2006
GB 30000.29-2013	Hazardous to the ozone layer	NEW
GB 30000.30-2013	Work safety warning signs	

China Reiterates Inspection Requirements for HazChem Import/Export

Competent authorities		
	AQSIQ	State Administration of Quality Supervision and Inspection and Quarantine
	CIQ	Local entry-exit inspection and quarantine bureau (CIQ)

AQSIQ reiterated its compulsory requirements on the inspection of entry-exit hazardous chemical products and their packaging in announcement, Order 30 - 2012.

China Reiterates Inspection Requirements for HazChem Import/Export

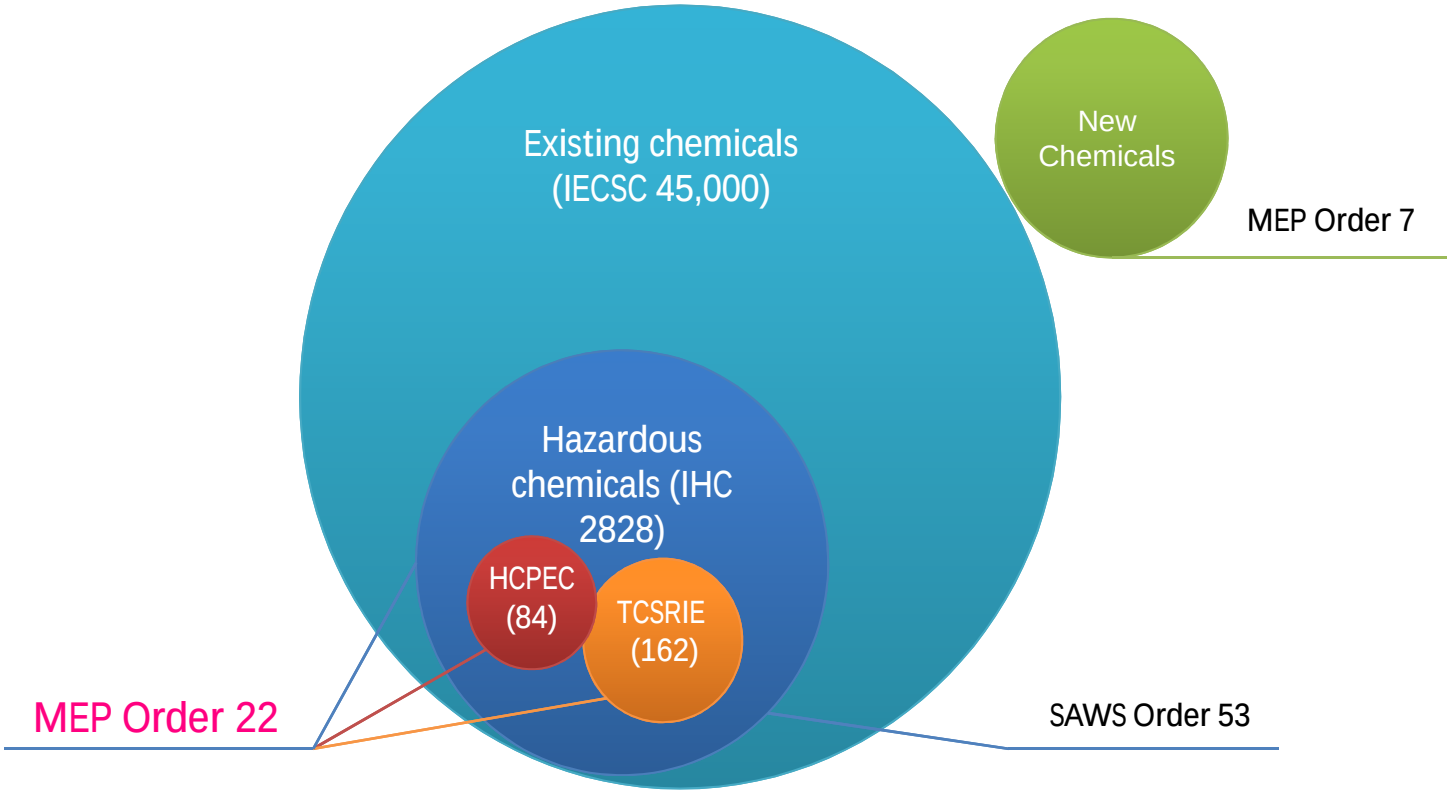
u Inspection Items on SDS/Label

- ü Main composition/constituents of the product, its physical-chemical properties and hazard category compliant with “GB30000.2~29”
- ü Label/SDS are compliant with GB15258-2009, GB/T16483-2008, GB/T17519-2013 in terms of the format and content.

u Inspection on the Package of Imported HazChem

- ü Identify whether the models, category, specification, unit quantity and mark of packaging meet Clause IV indicated in this Order.
- ü Package is marked with the appropriate (GHS) precautionary label and accompanied by its appropriate (GHS) Safety Data Sheet;

1 – Scope



IHC: Inventory of Hazardous Chemical
IECSC:Inventory of Existing Chemical Substances in China 2013
HCPEC: Catalogue of Hazardous Chemicals of Priority Environmental Concerns
TCSRIE: List of Toxic Chemicals Severely Restricted to be Imported into or Exported from China

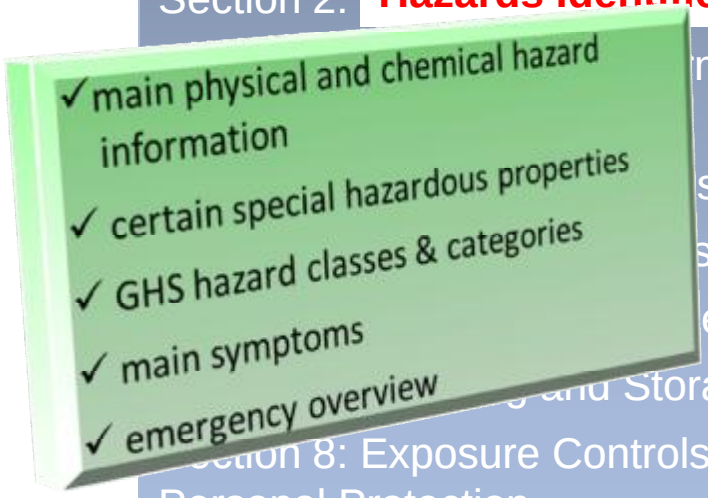
2 - SDS

GB/T 16483-2008

GB/T 17519-2013

Section1: Chemical Product & Company Information

Section 2: **Hazards Identification**



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s

sures

e Measures

and Storage

ection 8: Exposure Controls and Personal Protection

Section 9: Physical and Chemical Properties

Section 10: Stability and Reactivity

Section 11: Toxicological Information

Section 12: Ecological Information

Section 13: Disposal Considerations

Section 14: Transport Information

Section 15: Regulatory information

Section 16: Other information

2 - SDS

Special Requirements on China SDS

Section 1

Sub-section	China GHS
Product identifier	List the chemical name of your product in both English and Chinese. If available, provide the product code
Emergency no.	One emergency no. should be available for 24 hrs./7 days professional help and the number must be a Chinese domestic landline rather than cell phone.

Section 2

Sub-section	China GHS
Classification	GB 13690-2009 and "GB30000.2~29 National Standards"
Emergency overview	Ø Summary of hazard statement Ø Placed in the beginning of 2nd section Ø Bold characters or frame for emphasis

2 - SDS

Section 3

Sub-section	China GHS
Mixture information	Confidential ingredients do not have to be listed together with their concentration percentages/ranges, but the hazardous information should be indicated.

Others

Sub-section	China GHS
Section 8	A list of permissible concentrations, such as OEL values or biological limit values. GBZ 2.1-2007 shall be referred.
Section 11	10 subsection for 10 health hazards
Language	Simplified Chinese is required

Colorful Paint (in Chinese and English)

Hazard ingredients: 2-ethoxyethanol, 25-50%; Solvent X, 25-50%; Photoinitiator, 3-8%; C.I. Pigment Orange 20, 1%;

Danger

Combustible liquid. May be harmful if swallowed. Toxic if inhaled. Causes skin irritation. Causes serious eye irritation. May cause cancer. May damage fertility or the unborn child. Toxic to aquatic life with long lasting effects.

[Prevention] Keep away from heat/sparks/open flames/hot surfaces.-No smoking. Wear protective gloves/eye protection/face protection. Avoid breathing fume/mist/vapors/spray. Use only outdoors or in a well-ventilated area. Wash hands thoroughly after handling. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
Avoid release to the environment.

[Response] Use foam for extinction. Call a POISON CENTER or doctor/physician if you feel unwell. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician immediately. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF exposed or concerned: Get medical advice/attention. Collect spillage.

[Storage] Store in a well-ventilated place. Keep cool. Store locked up.

[Disposal] Dispose of contents/container in accordance with local/ regional/ national/ international regulations.

Please refer to the Safety Data Sheet

Supplier: REACH24H Post code: 312000
Address: xxx, Hangzhou, China Tel: +86-0571-87007555

Emergency phone number for chemical accidents: +86-XXXXXXXXXX

REACH24H GROUP 瑞欧 consulting

Product Identifier

Signal word, warning or danger

Hazard pictogram

Hazard statement

8 label elements

Precautionary statement

Prompt users to refer to SDS

Supplier information

Emergency telephone no.

3 - Label

Special requirements according to GB15258-2009

- Layout sequence of Hazard statements:
  1. Physical; 2. Human Health; 3. Environment.
- Label size

Volume of container or packaging/ L	Label dimensions (mm x mm)
≤ 0.1	Use a simplified label
> 0.1 ~ ≤ 3	50 x 75
> 3 ~ ≤ 50	75 x 100
> 50 ~ ≤ 1000	100 x 150
> 500 ~ ≤ 1000	150 x 200
> 1000	200 x 300

- Prompt users to refer to SDS
- Emergency telephone number
- Printing requirements of the label (e.g., color, border)

4 – HazChem Registration

Measures on HazChem Registration (SAWS Order 53)

ü Competent Authorities

--- NRCC - The National Registration Center for Chemicals of SAWS

--- Local registration offices

ü Who's Affected?

--- Domestic Manufacturers & Importers

ü When to Register?

--- Prior to the final acceptance of a newly-built chemical plant (Manufacturers) or Prior to any importing activities (Importers).

4 – HazChem Registration

ü What Chemicals (Scope)

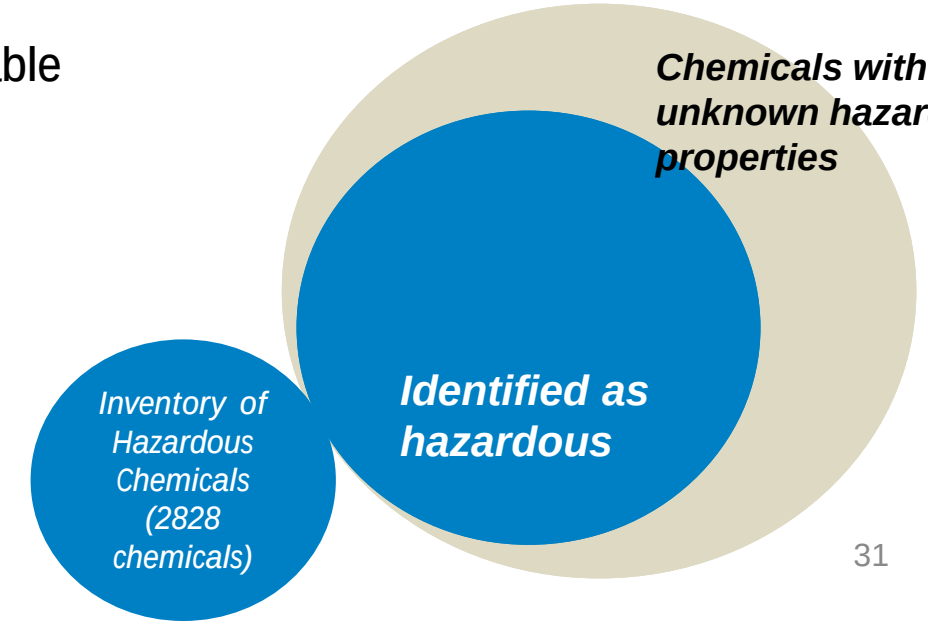
1. Chemicals listed in the Inventory of Hazardous Chemicals

   The 2015 version of the Inventory was published on May 1, 2015; replaces 2002 version.

2. Chemicals with unknown hazard properties but identified to be hazardous after hazard identification

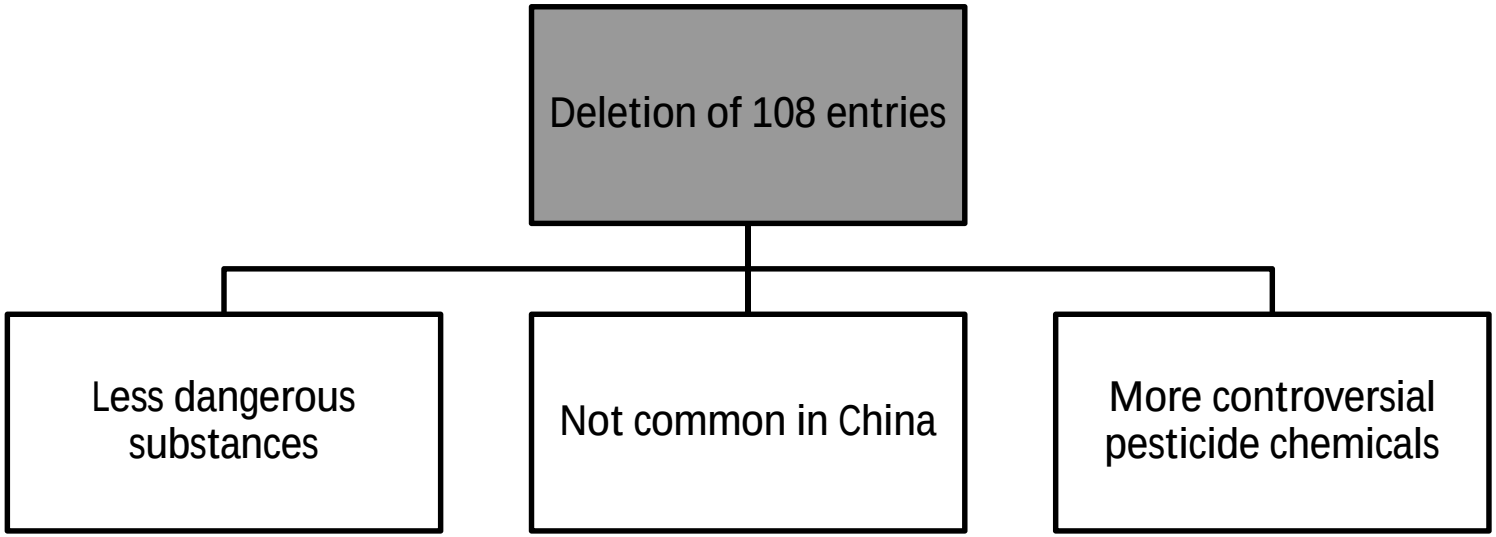
   Physical hazards identification available (SAWS Order 60)

ü What Chemicals (Type)



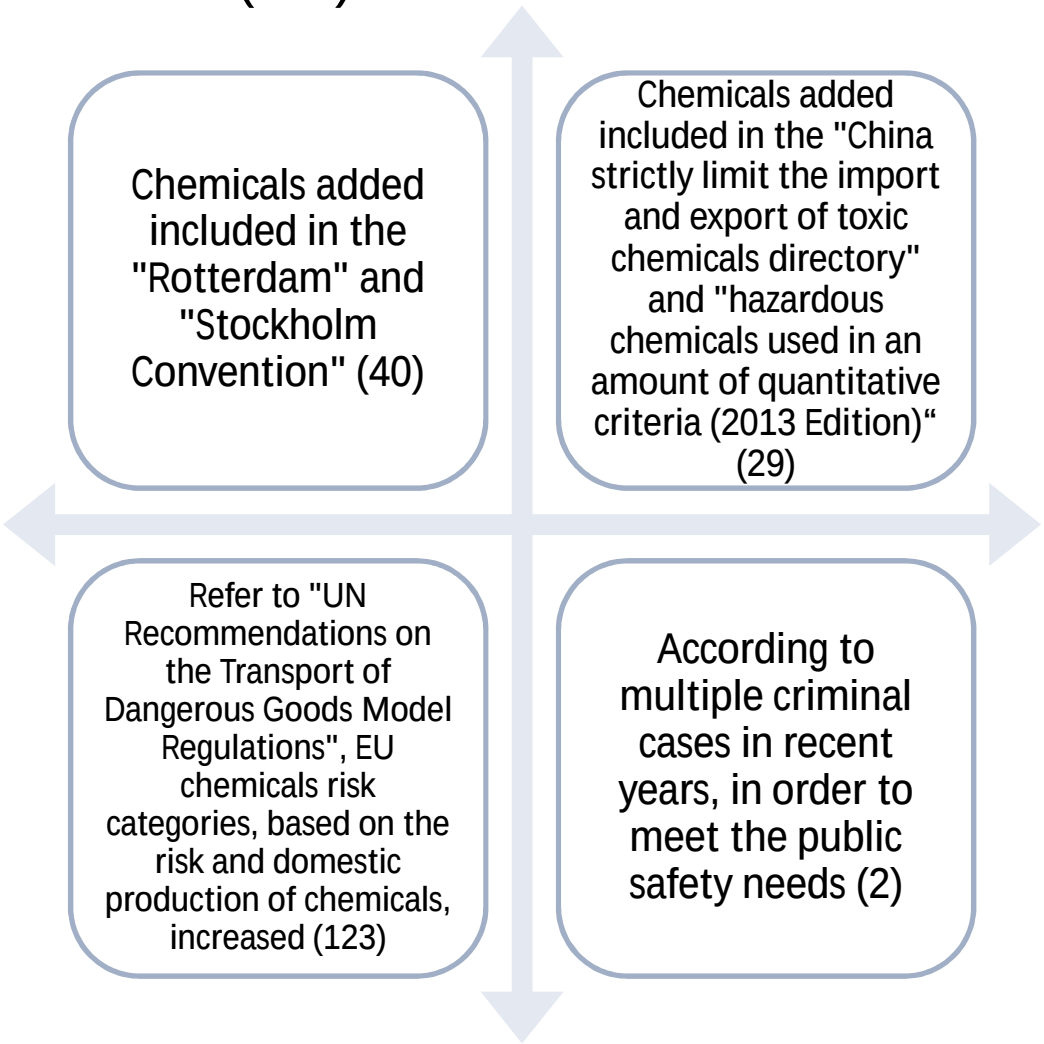
China Inventory of Hazardous Chemicals (2015) aka C&L Inventory - entered in force May 1, 2015

Comparison with the 2013 Draft Inventory



Comparison with the 2002 Version of the Inventory

Increased Chemical Entries (194)



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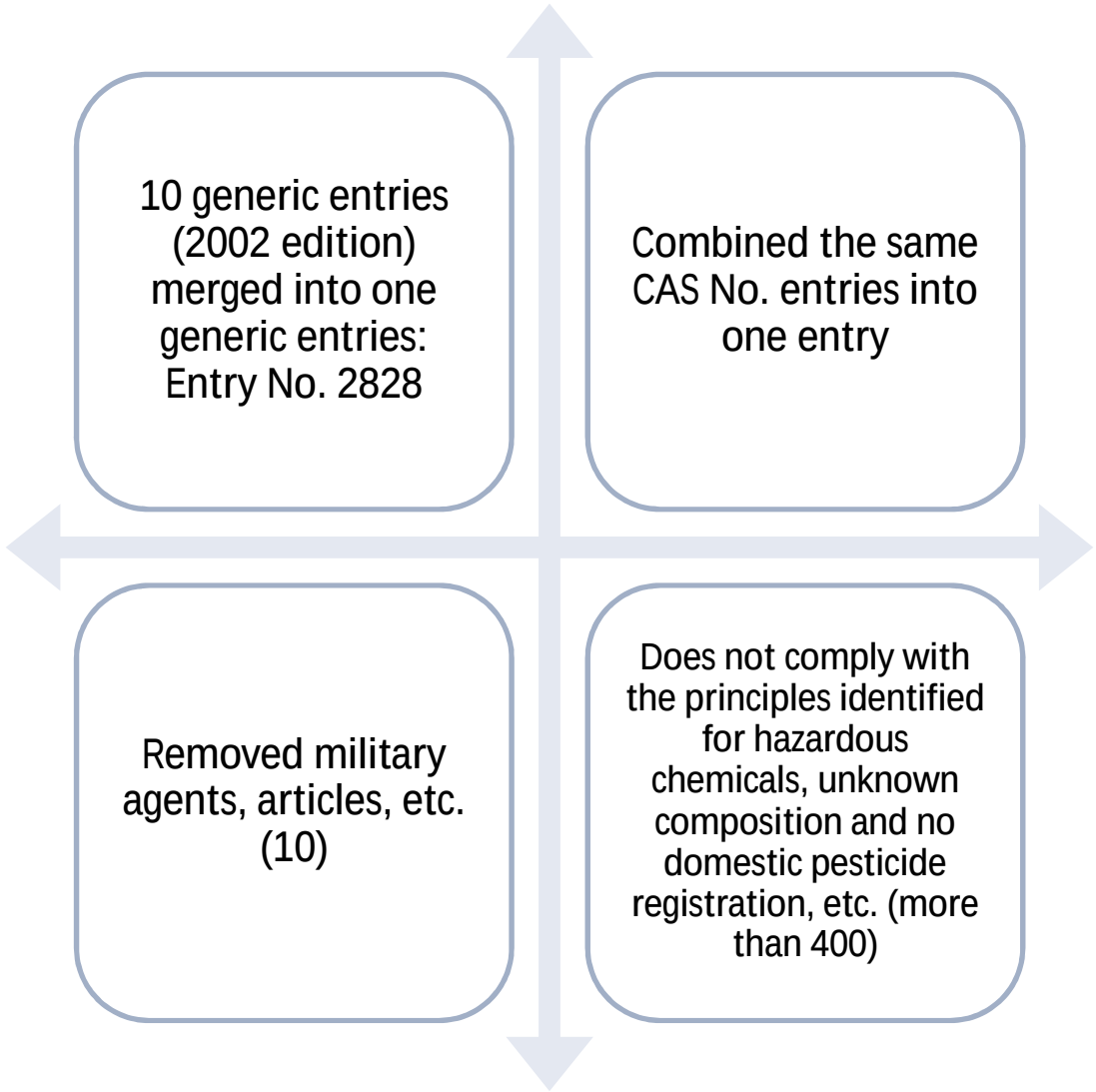

Guidance for the Implementation of China 2015 Inventory of Hazardous Chemicals (issued by SAWS on Aug 19)

Background

The 2015 Inventory of Hazardous Chemicals entered into force on May 1 to guide the administrative work of the 10 authorities involved in the administration of these chemicals as well as to help clarify industries' obligations under State Council Decree 591 and its sub-regulations. Adhering to the previous work plan and based on the FAQs about the Inventory (e.g., which products fall under the indefinite entry No. 2828), SAWS formulated the Implementation Guidance to further specify the implementation rules (main body of the document) under its own jurisdiction and to provide the official classification results of the listed chemicals.

To be more specific, chemical companies should refer to the Implementation Guidance to find out whether relevant products (70% threshold) require:

- (Physical) Hazard Identification and Classification
- Labeling and SDSs
- HazChem Registration
- Administrative Licensing in terms of production, use and operation.

Guidance for the Implementation of China 2015 Inventory of Hazardous Chemicals

The Classification Information Sheet of Hazardous Chemicals annexed to the Implementation Guidance looks similar to the Inventory but has two additional columns namely the “English Name” and “Hazard Category”, for example:

SN	Chinese Chemical Name	Chinese Alias	English Name	CAS No.	Hazard Category	Remark
1	阿片	鸦片	opium	8008-60-4	Specific target organ toxicity-Repeated exposure, Cat.2	
2	氨	液氨；氨气	ammonia; liquid ammonia	7664-41-7	Flammable gases, Cat.2 Gases under pressure Acute toxicity-Inhalation, Cat.3* Skin corrosion/irritation, Cat.1B Serious eye damage/eye irritation, Cat.1 Hazardous to the aquatic environment-Acute hazard, Cat.1	

- While following these classification results are generally taken as a mandatory requirement, the "lowest classification" and "incomplete classification" principles allow the industry to make their own decisions to a certain extent (i.e., assign higher sub-categories and supplement other hazards).

Tianjin Port Explosion on August 12

The hazardous chemicals stored or stacked at the explosion site amounted to approximately 3000 tons, including 800 tons of ammonium nitrate, 500 tons of potassium nitrate, 700 tons of sodium cyanide, and 40 other miscellaneous chemicals.

Latest statistics after the Tianjin Port explosion: The death toll now stands at 158 with 15 people remain missing and 474 in hospital.

What have we learned from the Tianjin Disaster?

ü Hazardous chemicals must be stored in dangerous goods warehouses which need to be examined and approved by supervision departments in China.

Relative Regulations:

- Measures on HazChem Registration (SAWS Order 53)
- General Principles in Storage of commonly used hazardous chemicals (GB 15603-1995)
- Storage and preservation of flammable goods (GB 17914-2013)
- Storage and preservation of corrosive goods (GB 17915-2013)
- Storage and preservation of toxic goods (GB 17916-2013)
- Guidance on the compilation of safety data sheet for chemical products(GB/T 17519-2013, GB/T 16483-2008)
- .....

Main focus on four aspects:

- Warehouse Construction
- Inventory Management
- Emergency Response
- Staff Training

Tianjin Explosion Prompts Chinese Ports to Scale Up HazChem Inspection

In the wake of the massive explosions that rocked Tianjin Port, many other ports have scaled up inspection of hazardous chemicals. In addition some ports have placed hazchem import/export activities on temporary hiatus.

Port name	Classes of dangerous goods restricted or rejected	Import/Export	Remark
Tianjin Port	All	Import & export	From Aug 17
Changshu Port	All	Import & export	From Aug 17
Chongqing Port	All	Import & export	
Huangpu Port	Only accepts Class 6/8/9/4.2 (UN 1384)	Import & export	Dongjiangkou Container Terminal, from Aug 14
	Except liners from Taiwan, barium carbonate and Class 9 DGs, other DGs are not accepted in warehouses		Guangzhou Port Group Huangpu Stevedoring Branch Co.,Ltd, from Aug 18
	Only accepts Class 2.2/3/4/5/6.1/8/9 (Under one proper shipping name, and not be mixed with general goods)		TQT Container Terminal
	Only accepts Class 6.1 (UN 1564)/Class 9		THS Container Terminal
Huangshi Port	All	Import & export	
Lianyungang Port	Class 1/2	Import & export	From Aug 17
Nantong Port	Class 3/6	Import & export	
Ningbo Port	/	Global transshipment	(M)SDS required
Qingdao Port	Class 4 (except sulfur); Class 5 (UN 2465, 2468); Not to be stocked in DG warehouses	Import & export	From Aug 17
Shanghai Port	/	Import & export	Vehicles carrying Class 2.1/2.3/5.2 DGs are prohibited from crossing Donghai Bridge in the direction of Yangshan deep-water port
Xiamen Port	All	Import & export	
Yangzhou Port	Only accepts Class 2.2/3/5.1/8/9		
Yichang Port	All	Import & export	
Zhangjiagang Port	Class 1/2/4.2/4.3	Import & export	From Aug 17
Zhanjiang Port	All	Import & export	
Zhuhai Port	All	Import & export	TZI Container Terminal

Advice for Compliance

- IDENTIFY your role in the supply chain of hazardous chemicals.

- CONFIRM if the hazardous chemicals are included in the specific catalogues or lists:
  - Inventory of Existing Chemical Substances in China 2013 (IECSC)
  - Inventory of Hazardous Chemical (IHC)
  - List of Toxic Chemicals Severely Restricted to be Imported into or Exported from China (TCSRIE)
  - Catalogue of Hazardous Chemicals of Priority Environmental Concerns (HCPEC)

- DETERMINE the strategies to comply with the regulations.

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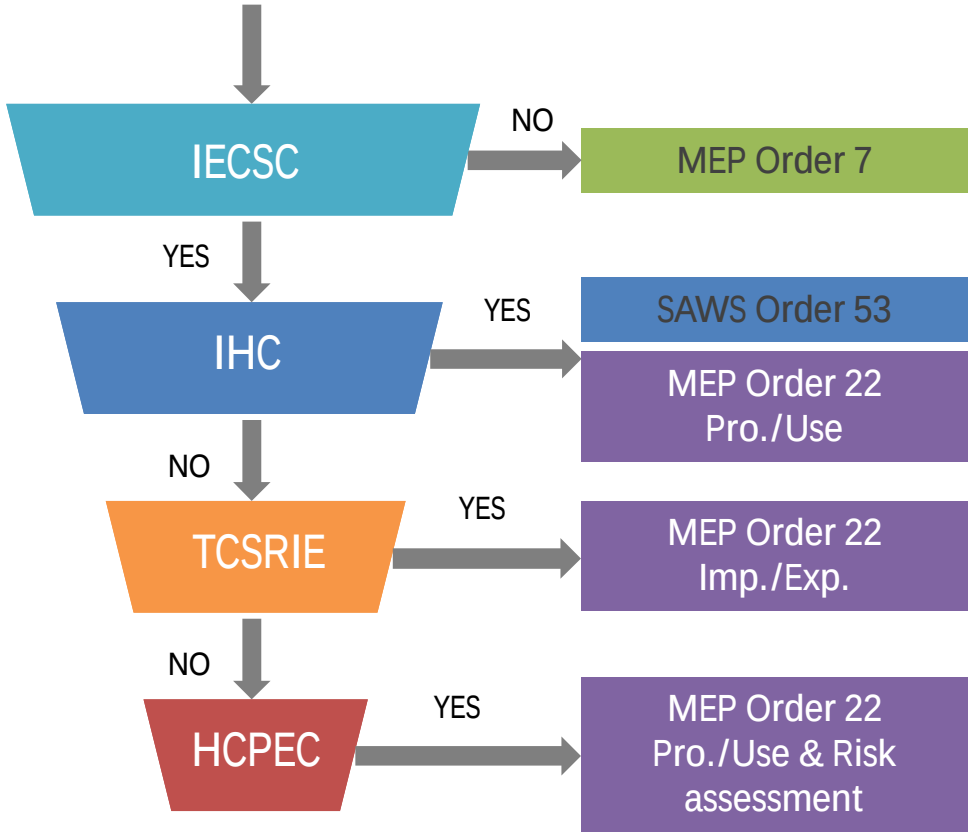

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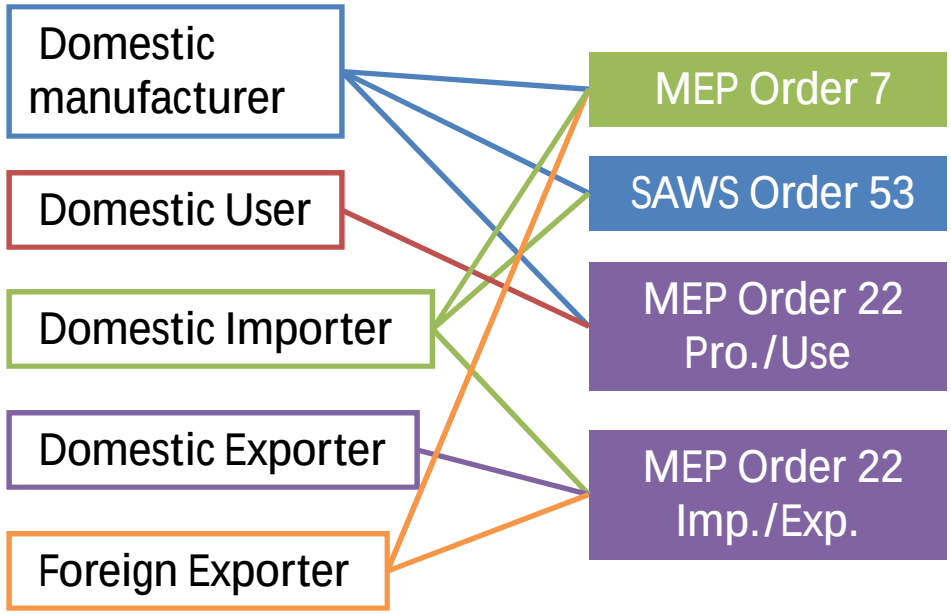


Part 2:
Taiwan's Chemical Substance Management under TCSCA/OSHA

Competent Authorities and Regulations

Official Name	Regulation of New and Existing Chemical Substances Registration (TCSCA Regulation of Registration)	Official Name	Regulations on New Chemical Substances Registration (OSHA Regulation of Registration)
Authorized by	TCSCA Article 7-6	Authorized by	OSHA Article 13
Applicable Scope	New Chemical Substance & Existing Chemical Substance	Applicable Scope	New Chemical Substance
Competent Authority	EPA's Department of Environmental Sanitation and Toxic Substance Control	Competent Authority	MOL/OSHA
Technical Support Organization	ERI/CRC	Technical Support Organization	SAHTECH/NCSR
Implementation	December 11, 2014	Implementation	January 1, 2015

Pre-Registration Work---Appoint a Third Party Representative

Registrant

Taiwanese Manufacturer

Taiwanese Importer

YES!

Power of Attorney (POA)


委託(授權)文件

Taiwanese TPR

Must be Authenticated/Notarized in the Court

Definition and Timeline of the TCSI

New chemical substance?
Existing chemical substance?

The Taiwan Chemical Substance Inventory or TCSI was established based on the achievements of the ECN (Existing Chemical Nomination).

Taiwan MOL concluded the ECN, the first Supplementary ECN (SECN) and the second Supplementary ECN (SSECN) respectively on Dec 31, 2010, on Aug 31, 2012 and on July 31, 2014. Through the ECN, SECN and SSECN, Taiwan's national existing chemical substance inventory (TCSI) was established.

勞動部
Ministry of Labor

- ECN — Duration: 11/2/2009 - 12/31/2010
- SECN — Duration: 6/1/2012 - 8/31/2012
- SSECN — Duration: 6/1/2014 - 7/31/2014
- Another ECN period was launched by EPA from 12/12/2014 to 3/31/2015
- The final version of the TCSI was released by MOL on 9/9/2015.

More Information About the TCSI

https://csnn.osha.gov.tw/content/home/Substance_Home.aspx

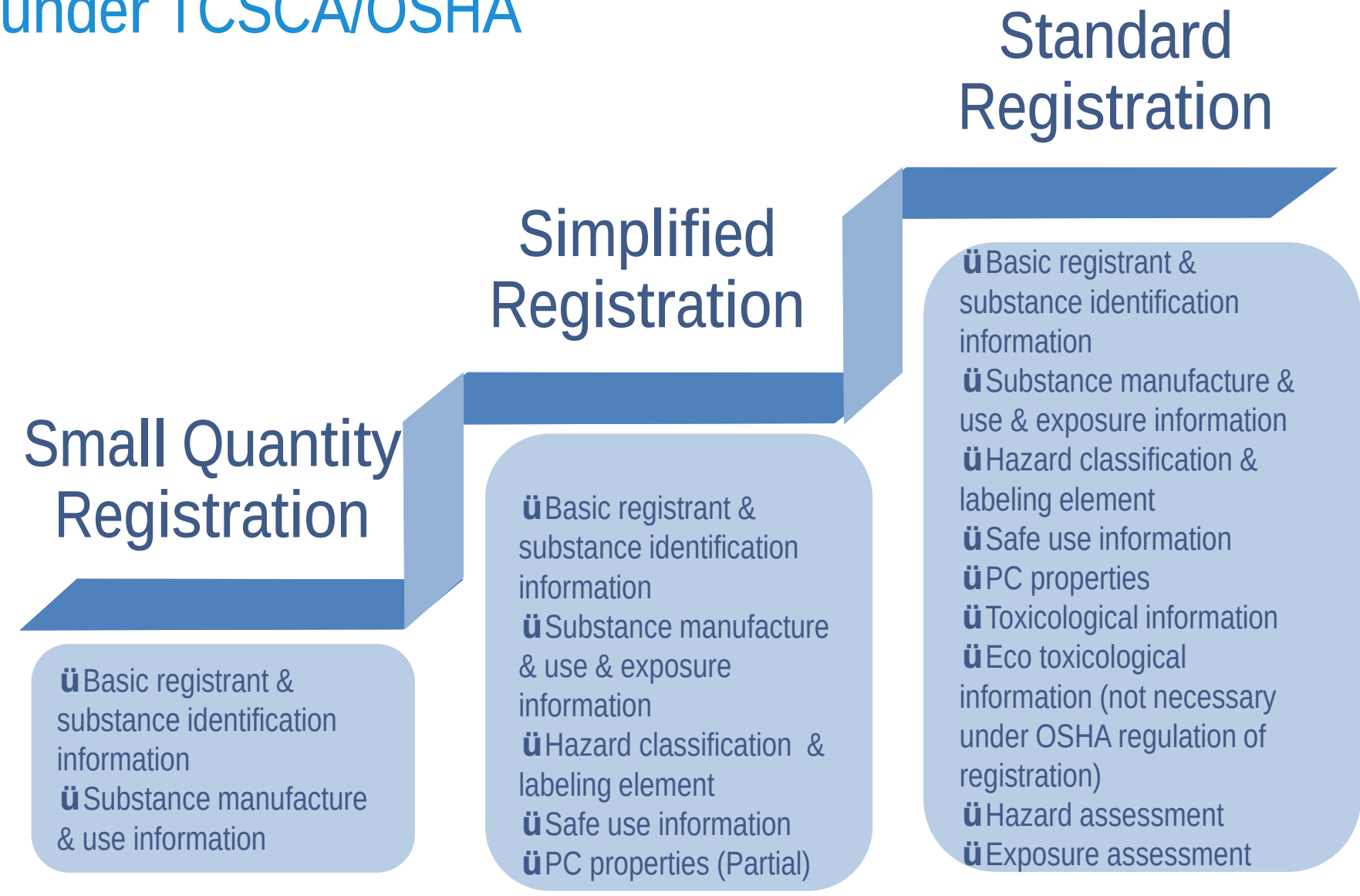
Characteristics

1. Latest update on Sep 9, 2015
2. Currently >100,000 substances, approximately 7,000+ more substances added after last update
3. Including general new chemicals, polymers, UVCB
4. Around 800 chemical substances (<1%) have been designated confidential w/ general name or serial no.
5. On-line inventory is only method available to determine a chemical's status
6. Search functionality: "quick search" and "advanced search" for single substances; and "multiple search" for up to 5 substances at a time.

New Chemical Substance Management under TCSCA/OSHA Regulation of Registration

a: Under the OSHA Regulation, a registrant does not need to submit exposure assessment if the substance is non-hazardous.
b: Under the TCSCA Regulation, a registrant does not need to submit hazard & exposure assessment if the annual quantity of the new chemical substance is less than 1000 tons; and a registrant does not need to submit exposure assessment if the substance is non-hazardous.

Data Requirements for New Chemical Registration under TCSCA/OSHA



Grace Period for New Chemical Substance Registration

Grace Period

Purpose: To ease the impact of both regulations;

Authorized by:

- Article 17 of the TCSCA regulation of registration;
- Article 12 of the OSHA regulation of registration

Grace Period

Period of Validity: 1 year;

Data Requirements: Same requirements as Small Quantity Registration. More specifically, basic information about the company, applied chemical and tonnage/usage

Validity of the Certificate

Registration Type	Valid Period	Extension
Standard Registration	5 years	NA
Simplified Registration	2 years	3 months prior to expiration
Small Quantity Registration	2 years	
PLC (>1 t/y) SQR	5 years	NA

Two approaches to list the qualified substances into the TCSI

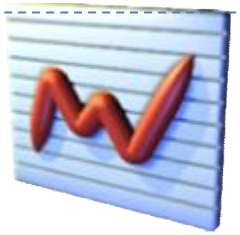
Existing Chemical Substance Phase 1 Registration (launched Sep 1, 2015)

Listed in the TCSI (updated in Sep 9)

Existing Chemical Substance

Over 100kg/a (avg. annual quantity from previous three years (2012, 2013, 2014)

CAS No. or Serial No.



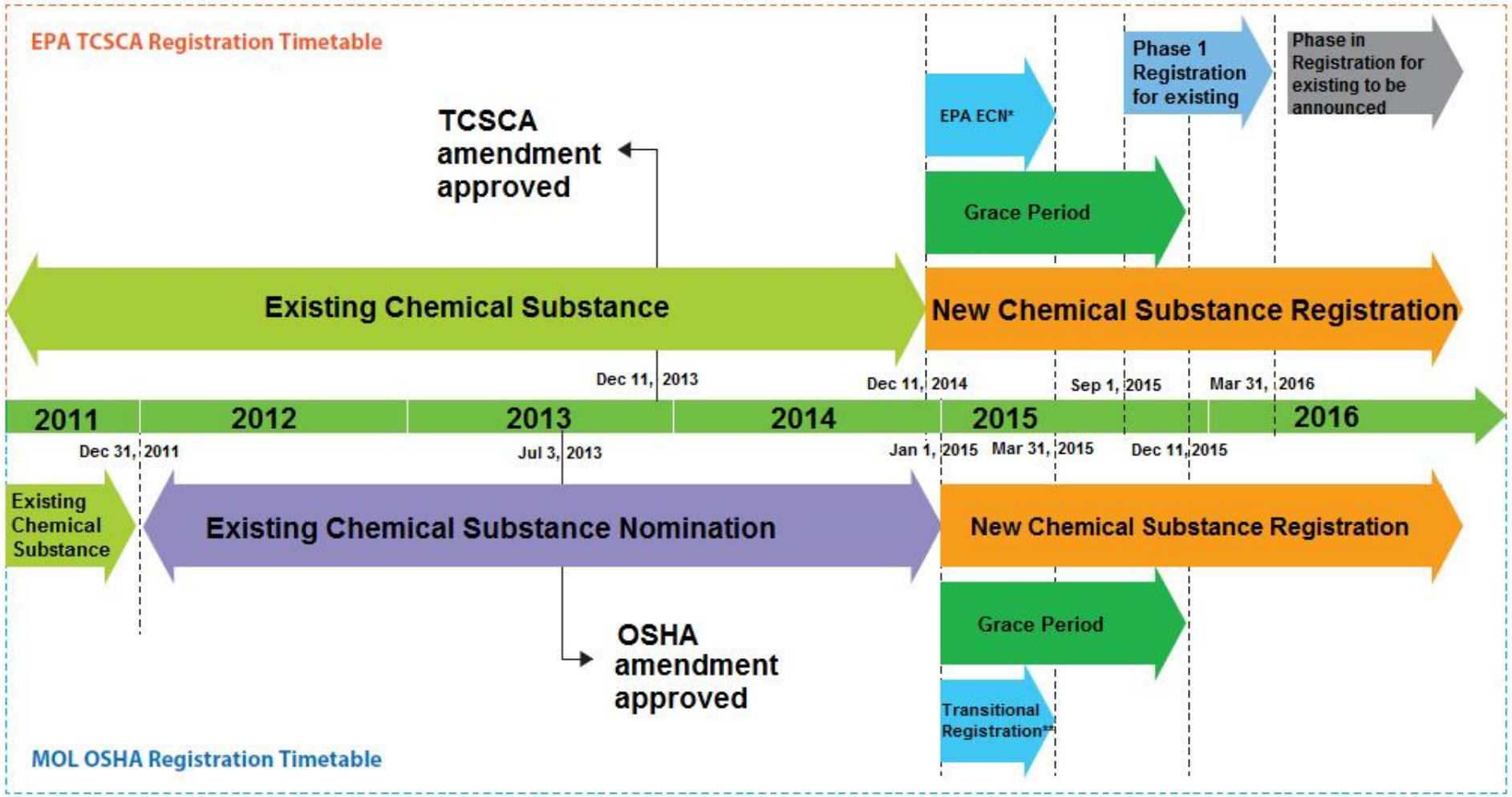
- Actual Annual Volume of the previous three years (2012, 2013, 2014)
- Estimated Volume of the year 2015

Data Requirements

Product Category

Industrial Category

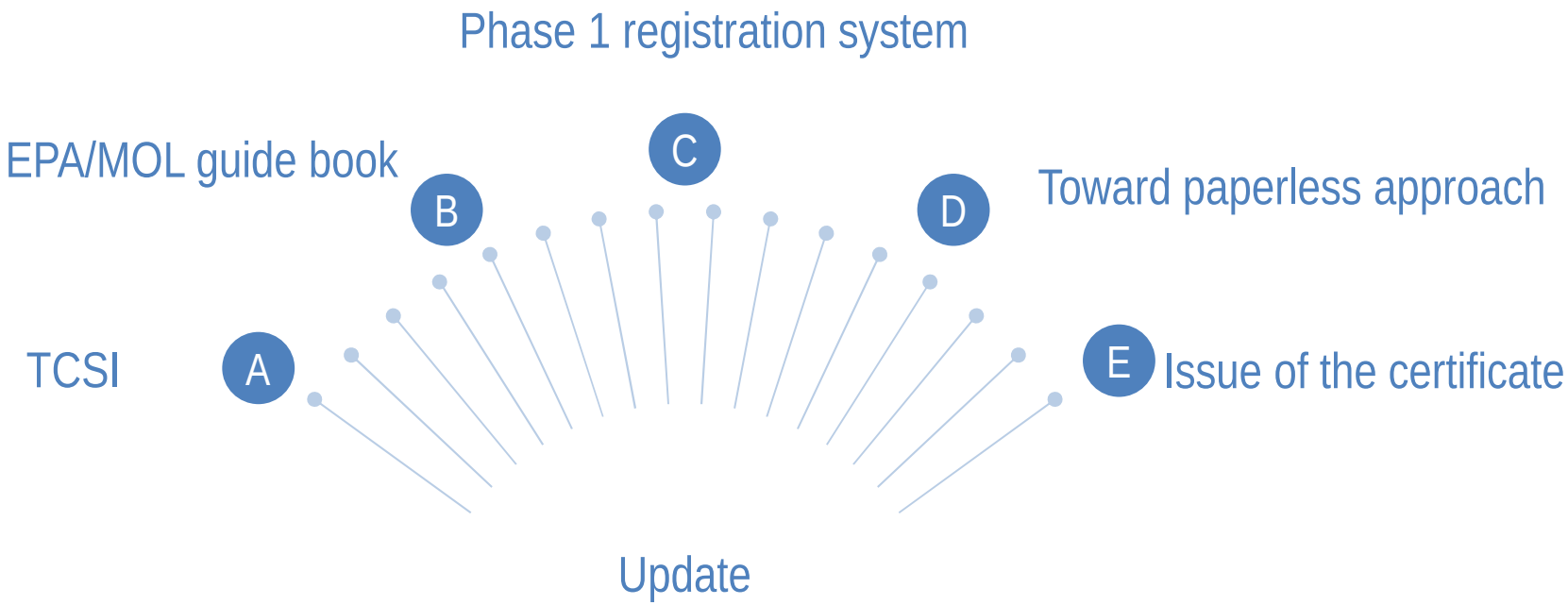
Timetable under TCSCA/OSHA Regulation of Registration



* ECN: Existing Chemical Nomination

** Transitional Registration: Registration measure for chemical substances manufactured or imported in Taiwan before the regulation came into effect

Latest Updates---Intelligence about supporting materials



Latest Updates---Single Window Mechanism

修正條文	現行條文	說　明
第十八條　中央主管機關得委託相關專業團體，辦理新化學物質之核准登記作業。 前項新化學物質核准登記案件之受理及登記文件之核發，得委託中央環境保護主管機關辦理之。	第十八條　中央主管機關得委託相關專業團體，辦理新化學物質之核准登記作業。	一、查行政院環境保護署主管之毒性化學物質管理法第七條之一與本部主管職業安全衛生法第十三條雖立法目的不同，但均屬化學物質源頭登記管理之規定，為配合建立單一窗口及統一發證機制，並建立相關主

- Draft Amendment
- Released on 4/23/2015 by MOL Public Announcement
- 10 days for soliciting opinions

Review/ approval

GHS in Taiwan

In Taiwan there are currently two regulations that have adopted GHS standards (UN GHS Rev. 3):

- "CLA Regulation" - Regulation of Labeling and Hazard Communication of Dangerous and Harmful Substances, Directive of the Executive Yuan Council of Labor Affairs, October 19, 2007 (CLA No. 0960145703) [Effective Date: December 31, 2008]
- "EPA Regulation" - Management Measures on Toxic Substances Labeling and Material Safety Data Sheet, December 17, 2007 (EPA No. 0960095329) [Effective Date: December 31, 2008]

Transition period

- Implemented from Dec 31, 2008 in 3 stages;
- Mandatory compliance is currently required for two lists (1062 + 1089 substances) by CLA, toxic chemical substances, and their mixtures - mainly chemicals with physical and health hazards;
- The third CLA list (1020 substances) was released in Oct 2013;
- Full implementation by Jan 1, 2016 (for chemicals with environmental hazards);
- Updated CNS 15030 Series Standards on C&L to be aligned with UN GHS Rev 4

Labeling

•According to Article 5-6 in CLA regulation, if the hazardous substances inside the containers are in mixtures, the hazardous ingredients on the label should indicate that the hazard of the mixture is in accordance with National Standards 150307 for Chemical Goods Classification and Labeling along with all of the ingredients that are physically hazardous or that are hazardous to health.

•Small Package: If the volume of the first container is 100 ml or less, then the container need only be labeled with the name, hazard or hazard pictogram and warning signal;
•Language on Labels: Traditional Chinese should be used as the standard. A foreign language may be used if necessary. Both Chinese and English chemical names should be indicated.

SDS

Appendix 5 of CLA regulation gives a template for Material Safety Data Sheet.
•The 16-sections MSDS is in accordance with UN GHS;
•The emergency telephone number for MSDS should be a phone number that is available at any time and available for consultation in the event of an accident.
•Toxic chemical substances that are obtained from custom tender and importation must have complete container and package markings, as well as the material safety data sheet, within four days after their withdrawal from customs. The toxic chemical substances are compounds, marks and material safety data sheets shall be formulated based on their hazardous properties after blending.

Language on SDS: Traditional Chinese should be used as the standard. Both Chinese and English chemical names should be indicated.

Latest News About the GHS in Taiwan

1. GHS Purple Book Revised 4th edition available in Traditional Chinese Language (Feb 6, 2015)

   http://ghs.osha.gov.tw/ENG/intro/news.aspx

2. A New System of Chemical Management Is Taking off in Taiwan for More Comprehensive Protection on Occupational Safety (Dec 31, 2014)

3. Regulation of Labeling and Hazard Communication of Hazardous Chemicals (Jul 3, 2014) - (The English version is for general reference. In case of discrepancy, the original version in Chinese shall prevail.)

4. Taiwan Announced Full Implementation of GHS by 2016 - Additional Fine May Be Levied Per Violation of Noncompliance (Mar 27, 2014)

Changes Related to SDS Content

Taiwan's Ministry of Labor amended “Labeling and general rules of dangerous and harmful substance" and renamed it “Labeling and general rules of hazardous chemicals“ on Jun 27, 2014.

	Labeling and general rules of dangerous and harmful substance	Labeling and general rules of hazardous chemicals
SDS heading	Material Safety Data Sheets	Safety Data Sheets
The title of section 1	Company information of products	Company information of chemicals
The subtitle of section 1	Item Name	Chemical Name
	Name, address and telephone of the manufacturer or suppliers	Name, address and telephone of the manufacturer, importer or supplier
The subtitle of section 2	Items hazard classification	Chemical Hazard Classification
The subtitle of section 3	Hazardous material composition	Hazardous composition
	Chinese and English name of Hazardous material composition	Chinese and English name of Hazardous composition

REACH24H China Regulatory Affairs Conference (CRAC 2015)

Thanks for your attention!

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