

New Chemical Notification, Hazard Classification, Hazard Communication in Japan and Korea

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Japan

- New Chemical Notification
- Classification
- Hazard Communication (MSDS & Label)

Korea

- New Chemical Notification
- Classification
- Hazard Communication (MSDS & Label)



Japan

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Various laws governing chemical control, hazard communication, and occupational safety

- Chemical Substance Control Law (CSCL) (“Kashinho”)
Prevention of damage to human health caused by environmental pollution derived from industrial chemicals.
- Industrial Safety and Health Law (ISHL)
Protection of workers.
- PRTR and Promotion of Chemical Management Law (PRTR)
Improvement of the chemical substance management by business operators and to protect the environment.

- Poisonous and Deleterious Substances Control Law (PDSCL)
Protection of human health
- Air Law – Air transport
ICAO TI (IATA) classification is adopted
- Ship Safety Law – Ship transport
IMDG classification is adopted
- Fire Service Law – Land transport and storage
Its own classification based on the physical/chemical hazards



2 Laws requiring New Chemical Notification:
(before “manufacturing” or “import”)

(1) Law Concerning the Evaluation of
Chemical Substances and Regulation of
their Manufacture, etc. (CSCL)

(“Kashinho”)

(2) Industrial Safety and Health Law (ISHL)

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- Existing and New Chemical Substances Inventory (ENCS) (under “CSCL”)
 - Commercial chemicals
 - Focuses on chemical substances which may pose unreasonable risk on human health or flora and fauna in the environment (to prevent environmental pollution)
- Industrial Safety and Health Law (ISHL) Inventory (under “ISHL”)
 - Chemicals in workplace
 - Focuses on carcinogens (to control carcinogens to protect workplace laborers from the exposure)

- Confidentiality is not available
- New v. Existing Chemical Substances
 - On ENCS/ISHL Inventories (“Existing Chemicals”)
 - Can be manufactured or imported into Japan
 - NOT On ENCS/ISHL Inventories (“New Chemicals”)
 - Must be notified

NOT on Japanese Chemicals Inventories

- Must be notified unless certain exemptions apply
 - Forms (test results)
 - Procedures
 - Notification and assessment of new chemical substances

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CSCCL Exemptions

- Articles and products packaged for final use*
- Natural Substances*
- Impurities (< 1%)
- R&D Chemicals*
- Small Volume Exemption (SVE)
 - Total quantity in Japan will not exceed 1 ton/year

CSCCL Exemptions

- Low Volume Production Exemption (LVE)
 - Must not exceed 10 tons/year (incl. the amount produced under SVE)
 - “Reduced Notification”
- Intermediates (substances used in closed system, and for export purposes only)

CSCCL Exemptions

- Polymers (99% rule)
 - New polymer: two or more monomers
 - Combination of monomers by which total weight percentage exceeds 99% in the new polymer fits the name of an existing polymer in ENCS

ISHL Exemptions

- Articles and products packaged for final use*
- Natural Substances*
- Impurities (< 10%)
- R&D Chemicals*
- Small Volume Exemption (SVE)
 - 1000 Kg/year (for each site)
- Polymer
 - ISHL polymer criteria
 - Polymer exemption application

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CSCCL Notification Schemes

- ENCS Inventory (maintained by Ministry of Economy, Trade and Industry – METI)
 - LISTED: may be imported or manufactured in Japan without further notification
 - NOT LISTED
 - Notify METI, Ministry of Health, Labor and Welfare (MHLW), and Ministry of Environment (MOE) [required forms – Ministerial Ordinance of New Chemical Notification Procedures]
 - The substance must be assessed by the government prior to manufacture/import

CSCCL Notification

- Low Molecular Weight Chemical Substances
 - Standard test requirement
- Polymer
 - Polymer Scheme Test

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ISHL Notification

- Low Molecular Weight Chemical Substances
 - Standard test requirement
 - Acceptance upon application
- Polymer
 - Polymer Criteria
 - Acceptance upon application
 - Polymer will not be added to the ISHL Inventory

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CSCL

- Class 1 Specified Chemicals
 - Virtually banned
- Class 2 Specified Chemicals
 - Permitted; volume & uses strictly controlled
- Types 1, 2 and 3 Monitoring Chemicals
 - Mandatory reporting volume (annually)

- MSDS
 - Pollutant Release and Transfer Register Law (PRTR)
 - Industrial Safety and Health Law (ISHL)
 - Poisonous and Deleterious Substances Control Law (PDSCL)
- Labeling
 - PDSCL
 - CSCL
 - Fire Services Law (FSL)
 - High Pressure Gas Control Law (HPGCL)
 - Household Products Quality Labeling Law (HPQLL)

- MSDS
 - PRTR
 - Any suppliers required to provide MSDS
 - Concentration cut-off ($\geq 1\%$ or $\geq 0.1\%$)
 - Content must be indicated to two significant figures (e.g. 1.6%)
 - ISHL
 - Industrial chemicals
 - Content % with range
 - Introduced GHS (GHS Implementation)
 - PDSCL
 - Required for all specified chemicals, specified and poisonous substances
 - Prescribed concentration cut-off
 - Exact content % must be provided on MSDS
- Labeling
 - ISHL
 - GHS implementation

- Labeling
 - PDSCCL
 - Mark: Poisonous / Deleterious (in Japanese)
 - Product name, chemical name, content %
 - Company name & address
 - Detoxicant (for organic phosphorous compounds)
 - FSL
 - FSL hazard classification
 - FSL package group
 - Chemical name & volume
 - FSL precautionary statement

- Labeling
 - HPGCL (for aerosol products)
 - HPGCL precautionary statement
 - Statement differs by the type of aerosol products
 - Text & size
 - HPQLL
 - Label statements (type of products: fiber/plastic)
 - CSCL
 - Class 2 specified chemicals (mandatory)
 - Chemical name, content %, company name, etc.
 - Precautionary statement (to prevent environmental pollution)

- GHS Implementation (MSDS & Labeling)
 - ISHL (Dec. 1, 2006) [listed substances]
 - 99 chemicals (label) [GHS pictograms, signal words, and hazard statements]
 - 640 chemicals (MSDS)
 - PDSCCL: Encouraging industry to adopt GHS
 - PRTR: Recommending GHS
 - FSL, HPGCL, HPQLL: Nothing changed

GHS Implementation

- Label (JIS Z 7251:2006)
 - Product Identification
 - Substance name
 - Signal word
 - Pictograms
 - Hazard statements
 - Precautionary statements
 - Company identification (incl. tel. no)

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GHS Implementation

- SDS (JIS Z 7250:2005) – Dec. 31, 2010
 - 16 sections
 - Identification
 - Hazard identification (GHS classification and label elements)
 - Composition/information on ingredients
 - Pictograms (pictograms may be in white and black diagrams, or may be replaced with the name of pictogram)
 - Toxicological information (aligned with that of GHS; route of exposure)

GHS Implementation – Japan

- Label & MSDS:
 - Product contains subject chemicals < 1% (Nov. 30, 2008)
 - Old MSDS (JIS Z 7250:2000) until Dec. 31, 2010
- Classification Results List (1,500 regulated chemicals) (<http://www.nite.go.jp/>)



KOREA

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Various laws governing chemical classification and labels

- Toxic Chemical Control Act (TCCA)
- Industrial Safety and Health Act (ISHA)
- Dangerous Goods Control Act (DGCA)
- High-Pressured Gas Safety Control Act (HPCGCA)
- Ship Safety Act (SSA)
- Civil Aviation Act (CAA)

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TCCA

- Introduction of new chemicals into the market
- Highly concerned chemicals (i.e. toxic, observational, prohibited/restricted chemicals from manufacture, import or use)

ISHA

- Occupational workplace safety and health
- Material Safety Data Sheet (MSDS)
- Hazardous substances prohibited from manufacturing, requiring permission, controlled hazardous substances, etc.



TCCA & ISHA

- All new chemicals must be reported
- All new chemical must undergo advance toxicity examination and toxicity research before placed on the market
 - Test data for skin irritation, eye irritation and skin sensitization (newly added – TCCA, June 2008)
- New v. existing chemicals
- Exemptions

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Existing Chemicals (TCCA):

- Chemical substances that have been circulated domestically for commercial use prior to Feb. 2, 1991 and published on Dec. 23, 1996 by the Minister of Environment
 - Korean Existing Chemical Inventory (KECI)
- Chemical substances that have undergone toxicity examination

New chemicals (TCCA & ISHA):

- Must be evaluated and notified
- Exemptions (“confirmation of exemptions” for exempt new chemicals)

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New Chemicals Exemptions

- Substances manufactured or imported in quantities 100kg or less annually (per manufacturer or importer)
- R&D
- Not on KECI but on the market before Feb. 1991 (evidence is required)
- Non-isolated intermediates

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New Chemicals Exemptions

- Chemicals used in a closed system (not intended to release)
- Chemicals manufactured or imported in the amount less than 10 tons annually for export purposes only OR for manufacturing chemicals to be exported entirely
- Polymers

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New Chemicals Exemptions (ISHA)

- New chemicals manufactured/imported only for export in their whole quantity

OR

- New chemicals for manufacturing other chemical which is only for export in their whole quantity, the gross cumulative weight by each chemical of which is 10 tons or less

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New Chemicals Exemptions (Polymers)

- Block copolymer & graft polymer (each block or stem listed in the KECI)
- 2% Rules
 - Polymer composed of monomers (excluding monomers whose weight percentage contained in the polymer is 2% or less) and have been listed on KECI.
- Low concern polymer

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TCCA Exemption Rule (June 2008)

Articles, machine or equipment

- Deleted from the Exemption List
- No need to apply for the certification of the Exemption in this newly revised TCCA

New Polymer composed of existing chemicals

- Added to the Exemption list
- Need to apply for the certification of exemption

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Notifications Requirements (MOL & MOE share submitted document for evaluation)

TCCA

- Full Notification
- Simplified Notification
- Notification with reduced test records

ISHA

- Submit a report form (on hazard risk assessment)
- Information on occupational safety and health
- Information on manufacture, usage and treatment
- Flowchart of manufacturing or use proces
- Submit complete toxicity review report to MOL (submitting toxicity data to MOE beforehand)

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Confidential Claim

- Chemical identity, testing data, use, etc. will be protected for 5 years
- Chemical information disclosed on foreign Inventories, websites, and/or classified by the Toxicity Review Results – Not Protected

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ISHA (Dec. 2006 – Jan. 2008)

- Hazardous Chemicals and mixtures
- 16 physical, 10 health and 1 environmental hazards
- Classification results (KOSHA list)

TCCA (Nov. 2007)

- Toxic Chemicals and mixtures
- Current system can be used during transitional period until the new system is settled



Label

- ISHA – GHS Label
- TCCA – present classification and labeling can be used during transitional period

MSDS

- ISHA – GHS MSDS

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Questions



Thank you

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