

Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals

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Item 4 (d) of the provisional agenda

Hazard communication: Other issues

Hands-on experience with GHS Eye hazard classification for consumer products: challenges and opportunities

Submitted by the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.)

1. Since 2015, GHS has been implemented in the European Union (EU) for the classification and labelling of mixtures via the CLP Regulation (EC n.1272/2008). The EU is one of the first jurisdiction applying GHS rules to consumer mixtures.
2. A.I.S.E. has supported several activities in order to support a smooth implementation of the new classification rules by the detergents and maintenance products sector. In particular, classification for eye effects resulted in some challenges.
3. Main ingredients for detergents are surfactants: on average 10-20% (similar to shampoo/shower gel); surfactants are often classified for severe eye damage Cat.1.
4. GHS additivity approach is often used in the EU for eye effects, as primary tool rather than as last resort (as intended), due to legal certainty issues with bridging principles, and/or due to lack of acceptance of historic animal test (e.g. LVET) and non-animal test (e.g. Isolated Chicken Eye with histopathology). As a result, most detergents (such as hand dish wash detergents) are classified for Serious eye damage when GHS additivity is used, despite their mild hazard profile.
5. However, poison centres data¹ showed that human exposure to detergents results in most of the cases in no effects or fully reversible symptoms; serious eye damage occurs rarely (<0.2% Magam study 2016). Therefore, it could be argued that GHS additivity approach on eye effects can over-predict hazards of detergents.
6. A potential solution lies on a harmonized GHS interpretation in the use of Bridging principles and related expert judgement (see ongoing discussion PCI informal Working group). This activity is essential for a correct, relevant and legally robust classification.
7. A scientific publication is under preparation and a summary will be soon published on A.I.S.E. website: <https://www.aise.eu>

¹ See https://www.aise.eu/documents/document/20161110144805-magam_ii_deat_2016short.pdf and https://www.aise.eu/documents/document/20161110143021-magam_ii_disc-2016-10-18.pdf

Hands-on experience with GHS Eye hazard classification for consumer products: challenges and opportunities

UN GHS Expert Sub-Committee 35th Meeting
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Roberto Scazzola,

A.I.S.E. (International Association for Soaps, Detergents and Maintenance Products)

UN GHS in the European Union

- UN GHS criteria introduced in EU via CLP Regulation n.1272/2008 on Classification, Labelling and Packaging
- Replacing previous systems (DPD orange pictograms *less labelling overall*).
- European Union is the only jurisdiction having fully implemented GHS criteria for general consumer chemical products.
- Since 2015 GHS is implemented on hazardous mixtures, relevant findings can be shared on its use for general consumer labels.

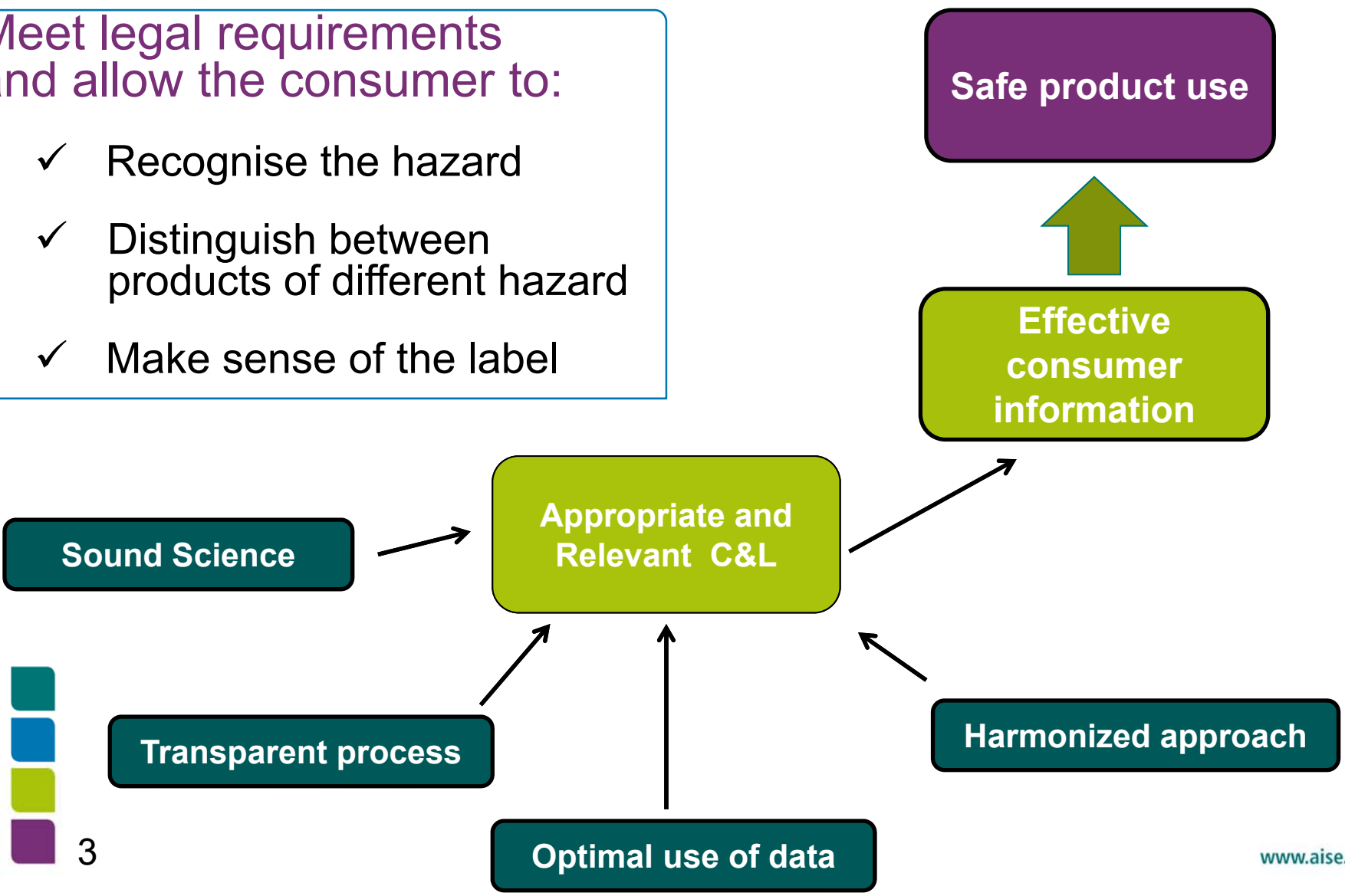


Hazard C&L for general public



Meet legal requirements and allow the consumer to:

- ✓ Recognise the hazard
- ✓ Distinguish between products of different hazard
- ✓ Make sense of the label



How does GHS tiered approach work?

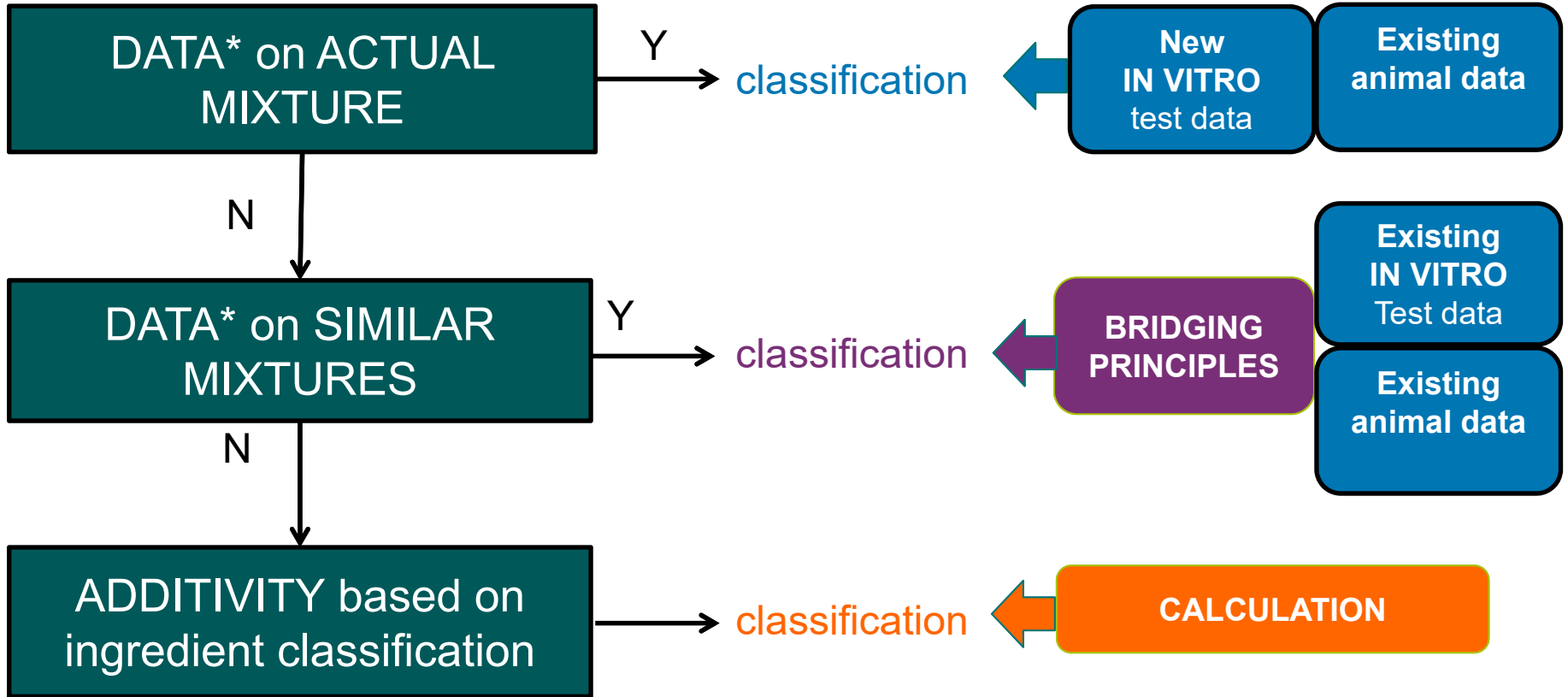
- In principle, GHS gives priority to the use of all available data, bridging principles, weight of evidence.

GHS additivity/calculation method only to be used if the above fails (*while DPD gave priority to either calculation or actual product animal test data as the first step*).

- In reality, complexity, uncertainty about interpretation (e.g. Bridging principles), and lack of non-animal tests, leads to frequent use of additivity method.



GHS - Good use of data hierarchy



*No human testing for classification purposes, and no new animal testing.
Data generation = *in vitro* methods

Focus on Eye effects







2015: CLP introduced UN GHS criteria in EU, replacing former DPD

- Classification and labelling for eye hazards more severe than DPD when using additivity/calculation method (e.g. lower cut-off values/concentration limits).
- No validated in vitro test for Eye irritation (Cat. 2)
- Broader use of Corrosive Pictogram (eye).



Classification for serious eye damage/eye irritation by additivity (DPD vs GHS/CLP)



DPD until 2015	Eye Cat1 Ingredients %	GHS/CLP
≥ 10 %, „Irritant“ „Risk of serious damage to eyes“ 	10 – 100	≥ 3 % DANGER , Eye Cat. 1 „Causes serious eye damage“ 
≥ 5 to < 10 %, „Irritant“ „Irritating to eyes“ 	5 – 10	
0 to < 5 %: no labelling	3 – 5	≥ 1 to < 3 % WARNING , Eye Cat. 2 „Causes serious eye irritation“ 
	1 – 3	
	0 – 1	0 to < 1 %: no labelling

Hand wash detergents with corrosive picto?



- Main ingredients for detergents are surfactants: on average 10-20% (similar to shampoo/shower gel); often classified for severe eye damage Cat.1.
- GHS additivity: mixture with surfactants Eye Cat.1 > 3% will be classified as Eye Cat. 1 (Corrosive pictogram, Signal word 'Danger' word).
- Several mild products such as hand dish wash detergents can therefore classified for Serious eye damage Cat. 1 if only additivity is used.



Typical C&L under DPD (until 2015)



A snapshot on Home Care Products (detergents, maintenance etc.):

Drain cleaners



Until GHS was implemented in EU via CLP 2015, the “corrosive pictogram” was only required for truly ‘corrosive for skin’ products (e.g. strong acid/alkaline mixtures such as Drain cleaners, Oven cleaners etc.).

Toilet cleaners



UN GHS classification for eye (additivity)



Drain cleaners










Toilet cleaners



New cut-off values using additivity resulted in a very broad use of corrosive pictogram (eye effect) also with mild and daily used products.

Accidental Exposures – Severity of Effects

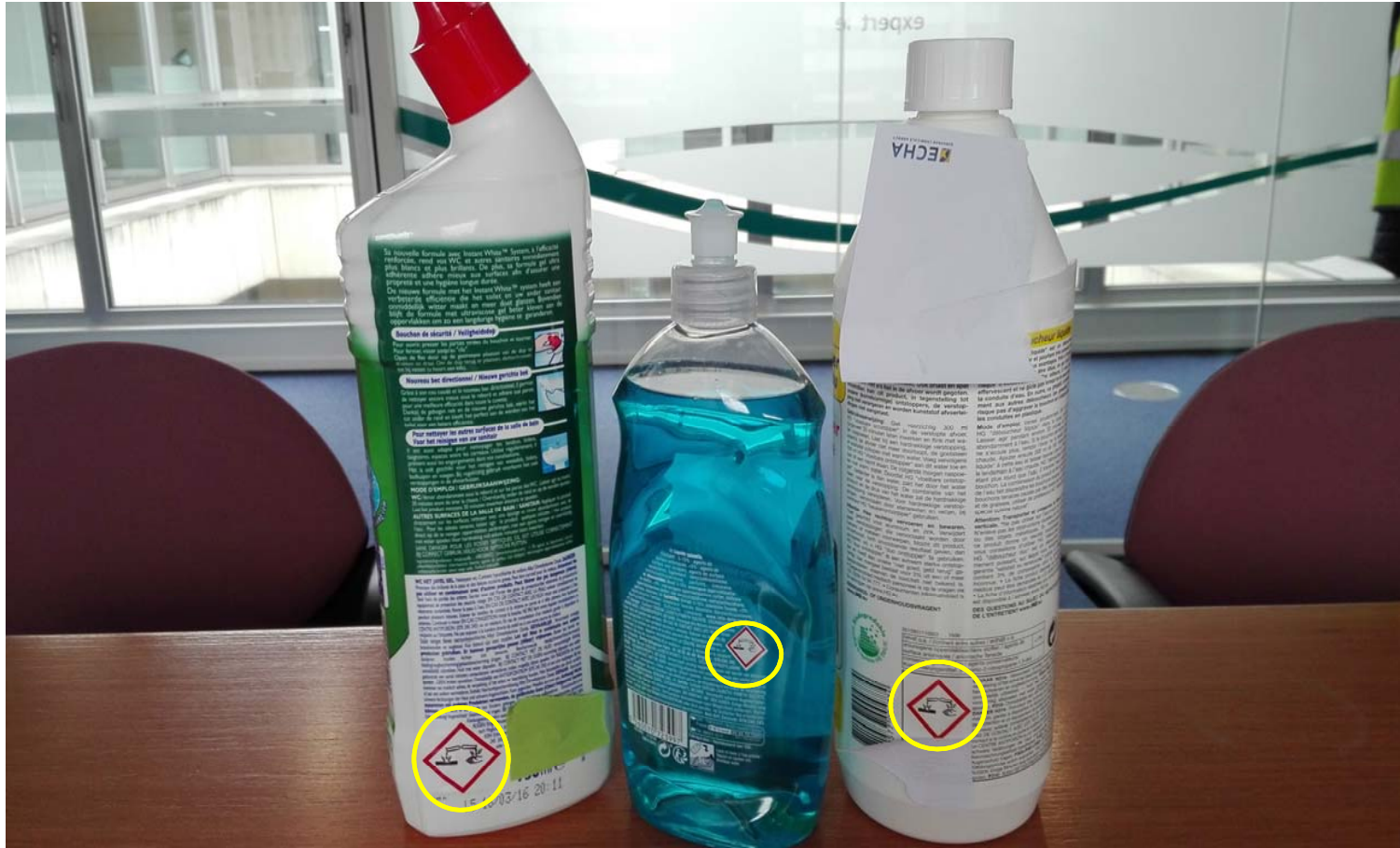


Products	Severity of effects	UN GHS / EU CLP classification
	Index*	Label pictogram (additivity approach)
Drain Cleaners	19	
Oven Cleaners	7	
Automatic Dishwashing Detergent	< 1	
Bathroom Cleansers	< 1	
Manual Dishwashing Detergent	< 1	
Heavy Duty Detergents	< 1	
All Purpose Cleaners	< 1	

Medical advice problematic for Poison centres (more difficult to distinguish truly corrosive)

*Data: Dr. Desel, Poison Control Centre, Göttingen 1996 - 2005

Very different hazard profile same pictogram?



Poison Centres experience on eye effects

2016 MAGAM DEAT+ DISC: eye exposures caused by cleaning products in DK, IT, DE, AT, IT, SK, CZ (171 Million population data collection 2013-2015 by Poison Centres) -

<http://dx.doi.org/10.3109/15563650.2016.1165952>

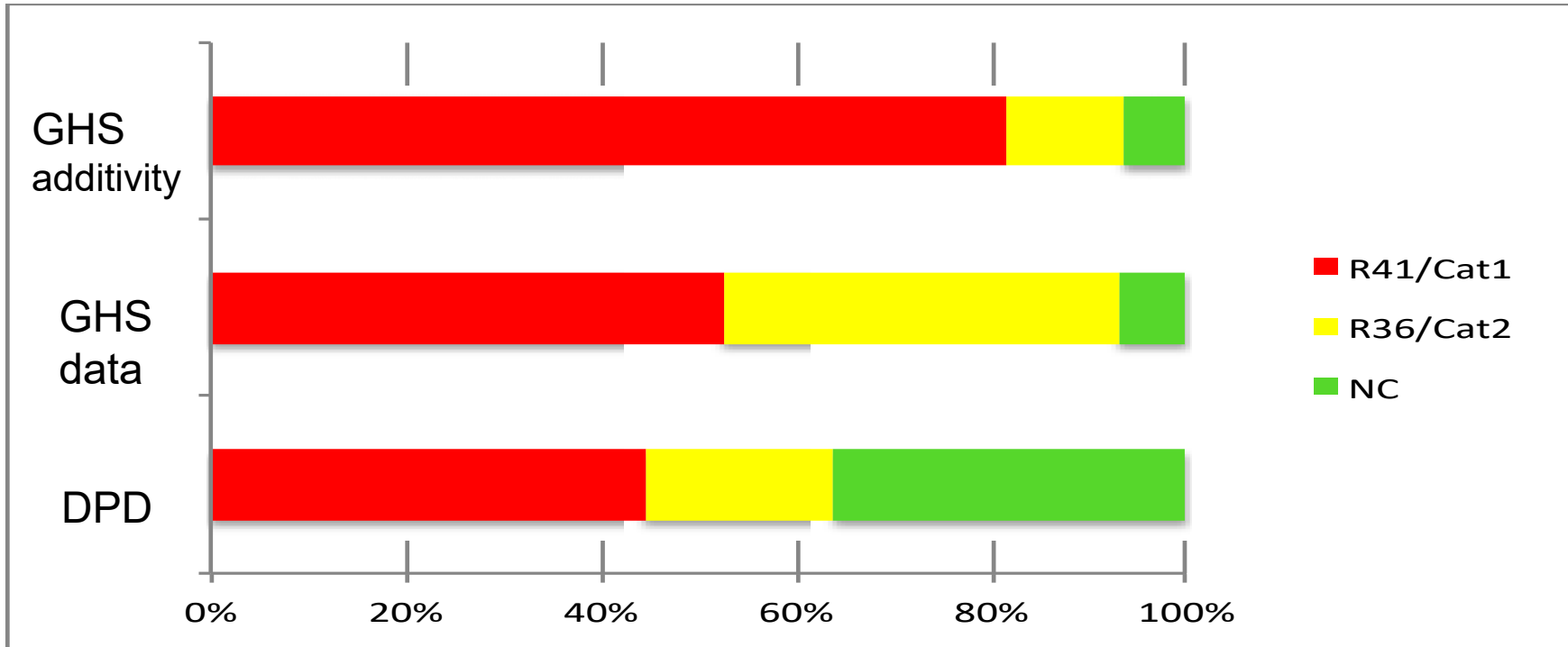
1126 exposures: 90.5% No or minor symptoms, 9.2% moderate and 0.2% severe (residual symptoms after 20 days).

Most of eye exposures with detergents resulted in no effects or fully reversible symptoms; serious eye damage occurs rarely (<0.2%).



Poison Control Centers Study 2013-15

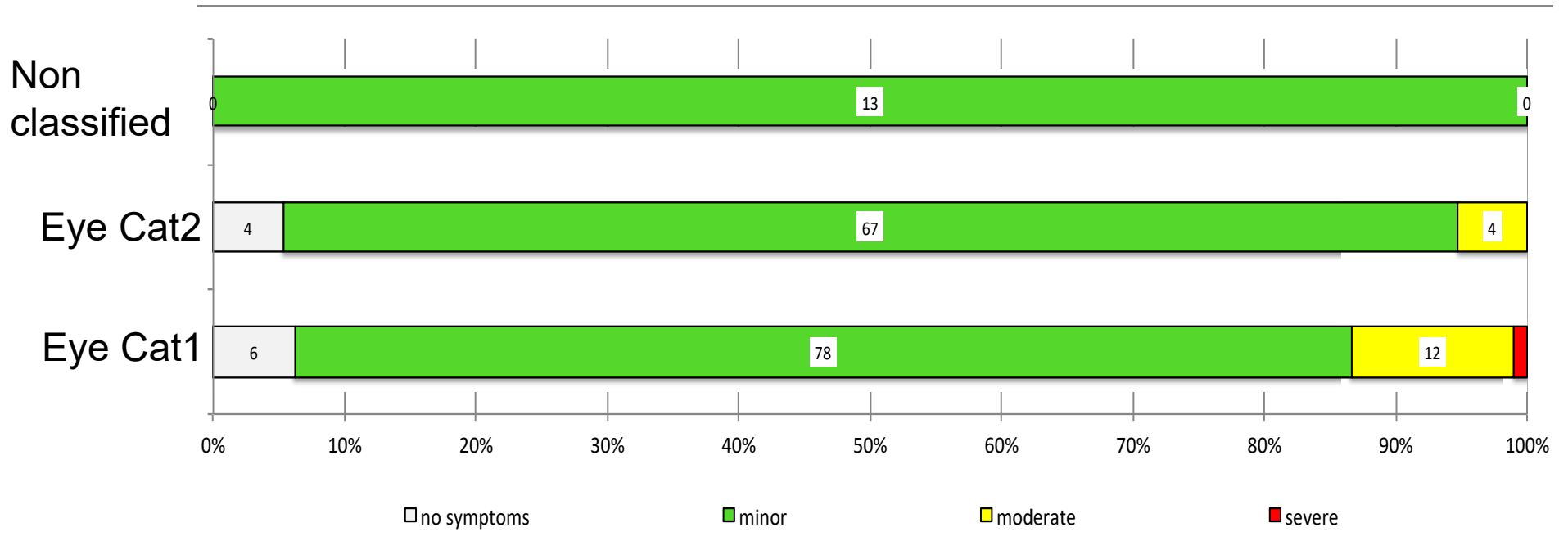
Retrospective Classification Eye effects



- DPD and GHS retrospective C&L, sub set 185 cases
- DPD **44% Cat.1**, 20% Cat.2, 36% NC
- GHS data (BPs, Exp.Jud) **52% Cat.1**, 40% Cat.2, 7% NC
- GHS additivity **82% Cat.1**, 12% Cat.2 , 6% NC.



Hazard classification and severity of symptoms



GHS C&L based on all available data (above) – is statistically the best predictor for medically relevant effects

(with PSS \geq 2: moderate or severe)



Assessment on eye exposure (MAGAM) and GHS classification



- **Hazard Classification is not per se a good predictor for severity** (85% of time: effects severity < hazard classification)
- **GHS C&L based on all available data (BPs) – is statistically the best predictor for medically relevant effects**
(with PSS \geq 2: moderate or severe)
- **GHS – based on additivity only – is statistically the worst predictor for severity**
(poor differentiation, >80% is Cat1)
- **Peer reviewed paper under finalization**



Consumer Relevance of C&L

Consumer research by A.I.S.E., Eurobarometer, ECHA

- EU Eurobarometer 2011: only 26 to 50% always read safety instructions before using for the first time a hazardous product (see http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_360_en.pdf)
- GHS Pictogram “Corrosive” is understood as corrosive / harsh chemicals by 54% but <1% recognize this as related to serious eye damage! (see <https://www.unece.org/fileadmin/DAM/trans/doc/2017/dgac10c4/UN-SCEGHS-34-INF05e.pdf>)
- GHS Pictograms comprehension is insufficient to understand Eye Hazard and to differentiate between eye damage and eye irritation.



Implications of UN GHS / EU CLP for the CONSUMER



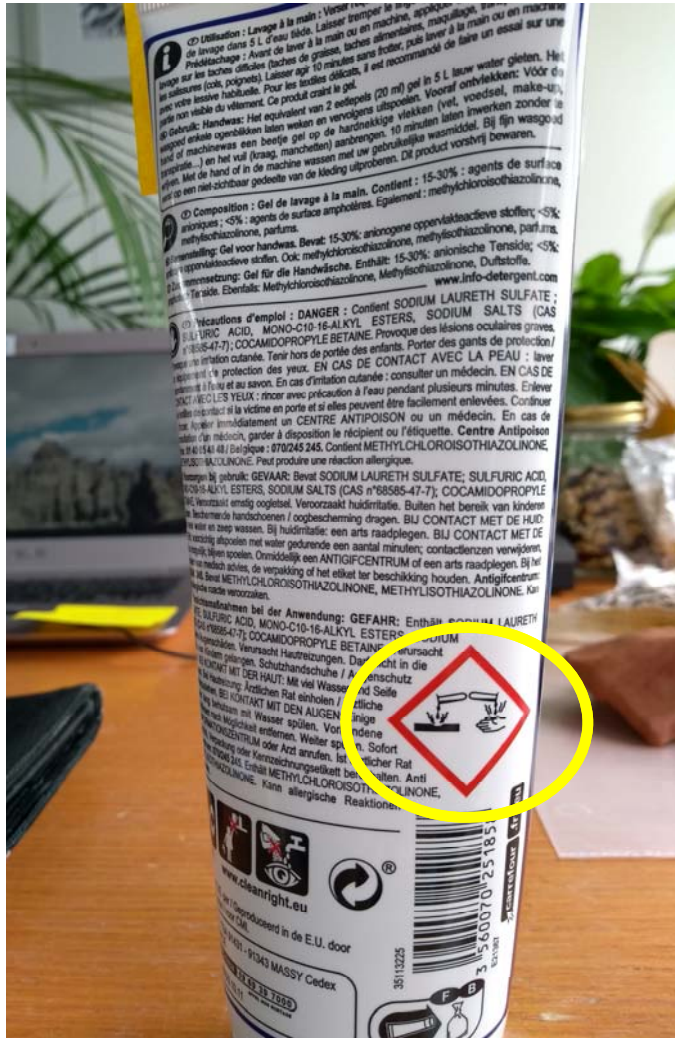
Many mild products (not previously classified) are now severely classified and labelled (Eye category 1):

- C&L does not fit with consumers' knowledge and experience (everyday used products with no special precautions...)
- Devaluation of warning labels: really hazardous products are no longer differentiated
- Confusion about what is dangerous & how to use, could lead to unsafe practices
- Poison centres difficulties to identify right medical advice



Relevant classification and labelling is essential for safe use by consumers

Hand wash detergent with corrosive picto



Are we providing a meaningful hazard communication to the general public?



Tiered approach, Bridging Principles and InVitro tests are essential



Potential over classification provided by additivity (eye effects) can be addressed with a correct use of the GHS tiered approach for mixture classification.

Using existing data on the mixture or on similar mixtures via bridging principles and expert judgement can provide a more appropriate and precise classification.

⇒ Ongoing activities on the clarifications on the implementation of Bridging principles under the PCI working group are relevant and useful.

⇒ Ongoing activities for the development of In vitro test (e.g. OECD) are also relevant.



Challenges and opportunities

- GHS additivity/calculation approach **is used very often in EU for eye effects, as primary tool rather than as last resort (as intended)**, due to legal certainty issues with bridging, and/or due to lack of validated in vitro study on Eye irritancy (Isolated Chicken Eye, etc.)
- Most mild detergents are classified Serious eye damage with GHS additivity (up to 80%)
- Human exposure to detergents results in no effects or fully reversible symptoms (>99%); serious eye damage occurs rarely.



Challenges and opportunities

- **GHS additivity approach can over-predict hazard** of detergents on eye (cf. in vivo animal and human data and *severity of accidental exposure effects*)
- This is **counter-productive** in driving safe use, because it devalues the safety message, is counter-intuitive, and creates confusion.
- **Harmonized GHS interpretation in the use of Bridging principles and expert judgement** is essential for a correct, relevant and legally robust classification.
- **OECD recognition In vitro tests** on eye effects is key

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