Chemical Regulations in Asia: Thailand, Malaysia, Indonesia, Philippines and activities on ASEAN level

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Agenda

- Thailand: Hazardous Substance Act and GHS implementation
- Malaysia: Occupational Health & Safety Act, CLASS and EHSNR
- Philippines: Republic Act 6969 and GHS implementation
- Indonesia: Ministry Decrees and GHS
- Activities on ASEAN level
Chemical legislations expressed per region
What is a Hazardous Substance?

- The term “hazardous” in relation to chemical substances is legally defined in the EU by the CLP-regulation*

- All substances fulfilling the criteria of at least one hazard class of the CLP-regulation are called hazardous

- The hazard classes comprise physico-chemical, human health and environmental hazards

- From the perspective of environmental protection, only a sub-group of substances defined as hazardous are relevant

* The definition of the CLP-regulation of a hazardous substance includes all its hazard classes: physico-chemical, human health and environmental hazards- and contains testing methods and cut-off values for deciding whether or not the criteria of a specific hazard class are met
THAILAND
Hazardous Substance Act
What is a “Hazardous Substance”? 

- An explosive
- An inflammable substance
- An oxidizing agent and peroxide substance
- A toxic substance
- An infectious substance
- A radioactive substance
- A mutagen
- A corrosive substance
- An irritating substance
- Other substances (whether chemical or else) which may be harmful to person, animal, plant, property or environment
Main legislation

The Hazardous Substance Act (B.E. 2535):


- Issued under the responsibility of the Ministry of Industry

- Due to the diverse characteristics and usage of the substances, enforcement is splitted over several agencies:
  - Food and Drug Administration (Ministry of Public Health)
  - Department of Industrial Works (DIW) (Ministry of Industry)
  - Department of Agriculture (DOA) (Ministry of Agriculture and Cooperatives)
  - Department of Fisheries (Ministry of Agriculture and Cooperatives)
  - Department of Livestock Development (Ministry of Agriculture and Cooperatives)
Registration of products and substances

Registration procedure

Hazardous Substances

- Industrial Products
  - Department of Industrial Works
- Household/ Public Healths, products
  - Food and Drug Administration
- Fishery Disinfectant
  - Department of Fisheries
- Pesticides In Plants
  - Department of Agriculture
- Pesticides Livestock
  - Department of Livestock Development
Upcoming changes

- The information center for Hazardous Substances will be re-organized. It acts as a coordinating center for collection and provision of information relating to hazardous substances. From 2014, the intention is for DIW to collect information on chemicals based on volume (≥ 0.1 tons/year, ≥ 100 tons/year, >1000 tons/year) and for listed substances of very high concern. The data requirements will depend on the volume and hazard.

- The information would be used to develop an Existing Chemical Inventory and a database containing chemical hazard information.

- Developments are currently being monitored, and Thailand is looking for opportunities for harmonization with other regional regulatory frameworks.

- Possibility to use Class 4 substances for Research & Development.
Classification of Hazardous Substances

The Hazardous Substance Act B.E.2535 (1992)

Class 1
Hazardous substance
Notifying of the Volume and product information; Producer, Importer, Exporter and Possessor

Class 2*
Hazardous substance
• Product Registration
• Notifying of manufacturing, import, export or possession for professional use

Class 3*
Hazardous substance
• Product Registration
• Licensing (Permit) for manufacturing, import, export and possession for professional use

Class 4
Hazardous substance
Totally Banned

*Industry + downstream user

Controlled substances can be searched: http://www2.diw.go.th/haz/Searchlist.asp
Company Registration

- All producers, importers, carriers and persons in possession of listed HS (class 1 - 3) must register at the “Office of Hazardous Substances”

- Relevant are listed HS and products containing them

- Registration process usually takes 2-3 weeks, certificate is valid for 5 years
Registration procedure

Documentation required prior to import, use, or possession of Class 2 and Class 3 HS

- Chemical Identity
- Details of physical form
- Environmental and physical data
- Relevant regulatory data from other jurisdictions
- MSDS
- Specification of product
- Illustration showing container and package
- Analysis report or sample for analysis
New Substances

- Contact authority to find out whether the substance is already regulated in Thailand
- No official inventory list of existing substances exists (only unofficial list at FDA)
- Close contact to the authorities is required in any case

If any ingredient of a product is not regulated a notification is necessary:

- Submission of Notification-Dossier (product composition, manufacturing process, Certificate of Free Sale, label, MSDS, toxicity data, use, analytical method…)
- Decision about whether substance is hazardous and which of the ministry will be assigned as responsible
In March 13 2012 GHS Notification rule was gazzetted following the 3rd revision of UN GHS, with a transition period of one year for substances and five years for mixtures.

For substances mandatory from March 13, 2013

For mixtures mandatory from March 13, 2017
THAILAND

- Regulation of all hazardous substances under “Hazardous Substance Act” which is under revision

- New Substances need to be notified

- GHS officially released in 2012, mandatory for substances 2013, for mixtures 2017
MALAYSIA
Occupat. Health & Safety Act
CLASS EHSNR
Main Legislation for Industrial Chemicals

- Occupational Health and Safety Act 1994 (mainly work place safety)
  - CPL-Regulation of Hazardous Substances 1997

will be revoked by:

- CLASS (Classification, Labeling and Safety Data Sheet regulation)
  - by DOSH (Department of Occupational Safety and Health)

- MITI (Ministry of International Trade and Industry) Initiative GHS in Malaysia

additionally:

- EHS Notification and Registration scheme (EHSNR) by DOE (Dep. Of Environment)
Final draft was submitted in July 2009

Expected to come into force end of 2013 (delay due to elections 2013 and changes in the authorities)

Draft “Industry Code of Practice (ICOP)” is available and in-use

Transition period:

- 1 year for substances
- 3 years for mixtures
Aim of CLASS

- Inventory of hazardous chemicals to be prepared including every chemical recipient for one calendar year (>1 MT/year)

- Product registration for GHS-classified products, versus the DOE EHS scheme which relates to substance reporting and risk management

- The information requirements: Product name, physical form (e.g. solid), company name, tonnage, overall product classification, compositional information

- Submissions are required every 5 years online through DOSH’s CIMS (Chemical Inventory Management System).
Environmentally Hazardous Subst. (EHSNR)

**Definition of EHS**

"An EHS is a substance that is included in the EHS Reference List, or if not on the list, must be assigned a hazard category under the GHS classification scheme, as implemented by the Department of Occupational Safety and Health Malaysia”

or

“Other substances that are considered substances of concern due to properties not covered by the GHS classification scheme”

**Main Exemptions:**

- Substances regulated under other acts (e.g. Pesticide or Poison act)
- Substances with low-volume (<0.1 t/a)
From 2009 to 2013 – set up initial inventory by encouraging importers and manufacturers of substances classified as hazardous to register and submit the notification

2013 to 2015 – start of evaluation and establish a priority list for risk assessment

2015 to 2017 – the risk assessment measures proposed on selected substances will be identified and substances will be managed by introducing some control measures to control the usage of that particular substance in the country

2017 onward – Control measures will be introduced
“Malaysian Chemical Register” will contain information about notified substances (only if notified by 3 or more companies)

Registration under the “Department of Environment” (https://www.e-ehs.doe.gov.my/)

At the present time, DOE only requests industries to submit the notification voluntarily and industries can continue to do the registration and notification on the following years

- It is voluntary, but highly recommended to take EHSNR seriously
- Industry might be forced to submit additional data and the substance might face restrictions
STEP 1: Pre-Notification

- Compile inventory list of all substances (pure or in mixtures or products) imported during the year

- Check whether the substances are hazardous:
  - Is it listed in “EHS Reference List” (online)? or
  - Is it listed in the “CMR Reference List” (online)? and
  - Does an agreed GHS classification exist?

⇒ If yes: only “basic notification” is required
STEP 1: Pre-Notification (contd.)

If substance is not on the lists or no GHS-classification is yet agreed on:

- manufacturer or importer has to assign the GHS-criteria by themselves, and if:
  - ... Substance is hazardous: Perform **detailed notification (+ basic)**, provide all necessary data and the classification itself
  - ... Substance is not hazardous: No notification necessary, but information have to be retained for 5 years and made available on request
  - ... No classification can be done: e.g. due to insufficient data, uncertainty in structure of substance, **submit all data and explanation why no classification is possible**
STEP 2: Notification

- Register company (online)

- Submit data for Basic Notification for each substance:
  - Substance Identification
  - Year of Notation
  - EHS Occurrence (pure, mixture, finished product)
  - Concentration Range
  - Annual Tonnage of Substance
  - Details of EHS Uses
STEP 2: Notification (contd.)

- Detailed Notification*:
  - EHS Identification
  - Physical and Chemical Properties (Formula, Structure, Weight)
  - Physical Hazards (Explosivity, Flammability…)
  - Hazards to Human Health (H-code)
  - Hazards to Aquatic Environment (LC/EC/Bioacc./…)

* Necessary only once, but should be updated with new data if available
Summary

MALAYSIA

- CLASS-Regulation waits for its implementation (Draft ICOP available and in-use)

- Environmentally hazardous substances should be notified within EHSNR (voluntary) (excluding pesticides…)
Philippines
Republic Act 6969
Republic Act 6969 (RA 6969): Toxic Substances and Hazardous and Nuclear Wastes Act

RA 6969 is an Act that directs the Department of Environment and Natural Resources (DENR) through the Environmental Management Bureau (EMB) to establish rules, regulations, and programs for controlling chemical substances and hazardous wastes in the Philippines.

The objective of the DENR is to reduce hazards and risks to human health and the environment due to improper use, management, disposal, and subsequent release and exposure to harmful substances.

The DENR-EMB has existing regulatory framework for GHS requirements that can accommodate the concept of hazard communication through the requirements on the use of SDS and strengthening the enforcement of labels.
DENR ADMINISTRATIVE ORDER NO. 29
Implementing Rules and Regulation of RA 6969

- Regulate, restrict or prohibit the importation, manufacture, processing, sale, distribution, use and disposal of chemical substances and mixtures that present unreasonable risk and/or injury to health or the environment

- Various Provisions of the IRR (DAO 29)
  - Title I. General Provisions & Administrative Procedures
  - Title II. Toxic Chemical Substances
  - Title III. Hazardous Wastes
  - Title IV. Common Provisions
  - Title V. Prohibited Acts & Penalties
  - Title VI. Final Provisions
Title II. Toxic Chemical Substances

(Existing Chemicals)

- Philippine Inventory of Chemicals and Chemical Substances (PICCS)

- Small Quantity Importation (SQI)

(New Chemicals)

- Pre-Manufacturing and Pre-Importation Notification (PMPIN)*

* All new chemicals (chemicals not included in the PICCS) must undergo PMPIN before manufacture or importation
The Philippines: Status of GHS Implementation by DENR - EMB

Transition Period

1. Three years of transition period after the effectivity of this Order shall be provided for complete and strict compliance for the following:
   • CCO Chemicals
   • PCL Chemicals (Probably 2013-2015)

2. Two years after the aforesaid transition period, this Order shall take effect on the High Volume Toxic Chemicals (Probably 2017)

3. A year after the aforesaid two periods, this Order shall take effect on Toxic Chemicals under the IATA and IMDG lists of dangerous goods (Probably 2018)

4. On the seventh year and thereafter, similar succession for their mixtures shall be followed (Probably 2020)
EMB has been continuing the promotion of GHS Basic Principles and awareness raising and capacity building through seminars and lectures.

EMB is collaborating with SPIK on the classification of chemicals thru a special project called “Technical Assistance and Training to Support DENR-EMB in the Adoption and Implementation of GHS Classification of Chemicals“.
The Philippines : Globally Harmonized System (GHS)

Implementation in 4 phases:

- Applied to pure chemicals in the PCL (64)
- High Volume chemicals
- Dangerous goods
- Mixtures and others
The Philippines: Specific requirements of GHS

Labeling or Re-labeling Requirements

- Product Identifier
- Supplier Identifier
- Chemical Identity
- Pictograms
- Signal Words
- Hazards Statement
- Precautionary Statement

Safety Data Sheet (SDS) Requirements

- Required elements in SDS are almost similar to the EU CLP regulation SDS updates
The Philippines : Building Block Approach

- Close to the UN GHS content, format and terminology in the UN Purple Book
- Consistent with DC transport rules in the UN Orange Book
- Align with the EU building block approach
- Implement all GHS hazard classes in the UN Purple Book
The Philippines: Omission of the following hazard categories

- Flammable liquids, Cat. 4
- Acute toxicity, Cat. 5
- Skin corrosion/irritation, Cat. 3
- Serious eye damage/eye irritation, Cat. 2B
- Aspiration hazard, Cat. 2
- Aquatic toxicity, Acute 2,3
- Ozone depleting chemicals is added
INDONESIA
GHS implementation
Indonesia: GHS Current status

- GHS is mandatory for substances both for domestic production and import since March 24, 2010
- Chemical Mixtures are voluntarily required to implement GHS, however after December 31, 2016, mixtures both for domestic production and import are obliged to implement GHS. Exemption: Small Medium Enterprise (SME)
Decree of Minister of Industry No. 87/M-IND/PER/9/2009 concerning **Globally Harmonized System** of Classification and Labeling of Chemicals

Decree of Minister of Industry No. 23/M-IND/PER/4/2013 (as Revision of Decree of Minister of Industry No. 87/M-IND/PER/9/2009) concerning **Globally Harmonized System** of Classification and Labeling of Chemicals

Decree of the Ministry of Industry No. 24/M-IND/PER/5/2006 regarding **Control on Production and Usage of Industrial Dangerous Substance** was enacted on May 9, 2006 in accordance With GHS

Decree of Director General of Agrochemical No. 21/IAK/PER/4/2010 concerning **Technical Training of GHS Implementation for Classification and Labelling of Chemicals**
GHS implementation

- Decree of Minister of Industry No. 23/M-IND/PER/4/2013 (as Revision of Decree of Minister of Industry No. 87/M-IND/PER/9/2009);

  - Safety Data Sheet (SDS) and label is an obligation for chemical substances
  
  - Every stakeholder who produce chemical substances is obliged to determine the hazard classification, to tag the hazard label onto the package and to compile SDS, to be reviewed and revised at least every 5 years
  
  - Every stakeholder who repackage chemical substance is obligated to tag label, name and address of re-packager, net weight, and to compile SDS
  
  - Every stakeholder as mentioned in this decree is obliged to submit a report to Director General of Manufacturing Industry Basis, Ministry of Industry
GHS Implementation

- GHS Classification and Labeling System shall apply to:
  - All chemicals, single substances or mixtures
  - Excluding pharmaceutical preparation, cosmetics, food, food additives, pesticide residues in food, articles
- Consumer products, including consumer healthcare
  - Function due to chemical content and used by consumer
  - Further provisions on types of consumer products shall be regulated by relevant Ministerial Regulations
- Product Identifier- identity of product contains name of chemical component of product and/ or trademark, identity number, eg. CAS, EC number or others
GHS, label and SDS

- Classification based on UN GHS 4th version,

- Labels shall be easily legible, clearly visible; not easily damaged or detached; not easily faded due to rays, air

- GHS labeling elements for chemicals, consumer products:
  - Producer, Supplier Identification
  - Product Identifier
  - Pictogram, Signal Words- provision on size, layout
  - Hazards Statements; “Statement of carefulness” might also be added

- Each chemical shall have GHS SDS

- Label, SDS shall use Bahasa Indonesia (other additional UN languages allowed)

- Label and SDS have to revised in the event of any changes, at least every 2 years (label) or 5 years (SDS), respectively
Indonesia: Report on Classification Label, SDS based on GHS

- Identifiers, Number(s)
- Trade Name
- HS / Tariff code
- Composition
- Classification and Danger Category
- Pictogram
- Signal Word
- Hazard Statements
- Precautionary Statements
- SDS
- Date Application Started
Activities on ASEAN level (Association of Southeast Asian Nations)
To answer the question how can ASEAN countries can establish an effective, efficient chemical management system and joint activities on safe handling of chemicals, they decided to establish the **ASEAN Chemical Safety Database (ACSD)**.

Information to be gathered shall includes two aspects:

- Information on laws and regulations and information on chemical properties and human health
- Environmental toxicity of chemical substances in each country
The aim of the ASEAN Chemical Safety Database is to:

1. To share information on chemical risks and hazards
2. To enhance transparency and reduce compliance risks and costs, through providing information on local regulations
3. To facilitate regulatory convergence among ASEAN and East Asian Countries
4. To reduce the cost of duplicative testing and the burden of assessment
ASEAN Chemical Safety Database (ACSD)

The information on laws and regulations is beneficial for both industry considering starting production and exports to other countries and administrative government agencies using regulations in other countries as guidelines.

Moreover, by summarizing and displaying existing toxicity information in a straight-forward list format, it becomes feasible for persons in charge of administrative government agencies to use the information when making decisions on control of substances in the future.

Furthermore, by making the information easily available, autonomous management within companies is promoted.

Finally, by displaying the information in a form that allows direct comparison, it is possible to expect a secondary effect where the rules on control substances in related countries will gradually converge toward a common understanding.
ASEAN Chemical Safety Database

Research Project Reports

Study on the Feasibility of and Information Infrastructure for the Future Chemicals Management Scheme in the Asian Region

By Sarisak Soontornchai

ERIA Research Project Report 2011-15

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Many thanks for your attention

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