



Introduction to Japan Regulations and GHS

Meghan O'Donnell
Pace Analytical
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Regulations

- ▶ Industrial Safety and Health Law (ISHL)
 - ▶ 1972
 - ▶ Administered by the Ministry of Health, Labor and Welfare
 - ▶ Regulates chemicals in the workplace with the purpose of protecting worker health
 - Regulates
 - New substances
 - Harmful substances (3)
 - Notifiable substances
 - ▶ First to introduce the Globally Harmonized System for Classification and Labeling of Chemicals (GHS)

Regulations

- ▶ New Substance Registration under ISHL
 - ▷ Prior to manufacture or import
 - ▶ Existing chemical substances before 1973 under the Chemical Substance Control Law (CSCL)
 - ▶ New substances under ISHL and published by government
 - ▶ Data required
 - ▷ Ames test and other chemical and company specific information
 - ▶ Full Exemption—for testing and research substances, reagent and sample substances, substances in consumer goods, existing substances

Chemical Substances Control Law

- ▶ Prevent environmental pollution and control chemical risks to human health, animals, and plants
 - ▷ Covers industrial chemicals
 - ▷ Initially implemented in 1974
 - ▶ Latest amendment published in 2009

- ▶ New Substance Registration under CSCL
 - ▶ Three ministries, three months in advance
 - ▷ METI
 - ▷ MHLW
 - ▷ MOE

CSCCL

▶ Exemptions

- ▶ Impurities
- ▶ Articles
- ▶ Naturally occurring substances
- ▶ R & D substances
- ▶ Substances regulated by other laws (i.e., cosmetics)

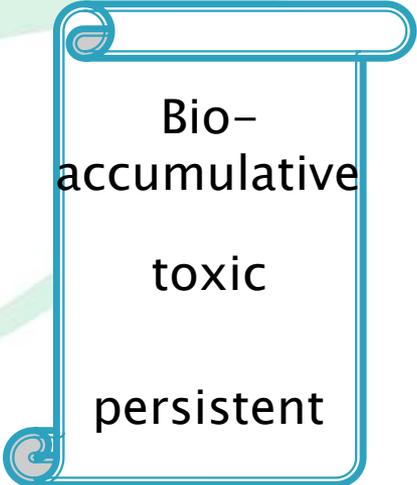
▶ Data required

- ▶ Designated toxicology and eco-toxicology data

CSCL

▶ Classifications of Chemicals

- ▶ General chemicals list
- ▶ Monitoring chemical substances list
- ▶ Priority assessment chemical substances list
- ▶ Class I or II specified chemical substances list



Bio-
accumulative

toxic

persistent

GHS in Japan

- ▶ Adopted United Nations GHS 4th Revision
- ▶ SDS requirement–Article 57–2 under ISHL
- ▶ Japanese language required on SDS and labels
- ▶ 16 Section SDS
 - ▷ Section 8 contains Japan OELs
 - ▷ Section 15 contains other regulatory information
 - ▶ Examples
 - ▷ ISHL
 - ▷ Poisonous and Deleterious Substances Control Law
 - ▷ Fire Service Act
 - ▷ Pollutant Release and Transfer Register

GHS in Japan

- ▶ Did not adopt the following GHS building blocks
 - ▶ Acute Toxicity Category 5
 - ▶ Skin Irritation Category 3
 - ▶ Aspiration Category 2



Poisonous and Deleterious Substances Control Law

- ▶ Enacted in 1950 to protect public health
- ▶ License requirement for a manufacturer, importer, and seller of a substance on the list
- ▶ Standards for storing, labeling, and transportation
- ▶ May impact labels if a substance is on the PDSCCL list

Fire Service Act

► Classification for physical and chemical hazards

| Category | Nature | Example |
|--------------|--|--|
| Category I | Oxidizing solids | Chlorates, inorganic peroxides, nitrates |
| Category II | Combustible solids | Sulfur, iron powder, magnesium |
| Category III | Spontaneously combustible & Water reactive | Potassium, sodium, alkaline earth metals |
| Category IV | Inflammable liquid | Alcohols, class I petroleum |
| Category V | Self reactive | Organic peroxides, nitro compounds |
| Category VI | Oxidizing liquid | Nitric acid, hydrogen peroxide |

Pollutant Release and Transfer Register

- ▶ Originated in 1999
 - ▷ Known as PRTR law
- ▶ Purpose
 - ▷ Management of chemical substances in relation to environmental protection
 - ▶ Specified substances
 - ▷ Class I
 - ▷ Class II
 - ▷ Specified Class I
 - ▶ Businesses report the release and transfer of chemical substances of concern under the PRTR reporting system and SDS system requirements
 - ▷ Example—ethylbenzene is a Class I substance that falls under PRTR reporting system and SDS requirements

The End!

Questions?

Thank you for reading

Please contact us with questions or give us a call to request a quote that meets your needs.

Amanda Lien

Amanda.Lien@pacelabs.com

612.246.8717

References

- ▶ Ashley Fisher, Pace Analytical, power point “Regulatory Club Presentation, International SDS Regulations: Japan”, September 2015
- ▶ http://www.chemsafetypro.com/Topics/Japan/Japan_PRTR_Law.html
- ▶ http://www.cirs-reach.com/Japan_CSCL/Japan_Industrial_Safety_and_Health_Law_ISHL.html
- ▶ <https://chemlinked.com/chempedia/japan-cscl-chemical-substance-control-law>
- ▶ www.japaneselawtranslation.go.jp/law/detail_download
- ▶ http://www.chemsafetypro.com/Topics/Japan/Japan_PDSCCL_Poisonous_and_Deleterious_Substances_Control_Law.html
- ▶ http://www.cirs-reach.com/Japan_CSCL/New_Japan_Chemical_Substances_Control_Law_CSCL.html
- ▶ <http://www.scas-eu.be/html/100111/news/02.html>
- ▶ http://www.chemsafetypro.com/Topics/Japan/Japan_New_Substance_Notification_CSCL_ISHL.html
- ▶ http://www.chemsafetypro.com/Topics/Japan/Japan_ISHL_Industrial_Safety_and_Health_Law.html
- ▶ GHS symbols and maps–Google images