GHS implementation in EU
- The CLP Regulation -

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Swedish Chemicals Agency

GHS Stocktaking Workshop for Central and Eastern Europe
Chisinau, Republic of Moldova
17-19 July 2012
Hazard classification - a cornerstone in EU chemicals legislation system

- Export and import
- Consumer Products
- Pollution
- Hazard / Risk
- Reach
- PPP
- BP
- Major Accidents
- Waste
- Worker Health and Safety
Classification plays a key role in REACH

✓ Included in the registration dossier for a substance;

✓ Triggers certain provisions e.g.:
  - exposure assessment and risk characterisation;
  - the obligation to provide a safety data sheet.

✓ CMR classification may lead to restrictions and the need to apply for authorisation.
Considerations when implementing GHS

- Existing national/regional legislation
- Sector-specific legislation
- What edition of the ”Purple Book” to use (biannual revision)
- Application of the ”building block approach”
Pre-GHS

National or regional criteria and labels

Substances:
Dir. 67/548/EEC  (DSD)

Preparations:
Dir. 1999/45/EC  (DPD)

National ordinance (KIFS)

GHS (2nd rev ed)

 Regulation (EC)
No 1272/2008

Förordning (EG) nr 1272/2008

Translation into official language of MS

www.kemi.se
CLP-Regulation
7 titles (62 articles) …

• Title I    General issues
• Title II   Classification
• Title III  Labelling
• Title IV   Packaging
• Title V    Harmonised classification and the C&L Inventory
• Title VI   Competent authorities and enforcement
• Title VII  Common and final provisions
... and 7 Annexes

- General criteria for classification & labelling
  - Physical hazards
  - Health hazards
  - Environmental hazards

- Specific rules for Labelling, Packaging

- List of harmonised classification and labelling for more than 4000 substances/substance-groups

- Translation table (from DSD/DPD to GHS)
# GHS Physical Hazard Classes/Categories

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Explosives</td>
<td></td>
</tr>
<tr>
<td>2.2 Flammable Gases</td>
<td></td>
</tr>
<tr>
<td>2.3 Flammable Aerosols</td>
<td></td>
</tr>
<tr>
<td>2.4 Oxidising Gases</td>
<td></td>
</tr>
<tr>
<td>2.5 Gases under pressure</td>
<td></td>
</tr>
<tr>
<td>2.6 Flammable Liquids</td>
<td></td>
</tr>
<tr>
<td>2.7 Flammable Solids</td>
<td></td>
</tr>
<tr>
<td>2.8 Self Reactive Chemicals</td>
<td></td>
</tr>
<tr>
<td>2.9 Pyrophoric Liquids</td>
<td></td>
</tr>
<tr>
<td>2.10 Pyrophoric Solids</td>
<td></td>
</tr>
<tr>
<td>2.11 Self Heating Chemicals</td>
<td></td>
</tr>
<tr>
<td>2.12 Water Reactive - emits Flammable Gas</td>
<td></td>
</tr>
<tr>
<td>2.13 Oxidising Liquids</td>
<td></td>
</tr>
<tr>
<td>2.14 Oxidising Solids</td>
<td></td>
</tr>
<tr>
<td>2.15 Organic Peroxides</td>
<td></td>
</tr>
<tr>
<td>2.16 Corrosive to Metals</td>
<td></td>
</tr>
</tbody>
</table>

### Hazard Category Details

- **Unstable**
  - Div 1.1
  - Div 1.2
  - Div 1.3
  - Div 1.4
  - Div 1.5
  - Div 1.6

- **Compressed gas**
  - Type A
  - Type B
  - Type C
  - Type D
  - Type E
  - Type F
  - Type G

- **Liquefied gases**
  - Type A
  - Type B
  - Type C
  - Type D
  - Type E
  - Type F
  - Type G

- **Refrigerated liquefied gases**
  - Type A
  - Type B
  - Type C
  - Type D
  - Type E
  - Type F
  - Type G

- **Dissolved gases**
  - Type A
  - Type B
  - Type C
  - Type D
  - Type E
  - Type F
  - Type G

- **Unstable**
  - Div 1.1
  - Div 1.2
  - Div 1.3
  - Div 1.4
  - Div 1.5
  - Div 1.6
### CLP Physical Hazard Classes/Categories

#### Hazard Class
- 2.1 Explosives
- 2.2 Flammable Gases
- 2.3 Flammable Aerosols
- 2.4 Oxidising Gases
- 2.5 Gases under pressure

#### Hazard Category

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Unstable</th>
<th>Div 1.1</th>
<th>Div 1.2</th>
<th>Div 1.3</th>
<th>Div 1.4</th>
<th>Div 1.5</th>
<th>Div 1.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressed gas</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquefied gases</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerated liquefied gases</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissolved gases</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Additional Classes
- 2.6 Flammable Liquids
- 2.7 Flammable Solids
- 2.8 Self Reactive Chemicals
- 2.9 Pyrophoric Liquids
- 2.10 Pyrophoric Solids
- 2.11 Self Heating Chemicals
- 2.12 Water Reactive - emits Flammable Gas
- 2.13 Oxidising Liquids
- 2.14 Oxidising Solids
- 2.15 Organic Peroxides
- 2.16 Corrosive to Metals

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[Sources: www.kemi.se]
# GHS Health Hazard Classes/Categories

## Hazard Class

### 3.1 Acute Toxicity
- Oral
- Dermal
- Inhalation

### 3.2 Skin Corrosion/Irritation

<table>
<thead>
<tr>
<th>Corrosive</th>
<th>Irritant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>1B</td>
</tr>
</tbody>
</table>

### 3.3 Serious Eye Damage/Irritation

| 1 |
| 2A |
| 2B |

### 3.4 Respiratory sensitizer & Skin sensitizer

| 1 | 1A | 1B |

### 3.5 Germ Cell Mutagenicity

| 1A | 1B | 2 |

### 3.6 Carcinogenicity

| 1A | 1B | 2 |

### 3.7 Reproductive Toxicity

| 1A | 1B | 2 |

### 3.8 STOT - Single Exposure

| 1 | 2 | 3 |

### 3.9 STOT - Repeated Exposure

| 1 | 2 |

### 3.10 Aspiration hazard

| 1 | 2 |
# CLP Health Hazard Classes/Categories

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Acute Toxicity</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Oral</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Dermal</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Inhalation</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>3.2 Skin Corrosion/Irritation</td>
<td>1A 1B 1C 2</td>
</tr>
<tr>
<td>3.3 Serious Eye Damage/Irritation</td>
<td>1 2</td>
</tr>
<tr>
<td>3.4 Respiratory sensitizer &amp;</td>
<td>1 1A 1B</td>
</tr>
<tr>
<td>Skin sensitizer</td>
<td>1 1A 1B</td>
</tr>
<tr>
<td>3.5 Germ Cell Mutagenicity</td>
<td>1A 1B 2</td>
</tr>
<tr>
<td>3.6 Carcinogenicity</td>
<td>1A 1B 2</td>
</tr>
<tr>
<td>3.7 Reproductive Toxicity</td>
<td>1A 1B 2 Lactation</td>
</tr>
<tr>
<td>3.8 STOT - Single Exposure</td>
<td>1 2 3</td>
</tr>
<tr>
<td>3.9 STOT - Repeated Exposure</td>
<td>1 2</td>
</tr>
<tr>
<td>3.10 Aspiration hazard</td>
<td>1</td>
</tr>
</tbody>
</table>
# GHS Environmental Hazard Classes/Categories

## Hazard Class

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Hazardous to the aquatic environment</td>
<td></td>
</tr>
<tr>
<td>Acute hazard</td>
<td>1 2 3</td>
</tr>
<tr>
<td>Long-term hazard</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>5.1 Hazardous to the ozone layer</td>
<td>1</td>
</tr>
</tbody>
</table>

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Kemikalieinspektionen
Swedish Chemicals Agency
## CLP Environmental Hazard Classes/Categories

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
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<tbody>
<tr>
<td>4.1 Hazardous to the aquatic environment</td>
<td>1</td>
</tr>
<tr>
<td>Acute hazard</td>
<td>1</td>
</tr>
<tr>
<td>Long-term hazard</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>5.1 Hazardous to the ozone layer</td>
<td>1</td>
</tr>
</tbody>
</table>
Stepwise introduction: substances

<table>
<thead>
<tr>
<th>DSD / CLP</th>
<th>From 1 December 2010</th>
<th>From 1 June 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>![X] DSD and CLP</td>
<td>![CLP] CLP</td>
</tr>
<tr>
<td>Labelling</td>
<td>![CLP] CLP</td>
<td>![CLP] CLP</td>
</tr>
</tbody>
</table>

- **Derogation**: deliveries of substances before 1 December 2010 are not required to be relabelled and repackaged before 1 December 2012.
- **NOTE!** Deliveries after 1 December 2010 of the same substance need to be relabelled and repackaged according to CLP.
### Stepwise introduction: mixtures

<table>
<thead>
<tr>
<th>DPD/ CLP</th>
<th>From 20 Januari 2009</th>
<th>From 1 June 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPD or CLP (optional)</td>
<td>!</td>
<td>CLP</td>
</tr>
<tr>
<td><strong>Labelling</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPD or CLP (optional)</td>
<td>!</td>
<td>CLP</td>
</tr>
</tbody>
</table>

- **Derogation:** deliveries of mixtures before 1 June 2015 are not required to be relabelled and repackaged before 1 June 2017.
- **NOTE!** Deliveries after 1 June 2015 of the same mixture need to be relabelled and repackaged according to CLP.
Translation from DSD to CLP: Health and environmental hazards
Translation from DSD to CLP: Physical hazards
EU-harmonised (and legally binding) classification and labelling

• Shall normally be done for all effects/hazard classes of active substances in:
  – plant protection products
  – biocidal products.

• Shall for other substances normally be done for substances that may be
  – Carcinogenic, Mutagenic or Toxic for Reproduction (CMR);
  – Respiratory sensitiser.

➤ Other effects may be considered on a case-by-case basis
<table>
<thead>
<tr>
<th>Index No</th>
<th>Intern. Chemical Identific.</th>
<th>EG No</th>
<th>Cas No</th>
<th>Classification</th>
<th>Labelling</th>
<th>Haz. Statem. Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>603-004-00-6</td>
<td>n-butanol</td>
<td>200-751-6</td>
<td>71-36-3</td>
<td>Flam. Liq. 3&lt;br&gt;Acute Tox. 4 (*)&lt;br&gt;STOT SE 3&lt;br&gt;Skin Irrit. 2&lt;br&gt;Eye Dam. 1&lt;br&gt;STOT SE 3</td>
<td>H226&lt;br&gt;H302&lt;br&gt;H335&lt;br&gt;H315&lt;br&gt;H318&lt;br&gt;H336</td>
<td>GHS02&lt;br&gt;GHS05&lt;br&gt;GHS07&lt;br&gt;Dgr</td>
</tr>
</tbody>
</table>

Table 3.2 (DSD format)

<table>
<thead>
<tr>
<th>Index No</th>
<th>Intern. Chemical Identific.</th>
<th>EG No</th>
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<tr>
<td>603-004-00-6</td>
<td>n-butanol</td>
<td>200-751-6</td>
<td>71-36-3</td>
<td>R10&lt;br&gt;Xn; R22&lt;br&gt;Xi; R37/38-41&lt;br&gt;R67</td>
<td>Xn&lt;br&gt;R: 10-22-37/38-41-67&lt;br&gt;S: (2-)7/9-13-26-37/39-46</td>
</tr>
</tbody>
</table>
Submission of proposals for harmonised classification and labelling

Industry ➔ MS CA

Proposals
- Via a Member State Competent Authority (if the substance is listed in Annex VI of CLP and already classified for the hazard covered by the proposal)
- Directly to ECHA (by MS or M/I/DU) (all other cases)

Risk Assessment Committee (RAC)

opinion

European Commission

the REACH (and CLP) Committee (ATP procedure)

Publication in EU-OJ
# Main Obligations for Suppliers

<table>
<thead>
<tr>
<th></th>
<th>Classification</th>
<th>Labelling &amp; Packaging</th>
<th>SDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturers (of substances)</td>
<td>X</td>
<td>X</td>
<td>(X)</td>
</tr>
<tr>
<td>Importers (into EU/EES)</td>
<td>X</td>
<td>X</td>
<td>(X)</td>
</tr>
<tr>
<td>Downstream users (incl. producers of mixtures)</td>
<td>X*)</td>
<td>X</td>
<td>(X)</td>
</tr>
<tr>
<td>Distributors (incl. retailers)</td>
<td>X*)</td>
<td>(X)</td>
<td></td>
</tr>
</tbody>
</table>

*) May use the classification derived by an actor in the supply chain.

**NOTE!**
- Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging. (Art. 4.9)
- Substances and mixtures shall not be **placed on the market** unless they comply with this Regulation. (Art. 4.10)
Additional obligations for suppliers

- **Update classification and labelling**
  Be aware of new information and reclassify when necessary without undue delay *(Article 15 & 30)*

- **Keep information available**
  To assemble and keep available all the information required for the purposes of classification and labelling for a period of at least 10 years *(Article 49)*

- **Notify ECHA**
  Producers and Importers to notify to ECHA the classification and labelling elements *(Article 40)*
The Classification and Labelling Inventory

Article 39 - 40:

Importers and Manufacturers of substances shall notify the substance if it is placed on the market, and

- is classified as hazardous, irrespective of the quantity, or
- is subject to registration under the REACH Regulation

Importers of mixtures shall notify a substance in the mixture if

- classified as hazardous and is present above the relevant concentration limit (cut-off value), which results in the classification of the mixture as hazardous according to the CLP Regulation, or
- is subject to registration under the REACH Regulation

Can be joint submissions by groups of importers or manufactures
Main obligations and roles for Member states

- Interface between EC and national law (Amend existing nat. legislation)
- Harmonised classification of substances → take part in RAC
- Enforcement (system of official controls; introduce penalties for non-compliance) → take part in FORUM
- Establish national helpdesk → take part in HelpNet
- Appointment of Competent Authorities (for those tasks + Pois. Centr.)
- Guidance and training (MS CA need to communicate with practitioners!)
- Watchdog - monitoring and addressing problems

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GHS is a living system

Biannually

UN ECOSOC

Biannually

UN CE TDG/GHS

Twice a year
(July+Dec)

UN SCE TDG
(Physical hazards)

UN SCE GHS

OECD Task Force
Classification and Labelling
(Health & Environment)
Art. 53: Adaptation to technical and scientific progress (ATP)

ATP 1  (Annex VI rev.)

ATP 2  (GHS 3rd rev. ed.)

ATP 3  (Annex VI rev.)

ATP 4  (GHS 4th rev. ed.)

Regulation (EC) No 790/2009

Regulation (EC) No 286/2011

Regulation (EC) No xxx/2012

(early 2013)
Resources on the web

Classification Legislation (CLP, DSD, DPD, Test Methods)

ECHA: Introductory guidance on the CLP

ECHA: Guidance on the application of the CLP criteria

ECHA: Guidance on Labelling and Packaging

ECHA: Guidance on preparing dossiers for harmonised C&L

ECHA: Guidance on notification in the C&L inventory

ECHA: C&L Inventory database (searchable)

http://apps.echa.europa.eu/registered/registered-sub.aspx#search
ECHA: Information of registered (REACH) substances (searchable)
Thank You for Your Attention