Overview of the Regulatory Framework for Biocidal Products in Malaysia & Thailand

Asian-European Biocides Regulatory Summit, Singapore 1-2 September 2014
Content

- Introduction to Biocides
- Biocidal Products in EU

- Malaysia: Pesticides Act of 1974
Plant Protection Products

- Horticulture
- Forestry
- Home & Garden
- Agriculture
- Amenity

Biocidal Products

Disinfectants (PT 1-5)
- Food and feed area
- Veterinary hygiene
- Drinking water
- Disinfectants & algaecides
- Human hygiene

Pest control (PT 14-20)
- Rodenticides
- Avicides
- Molluscicides, vermicides...
- Piscicides
- Insecticides, acaricides
- Repellents and attractants
- Control of other vertebrates

Preservatives (PT 6-13)
- For wood
- For film
- Slimicides
- For construction materials
- For liquid-cooling & processing systems
- For products during storage
- For fibre, leather, rubber and polymerised materials

Others products (PT 21-22)
- Antifouling products
- Embalming & taxidermist fluids
**Biocidal product:**
any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the *intention of* destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any *harmful organism* by any means other than mere physical or mechanical action

‘*harmful organism*’ means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

<table>
<thead>
<tr>
<th>Define the intended purpose of the product</th>
<th>PPP</th>
<th>Biocide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria of the target organism</td>
<td>Detrimental to plant or plant products</td>
<td>Detrimental to other areas</td>
</tr>
<tr>
<td>The place where the product is applied to achieve the principal intended action</td>
<td>Protection against harmful organisms to plants and plant products</td>
<td>Products used for a general hygiene purpose</td>
</tr>
</tbody>
</table>
## Biocidal Product Types

<table>
<thead>
<tr>
<th>Main Group</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disinfectants</strong></td>
<td>1</td>
<td>Human hygiene</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Disinfectants and algaecides not intended for direct application to humans or animals</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Veterinary hygiene</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Food and feed area</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Drinking water</td>
</tr>
<tr>
<td><strong>Preservatives</strong></td>
<td>6</td>
<td>Preservatives for products during storage</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Film preservatives</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Wood preservatives</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Fibre, leather, rubber and polymerised materials preservatives</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Construction material preservatives</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Preservatives for liquid-cooling and processing systems</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>Slimicides</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>Working of cutting fluid preservatives</td>
</tr>
<tr>
<td><strong>Pest Control</strong></td>
<td>14</td>
<td>Rodenticides</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>Avicides</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>Molluscicides, vermicides and products to control other invertebrates</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>Piscicides</td>
</tr>
<tr>
<td></td>
<td>18</td>
<td>Insecticides, acaricides and products to control other arthropods</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>Repellents and attractants</td>
</tr>
<tr>
<td><strong>Other Biocidal Products</strong></td>
<td>20</td>
<td>Control of vertebrates</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>Antifouling products</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>Embalming and taxidermist fluids</td>
</tr>
</tbody>
</table>
• Malaysia
• Thailand
MALAYSIA

Pesticides Act of 1974

- Pesticides Board (Government Agencies)

- Implemented under the responsibility of the Department of Agriculture including “Code of Conduct on the Distribution and Use of Pesticide”

- 7 Subsidiary legislations regarding registration, importation, licensing, labelling, etc

- Amendments include heavier penalties, importation of registration sample/analytical standards, possession/use of unregistered pesticides or unapproved use of pesticides, disposal charges, etc.
7 Subsidiary Legislations

- Pesticides (Registration) Rules 1976 (Amendment 2008)
- Pesticides (Importation for Research and Education Purposes) Rules 1981 (Amendment 1987)
- Pesticides (Labelling) Regulations 1984
- Pesticides (Licensing For Sale and Storage For Sale) Rules 1988 (Amendment 2007)
- Pesticides (Highly Toxic Pesticides) Regulations 1996 (Amendment 2004)
- Pesticides (Advertisement) Regulations 1996
- Pesticides (Pest Control Operators) Rules 2004
Other Laws

- **The Hydrogen Cyanide (Fumigation) Act 1953**: HCN or CH$_3$Br
- **The Environmental Quality Act 1974**: pesticide waste disposal factories → environment
- **The Food Act 1983**: pesticide residues in food
- **The Occupational Safety and Health Act 1994**: safety & health of workers
Pesticides Act of 1974

1. **“Pest”** includes bacteria, virus, fungi, weeds, insects, rodents, birds, other plants/animals.

2. **“Pesticide”** means substance/preparation containing $\geq 1$ AI as one of its constituents.

3. **“Active Ingredient (AI)”** means an ingredient as listed in the “First Schedule”.
Importation of Biocidal Products into Malaysia

• Check whether **Active Ingredient** in biocidal product is listed in “First Schedule” of the Pesticides Act of 1974.

• If “Yes” → the product must be **registered & approved** from Malaysia DOA accompanying with Customs clearance.

• If “No” → importer to send official request to DOA (the Director of Pesticides Control Division, Mr. Halimi Bin Mahmud: halimi@doa.gov.my) → obtained consent from the authority.

**Section 7-13: Control of the Importation and Manufacture of Pesticide**
First Schedule
(Section 2)
List of Pesticides

EXPLANATION
1. In the following list the common name and the chemical name or, if no common name is provided, the chemical name only, determine the identity of a pesticide.

2. The sign (\text{~}) indicates continuity of spelling and is used where a word or name is broken up owing to limitation of space.

Common Names Chemical Names

- \(5',6',6'\)-trihydro-\(2'H\)-pyran)-12-yl\(,6\)-dideoxy-4-O,\(,6\)-dideoxy-3-O-methyl-a-L-arabino-hexopyranosyl,\(,6\)-methyl-a-L arabino-hexopyranoside
- \(5',6',6'\)-trihydro-\(2'H\)-pyran)-12-yl\(,6\)-dideoxy-4-O,\(,6\)-dideoxy-3-O-methyl-a-L-arabino-hexopyranoside
- a-L-arabino-hexopyranoside
- acephate: O,S-dimethyl acetylphosphoramidodithioate
- acetamiprid (E)-\(\text{~}\)=N-\(\text{~}\)\{6-chloro-3-pyridyl\}methyl]-N2-cyano-N1= methylacetimidine
- acetochlor: 2-chloro-N-ethoxymethyl-6' ethylacetoc-o-toluamide
- acifluorfen: 5-(2-chloro-a,a,a-trifluoro-p-todyloxy)-2-\(\text{~}\)= (including salts) nitrobenzoic acid
- aclonifen: 2-chloro-6-nitro-3-phenoyantline
- acrinathrin (\text{~})3-cyano-3-phenoxynbenzyl (\text{~})\{1R,3S\}2,2,\(\text{~}\)=
- \(\text{~}\)\{2-(2,2,2-trifluoro-1= trifluoromethylthoxycarboxybenzyl\}vinyl\}=
cyclopropene-carboxylate

http://www.doa.gov.my/c/document_library/get_file?uuid=8b9523a8-23de-4047-a1ce-36158903e334&groupId=38257
Registration Requirements:

- Technical Data
- Information on the Biocidal Product (technical AI and/or formulation)

FAO/WHO Specifications for Pesticides:

Malaysian Standards Specifications:
Registration Requirements

- Locally Registered companies

- Submission Address: Secretary, Pesticides Board, Department of Agriculture (DOA), Jalan Gallagher, 50480 Kuala Lumpur, MALAYSIA

- Application Forms

- Submissions made prior to Desired Registration Date

- Registration Certificate is valid for 3 years

- Fees: Application Fees = 1,500 MRY (~ 470 USD)
  Registration Fees = 500 – 3,500 MYR (~ 160 USD, up to hazard class)
Registration Requirements:

- Product Identity
- Physical & Chemical Properties
- Method of Analysis
- Impact on Human and Animal (mammalian toxicological data)
- Residues
- Fate and Behavior
- Effects on Non-target Species
- Efficacy Data and Information
Testing Requirements:

- Residuals Test
- Environmental Fate and Behaviour
- Ecotoxicology Test Data (effects on terrestrial vertebrates/aquatic species/bees and other arthropod species/earthworms and other soil micro-organisms/non-target organisms [flora and fauna])
Pesticides (Labelling) Regulations 1984

Registration & Labelling Requirements

Registration Number

LRMP/R1/xxxx
Pesticides (Licensing for Sale and Store for Sale) Regulations 1988

Pesticides Board

Training Course for Dealers/Sellers

Sale and Store for Sale

LICENSE
Pesticides Act 1974
and
CLASS Regulations 2013

- Classification
- Packaging
- Labelling
- Inventory
- Safety Data Sheet (SDS)
- Confidential Business Information (CBI)
THAILAND

HAZARDOUS SUBSTANCE ACT B.E. 2535 (1992)

- Issued under the responsibility of the Ministry of Industry (MOI)
- Due to the diverse characteristics and usage of the substances, enforcement is split over 6 agencies:
  - Department of Agriculture (DOA)
  - Department of Fisheries (DOF)
  - Department of Livestock Development (DLD)
  - Food and Drug Administration (FDA)
  - Department of Industrial Works (DIW)
  - Department of Energy Business (DOEB)
Classification of Hazardous Substance

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

The Hazardous Substance Act B.E.2535:

Notification of Ministry of Industry “List of Hazardous Substance” B.E. 2556 (2013) :
Food and Drug Administration (FDA): Hazardous Substances Control Group

The hazardous substances used in household or public health products, include:

1. Public health pesticides
2. Cleaning products
3. Disinfectants
4. Other consumer products
<table>
<thead>
<tr>
<th>Type of Hazardous Substance</th>
<th>Example</th>
</tr>
</thead>
</table>
| **Type 1 hazardous substance** | - Cleaning products  
- Adhesives containing alkyl  
- Swimming pool disinfectants |
| **Type 2 hazardous substance** | - Household and public health pesticides  
- **Cleaning products/disinfectants** (except any products containing the type 1 or type 3 hazardous substances as active ingredients) |
| **Type 3 hazardous substance** | - Household and public health pesticides containing chlorpyrifos or pyrethroids as active ingredients  
- **Cleaning products/disinfectants** containing acids, alkalines, or aldehydes as active ingredients |
| **Type 4 hazardous substance** | - DDT, chlordane or dieldrin |
Data Requirements for Registration

1. Application form
2. Product labels
3. Product formula (100% composition) compare with WHO Specification (if any)
4. Manufacturing, packaging and labeling processes
5. Physical and chemical properties of hazardous substance product
6. Qualitative and Quantitative analysis
7. Toxicological data
8. Safety data sheet (SDS) of product or of all ingredients declared in the formula
9. Efficacy Test result (in case of pesticide, disinfectant and bleach)
10. Environmental effect
11. Utilization, recommendation rate
12. Certificate of Analysis of active ingredient content (except technical grade and premix)
13. Certificate of Free Sales (only the imported products of pesticides)
14. Copy of import/ manufacturing license
Technical data:

**Toxicity:**
1. Acute toxicity; oral, dermal, inhalation
4. Respiratory or skin sensitization: OECD 406, OECD 429
5. Germ cell mutagenicity:
   - *in vivo* heritable germ cell mutagenicity test i.e. OECD 478, OECD 485
   - *in vivo* somatic cell mutagenicity test i.e. OECD 474, OECD 475, OECD 484
   - mutagenicity test in germ cells i.e. OECD 483
   - genotoxicity test in germ cells, somatic cells (OECD 486)
   - *in vitro* mutagenicity test (OECD 476)
Technical data:

- **Toxicity:**
  6. Carcinogenicity
  7. Reproductive toxicity
  8. Specific target organ systematic toxicity – Single exposure
  9. Specific target organ systematic toxicity - Repeated exposure
  10. Aspiration hazard

- **Environmental effect:**
  1. Aquatic Acute and Chronic toxicity Test
  2. Biotic and Abiotic degradation Test
  3. Bioconcentration factor (soil and water)

- **Efficacy:**

  [Link to Efficacy Information](http://www.fda.moph.go.th/psiond/fda_efficacy.htm)
In March 13, 2012 GHS Notification rule was gazette following the 3rd revision of UN GHS

Classification:

<table>
<thead>
<tr>
<th>Physical hazard (16)</th>
<th>Health hazard (10)</th>
<th>Environmental hazard (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explosives</td>
<td>Acute toxicity</td>
<td>Hazardous to the aquatic environment</td>
</tr>
<tr>
<td>Flammable gases</td>
<td>Skin corrosion/irritation</td>
<td>Hazardous to the ozone environment</td>
</tr>
<tr>
<td>Flammable aerosols</td>
<td>Serious eye damage/eye irritation</td>
<td></td>
</tr>
<tr>
<td>Oxidizing gases</td>
<td>Respiratory or skin sensitization</td>
<td></td>
</tr>
<tr>
<td>Gases under pressure</td>
<td>Germ cell mutagenicity</td>
<td></td>
</tr>
<tr>
<td>Flammable liquids</td>
<td>Carcinogenicity</td>
<td></td>
</tr>
<tr>
<td>Flammable solids</td>
<td>Reproductive toxicity</td>
<td></td>
</tr>
<tr>
<td>Self-reactive substances and mixtures</td>
<td>Specific target organ toxicity - Single exposure</td>
<td></td>
</tr>
<tr>
<td>Pyrophoric liquids</td>
<td>Specific target organ toxicity - Repeated exposure</td>
<td></td>
</tr>
<tr>
<td>Pyrophoric solids</td>
<td>Aspiration hazard</td>
<td></td>
</tr>
<tr>
<td>Self-heating substances and mixtures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substances and mixtures which, in contact with water, emit flammable gases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxidizing liquids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxidizing solids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organic peroxides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrosive to metals</td>
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</tr>
</tbody>
</table>
GHS Implementation in Hazardous Substances Products for Household and Public Health Use

Labelling: The basic elements on labels required in Thailand (B.E. 2555 Annex, Table 1) are to be consistent with the 3rd revised edition of the UN GHS:

1. Pictograms
2. Signal Words
3. Hazard Statements
4. Precautionary Statements
5. Product or Chemical Identifier
6. Supplier Identification

http://www.fda.moph.go.th/psiond/fda_label.htm

SDS: English or Thai (follow the government form)

On 29 January 2013, Food and Drug Administration (FDA) updated the list of hazardous substances used in households under the Hazardous Substance Act resulting from recategorization of several substances (http://eis.diw.go.th/haz/pdf/announce56.pdf).

According to the list, FDA shall be responsible for control of hazardous substances in List (4) (household and cleaning products, public health pesticides, disinfectants, water and drill chemical treatment and cyanoacrylate adhesives), annexed to the Notification.

The following authorities shall be responsible for control of hazardous substance to be in compliance with the Hazardous Substance Act B.E. 2535 (1992):

1. Department of Agriculture shall be responsible for control of hazardous substances in List 1, annexed to this Notification.
2. Department of Fisheries shall be responsible for control of hazardous substances in List 2, annexed to this Notification.
3. Department of Livestock Development shall be responsible for control of hazardous substances in List 3, annexed to this Notification.
4. Food and Drug Administration shall be responsible for control of hazardous substances in List 4, annexed to this Notification.

Registration procedure

An applicant submits the application (Wor Ohr./Sor Tor.1) and required documents

The officer checks the completeness of the submitted documents

- Complete
- Incomplete
- Reject

- The applicant submits additional documents

The application and its related documents are evaluated / considered by the officers / working group/subcommittee

- Approve: Product Registration Certificate
- Not approve: Letter of Denial
- Notice of deficiency: Notify applicant to correct / submit additional documents

Deadline for resubmission of additional documents
- 30 days for the 1st resubmission
- 20 days for the 2nd resubmission
- If failure to meet deadlines, the application will be rejected
Thank you for your attention