Stakeholders consultations on Info Cards and Brief Profiles

Workshop on Substance Brief Profiles

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Contents

- 1st Written Consultation
  - Overview
  - Main topics, main changes, open issues
- 2nd Written Consultation
  - Overview
  - Main topics, main changes, open issues

1st written consultation

Overview

- Aim of the consultation was to gather feedback on ICBP based on workshop (December 2013) material, extended with background information and examples
  - Focus on the Infocards, substance ID, Hazardous properties, C&L information and Regulatory processes

- Consultation took place from 18 February to 4 April
- ECHA received in total 31 comments from two Accredited Stakeholders Organisations (CEFIC and EUROMETAUX) and two Member State Competent Authorities (France Helpdesk and Germany's Federal Office for Chemicals (BAuA))

General comments

- Project was initiated to improve the search, linkage of substances and identification of InCHI and molecular formulas.

- Examples from other websites were reviewed and taken into account. Manual editing of the ICBP is not possible due to the amount of substances.

- Terminology was improved

- ECHA confirmed that publication of D(M)NEL values was in scope, further discussion in the second round of comments.

Classification and labelling (C&L)

The feedback revealed concerns on the diversity of the notified information and how the proposed aggregation of the C&L could be misleading to the user:

- Differentiate more clearly between notified and agreed (Joint submission) data

In order to keep the level of transparency on the data available and address the concerns, ECHA proposed a new approach and display rules for C&L in InfoCard and Brief Profiles (Graphical design improvement will also take place)

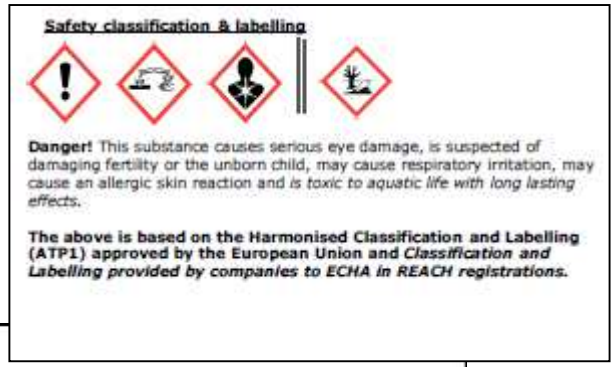
C&L – ECHA proposal

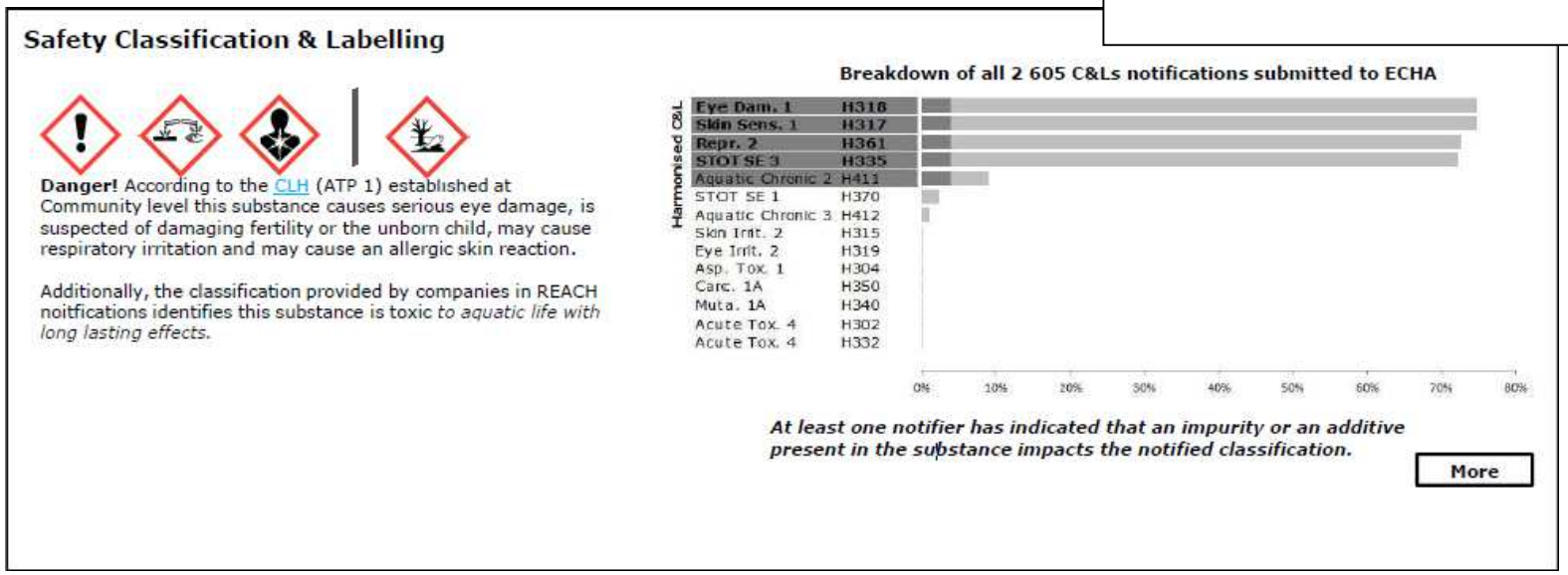
Infocard		
CLH	**REG**	**NOTIF**
Y		
Y	+	
Y	+	N
Y		N
	Y	
	Y	N
		Y

Brief Profile		
CLH	**REG**	**NOTIF**
Y		
Y	+	
Y	+	+
Y		+
	Y	
	Y	+
		Y

C&L – ECHA proposal

Example 1:
CLH + additional C&L from
Registered dossier (BPA)





C&L – ECHA proposal

Example 2:
CLH + additional C&L from
Registered dossier + additional C&L
from C&L notifications (Chromium VI)

Safety classification & labelling

Danger! This substance is fatal if inhaled, may cause genetic defects, causes damage to organs through prolonged or repeated exposure, may cause cancer, is very toxic to aquatic life with long lasting effects, is toxic in contact with skin, is toxic if swallowed, causes severe skin burns and eye damage, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility or the unborn child, may cause an allergic skin reaction and may cause allergy or asthma symptoms or breathing difficulties if inhaled.

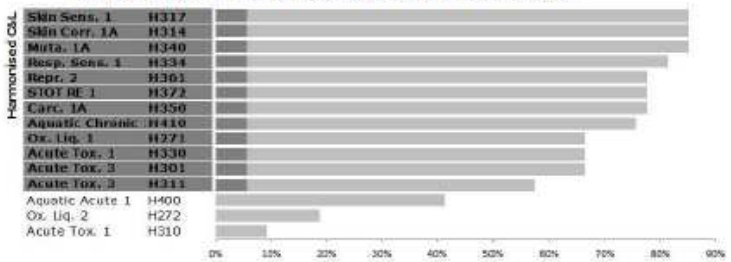
The above is based on the Harmonised Classification and Labelling (ATP1) approved by the European Union.

Safety Classification & Labelling

Danger! According to the CLH (ATP 1) established at Community level this substance is fatal if inhaled, may cause genetic defects, causes damage to organs through prolonged or repeated exposure, may cause cancer, is very toxic to aquatic life with long lasting effects, is toxic in contact with skin, is toxic if swallowed, causes severe skin burns and eye damage, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility or the unborn child, may cause an allergic skin reaction, and may cause allergy or asthma symptoms or breathing difficulties if inhaled.

Additionally, the Classification provided by companies in CLP notifications identifies this substance is very toxic to aquatic life, may intensify fire (oxidiser) and is fatal in contact with skin.

Breakdown of all 497 C&Ls notifications submitted to ECHA



At least one notifier has indicated that an impurity or an additive present in the substance impacts the notified classification.

More

2nd written consultation

Overview

- Written consultation from 8 July to 8 September 2014 (last comments received on 16 September)
  - Focus on the Brief Profiles Scientific Data Processing specifications (Phy-Chem properties, Environmental Fate and Pathways, Ecotox and Tox information)

- Feedback received from 3 ASO and 1 MSCA
  - Total of 37 comments

Main topics

Main topics

- Usable / processable data definition
- Aggregation & Prioritisation methods
- Level of detail presented per study result (data blocks)
- Presentation / displayed related issues (graphical and semantic)

Usable / processable data (I)

- EITHER comes from an endpoint summary record OR comes from an endpoint study record flagged as:
  - Key study or Weight of Evidence study

  and
  - Reliability 1 or 2
- Has a complete set of numerical / picklist values provided

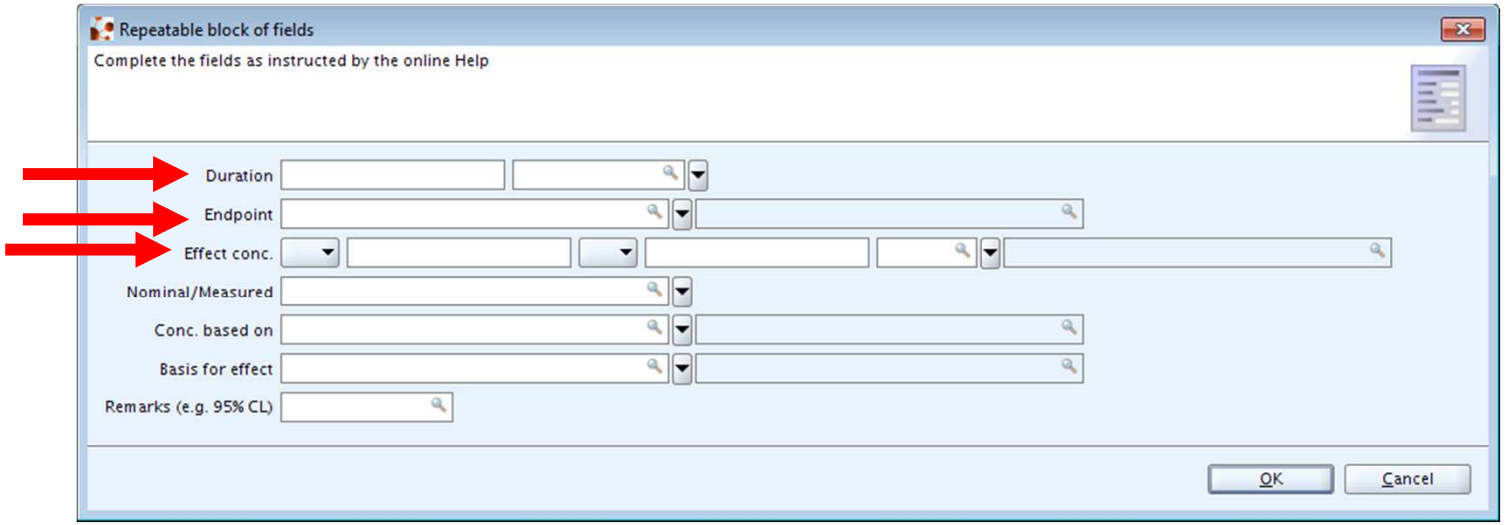
  Example 1
  - DN(M)EL thresholds value are only use if *type of threshold* is selected, value exist **and** *units* are select

Usable / processable data (I)

- *Has a complete set of numerical / picklist values provided*

  Example 2

  - Long term toxicity to fish study results are only used if: *Endpoint* type, *duration, Effect concentration* and *units* are provided



Usable / processable data (II)

- Where picklist values are provided they must be those defined as processable

  Example

  - "*Other:*" picklist option is not processed

- Where numerical value(s) are provided they must have associated unit(s) **AND** must be those defined as processable (some units cannot be handled by the summarisation logic)

  Examples

  - Standard units must be provided: "*Other:*" not processed
  - in pH and surface tension endpoints concentrations provided in ppb; vol%; other:, are not processed

Aggregation & prioritisation methods (I)

- **RANGE** of values
  - method to be extended to (eco)toxicological endpoints (including acute toxicity and repeated dose toxicity)

- **CONCATENATED DISTINCT** values

- **MOST CONSERVATIVE** of values
  - Other Toxicological endpoints

Aggregation & prioritisation methods (II)

- **PRIORITISATION** applied to **display** most relevant results (up to 5) (in case more than one dose descriptor or endpoint is available per study record)

  Main criteria:

  - effect concentration & dose descriptor | species | duration | units

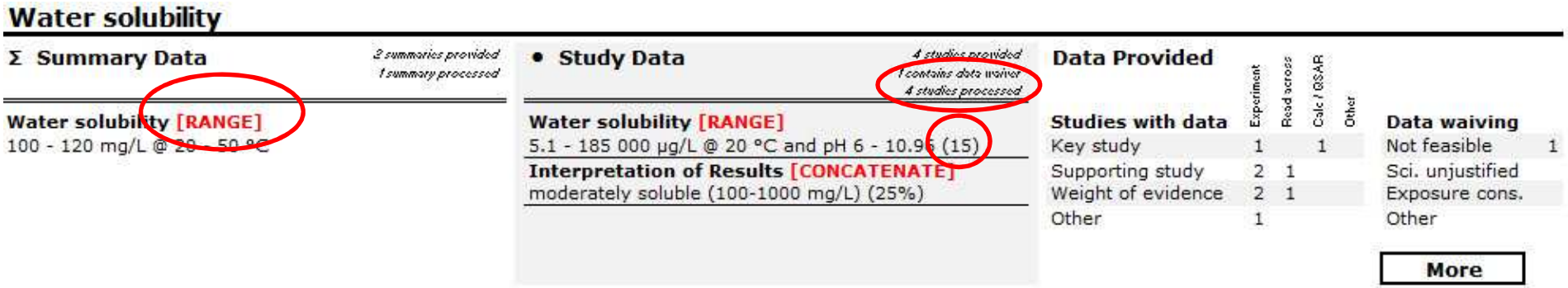
  Examples:

  - in "long term toxicity to fish", NOEC is preferred to EC10
  - in "acute toxicity" a test performed in rat is prioritised over a test performed in a mouse

Aggregation & prioritisation methods (III)

Layout to be improved

- Specific icon per aggregation method
- label “XX presented below” replaced by “XX studies processed”
- Inclusion of number of results ()
- Tooltips and helps to explain methods applied



Example (I)

Substance name: Lead **EC number:** 231-100-4

Section / Endpoint: PNEC

	PNEC aqua (freshwater)	PNEC aqua (marine water)	PNEC STP	PNEC sediment (freshwater)	PNEC sediment (marine water)	PNEC soil	PNEC oral
Summary 1	6.5 µg/L	3.4 µg/L	100 µg/L	174 mg/kg sediment dw	164 mg/kg sediment dw	147 mg/kg soil dw	10.9 mg/kg food
Summary 2	3.1 µg/L	3.5 µg/L	100 µg/L	174 mg/kg sediment dw	164 mg/kg sediment dw	212 mg/kg soil dw	10.9 mg/kg food

Predicted No-Effect Concentration (PNEC)

Σ Summary Data [RANGE]

2 summaries provided
2 presented below

The Predicted No-Effect Concentration (PNEC) value is the concentration of a substance below which adverse effects in the environment are not expected to occur.

Hazard to AQUATIC ORGANISMS	Concentration
Freshwater	3.1-6.5 µg/L
Marine water	3.4-3.5 µg/L
Intermittent releases	-
Sewage treatment plant	100 µg/L
Sediment (freshwater)	174 mg/kg sediment dw
Sediment (marine water)	164 mg/kg sediment dw

Hazard for AIR	Concentration
Air	-
Hazard for TERRESTRIAL ORGANISMS	
Soil	147-212 mg/kg soil dw
Hazard for PREDATORS	
Secondary poisoning	10.9 mg/kg food

Example (II)

Substance name: Lead **EC number:** 231-100-4

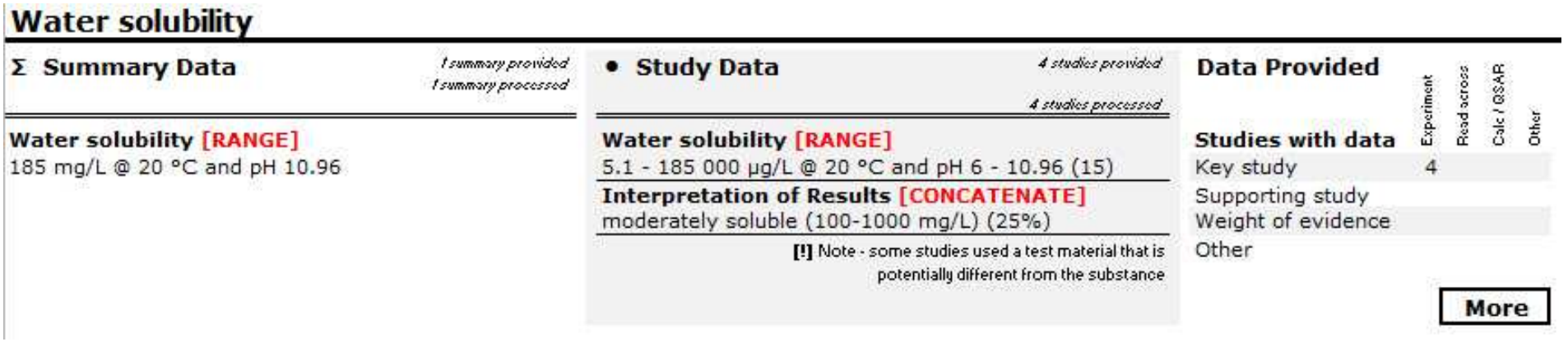
Section / Endpoint: Water Solubility

	Type of Study	Reliability	Measurment	T cond	pH cond	Test material identical	Interpretation of Results
Study 1	Key Exp	1	185 mg/L	20 °C	10.96	yes	moderately soluble (100-1000 mg/L)
Study 2	Key Exp	1	187.5 µg/L 62.2 µg/L 607 µg/L 156.6 µg/L 3211.2 µg/L 520.3 µg/L	-	8 8 7 7 6 6	No	-
Study 3	Key Exp	1	926.7 µg/L 428.9 µg/L 177.6 µg/L 43.3 µg/L	-	6 6 6 6	No	-
Study 4	Key Exp	1	428.9 µg/L 43.1 µg/L 14.2 µg/L 5.1 µg/L	-	6 6 6 6 6	No	-
Summary	*NA*	*NA*	185 mg/L	20 °C	10.96	*NA*	*NA*

Example (II)

Substance name: Lead **EC number:** 231-100-4

Section / Endpoint: Water Solubility



Water solubility

Σ Summary Data *1 summary provided* *1 summary processed*

Water solubility [RANGE]
185 mg/L @ 20 °C and pH 10.96

• Study Data *4 studies provided* *4 studies processed*

Water solubility [RANGE]
5.1 - 185 000 µg/L @ 20 °C and pH 6 - 10.96 (15)

Interpretation of Results [CONCATENATE]
moderately soluble (100-1000 mg/L) (25%)

[!] Note - some studies used a test material that is potentially different from the substance

Data Provided

Studies with data	Experiment	Read across	Calc / QSAR	Other
Key study	4			
Supporting study				
Weight of evidence				
Other				

More

Example (III)

Substance name: Ziram **EC number:** 205-288-3

Section / Endpoint: Short term to fish

	Type of Study	reliability	duration	Dose descriptor	value
Study 1	Exp key	1	96h 96h	LC50 LC100	0.0097 mg/L 0.022 mg/L
Study 2	Exp support	1	96h 96h	LC50 NOEC	0.57 mg/L 0.33 mg/L
Study 3	Exp support	1	96h 96h	LC50 LC100	1.7 mg/L 1.7 mg/L
Summary					

Short term toxicity to fish

Σ Summary Data *1 summary provided*

No automatically processable summary data provided

• Study Data *3 studies provided* *1 study processed*

LC50 (96 hr) - 0.0097 mg/L
LC100 (96 hr) - 0.022 mg/L

Data Provided

Studies with data	Experiment	Read across	Calc / QSAR	Other
Key study	1			
Supporting study	2			
Weight of evidence				
Other				

More

Example (IV)

Substance name: chromium trioxide **EC number:** 215-607-8

Section / Endpoint: Repeated dose toxicity

	type	reliability / justification	test type	species	route	Dose descriptor	value	Test material identical
study 1	Data waiving	exposure considerations			oral			
study 2	WoE RA	1	subchronic	Rat	oral	no NOAEL identified	62.5 mg/L drinking water	NO
study 3	WoE RA	1	combined repeated dose and reproduction / dev. screening	Rat	oral	NOAEL	> 400 ppm	NO
study 4	WoE RA	1	combined repeated dose and reproduction / dev. screening	mouse	oral	LOAEL NOAEL	400 ppm > 400 ppm	NO
study 5	WoE RA	1	subchronic	mouse	oral	no NOAEL identified	62.5 mg/L drinking water	NO
study 6	WoE exp	1	subchronic	mouse	Inhalation	LOAEC	1.81 mg/m³ air	yes
study 7	WoE exp	2	subchronic	mouse	Inhalation	LOAEC	3.63 mg/m³ air	yes
study 8	Data waiving	other justification			dermal			
Summary	*NA*	*NA*	-	-	Inhalation	LOAEC	1.81 mg/m³ air	*NA*

Example (IV)

Substance name: chromium trioxide **EC number:** 215-607-8

Section / Endpoint: Repeated dose toxicity

Repeated dose toxicity [PRIORITISED] [RANGE]

Σ Summary Data *1 summary provided 1 presented below*

Inhalation route - systemic effects
LOAEC 1.81 mg/m3 (-, -)

• Repeated dose - oral *5 studies provided 1 contains data waiver 4 studies processed*

Subchronic – no NOAEL identified (rat) - 62.5 mg/L drinking water

Combined rept. dose and reproduction / dev. Screening – NOAEL (rat)
> 400 ppm

[!] Note - some studies used a test material that is potentially different from the substance

Data Provided	Experiment	Read across	Calc / QSAR	Other
Studies with data				
Key study				
Supporting study				
Weight of evidence		4		
Other				

Data waiving	
Not feasible	
Sci. unjustified	
Exposure cons.	1
Other	

More

• Rept. dose - dermal *1 study provided 1 contains data waiver*

Data waiving: Other justification (1)

Data Provided	Experiment	Read across	Calc / QSAR	Other
Studies with data				
Key study				
Supporting study				
Weight of evidence				
Other				

Data waiving	
Not feasible	
Sci. unjustified	
Exposure cons.	
Other	1

More

• Rept. dose - inhalation *2 studies provided 2 studies processed*

Subchronic LOAEC (mouse)
1.81 - 3.63 mg/m³ air (2)

Data Provided	Experiment	Read across	Calc / QSAR	Other
Studies with data				
Key study				
Supporting study				
Weight of evidence		2		
Other				

Data waiving	
Not feasible	
Sci. unjustified	
Exposure cons.	
Other	

More

Other main topics

- Level of detail presented per study result (data blocks)

  First release limited in scope and level of complexity:

  - Repeated dose toxicity study data included
  - IUCLID 6 improvements may trigger a review of level of detail presented (study data)
- Presentation / displayed related issues (graphical and semantic)
  - Graphic presentation to be refined during graphical design implementation (contract in place). Semantics (labels) already under revision to address identified concerns.

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