



GHS in China and Korea
— Regulation for GHS and Actions Required to Business —

Present Status of GHS in Japan

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Topics

- 1. Current status of the GHS in Japan**
- 2. Classification Project by the Government for Regulated Chemicals**
- 3. GHS implementation in the Law required label and MSDS**



Toward the implementation of the GHS (1)

- In 2001: UNCETDG/GHS 1st meeting of the GHS subcommittee
Japanese government inter-ministerial committee
(MHLW, METI, MOE, MIC, MAFF, MLIT, MOFA)**
- In 2003: Publication of the GHS document (purple book)**
- In 2004: Japanese version of the GHS document
(translation completed)**
- In 2005: Industrial Safety and Health Law amendments (MHLW)
⇒ Introduction of the GHS (pictograms, MSDS, etc).
Government Project
⇒ Classifying substances regulated by laws with the GHS
criteria (1424 substances FY 2005 - 2006).
⇒ Developing “Classification Manual” & “Technical
Guidance”
JIS for MSDS (Z 7250) revised corresponding to the GHS
by JIS committee**



Toward the implementation of the GHS (2)

**In 2006: New JIS for labels (Z 7251) corresponding to the GHS
METI**

**⇒ Classification results of Substances in Government
Project was revised (FY 2006 - 2007).**

In 2007: METI

**⇒ Drafting new JIS for classification corresponding to the
GHS.**

**⇒ Revising “Classification Manual” & “Technical Guidance”
(FY 2007 - 2009).**

Japanese government inter-ministerial committee

**⇒ “Concept of risk assessment on consumer product
exposure for GHS labelling”**



Toward the implementation of the GHS (3)

**In 2008: New JIS for classification corresponding to the GHS (FY
2008-2009)**

National Institute of Technology and Evaluation (NITE)

**⇒ “Guidance on risk assessment method of consumer
product for GHS labelling”**



2. Classification Project by the Government for Regulated Chemicals

Classification Project by Japanese Government (1)

■ Substances classified

⇒ substances & mixtures specified in the following laws

1. Industrial Safety and Health Law (労働安全衛生法; 安衛法)
2. Poisonous and Deleterious Substances Control Law (毒物及び劇物取締法; 毒劇法)
3. Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR Law) (特定化学物質の環境への排出量の把握等及び管理の改善の促進に関する法律; 化管法)

Classification Project by Japanese Government (2)

- **Substances classified**

⇒ **substances & mixtures specified in the following laws**

4. Rotterdam Convention (PIC Convention - Prior Informed Consent): Substances listed in Annex III

5. Chemical Substances Control Law (CSCL) (化学物質の審査及び製造等の規制に関する法律; 化審法): Class II specified chemical substances (第二種特定化学物質)

- **Labels/MSDS are required by these laws**

- **GHS/JIS format are recommended/required**



“Classification Manual”

- **The Classification Manual was prepared by the inter-ministerial committee.**
- **The Classification Manual specified hazard data sources as follows;**

Priority 1: Search through this group of information sources, and adopt relevant descriptions or data if any.

Priority 2: Use this group of information sources if no available data are found out in Priority 1.

Priority 3: Just for reference, not immediately adopted.



Examples of Priority 1 Information Sources (1)

- **“SIDS Report” by OECD**
- **“Environmental Health Criteria (EHC)” by WHO/IPCS**
- **“IARC Monographs” by WHO/IARC**
- **“Joint Meeting on Pesticide Residue (JMPR) Report” by FAO/WHO**
- **“ACGIH Documentation of the threshold limit values for chemical substances” by ACGIH**
- **“Occupational Toxicants Critical Data Evaluation for MAK Values and Classification of Carcinogens” by Deutsche Forschungsgemeinschaft (DFG)**




Examples of Priority 1 Information Sources (2)

- **“EU Risk Assessment Report” by EU**
- **“Technical Report” by European Center of Ecotoxicology and Toxicology of Chemicals (ECETOC)**
- **“Patty’s Toxicology”**
- **“U.S. National Toxicology Program (NTP) Report”**
- **“Integrated Risk Information System (IRIS)” by US EPA**
- **“Agency for Toxic Substances and Disease Registry (ATSDR)”**



Examples of Priority 2 Information Sources

- **NIOSH: RTECS**
- **WHO/IPCS: ICSC Cards**
- **International Uniform Chemical Information Database (IUCLID)**
- **Sittig's Handbook of Toxic and Hazardous Chemicals and Carcinogens (4th edition, 2002)**



“Classification project” & “Technical Guidelines”

- **The Technical Guidelines were established for smooth running of the project.**
- **The Technical Guidelines describe the methods (simplified/detailed provisional local rules) to determine the category from existing data and previous classification.**
- **Additional information (e.g. consultation with experts on more detailed scientific papers or use of house-data) may lead to different classification results.**

Technical Guidelines; Example of local rules for < Carcinogenicity >

Japan GHS	IARC	JSOH	ACGIH	EPA 1986	EPA 1996	EPA 2005	NTP	EU
1A	1	1	A1	A	K/L	CaH	K	1
1B	2A	2A	A2	B1		L	R	2
2	2B	2B	A3	B2		S		3
No category	3		A4	C, D	CBD	I		
	4		A5	E	NL	NL		



Classification Results by Japanese Government (1)

<Not authorized> <Not compulsive>

- The classification results can be quoted and copied freely for preparing MSDS and labels.
- Those who quote or copy the classification results should take the responsibility for the description of MSDS and labels prepared by quoting or copying the results.
- The results were produced by classification procedure mainly based on the information sources specified in the “Classification Manual” and on the criteria/methods specified in the “Technical Guidelines”.



Classification Results by Japanese Government (2)

<Not authorized> <Not compulsive>

- It is allowed to prepare MSDS and labels differently based on other literatures and test results.
- The classification results are posted on NITE (National Institute of Technology and Evaluation) website.



Other activities for GHS implementation by Japanese Government / Ministry

- **“Classification Manual” and “Technical Guidelines” will be revised in 2009.**
 - **Matching GHS 2nd revised edition.**
 - **Coalescing Manual and Guidelines, etc.**
- **Publication of the National Standard JIS in 2009.
(Classification of chemicals based on GHS)**
 - **Now under consideration.**



Other activities for GHS implementation by Japanese Government / Ministry

- **The classification results were reviewed by METI.**
 - **The classification result of the object substances of “PRTR Law (化管法)” is reviewed. : FY 2007-2008
(Aiming at the elaboration of the “Classification Manual” and “Technical Guidelines”)**
 - **Freely comment on the classification results, and publicize these comments in GHS-NET website (<http://www.ghs-net.jp/>) for ready reference.**



Other activities for GHS implementation by Japanese Government / Ministry

- **Development of GHS classification tool for mixture (computer software) by METI**
 - **Most of the substances distributed in the market are mixture**
 - **Developed in FY 2005-2006**
 - **Downloadable at METI website**
 - **Due to be revised to conform to GHS 2nd revised edition and JIS in FY2008 (English version under preparation)**



Other activities for GHS implementation by Japanese Government / Ministry

- **GHS model MSDS established by MHLW**
 - **Preparation of MSDS conforming to GHS based on the classification results by Japanese Government serving as an example for industrial companies: FY 2007-2008**
 - **Publicized on Japan Industrial Safety and Health Association website: 658 substances (as of July 25, 2008)**



Other activities for GHS implementation by Japanese Government / Ministry

- **GHS model label established by MHLW**
 - **Preparation of label conforming to GHS based on the classification results by Japanese Government serving as a sample for industrial companies: FY 2007-2008**
 - **Publicized on Japan Industrial Safety and Health Association website: 101 substances (as of Jan.11, 2008)**



Other activities for GHS implementation by Japanese Government

Risk-based Labeling for consumer products

- **GHS 1.4.10.5.5.2 & ANNEX 5 Consumer product labelling based on the likelihood of injury**
 - **Competent authorities may authorize consumer labelling systems providing information based on the likelihood of harm (risk-based labelling). In the latter case the competent authority would establish procedures for determining the potential exposure and risk for the use of the product.**



Other activities for GHS implementation by Japanese Government

- **Establishment and publication of “Concept of risk assessment on consumer product exposure for GHS labeling”**
 - **It is unnecessary to include information about the health hazard on the labels of products containing chemicals whose risks have been assessed in accordance with the concept of risk and assessment procedures and that, as a result of this assessment, it has been determined that the health risk are not at a level for concern.**



Other activities for GHS implementation by Japanese Government

- **Establishment and publication of “Concept of risk assessment on consumer product exposure for GHS labeling”**
 - **The labeling concept applies only to chronic health hazards resulting from the use of consumer products to which the amount and duration of exposure by consumers is generally limited.**
 - **“Guidance on risk assessment method of consumer product for GHS labeling” is established and published by NITE based on this concept.**



3. GHS implementation in the Law required label and MSDS

Major Japanese Laws/Acts requiring labelling or MSDS

Laws/Acts	Label required	MSDS required
Industrial Safety and Health Law (安衛法)	○	○
Poisonous and Deleterious Substances Control Law (毒劇法)	○	○
PRTR Law (化管法)		○
CSCCL (化審法)	○	



GHS implementation in JIS

- **JIS Z 7250 for MSDS was revised in 2005**
 - nearly the same as GHS
 - Transitional period: MSDS in former JIS format valid for the next 5 years
- **JIS Z 7251 for labelling was newly introduced in 2006**
 - nearly the same as GHS
 - new system: no transitional period
- **Drafting new JIS for classification corresponding to the GHS**
 - Considering of New JIS started in 2007
 - Classification corresponds to GHS 2nd revised edition
 - To be finalized in 2009



Reference of JIS in Japanese Laws/Acts

- **Industrial Safety and Health Law**
 - **Compliance to JIS is equivalent to compliance to ISHL regarding the labeling and MSDS requirement (notified in the circular notice(通達)*)**
- **Other regulations**
 - **毒劇法, 化管法, and 化審法 (all requiring labeling/MSDS) accept labeling/MSDS conforming to JIS as a compliance to the regulations thereof.**

* Internal document used in the government bodies circulated among related organization and personnel, concerning mainly of the interpretation, operation or principles of regulations.

Reference of JIS in Japanese Laws/Acts

Status of reference	安衛法	毒劇法	化管法	化審法
Use of JIS required practically	○			
Legal requirements are filled by using JIS	○	○	○	○
Includes requirement not included in JIS		○		
Compliance to JIS is recommended, while not required		○	○	

Labelling and MSDS required by the Industrial Safety and Health Law (安衛法); mandatory for designated substances

- “表示対象物質 Harmful Substances whose names, etc., are to be indicated (on the label of the container or package)”
 - 100 substances (and mixtures that contains these substance at or above the threshold cut-off values)
 - 2 substances will be added in April 2009
 - Nickel compounds (powder only except for nickel carbonyl)
 - Arsenic and its compounds (except for arsine and gallium arsenide)
 - Arsenic trioxide will be integrated with “arsenic and its compounds” to make only one net increase of designated substances.
 - Labeling of the container or package is mandatory



Labelling and MSDS required by the Industrial Safety and Health Law (安衛法); mandatory for specified substances

- “通知対象物質 Notifiable Substances for which delivering MSDS is required”
 - 640 substances (and mixtures that contains these substance at or above the threshold cut-off values)
 - It is mandatory to deliver MSDS to receiver of products containing these substances



Labelling and MSDS requirement by “Industrial Safety and Health Law (安衛法)”

- **Mandatory for those who transfer or provide targeted chemicals.**
- **MSDSs and Labels must be prepared according to “JIS (Japanese Industrial Standards)” format which corresponds to the GHS.**
- **Industrial Safety and Health Law amendment came into force: Dec.1 2006**
 - **Full implementation date: Dec.1 2008**
 - **Expiry date for MSDS based on the old JIS: Dec.31 2010**



Poisonous and Deleterious Substances Control Law (毒劇法)

- **Labelling and MSDS are required for poisonous and deleterious substances.**
- **GHS label is not required in this law.**
- **However, the use of GHS labeling is recommended by Ministry of Health, Labour and Welfare, on the basis that the dissemination of GHS system will enhance the implementation of essential health hazard preventive measures based on this law and the appropriate and safe handling of each chemical by users, resulting in the mitigation of health hazard caused by the whole preparation including poisonous and deleterious substances.**
- **The introduction of GHS to this law is yet to be determined.**

MSDS required by the PRTR Law

- **MSDS are required for Class 1 Designated Substances (第一種指定化学物質; 354 substances) and Class 2 Designated Substances (第二種指定化学物質; 81 substances) under PRTR Law**
- **These substances are revised to 462 substances as Class 1 Designated Substances and 100 substances as Class 2 Designated Substances. It will be enforced from October 2009**

http://www.env.go.jp/chemi/prtr/archive/target_chemi/chemicals_list_en.xls

- **“Interim Report of the Joint Meeting for Revising the PRTR Law”, published in July 2008, recommended discussion on possibility for MSDS conformity with**

GHS (特定化学物質の環境への排出量の把握等及び管理の改善の促進に関する法律に基づく第一種指定化学物質及び第二種指定化学物質の指定の見直しについて(答申)平成20年7月、中央環境審議会)

Chemical Substances Control Law (CSCCL) **(化学物質の審査及び製造等の規制に関する法律)**

- **2009年2月、改正法案を国会に提出。**
A bill to amend the CSCCL was submitted to the Diet in Feb 2009.
- **すべての工業化学物質を対象に、一定以上の製造・輸入の届出を求め、事業者からの有害性・ばく露情報をもとに国が段階的なリスク評価を行って第二種特定化学物質を特定。(良分解性物質も含む。)**

Production or import of any industrial chemical above certain amount should be reported. The Government will conduct tiered risk assessment, based on the hazard and exposure information submitted by industry, and identify Class II Specified Chemical Substances. This includes degradable chemicals.

Chemical Substances Control Law (CSCL) **(化学物質の審査及び製造等の規制に関する法律)**

- **第一種特定化学物質の必須用途を認め、その容器、包装、送り状への環境の汚染を防止するための措置等の表示を義務化。**
Essential use of Class I Specified Chemical Substances is exempted. Products containing these substances should be labelled with information such as pollution prevention measures on their container, packaging or invoice.
- **改正後の表示事項や事業者から提出を求める有害性情報とGHSとの関連については、政令・規則等における検討事項**
Further consideration is needed in the ordinances and regulations under CSCL on the relationship between GHS and such issues as the new labelling requirement and the hazard information to be submitted by industry.



Summary

- **Classifications of a considerable number of substances have been conducted in Japan.**
- **Use of classification results is not compulsory. Users have discretion on their use.**
- **Some instruments to assist classification, such as guidance document and computer programs, have been developed, and some of them are now under revision for improvement.**
- **Classification of mixtures requires further efforts.**