



CIRS



Japan Environmental Management
Association for Industry

Global GHS Training Course

No.5 – Japan GHS Features and Chemical Regulations



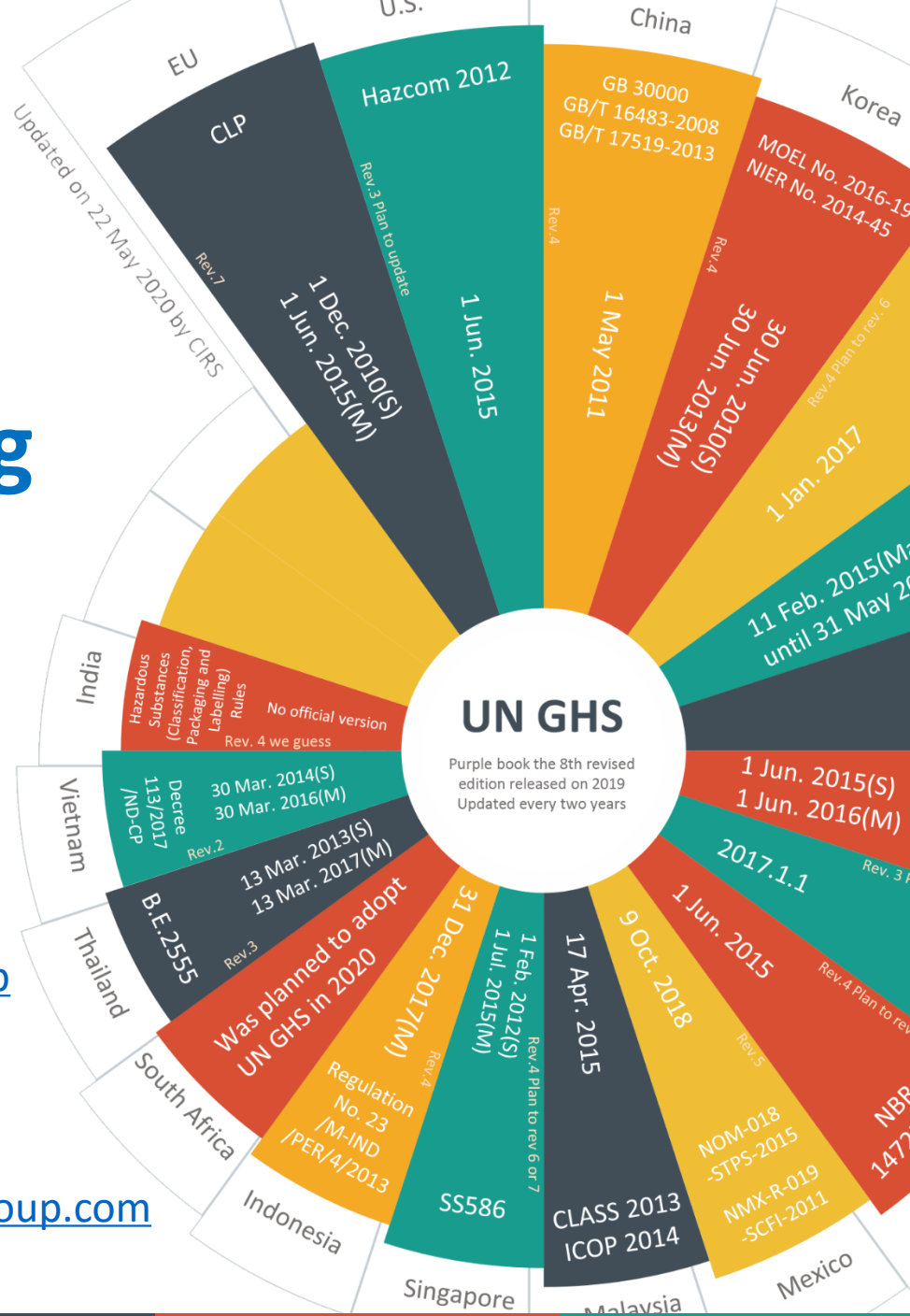
Dr. Hou Rong
JEMAI

E-mail: hou-rong@jemai.or.jp



Mr. Ethan Zheng
CIRS

E-mail: ethan.zheng@cirs-group.com



Contents



1. About JEMAI



2. Overview of Chemical Regulations & Updates



3. GHS Implementation & Updates of JIS



4. Summary



5. Q&A

1. About JEMAI



- JEMAI: The Japan Environmental Management Association for Industry
- Established: September 1962
- JEMAI' s Activities:
 - Environmental Assessments;
 - Technology Developments;
 - Surveys Regarding Pollutions;
 - Global Environmental Issues etc.



Learn more about JEMAI here:

<http://www.jemai.or.jp/>

2. Overview of Chemical Regulation



PRTR(化管法)

➤ Purpose:

To promote voluntary improvement of management of chemical substances by business operators and to prevent any impediments to the preservation of the environment through

- Establishment of the Pollutant Release and Transfer Registers (PRTR) system, which confirms release amounts, etc. of specific chemical substances in the environment ;
- Safety Data Sheets (SDS) system, which provides information concerning the properties and the handling of specific chemical substances.

➤ Competent Authority :

- METI(Ministry of Economy, Trade and Industry)
- MOE(Ministry of the Environment)



English Information Resource for PRTR Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?printID=&re=01&id=101&vm=02>

Regulated Substances(PRTR)

Category and #	Requirement
Specific Class I (15 substances) Designated Chemical Substances	<ul style="list-style-type: none"> Selected from Class I designated chemical substances due to their carcinogenic properties ; Subject to both PRTR reporting ($\geq 0.5\text{t/a}$) and SDS requirement($\geq 0.1\text{wt}\%$).
Class I (447 substances) Designated Chemical Substances	<ul style="list-style-type: none"> Subject to both PRTR reporting ($\geq 1\text{t/a}$) and SDS requirement($\geq 1\text{wt}\%$).
Class II(100 substances) Designated Chemical Substances	<ul style="list-style-type: none"> Subject to SDS requirement only($\geq 1\text{wt}\%$).

Exemptions :

- Products that contain the specified chemical substances but less than specified concentration limits;
- A product's chemical substances are sealed and is used with the specified chemical substances sealed;
- Products for general consumers (example: detergents, lubricants, insecticides, insect repellents) ;
- Recyclable resources(example: empty can, waste metal);
- Solid products(example: tubes, plates)

English Information Resource for Specific Substances list under PRTR:

https://www.nite.go.jp/en/chem/chrip/chrip_search/intSrhSpclst?_e_trans=&slScNm=RJ_02_001

Requirements for Importers

➤ PRTR Reporting:

- Business operators whose operations fall under the 24 types of business operations specified in the government ordinance; or
- Business operators who employ over 21 employees during their regular business operations; or
- Business operators who handle ≥ 1 t /a of any chemical substance specified in the "Class I Designated Chemical Substances" (or ≥ 0.5 t/a of the Specific Class I Designated Chemical Substances).

➤ Providing SDSs (Obligation)

- Specified Class I Designated Chemical Substances(≥ 0.1 wt%);
- Class I Designated Chemical Substances (≥ 1 wt%);
- Class II Designated Chemical Substances (≥ 1 wt%) .

➤ Labeling on such products is **strongly recommended**(Make Efforts)

ISHL(安衛法)

➤ Purpose:

To secure the safety and health of workers in workplaces, as well as to facilitate the establishment of a comfortable working environment.

➤ Competent Authority :

- MHLW(Ministry of Health, Labour and Welfare)



English Information Resource for ISHL Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=1926&vm=&re>

Regulated Substances(ISHL)

Category and #	Requirement
New Chemicals Substances	<ul style="list-style-type: none"> Approval required before manufacturing or importing.
Prohibited to Manufacturing (8 substances)	<ul style="list-style-type: none"> Prohibited from manufacturing or importing.
Requiring Permission for Manufacture(8 substances)	<ul style="list-style-type: none"> Permission required before manufacturing or importing.
Requiring Labeling and Delivery of Documents(SDSs) (640 Substances)	<ul style="list-style-type: none"> Required to labeling and delivery of documents(SDSs)when transferring or providing any of the subject chemical substances.
Others (Specified Chemical Substances; Organic Solvents etc.)	<ul style="list-style-type: none"> Specific measures required during manufacturing and handling (e.g. Local ventilation ; Protective equipment, Medical checkup etc.)

English Information Resource for Regulated Substances list under ISHL:

https://www.nite.go.jp/en/chem/chrip/chrip_search/sltLst

Requirements for Importers

➤ Notification of New Chemical Substances:

Category	Requirement
Standard Notification	<ul style="list-style-type: none"> • Tonnage $\geq 100\text{gk/y}$; • AMES testing is required; • Other information (manufacturing process, reaction formula, etc.); • The substance name will be published within 1 year after approval.
Small Volume Notification	<ul style="list-style-type: none"> • Tonnage $< 100\text{kg/y}$; • No testing is required; • Apply per year or Apply for 2 years at one time.
Confirmation	<ul style="list-style-type: none"> • Measures have been taken to prevent workplace exposure ; • The substance is not well known as carcinogen in foreign country. • Contact with MHLW before proceeding confirmation is necessary.
Full Exemption	<ul style="list-style-type: none"> • Substance for testing and research purposes, reagent, sample for business, sealed in machine, substance in consumer goods and existing chemical substances under ISHL.

Requirements for Importers_(Cont'd)

➤ Providing SDSs and Labeling:

[Obligation]

- Appended Table 3 & Table 9 of Order of Enforcement of ISHL(640 substances);
- Mixtures containing any of the above (The cut-off value is defined for each substance).

[Make Efforts]

- Substances/mixtures which are classified as hazardous according to JIS Z7253.

[Exemption]

- Regulated by other laws(Pharmaceutical Medical Equipment Law , Agricultural Chemicals Control Law);
- Solid products (a product which stays as a solid whilst being handled and never turns into powder or granulated form);
- A product' s chemical substances are sealed;
- Products for general consumers.

PDSCL(毒劇法)

➤ Purpose:

To provide necessary control on Poisonous Substances and Deleterious Substances from the viewpoint of health and hygiene.

➤ Competent Authority :

- MHLW(Ministry of Health, Labour and Welfare)



English Information Resource for PDSCL Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=2595&vm=04&re=01>

Regulated Substances(PDSCL)

Category and #	Description
Poisonous Substances (approx. 130)	<ul style="list-style-type: none"> Defined as substances which may cause severe damage to human physiological function; Designated in Table 1 of the Law and Article 1 of the Cabinet Order for the Designation of the Poisonous and Deleterious Substances.
Deleterious Substances (approx. 400)	<ul style="list-style-type: none"> Defined as substances which may cause relatively light damage to human physiological function; Designated in Table 2 of the Law and Article 2 of the Cabinet Order for the Designation of the Poisonous and Deleterious Substances.
Specified Poisonous Substances (approx. 10)	<ul style="list-style-type: none"> These are extremely poisonous among poisonous substances and are defined as substances which have high possibility of the harm for the person depending on the direction for uses; Designated in Table 3 of the Law and Article 3 of the Cabinet Order for the Designation of the Poisonous and Deleterious Substances.

English Information Resource for Regulated Substances list under PDSCL:

<http://www.nihs.go.jp/law/dokugeki/edokugeki.html>



Several Ways for Designation:

Stating only substance name

Pure substance: Poisonous/Deleterious Substances(**Yes**)

Preparation containing it: Poisonous/Deleterious Substances(**No**)

Stating substance name and its preparation

Both pure substance and preparation containing it at any % are

Poisonous/Deleterious Substances.

Stating substance name and its preparation with threshold

Both pure substance and its mixture containing it (more than threshold) are

Poisonous/Deleterious Substances.

Requirements for Importers

➤ **Manufacture/Import, Sales Registration:**

- Business operators acquire license of manufacture/import(renewal required every 5years) , sales(renewal required every 6years)of Poisonous Substances, Deleterious Substances, or Specified Poisonous Substances;
- The conditions of storage and transfer should meet the requirements under the law.

➤ **Providing SDSs and Labeling (Obligation)**

- Poisonous Substances, Deleterious Substances, or Specified Poisonous Substances and the substances with concentration exceeding the specified limit value where they are present in mixtures;
- The word "Poisonous substance" or "Deleterious substance" should be indicated on labels.

医薬用外毒物

医薬用外劇物

NOTE: PDSCL is applicable to the intentionally added substances. If the product containing Poisonous/ Deleterious Substances, or Specified Poisonous Substances as an impurity, then it is out of the scope of PDSCL.

CSCL(化審法)

➤ Purpose:

To prevent environmental pollution by chemical substances that pose a risk to human health or the environment.

➤ Competent Authority :

- MOE(Ministry of the Environment)
- METI(Ministry of Economy, Trade and Industry)
- MHLW(Ministry of Health, Labour and Welfare)



English Information Resource for CSCL Law:

<http://www.japaneselawtranslation.go.jp/law/detail/?id=1957&vm=&re=>

Regulated Substances(CSCL)

Category and #	Requirement
New Chemicals Substances	<ul style="list-style-type: none"> Approval required before manufacturing or importing.
Class I Specified Chemicals (33 substances) persistent, bio-accumulative, toxic	<ul style="list-style-type: none"> Permission required before manufacturing or importing. (virtually prohibited except essential uses)
Monitoring Chemical Substances(38 substances) persistent and bio-accumulative	<ul style="list-style-type: none"> Annual report required if the volume of M/I is $\geq 1\text{kg/y}$; Authority may ask manufacturers /importers to investigate long-term toxicity.
Class II Specified Chemicals (23 substances) toxic and high risk	<ul style="list-style-type: none"> Notification of planned M/I quantity required before M/I and actual amounts after M/I.
Priority Assessment Chemicals (226 substances)	<ul style="list-style-type: none"> Annual report if the volume of M/I is $\geq 1\text{t/y}$; Authority may ask manufacturers/importer to provide more hazard data.
General Chemicals (approx. 28,000 substances)	<ul style="list-style-type: none"> Annual report required if the volume of M/I is $\geq 1\text{t/y}$.

Requirements for Importers

➤ Notification of New Chemical Substances:

Category	Requirement
Standard Notification	<ul style="list-style-type: none"> • Data required: Biodegradability study, Partition coefficient; Bioaccumulation study etc. • The substance name will be published in 5 years after approval; • Foreign company allowed to be notifier.
Low Volume Confirmation (Amended January 2019)	<ul style="list-style-type: none"> • Tonnage $\leq 10\text{t/y}$; • Data required: Biodegradability study, Bioaccumulation study; • Only domestic manufacturer/importer could be notifier.
Small Volume Confirmation (Amended January 2019)	<ul style="list-style-type: none"> • Tonnage $\leq 1\text{t/y}$; • No testing data required; • Only domestic manufacturer/importer could be notifier.
Other Prior Confirmation	<ul style="list-style-type: none"> • For intermediate, substances used in closed system, and polymer of low concern; • Relevant supporting documents are required; • Only domestic manufacturer/importer could be notifier.

Requirements for Importers (Cont'd)

➤ Amendment to LVC and SVC :

Category	Upper Limit per Manufacturer/Importer	Upper Limit across Japan
Small Volume Confirmation(SVC)	1t/y As M/I volume	1t/y As M/I volume
Low Volume Confirmation(LVC)	10t/y As M/I volume	10t/y As M/I volume

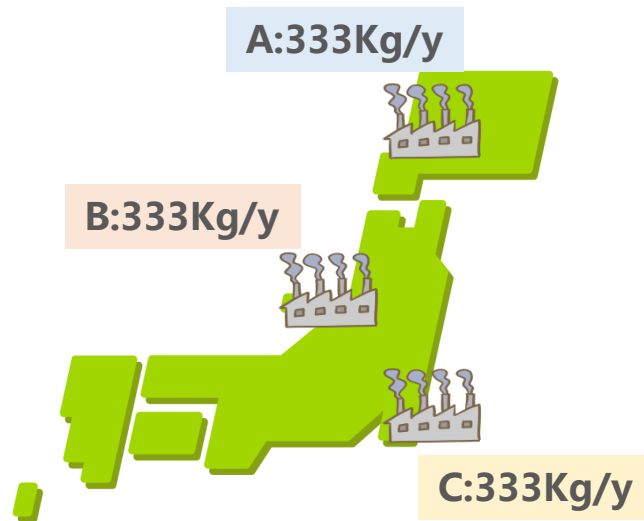


Category	Upper Limit per Manufacturer/Importer	Upper Limit across Japan
Small Volume Confirmation(SVC)	1t/y As M/I volume	1t/y As environmental emission volume
Low Volume Confirmation(LVC)	10t/y As M/I volume	10t/y As environmental emission volume

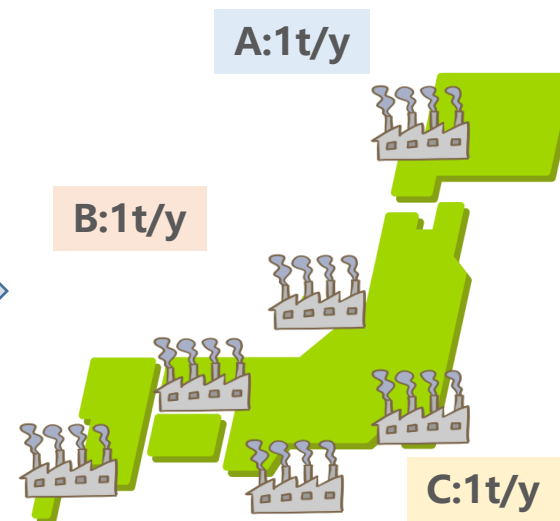
Requirements for Importers (Cont'd)

➤ Amendment to LVC and SVC :

Before Amendment



After Amendment



Example for SVC:

Use Category: Ink or Toners

Emission Factor: 0.1

Upper Limit Volume (Across Japan) : 1t/y (As environmental emission volume)

Environmental emission volume : 3t (import volume of 3 companies) x 0.1 (emission factor) = 0.3t/y

Requirements for Importers (Cont'd)

➤ Amendment to LVC and SVC :

Use Certificate are required and could be either of:

- Contract, Quality Assurance Form, Invoice etc.;
- SDS stating specific use, with signature/seal of user;
- Template developed by authority.

Information requirement for Use Certificate:

- Name of the new chemical substances;
- Use number and use category;
- User information.

Emission Factor:

<https://www.nite.go.jp/chem/kasinn/tokureikeisuu.pdf>

Template for Use Certificate:

https://www.meti.go.jp/policy/chemical_management/kasinhou/todoke/shinki_shoryo_index.html

Requirements for Importers (Cont'd)

➤ Annual Reporting :

Subject to Annual Reporting:

- More than 1t/y of General Chemical Substances($\geq 10\text{wt}\%$);
- More than 1t/y of Priority Assessment Chemical Substances($\geq 1\text{wt}\%$);
- More than 1kg/y of Monitoring Chemical Substances;
- More than 1kg/y of Class II Specified Chemical Substance.

Submission Period:

From April 1 and June 30

(Note: Submission by using hard copy is extended to July 31 in this year)

Check the schedule and requirements here:

https://www.meti.go.jp/policy/chemical_management/kasinhou/general-chemical.html

3.GHS Implementation

化学品を取り扱う事業者の方へ

—GHS対応—
化管法・安衛法・毒劇法における
ラベル表示・SDS提供制度

「化学品の分類および表示に関する
世界調和システム(GHS)」に基づく
化学品の危険有害性情報の伝達



平成29年11月

 経済産業省
Ministry of Economy, Trade and Industry

 厚生労働省
Ministry of Health, Labour and Welfare

- GHS Implementation
- Updates of JIS

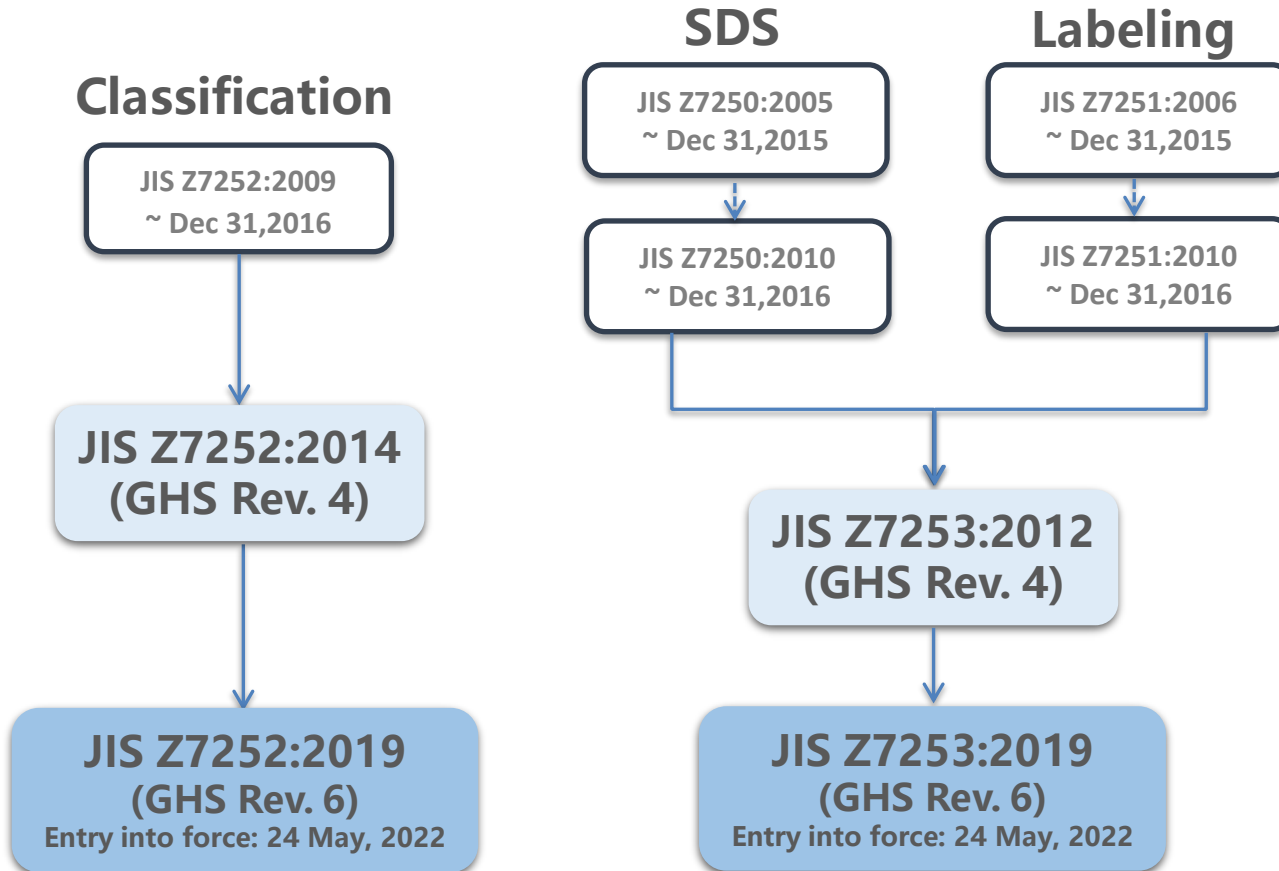
GHS Implementation

➤ Substances Scope of SDS/Labeling :

Law	Subject Substances	SDS	Labeling
PRTR	Designated Chemical Substances	Obligation	Make Efforts
ISHL	Appended Table 3 & Table 9 (640 substances)	Obligation	Obligation
	Mixtures containing any of the above (The cut-off value is defined for each substance)	Obligation	Obligation
	Classified as hazardous	Make Efforts	Make Efforts
PDSCL	Poisonous & Deleterious Substances	Obligation	Obligation

GHS Implementation (Cont'd)

➤ Standards for SDS/Labeling :



GHS Implementation_(Cont'd)

➤ Classification :

The Japanese government has classified about 3,800 substances which are subject to SDS/Label. The classifications have been published on the NITE website.

- According to JIS Z7252:2014(Latest Version JIS Z7252:2019) for the classifications;
- The classifications is not legally binding;
- The classifications are not always the same as the harmonised classifications of the CLP regulation.

GHS Implementation_(Cont'd)

➤ Comparison with GHS(Rev.4) for Classification:

Health hazards	GHS	Japan	EU	China	USA
	Rev.4	JIS Z 7252:2014	CLP	GB30000	HCS
Acute toxicity , oral	Category 1 ~ 5	Category 1 ~ 4	Category 1 ~ 4	Category 1 ~ 5	Category 1 ~ 4
Acute toxicity, dermal	Category 1 ~ 5	Category 1 ~ 4	Category 1 ~ 4	Category 1 ~ 5	Category 1 ~ 4
Acute toxicity, inhalation	Category 1 ~ 5	Category 1 ~ 4	Category 1 ~ 4	Category 1 ~ 5	Category 1 ~ 4
Skin irritation/corrosion	Category 1A,1B,1C,2,3	Category 1A,1B,1C,2	Category 1A,1B,1C,2	Category 1A,1B,1C,2,3	Category 1A,1B,1C,2
Serious damage to eyes/ eye irritation	Category 1,2A,2B	Category 1,2A,2B	Category 1 ~ 2	Category 1,2A,2B	Category 1,2A,2B
Aspiration hazard	Category 1 ~ 2	Category 1	Category 1	Category 1 ~ 2	Category 1

Environmental hazards	GHS	Japan	EU	China	USA
	Rev.4	JIS Z 7252:2014	CLP	GB30000	HCS
Acute aquatic toxicity	Category 1 ~ 3	Category 1 ~ 3	Category 1	Category 1 ~ 3	None
Chronic aquatic toxicity	Category 1 ~ 4	Category 1 ~ 4	Category 1 ~ 4	Category 1 ~ 4	None
Hazardous to the ozone layer	Category 1	Category 1	Category 1	Category 1	None

GHS Implementation (Cont'd)

➤ SDS Headings:

- | | |
|--|---------------|
| 1. Identification | 1 化学品及び会社情報 |
| 2. Hazard identification | 2 危険有害性の要約 |
| 3. Composition | 3 組成及び成分情報 |
| 4. First aid measures | 4 応急措置 |
| 5. Fire fighting measures | 5 火災時の措置 |
| 6. Accidental release measures | 6 漏出時の措置 |
| 7. Handling and storage | 7 取扱い及び保管上の注意 |
| 8. Exposure controls/personal protection | 8 ばく露防止及び保護措置 |
| 9. Physical and chemical properties | 9 物理的及び化学的性質 |
| 10. Stability and reactivity | 10 安定性及び反応性 |
| 11. Toxicological information | 11 有害性情報 |
| 12. Ecological information | 12 環境影響情報 |
| 13. Disposal information | 13 廃棄上の注意 |
| 14. Transport information | 14 輸送上の注意 |
| 15. Regulatory information | 15 適用法令 |
| 16. Other | 16 その他の情報 |

GHS Implementation_(Cont'd)

➤ SDS (Section 3: Composition):

PRTR:

- Indicate the subject substances name on SDS **is legally binding;**
- The percentages of subject substances in products is legally binding to indicate **in two significant digit.** (Example: **5% X** ; **5.0%O**)

ISHL:

- Indicate the subject substances name on SDS **is legally binding;**
- Allowed to using a range of percentages for subject substance(Example:10~20%; <10%).

PDSCL:

- Indicate the subject substances name and its percentages on SDS /Label **is legally binding.**

GHS Implementation (Cont'd)

➤ SDS (Section 8: Exposure controls/personal protection)

How to check exposure limit values?

Japan Society for Occupational Health
(日本産業衛生学会)

<http://www.sanei.or.jp/>



日本産業衛生学会
Japan Society for Occupational Health

○ お問い合わせ

○ 学会概要 ○ 入会案内 ○ 定款・規定 ○ 産業保健専門職の倫理指針 ○ リンク

会員ログイン
会員番号 [半角8数字]
パスワード
ログイン
パスワードを忘れた方はこちら

日本産業衛生学会より東北地方太平洋沖地震への対応についてのお知らせ

○ 更新履歴

17.08.10
研究費等公募情報を更新しました

17.08.10
厚生労働省からの案内を追加しました

17.08.07
教員・研究員募集のご案内を更新しました

17.08.03
日本産業衛生学会のビジョン2017-2018と今後の活動について会員向けサイトに掲載しました。ログイン後閲覧可能です。

17.07.20
厚生労働省からの案内を追加しました

○ コンテンツ content

> English

> 行事 Events

> 話題 Topics

> 報告 Reports

> 情報検索 Information

> 部会コーナー Section

> J Occup health
J Occup health

> Sandyo Eiseigaku Zasshi
産業衛生学雑誌

> Occupational Exposure Limits
許容濃度の勧告

> よくある質問 Q&A

GHS Implementation (Cont'd)

➤ SDS (Section 8: Exposure controls/personal protection)

詳細は投稿規定をご覧ください。投稿規定(PDF)

Good Practice Samples

産業保健専門職の生涯教育の教材となる良好実践事例(GPS)を募集しています。

第61回 日本職業・保健衛生学会学術大会
働く人の健康と実学への橋渡し
産業保健と実学教育のクロスリンク

投稿期間 11月30日(土)-12月1日(日)

投稿先 学術雑誌センター (仮定) (仮定)

投稿先 学術雑誌センター (仮定) (仮定)

過去の掲載論文の閲覧は、発行バックナンバー
早期公開および過去の掲載論文の閲覧は、J-STAGEのサイト

産業衛生学雑誌

(C) Japan Society for Occupational Health.

2013年 第55巻
1号 1月 2号 3月 3号 5月 4号 7月 5号 9月 6号 11月
2012年 第54巻
1号 1月 2号 3月 3号 5月 4号 7月 5号 9月 6号 11月
2011年 第53巻
1号 1月 2号 3月 3号 5月 4号 7月 5号 9月 6号 11月
2010年 第52巻
1号 1月 2号 3月 3号 5月 4号 7月 5号 9月 6号 11月

[海外における就業上の措置に関する論文調査…横川智子\(ほ\)](#)

[わが国の産業医の平成14年から20年までの就退職数とその徴…一瀬豊日\(ほか\)](#)

第61回労働衛生史研究会
平成24年度九州地方学会
第71回日本産業衛生学会東北地方会

許容濃度等の勧告(2012年度)

許容濃度等の勧告(2012年度)

表1-1. 許容濃度

物質名 [CAS No.]	化学式	許容濃度		経皮 吸収	発がん 分類	感作性分類		提案 年度
		ppm	mg/m ³			気道	皮膚	
アクリルアミド [79-06-1]	CH ₂ =CHCONH ₂	-	0.1	皮	2A		2 ⁺	'04
アクリルアルデヒド [107-02-8]	CH ₂ =CHCHO	0.1	0.23					'73
アクリル酸メチル [96-33-3]	CH ₂ =CHCOOCH ₃	2	7				2	'04
アクリロニトリル [107-13-1]	CH ₂ =CHCN	2	4.3	皮	2A ⁺			'88
アセトアルデヒド [75-07-0]	CH ₃ CHO	50*	90*		2B			'90
アセトン [67-64-1]	CH ₃ COCH ₃	200	470					'72
o-アニシジン [90-04-0]	H ₃ COC ₆ H ₄ NH ₂	0.1	0.5	皮	2B			'96
p-アニシジン [104-94-9]	H ₃ COC ₆ H ₄ NH ₂	0.1	0.5	皮				'96
アニリン [62-53-3]	C ₆ H ₅ NH ₂	1	3.8	皮			1 ⁺	'88
2-アミノエタノール [141-43-5]	H ₂ NCH ₂ CH ₂ OH	3	7.5					'55
アリアルアルコール [107-18-6]	CH ₂ =CHCH ₂ OH	1	2.4	皮				'78
アルシン [7784-42-1]	AsH ₃	0.01	0.032					'92
		0.1*	0.32*					
アンチモンおよびアンチモン化合物 (Sbとして、スナピンを除く) [7440-36-0]	Sb	-	0.1					'91
アンモニア [7664-41-7]	NH ₃	25	17					'79
イソブチルアルコール [78-83-1]	(CH ₃) ₂ CHCH ₂ OH	50	150					'87
イソプロチオラン [50512-35-1]	C ₁₂ H ₁₈ O ₂ S ₂	-	5					'93
イソプロピルアルコール [67-63-0]	CH ₃ CH(OH)CH ₃	400*	980*					'87
イソペンチルアルコール [123-51-3]	(CH ₃) ₂ CHCH ₂ CH ₂ OH	100	360					'56
一酸化炭素 [630-08-0]	CO	50	57					'71
インジウムおよびインジウム化合物 [7440-74-6]	In	(表II-1)	(表II-1)					'07
エチルアミン [75-04-7]	C ₂ H ₅ NH ₂	10	18					'79
エチルエーテル [60-29-7]	(C ₂ H ₅) ₂ O	400	1,200					('97)
エチルベンゼン [100-41-4]	C ₆ H ₅ C ₂ H ₅	50	217		2B			'01

GHS Implementation(Cont'd)

➤ SDS (Section 15:Regulatory information)

JCIA (Japan Chemical Industry Association)-GHS compliance guidelines:

- PRTR(化管法)
- ISHL(安衛法)
- PDSCL(毒劇法)
- Explosives Control Law(火薬類取締法)
- High Pressure Gas Safety Law(高压ガス保安法)
- Fire Service Law(消防法)
- CSCL(化審法)
- Ships Safety Law(船舶安全法)
- Marine Pollution Prevention Law(海洋汚染防止法)

Recommended to list in section 15 if relevant:

- Air pollution control Law(大気汚染防止法);
- Water pollution control Law(水質汚濁防止法);
- Food Sanitation Law(食品衛生法);
- Pharmaceutical Affairs Law(薬事法) etc.



Note: Domestic laws and regulations (PRTR; ISHL; PDSCL) should be indicated on Section15 clarified on revised JIS.

GHS Implementation_(Cont'd)

➤ When/How to provide SDS

How to provide SDS?


SDS can be provided in hard copy or digital format. A supplier can provide an SDS by fax, e-mail or by placing directly on a supplier' s website, if the recipient agrees.

When to provide SDS?

- SDS must be provided before supplying the product which includes the specified substances.
- The supplier of the SDS must provide the recipient with an updated SDS promptly if there are amendments to the SDS.

GHS Implementation (Cont'd)

➤ Labeling

アセトン (Acetone)	
成分: アセトン	OAS番号: 67-64-1
	Product identifier
危険	Signal Word(s)
危険有害性情報 引火性の高い液体及び蒸気 強い眼刺激 呼吸器への刺激のおそれ 眼炎又はは目のまぶしさ 生殖能又は胎児への悪影響のおそれの疑い 長期にわたる、又は反復ばく露による中枢神経系、呼吸器、消化管の障害 注意書き 【安全対策】 使用前に取扱説明書を読み取る。すべての安全注意を読み理解するまで取り扱わないこと。 熱/火花/煙火/高温のものによる着火源から遠ざかること。—禁煙。 容器を密閉しておくこと。 容器を移動すること/アースをとること。 防爆型の電気機器/換気装置/照明機器を使用すること。 火花を生じさせない工具を使用すること。 静電気放電に対する予防措置を講ずること。 閉じ込め/ガス/ガス/ミスト/蒸気/スプレーの吸入を避けること。 吸じん/煙/ガス/ミスト/蒸気/スプレーの吸入を避けること。 取扱後はよく手を洗うこと。 この製品を使用するときに、飲食又は喫煙をしないこと。 屋外又は換気のよい場所でのみ使用すること。 保護手袋/保護衣/保護眼鏡/保護面を着用すること。 【応急措置】 皮膚(又は髪)に付着した場合: 直ちに汚染された衣類を全て脱ぐこと。皮膚を流水/シャワーで洗うこと。 吸入した場合: 空気の新鮮な場所に移し、呼吸しやすい姿勢で休息させること。 眼に入った場合: 水で数分間注意深く洗うこと。次にコンタクトレンズを着用していない限り、両目を洗浄すること。 ばく露又はばく露の懸念がある場合: 医師の診断/手当を受けること。 気分が悪い時は医師に連絡すること。 気分が悪いときは、医師の診断/手当を受けること。 服の腐食が疑われる場合: 医師の診断/手当を受けること。 火災の場合: 消火するために適切な消火剤を使用すること。 【保管】 換気のよい場所で保管すること。容器を密閉しておくこと。 換気のよい場所で保管すること。遠く/よく立て置くこと。 【廃棄】 内容物/容器を適切な廃棄の許可を受けた専門の廃棄物処理業者に依頼して廃棄すること。 【その他の危険有害性情報】 情報なし 供給者: ○○○株式会社 消防法: 第4類引火性液体、第一石油類水溶性液体、危険等級Ⅱ、 火気厳禁 国連番号: 1090 指針番号: 127 ロットNo. XYZ0123	Hazard Pictogram(s) Hazard Statement(s) Precautionary Statement(s) Others (domestic regulations)
Company Identification	

Note 1: According to the revision of the ISHL on June 1, 2016, the obligation to indicate all the name of subject substances on label has been deleted since the substances expanded to 640.

Note 2: Indicate "danger division" under Fire Service Law.

Note 3: Special requirements under PDSCL.

医薬用外毒物

医薬用外劇物

Update of JIS (GHS Rev.4→GHS Rev.6)

➤ Revision of JIS Z 7252(Classification)

- Added new hazard classes(Desensitized Explosive: Category 1~4);
- Revised to relevant terms used for hazard classes;
(Example: hazard class 'combustible or flammable gas' → 'flammable gas' etc.)
- Revised the classification criteria for aerosol;

.....

.....

etc.

JIS Z7252:2019
(GHS Rev. 6)

Entry into force: 24 May, 2022

➤ Revision of JIS Z 7253(SDS & Labeling)

- The pictogram should be only indicated **with the red frame**;
- Domestic laws and regulations (PRTR;ISHL;PDSCL) should be indicated on **Section15**;
- Indicated the Obligation/Make Efforts for each item of SDS on **Table D1 JIS Z7253:2019**;

.....

.....

etc.

JIS Z7253:2019
(GHS Rev. 6)

Entry into force: 24 May, 2022

Update of JIS(Cont'd)

Sample: Table D1 of JIS Z7253:2019

項目 Category	項目名 Category Name	小項目名 Sub-Category Name	必須/任意 Obligation/ Make Efforts
1	化学品及び会社情報 Identification	化学品の名称 Product Name	必須 Obligation
		供給者の会社名、住所及び電話番号 Details information of the supplier	必須 Obligation
	
		国内製造事業者の情報（了解を得た上で） Information of the domestic manufacturers (with consent)	任意 Make Efforts
2	危険有害性の要約 Hazards Identification	化学品のGHS分類 Classification of the substance or mixture	必須 Obligation
		GHSラベル要素 Label elements	必須 Obligation
		GHS分類に関係しない又は GHS分類で扱われ ない他の危険有害性 Other hazards	任意 Make Efforts
	
.....

Useful information and tool for Classification:



Classification by GHS related Ministries:

http://www.safe.nite.go.jp/english/ghs/ghs_download.html (EN&JP)

GHS classification guidance:

http://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25ver1.1jenter_re.pdf (JP)

The GHS Mixture Classification System:

http://www.meti.go.jp/policy/chemical_management/int/ghs_auto_classification_tool_ver4_EG.html (EN&JP)

*The System does not classify Physical hazards automatically. Users have to enter the data on their own for Physical hazards. For the Health hazards and the Environmental hazards, the System provides classification automatically.

SDS/Labeling model:

http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_LST2.aspx (JP)

4. Summary

- Reviewed the purpose and requirements on PRTR, ISHL, PDSCL and CSCL;
- Notification for new chemical substance is required under CSCL and ISHL, However, the thresholds are different;
- Submission of reporting is required under CSCL and PRTR at the specific condition;
- SDS and Labeling is required under PRTR(*Make the efforts for labeling), ISHL, PDSCL.

Our Service:

- **Inventory Search for New Chemical Substances;**
 - **Dossier Preparation and Submission of New Substance Notification;**
 - **Preparation of SDS and Labeling according to relevant regulations and JIS;**
 - **Communication with Competent Authorities and Experts;**
 - **Training and Consultancy for comply the regulation in Japan.**
-etc.

If you have any needs or questions, please feel free to contact us at chemical@jemai.or.jp



Q&A Session



(Q) Does it necessary to prepare the SDS/Labeling for testing sample?

(Q) Are there any regulations regarding labeling size and color?

(Q) Are there any penalties for violating the obligation to provide SDSs?

For more Q&A related GHS under PRTR, ISHL, PDSCL

PRTR Q&A: http://www.meti.go.jp/policy/chemical_management/law/qa/3.html

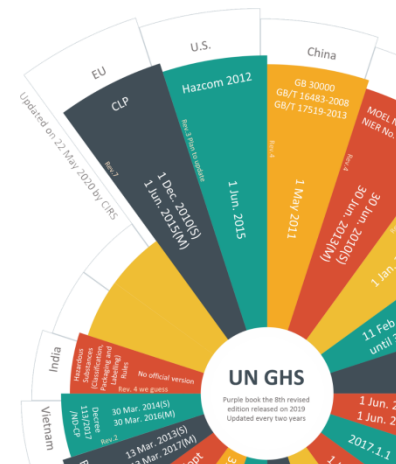
MHLW Q&A: https://www.mhlw.go.jp/stf/newpage_11237.html

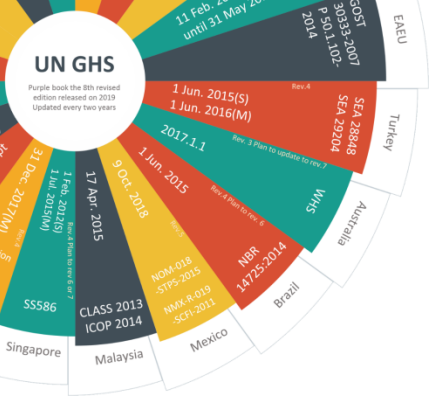
PDSCL Q&A: <http://www.nihs.go.jp/mhlw/chemical/doku/situmon/qa.pdf>

Please use the below link to follow this series event for more updates:

<http://www.cirs-reach.com/news-and-articles/2020-CIRS-Training-Courses-Global-GHS.html>

Global GHS Training Courses 2020 CIRS





Thank you for your attention



Dr. Hou Rong
JEMAI
E-mail: hou-rong@jemai.or.jp



Mr. Ethan Zheng
CIRS
E-mail: ethan.zheng@cirs-group.com

