New Chemical Regulation in Malaysia

Webinar, 18 July 2013, 9:00am BST
Today’s webinar - aims

- Hear about the current status of GHS implementation in the country, covering classification, SDSs and labelling;
- To look at the notification and registration scheme for environmentally hazardous substances;
- Hear about a company’s experiences under the current regulatory framework.
Speakers

Dr Gunnar Kahl, Managing Director, Dr Knoell Consult Thai Co. Ltd;

Dr Samer Aburous, Global Notification Manager, Global Product Compliance, Symrise AG;

Chair: Geraint Roberts, Briefing and Global Content Editor, Chemical Watch.
Q&A session

Please submit questions during the webinar using your chat box.

If you have any unanswered questions please submit them to the Chemical Watch Forum, after the webinar.

http://forum.chemicalwatch.com
GHS implementation in Malaysia

New Chemical Regulation in Malaysia
Webinar; 18.07.2013

By Dr. Gunnar Kahl, Dr. Piyatida Pukclai, Wipawadee Sae Pueng
The knoell group

- Full service provider for regulatory affairs worldwide

- Representations in Europe (DE, NL, CH, UK, ES), China, Thailand, and USA (latest development: integration of the company CPS (Critical Path Services)) with in total more than 400 employees

- Partner organizations worldwide

- Business fields: Industrial Chemicals, Agrochemicals, Biocides, Pharmaceuticals, Veterinary Medicine, Medical Devices, Cosmetics, Training

- Services comprise of regulatory and strategic consulting, task force and consortia management, GHS-services and much more

- For details see our homepage
Area 330,000 km²

Inhabitants 29 Mio

Gross Domestic Product 2012 278 bn USD

Economy
- Rubber and oil palm processing
- Petroleum production
- Agriculture
Malaysia’s Chemical Sub Sectors

Structure of Chemicals Industry

- **Chemicals & Chemical Products**
  - Agricultural Chemicals
  - Pesticides, Fertilizers
  - Household Chemical preparations
  - Inorganic Chemicals
  - Industrial Gases
  - Paints, Vanishes
  - Oleo-Chemicals
  - Petroleum Products
  - Plastic Products
  - Plastic Resins

Source: MITI (Ministry of International Trade and Industry)
GHS Setup in Malaysia

- Thailand and Malaysia was chosen by UNITAR as countries to join the implementation program 2010-2012
- Malaysia National Coordinating Committee for the Implementation of GHS (NCCGHS) was brought into life
- MS 1804:2008* is the standard for GHS

* Malaysian Standard on Globally Harmonised System (GHS) For Classification and Labelling of Chemicals
GHS Setup in Malaysia

GHS National Coordinating Committee (NCCGHS)

GHS Technical Working Group (TWGGHS)

Industrial Workplace (DOSH)

Pesticides (PB)

Transport (MOT)

Consumer Products (MDTCC)

DOSH : Dep. of Occupational Safety and Health, Min. of Human Resources
PB : Pesticides Board, Min of Agriculture
MDTCC: Min. of Domestic Trade, Co – Operatives and Consumerism
MOT : Ministry of Transport

Source : MITI
Implementation following the 3rd revision of UN GHS

CLASS regulations will be used for classification in future

“Occupational Safety and Health (Chemicals classification, Labeling And Safety data Sheet) regulations 201X”

Industry Code Of Practice (ICOP) already published
CLASS regulations will be used for classification (for workplace and industry)

Final draft was submitted in July 2009

Expected to be in force end of 2013

Existing regulations (Occupational Safety and Health Act 1994 and – Regulation 1997) will be revoked

Transition period:  1 year for substances
                   3 years for mixtures
Main principles of CLASS/GHS

- 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).
## Sectors influenced by GHS

<table>
<thead>
<tr>
<th>Sectors</th>
<th>GHS influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industrial Workplace</td>
<td>Safer work environment through hazard communication and practices for safe handling and use (CLASS and MS1804:2008)</td>
</tr>
<tr>
<td>Transport Sector</td>
<td>Safer transport through common signals and precautionary statements; Avoids duplication of testing; Facilitates international trade</td>
</tr>
<tr>
<td>Agricultural Sector</td>
<td>Incorporation into international agreements (FAO/WHO); Provide clear and transparent messages on health and safety (label and SDS)</td>
</tr>
<tr>
<td>Consumer Sector</td>
<td>Label provides important source of hazard information; Harmonized hazard communication (pictograms, signal words…)</td>
</tr>
</tbody>
</table>
Duties under CLASS

**Principal Supplier**
- Manufacturer
- Formulator
- Importer
- Recycler
- Reformulator

**Classification**
- Packaging
- Labelling
- SDS

**Subsidiary supplier**
- Repacker
- Distributor
- Retailer

**Inventory**
- Manufacturer
- Importer
Duty of manufacturer / importer

Classification according to ICOP (Industry Code of Practice) on Chemical Classification and Hazard Communication (from DOSH)

1) Stick to list of classified chemicals (ICOP Part 1)
2) For substances (and mixtures) not listed, ICOP Part 2 applies
3) Use classification under EU-CLP or Malaysian CPL if already available

Maintain records and data for inspection
### Classification: Physical Hazards

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>2. Oxidising Liquids</td>
<td>10. Gases under Pressure</td>
</tr>
<tr>
<td>7. Flammable Aerosols</td>
<td>15. Substances which on contact with water emits flammable gases</td>
</tr>
</tbody>
</table>
Classification: Health Hazards

1. Acute Toxicity (Oral/Dermal/Inhalation)
2. Germ Cell Mutagenicity
3. Carcinogenicity
4. Reproductive Toxicity
5. Specific Target Organ Toxicity (Single)
6. Specific Target Organ Toxicity (Repeated)
7. Skin Corrosion/Irritation
8. Serious Eye Damage/ Eye Irritation
9. Respiratory Sensitisation
10. Skin Sensitisation
11. Aspiration Hazard
Classification: Environmental Hazards

1. Hazardous to Aquatic Environment (acute)
2. Hazardous to Aquatic Environment (chronic)
3. Hazardous to the ozone layer
Packaging

- To be designed & constructed so contents shall not escape
- Materials used are strong & not susceptible to attack by contents
- Strong to meet the stress & strain of handling
- Design with fastening devices can be repeatedly fastened without contents escaping
- Fitted with seals –once the packaging is opened, the seals are broken
Supplier required to label every package of hazardous chemicals with the following information:

- Product identifier
- Chemical name and composition
- Supplier identification
- Signal words
- Hazard statements
- Hazard pictograms
- Precautionary statements

Text in both English and National Language
If the container ≤125 ml, supplier may label with:

- Product identifier
- Statement: “read SDS before use”
- Supplier identification
- Hazard pictogram
- Signal word

If the signal word “Danger” is used, the signal word “Warning” must not be used.

The label shall be firmly affixed to one or more surfaces of the packaging so that the label can be read horizontally when the packaging is set down in its normal position.

When not practicable to label due to the nature of the container use tagging.
Safety Data Sheet (SDS)

- Furnish up-to-date SDS to each hazardous chemical supplied
- Contain 16 sections
- Revise SDS if:
  - new information on the hazardous chemical
  - more than 5 years have elapsed since last date of preparation/revision
  - directed by officer
- Written in National Language and English
SDS sections

- Identification of the hazardous chemical and supplier
- Hazards identification
- Composition information on ingredients
- First aid measures
- Fire fighting measures
- Accidental release
- Handling and storage
- Exposure controls, personal protection
- Physical, chemical properties
- Stability and reactivity
- Toxicological information
- Ecological information
- Disposal considerations
- Transport information
- Regulatory information
- Other information
Inventory of Hazardous Chemicals

- Duty of importer and manufacturer to prepare and submit an inventory of hazardous chemical imported/supplied for:
  - 1 calendar year activity
  - quantity exceeding 1 metric ton per year

- Inventory contains information on
  - Product identifier
  - Name (including CAS no. where applicable)
  - Composition of hazardous ingredients of mixture
  - Hazard classification
  - Total quantity supplied/imported

- Submit Inventory first time 3 years after gazetting of CLASS
Confidential Business Information (CBI)

- CBI is information which is not known by the competitor or which is protecting intellectual property rights and business.
- Confidential Information may only be the name of a chemical and its concentration, everything else has to be disclosed.
- The chemical name might be replaced by a generic name (e.g. Phenol derivative instead of 1,4-dihydroxybenzene).
- Exact concentration may be replaced by concentration range (e.g. 30-40% instead of 35%).
## GHS Differences

Categories / Classes not implemented (compared to the 3rd Revision)

<table>
<thead>
<tr>
<th>GHS Excluded</th>
<th>EU UN 3rd revised</th>
<th>Malaysia UN 3rd revised</th>
<th>Thailand UN 3rd revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flamm. Liq.</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Acute Tox.</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Skin irritation</td>
<td>3</td>
<td>3</td>
<td>3 (not separated into 1A-1C, Simply Category 1)</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>2 (not separated into 2A and 2B)</td>
<td>2 (not separated into 2A and 2B)</td>
<td></td>
</tr>
<tr>
<td>Sensitisation</td>
<td></td>
<td>2 (not separated into 1A and 1B)</td>
<td></td>
</tr>
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</table>
## GHS Differences

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</thead>
<tbody>
<tr>
<td>Aspiration hazard</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic Acute</td>
<td>2, 3</td>
<td>2, 3</td>
<td></td>
</tr>
<tr>
<td>Labelling for Explosive</td>
<td></td>
<td></td>
<td>Category 1.5 and 1.6 include transport label</td>
</tr>
<tr>
<td>SDS</td>
<td>Regulated by REACH</td>
<td>Part of GHS</td>
<td>Part of GHS</td>
</tr>
<tr>
<td>Language</td>
<td>National</td>
<td>National and English</td>
<td>Thai</td>
</tr>
</tbody>
</table>
In EU additional Hazard Statements exist which were taken over from the old EU-regulation

Confidential Business Information: Malaysian ICOP includes a Part regarding CBI issues and an Appendix regarding Generic names for substances. In EU CBI can be claimed under REACh and alternative names for chemicals can be generated according to CLP-Regulation
Hazardous Substance Registration in Malaysia and Thailand

New Chemical Regulation in Malaysia
Webinar; 18.07.2013

By Dr. Gunnar Kahl, Dr. Piyatida Pukclai, Wipawadee Sae Pueng
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 (EU 1272/2008) 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
Main Legislation for Industrial Chemicals

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

will be revoked by:

- CLASS (Classification, Labeling And Safety data Sheets)/GHS for workplace and industry (to be issued soon)
  - by DOSH (Department of Occupational Safety and Health)

additionally:

- EHS Notification and Registration scheme (EHSNR) by DOE (Dep. Of Environment)
The ultimate aim of EHSNR

- To enhance safety of human health and environmental protection by reducing the risks of chemicals
- To strengthen chemical management in Malaysia
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”

* The EHS reference list is based on the Annex VI of EU CLP-regulation
Exemptions:

- Substances regulated by other legislation (viz. Pesticides and Pharmaceuticals)
- Substances on exemption list, e.g.:
  - naturally occurring materials
  - impurities
  - by-products
  - low-volume (< 1 t/a)
  - substances for research, development, or export
  - substances for test marketing
  - polymers
From 2009 to 2012 – set up initial inventory by encouraging importers and manufacturers of substances classified as hazardous to register and submit the notification.

2013 to 2014 – start of evaluation and establish a priority list for risk assessment.

2015 to 2016 – 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.
**Environmentally Hazardous Subst. (EHSNR)**

<table>
<thead>
<tr>
<th>ANNUAL TONNAGE (MT)</th>
<th>PROPOSED YEAR FOR NOTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 100</td>
<td></td>
</tr>
<tr>
<td>10 - 100</td>
<td>Initial Baseline Data Collected</td>
</tr>
<tr>
<td>1 - 10</td>
<td></td>
</tr>
</tbody>
</table>

*additionally subst. with GHS class. “Chronic 1” should be registered no matter what tonnage level*
"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/](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

- Supposed to become mandatory after publication of CLASS

- It is voluntary at the moment, 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
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; local agency necessary)

- Submit data for Basic Notification for each substance (to be repeated annually based on data of previous year; until June):
  - 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 (information necessary to reach GHS-classification)*:
  - EHS Identification
  - Physical and Chemical Properties (Formula, Structure, Weight)
  - Physical Hazards (Explosivity, Flammability…)
  - Hazards to Human Health (Toxicity, Mutagenicity,…)
  - Hazards to Aquatic Environment (LC, EC, Bioacc., …)

Final Classification and H-Statements are required

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

- For cases where the overseas supplier wants to protect confidential business information
- Local agency registers online at DOE
- Local agency additionally registers overseas supplier for a certain substance
- Oversea supplier receives link and password to be able to enter confidential information by themselves.
THAILAND
Thailand

<table>
<thead>
<tr>
<th>Area</th>
<th>$513,115 \text{ km}^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhabitants</td>
<td>$67 \text{ Mio}$</td>
</tr>
<tr>
<td>Gross Domestic Product 2012</td>
<td>$366 \text{ bn USD}$</td>
</tr>
<tr>
<td>Economy</td>
<td>45% Industry (11% Automobile Manufact.)</td>
</tr>
<tr>
<td></td>
<td>12% Agriculture</td>
</tr>
<tr>
<td></td>
<td>6% Tourism</td>
</tr>
</tbody>
</table>
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)
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 required likely to 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 opportunities to advocate for harmonisation with other regional regulatory frameworks on chemical inventories.
The Hazardous Substance Act B.E.2535 (1992)

**Classification of Hazardous Chemicals**

- **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 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](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

Registration of products and substances

Hazardous Substances

- Industrial Products
  - Department of Industrial Works
- Household/Public Healths, products
  - Food and Drug Administration
- Fishery Disinfectant
  - Department of Fisheries
- Pesticides for Plants
  - Department of Agriculture
- Pesticides Livestock
  - Department of Livestock Development
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
- SDS
- Specification of product
- Illustration showing container and package
- Analysis report or sample for analysis
New Substance Registration

- 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, SDS, toxicity data, use, analytical method…)
- Decision about whether substance is hazardous and which of the ministry will be assigned as responsible
MALAYSIA

- Environmentally hazardous substances should be notified within EHSNR (excluding pesticides...)
- Basic + Detailed notification
- External notification possible to protect confidential business information

THAILAND

- Regulation of all hazardous substances under “Hazardous Substance Act” (including pesticides...)
- Class 4 substances are banned
- New Substances need to be notified
Chemical Regulations in Malaysia

Dr. Samer Aburous
Symrise AG

Samer Aburous, Malaysia Webinar, Chemical Watch Webinar, 18 July 2013
Overview

- Regulatory Systems
- EHS Notification System
  - Implementation and concerns
- Malaysian Standards on GHS
SYMRISE AG
AT A GLANCE

- Global supplier of
  - Fragrances,
  - Flavourings and
  - Cosmetic Active Ingredients

- More than 30,000 products used in perfume, cosmetics and food industry.

- Products sold in over 160 countries.
Regulatory systems

- EHS Notification
  - **in short:** a scheme to collect information from the chemical industry about environmentally hazardous substances in Malaysia.

- Malaysian Standards on GHS.
  - **in short:** a system to meet the global requirements for a harmonized system of Classification and labelling of chemical substances.
EHS Notification System

Which substances are covered?

EHS Definition:
- is a substance that is assigned a hazard category under the GHS classification scheme or is present on a proscribed list of internationally recognised substances of special concern.
- 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.
- .... the EHS N&R scheme is for environmentally hazardous substances only.

What to do?
- Stay on the safe side.
- implementing the wider definition and covering all substances of environmental concerns.
EHS Notification System

Which substances are covered?

- **Scope:**
  - not covered by other notification or registration schemes in Malaysia.
  - Exemptions based on origin/properties, application, volume, and supply chain direction

- Take care of unusual uses of your substance
- Take care of unusual origin of your substance
- Understand the composition of your substance. Define contained constituents and impurities.
- Define volume per importer/manufacturer
- Define your position in the supply chain
EHS Notification System

How to prepare?

1. Inventory of substances in Malaysia
2. Define listed substances
3. Define self-classified substances
4. Define volumes per importer/manufacturer
5. Basic Notification
6. Detailed Notification
7. Prepare needed data
8. Define your deadlines
EHS Notification System - Concerns

Substance Identity

- How to treat “multi-constituent” substances.
- What is the definition of an impurity?

Indirect import

- How to cover indirect imports of substances with complex supply chains.

External Notification and CBI

- Non-Malaysian suppliers need to submit notification data as part of the notification made by the Malaysian Client.
- How secure is the online system to prevent leakage of CBI
EHS Notification System- Concerns

Bulk notification

- The available notification system enables notification of *individual* substances only.
- No way of bulk submission (e.g. XML format) for long notification lists.
Malaysian Standards on GHS

- Standards on GHS were approved in 2008 by MITI
- GHS will use CLASS regulations (Chemicals Classification, Labelling and SDS) for classification purposes.
- CLASS regulations are still under review.

Managed by different agencies including:

- Department of Occupational Safety and Health (DOSH)
- Ministry of Human Resources (MOHR)
- Department of Agriculture (DOA)
- Ministry of Agriculture and Agro-based industry (MOA)
Malaysian Standards on GHS

Implementation and being in compliance

Are you affected?
- Manufacturer, importer, formulator, distributor,.. 

What are your duties?
- Classification
  - Define your classification guidance
- Labelling
  - Data and language
- SDS
  - Data and language (use dual language)
- Recordkeeping
  - Prepare and keep an annual inventory of substances
Key Words of Compliance

- Training
- Proactivity
- Readiness
- Documentation
Thank you for your attention

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If you have any unanswered questions please submit them to the Chemical Watch Forum, after the webinar.

http://forum.chemicalwatch.com
Thank you for attending

A downloadable recording of this presentation (with slides) will be available shortly.

If you have any questions, please contact Lorna (lorna@chemicalwatch.com)

NEXT

Turkey: New CLP Regulation - 26 September
www.chemicalwatch.com/turkey-webinar
WE WILL RESUME SHORTLY...

Thank-you for your patience