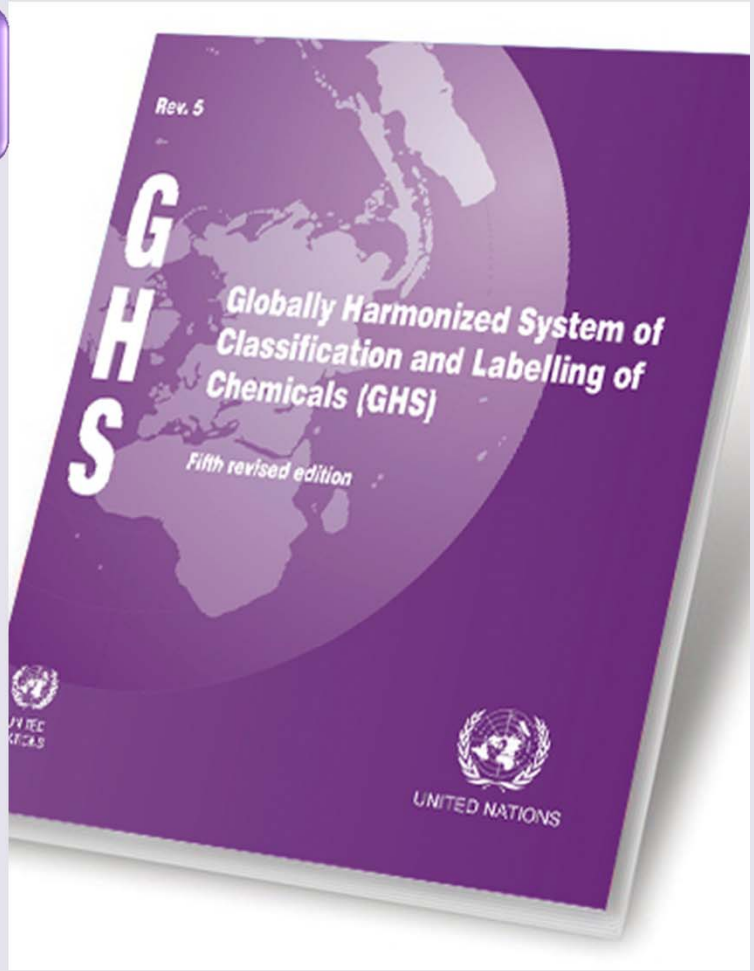
Chemical Business Association

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…

BIENNIUM 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:

GHS Rev.1	Adopted	December 2004
	Published	2005
GHS Rev.2	Adopted	December 2006
	Published	2007
GHS Rev.3	Adopted	December 2008
	Published	2009
GHS Rev.4	Adopted	December 2010
	Published	2011
GHS Rev.5	Adopted	December 2012
	published	2013
GHS Rev.6	Adopted	December 2015
	Published	2016
GHS Rev.7	Adopted	December 2016
	Published	
GHS Rev.8	Biennium started	January 2017

AS GHS UPDATES SO DOES CLP…

* Adaptation to Technical Progress (ATP)

PUBLISHED CHANGES TO REGULATION

1st ATP	Changed to Annex VI tables 3.1 & 3.2 - Lists of substances
2nd ATP	Updated CLP to apply changes within the 3rd revised edition of GHS
3rd ATP	Changed to Annex VI tables 3.1 & 3.2 - Lists of substances
4th ATP	Updated CLP to apply changes within the 4th revised edition
5th ATP	Changed to Annex VI tables 3.1 & 3.2 - Lists of substances
6th ATP	Introduced Croatian H and P statements - List of substances
7th ATP	Changed to Annex VI tables 3.1 & 3.2 - Lists of substances
8th ATP	Updated CLP to apply changes in the 5th revised edition
9th ATP	Changed to Annex VI tables 3.1 & 3.2 - Lists of substances

CLP IN A NUTSHELL

77

- RECITALS
  - Regulatory intent

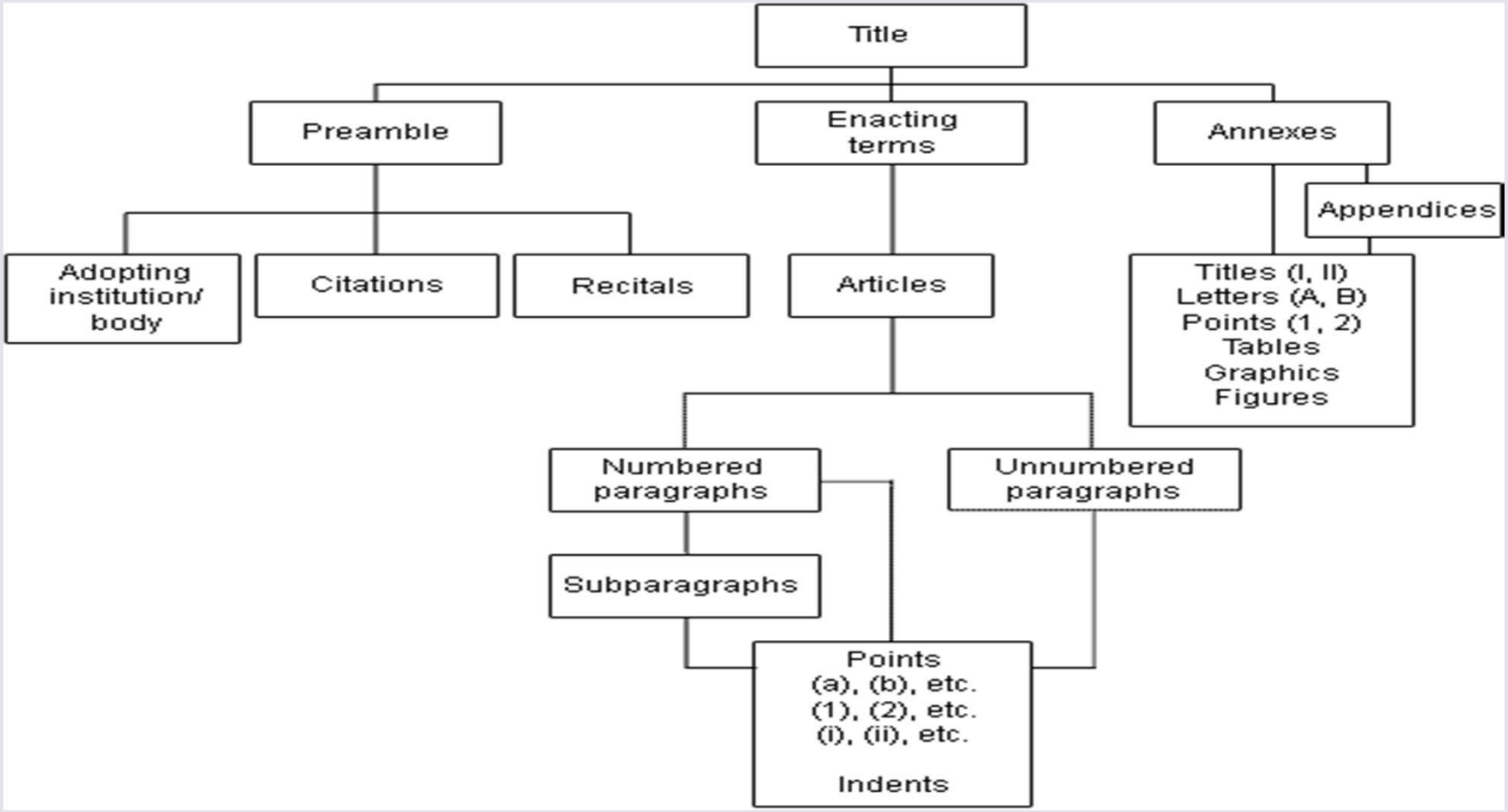
62

- ARTICLES
  - Legal text

8

- ANNEXES
  - Tables, lists and general principles

EU INTERINSTITUTIONAL STYLE GUIDE



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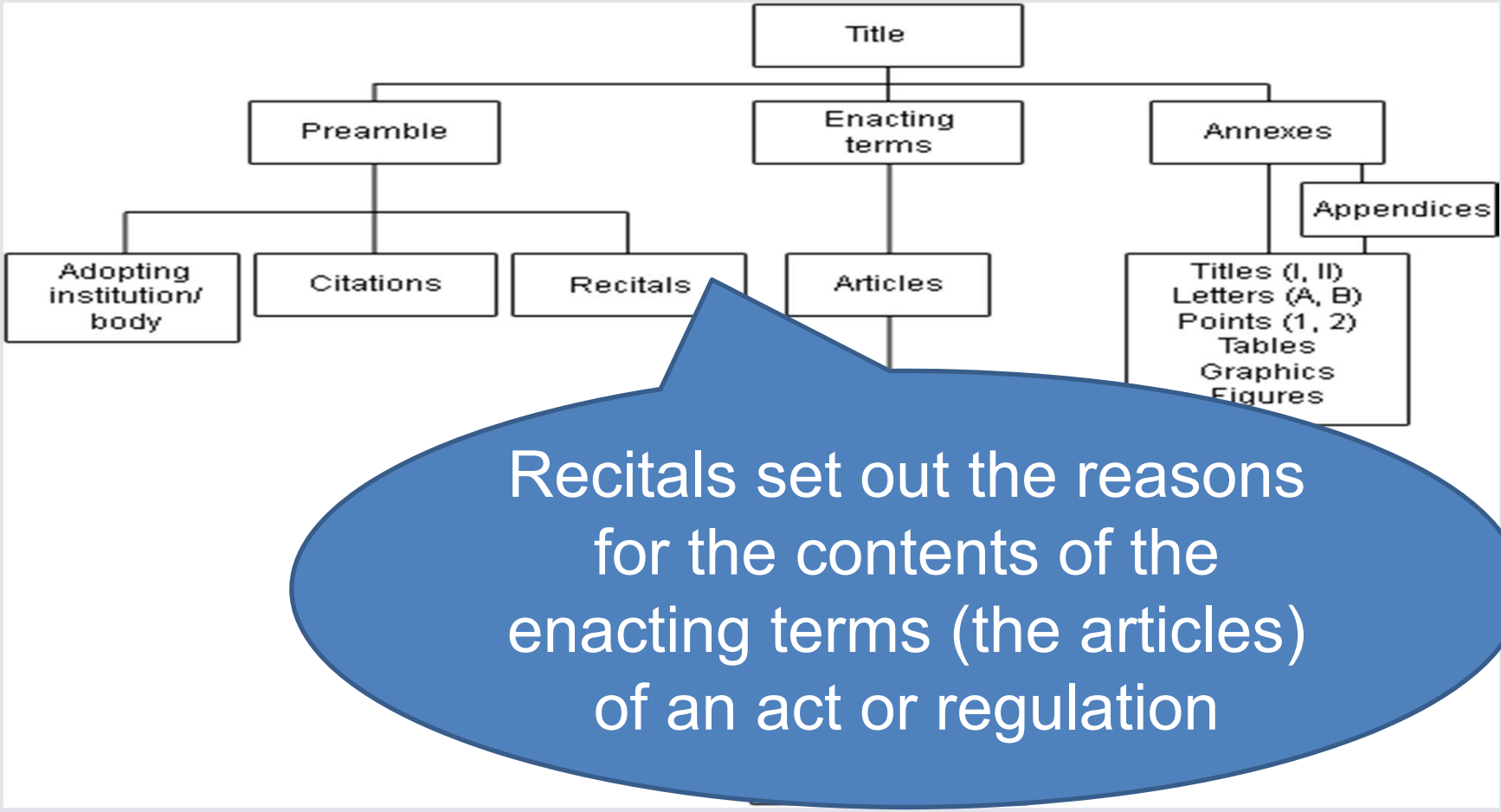


RECITAL 16

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.

RECITAL 16

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…

RECITAL 16 (Cont…)

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.

RECITAL 17

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
    - Raw materials
    - Processing
  - Data availability
    - 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

ADDITIONAL DATA

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

DATA INTERPRETATION

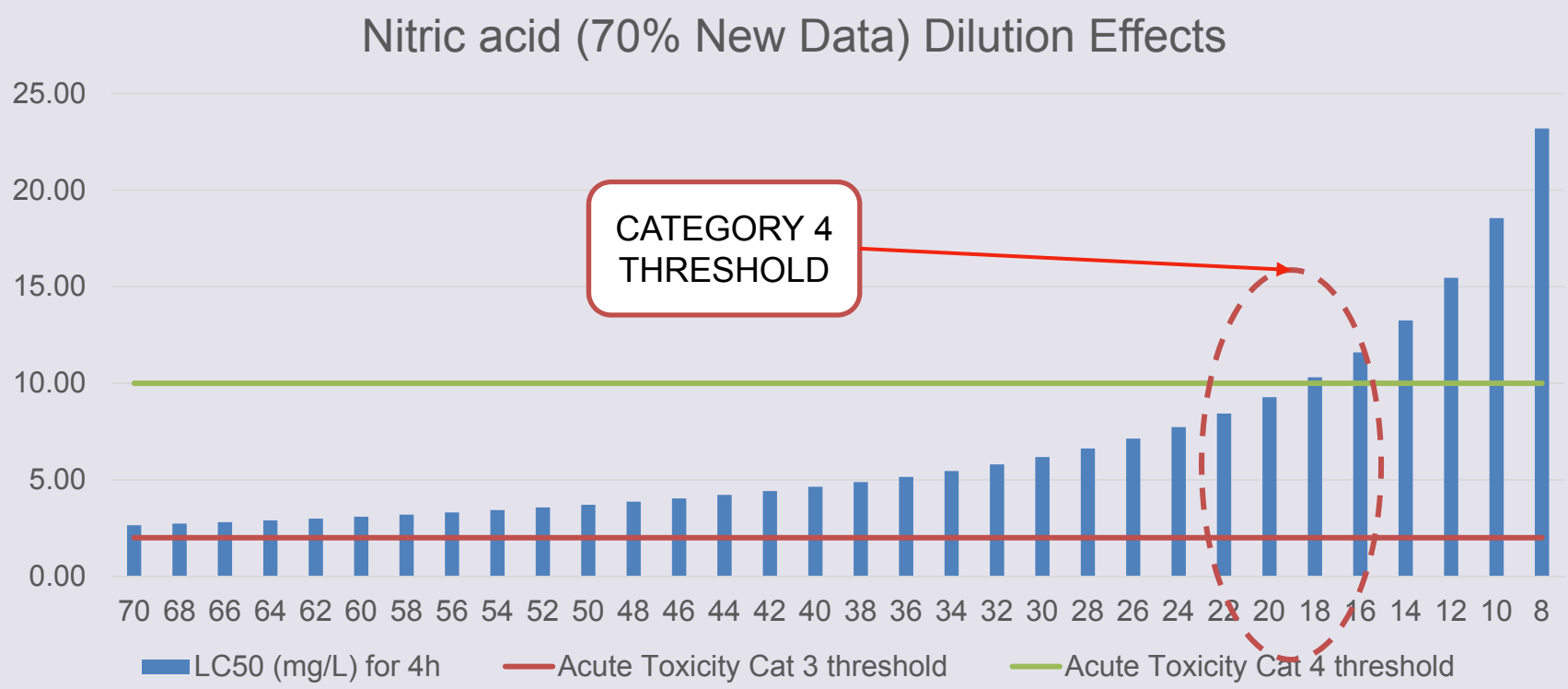
NITRIC ACID

- 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%



DATA INTERPRETATION

MSCA PROPOSAL

Concentration	Classification
≤10.5%	Not classified by inhalation
>10.5% to <21%	Acute Tox. Cat.4 (Inhalation)
≥21% to ≤70%	Acute Tox. Cat.3 (Inhalation)
>70%	Acute Tox. Cat.1 (Inhalation)

INDUSTRY POSITION

Concentration	Classification
≤13%	Not classified by inhalation
>13% to ≤26%	Acute Tox. Category 4 (Inhalation)
>26% to 100%	Acute Tox. Category 3 (Inhalation)

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