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

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Agenda

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

Korea
- New Chemical Notification
- Classification
- Hazard Communication (MSDS & Label)
Japan
Chemical Control Law

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)
• 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)
New Chemical Notification

- 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
CSCL 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
New Chemical Notification

CSCL 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)
CSCL 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
CSCL 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
CSCL Notification

• Low Molecular Weight Chemical Substances
  – Standard test requirement

• Polymer
  – Polymer Scheme Test
New Chemical Notification

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
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)
Hazard Communication

• 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)
Hazard Communication

- **MSDS**
  - **PRTR**
    - Any suppliers required to provide MSDS
    - Concentration cut-off (≥ 1% or ≥ 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
Hazard Communication

• Labeling
  – PDSCL
    • 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
Hazard Communication

- 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)
Hazard Communication

- GHS Implementation (MSDS & Labeling)
  - ISHL (Dec. 1, 2006) [listed substances]
    - 99 chemicals (label) [GHS pictograms, signal words, and hazard statements]
    - 640 chemicals (MSDS)
  - PDSCL: 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)
GHS Implementation

  - 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)

• Classification Results List (1,500 regulated chemicals) (http://www.nite.go.jp/)
KOREA
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)
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.
New Chemical Notification

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
New Chemical Notification

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)
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
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
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
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
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
New Chemical Notification

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 process
- Submit complete toxicity review report to MOL (submitting toxicity data to MOE beforehand)
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

- 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
Thank you

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