LINKING SEVESO WITH CLP MAKES SELF-CLASSIFICATION A REALITY WE HAVE TO COME TO TERMS WITH!
CLP (EC) 1272/2008

PURPLE BOOK

- Implemented GHS rev.2
  - Adopting
    - All twenty seven (27) of the GHS hazard classes;
      - Sixteen physical;
      - Ten health; and
      - One environmental
    - Seventy seven (77) of the eighty four (84) GHS hazardous categories
GHS/CLP IS DYNAMIC…

BIENNIIUM REVIEW CYCLE

- 9 ATPs issued since 2008
  - 3 amend CLP
    - To adopt GHS revisions
  - 6 introduced new or revised classifications for substances
- 3 more in negotiation
**GHS CYCLE**

**UPDATED EVERY TWO YEARS:**

<table>
<thead>
<tr>
<th>GHS Rev.</th>
<th>Adopted</th>
<th>Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rev. 1</td>
<td>December 2004</td>
<td>2005</td>
</tr>
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<td>Rev. 2</td>
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<td>Rev. 3</td>
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<td>Rev. 5</td>
<td>December 2012</td>
<td>2013</td>
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<td>Rev. 6</td>
<td>December 2015</td>
<td>2016</td>
</tr>
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<td>Rev. 7</td>
<td>December 2016</td>
<td></td>
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<tr>
<td>Rev. 8</td>
<td>Biennium started</td>
<td>January 2017</td>
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### PUBLISHED CHANGES TO REGULATION

<table>
<thead>
<tr>
<th>ATP</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>1st ATP</strong></td>
<td>Changed to Annex VI tables 3.1 &amp; 3.2 - Lists of substances</td>
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<tr>
<td><strong>2nd ATP</strong></td>
<td>Updated CLP to apply changes within the 3rd revised edition of GHS</td>
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<td><strong>3rd ATP</strong></td>
<td>Changed to Annex VI tables 3.1 &amp; 3.2 - Lists of substances</td>
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<tr>
<td><strong>4th ATP</strong></td>
<td>Updated CLP to apply changes within the 4th revised edition</td>
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<tr>
<td><strong>5th ATP</strong></td>
<td>Changed to Annex VI tables 3.1 &amp; 3.2 - Lists of substances</td>
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<tr>
<td><strong>6th ATP</strong></td>
<td>Introduced Croatian H and P statements - List of substances</td>
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<tr>
<td><strong>7th ATP</strong></td>
<td>Changed to Annex VI tables 3.1 &amp; 3.2 - Lists of substances</td>
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<tr>
<td><strong>8th ATP</strong></td>
<td>Updated CLP to apply changes in the 5th revised edition</td>
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<tr>
<td><strong>9th ATP</strong></td>
<td>Changed to Annex VI tables 3.1 &amp; 3.2 - Lists of substances</td>
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</tbody>
</table>

*Adaptation to Technical Progress (ATP)*
CLP IN A NUTSHELL

77
• RECITALS
  • Regulatory intent

62
• ARTICLES
  • Legal text

8
• ANNEXES
  • Tables, lists and general principles
Recitals set out the reasons for the contents of the enacting terms (the articles) of an act or regulation.
Responsibility for the identification of hazards of substances and mixtures and for deciding on their classification should mainly lie with manufacturers, importers and downstream users of those substances or mixtures, regardless of whether they are subject to the requirements of Regulation (EC) No 1907/2006. In fulfilling their responsibilities for classification, downstream users should be allowed to use the classification of a substance or mixture derived in accordance with this Regulation by an actor in the supply chain, provided that they do not change the composition of the substance or mixture.

Responsibility for classification of substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006 should mainly lie with the manufacturers, producers of articles and importers. However, there should be a possibility to provide for harmonised classifications of substances for hazard classes of highest concern and of other substances on a case-by-case basis which should be applied by all manufacturers, importers and downstream users of such substances and of mixtures containing such substances.
Responsibility for the identification of hazards of substances and mixtures and for deciding on their classification should mainly lie with manufacturers, importers and downstream users of those substances or mixtures...
However, there should be a possibility to provide for harmonised classifications of substances for hazard classes of highest concern and of other substances on a case-by-case basis which should be applied by all manufacturers, importers and downstream users of such substances and of mixtures containing such substances.
Where a decision has been taken to harmonise the classification of a substance for a specific hazard class or differentiation within a hazard class by including or revising an entry for that purpose in Part 3 of Annex VI to this Regulation, the manufacturer, importer and downstream user should apply this harmonised classification, and only self-classify for the remaining, non-harmonised hazard classes or differentiations within the hazard class.
WHY SELF-CLASSIFY?

• Many valid reasons
  • Multiple classification exist
    o Raw materials
    o Processing
  • Data availability
    o Indicates
      ▪ Alternative hazard(s)
      ▪ New hazard(s)
  • Data interpretation
MULTIPLE CLASSIFICATIONS

FERROUS SULPHATE

- **REACH Registration dossier**
  - Two valid classifications
    - Based on Nickel content
    - >30ppm Skin sensitizer
  - Therefore, companies will analyse nickel content and classify accordingly
ISOCYANATE

2008 CLP annex VI entry

- Acute Toxicity Inhalation
  - Category 3*
- REACH registration submitted
  - Data showed Category 1
- Self-classified by industry
  - Hazard communication
  - Responsible Care® commitment
ADDITIONAL DATA

PRECAUTIONARY

- Could stay with Annex VI classification
  - Self classified due to:
    - Increased hazard
    - Uses of material
  - Major Seveso impact
    - LT = 5T not 50T
- Annex VI now updated accordingly
NITRIC ACID

- Proposal May 2013
  - Assign toxicity classifications
    - DSD / DPD
      - T+; R26
    - CLP
      - Acute Tox. Cat 1 (Inhalation)
        - H330
      - Ox. Liq. 2 > 99%
        - H272

- Industry produced additional data regarding 70% conc
  - Further testing undertaken
    - Acute Tox. Cat 3 (inhalation) confirmed
    - REACH dossier updated
NITRIC ACID and SEVESO

ACUTE TOXICITY CATEGORY 3 BY INHALATION AT ≤70%

Nitric acid (70% New Data) Dilution Effects

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# DATA INTERPRETATION

## MSCA PROPOSAL

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Classification</th>
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<tbody>
<tr>
<td>≤10.5%</td>
<td>Not classified by inhalation</td>
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<tr>
<td>&gt;10.5% to &lt;21%</td>
<td>Acute Tox. Cat.4 (Inhalation)</td>
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<tr>
<td>≥21% to ≤70%</td>
<td>Acute Tox. Cat.3 (Inhalation)</td>
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<tr>
<td>&gt;70%</td>
<td>Acute Tox. Cat.1 (Inhalation)</td>
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</tbody>
</table>

## INDUSTRY POSITION

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤13%</td>
<td>Not classified by inhalation</td>
</tr>
<tr>
<td>&gt;13% to ≤26%</td>
<td>Acute Tox. Category 4 (Inhalation)</td>
</tr>
<tr>
<td>&gt;26% to 100%</td>
<td>Acute Tox. Category 3 (Inhalation)</td>
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</tbody>
</table>
IN SUMMARY

SELF-CLASSIFICATION

- Is a fact of life…
  - Written into the CLP regulation
    - Seveso linked to CLP!!
- There are valid reasons for its existence