

HelpNet CLP Workshop: summary of discussions

Time: Monday 17 October 2016, 9:30 – 17:30
Place: Avenue d'Auderghem 45, meeting room F. Braun,
DG GROW, European Commission, Brussels

The HelpNet CLP Workshop was organised back-to-back with the A.I.S.E. workshop on the 'Classification & labelling of detergents and cleaning products under CLP'. This document summarises the ideas discussed during the CLP Workshop and the agreed conclusions¹.

1. Opening of the workshop

The moderator, Outi TUNNELA (ECHA), welcomed the participants² and presented the order of the day's discussion. A tour de table was done. The agenda was adopted with no further comments.

2. Classification and labelling related to form and use

Jonas FALCK (SE) gave a presentation on the significance of the terms 'form or physical state' and 'reasonably expected use' in the context of classification and labelling. The aim of the presentation was to have a discussion on real cases with respect to the wording used in the *Guidance on the application of the CLP Criteria*.

The starting point for discussion were practical cases, for example, a paint classified as STOT RE 1, H372 (Causes damage to lungs through prolonged or repeated exposure by inhalation). However, the product as placed on the market is thick and sluggish (no dusting occurs). SE asked about possible derogations for classification or labelling in such a case. Some participants mentioned that the exposure and life cycle should not be taken into account when classifying such a mixture. The question arose: how far can the workers' protection take care of the hazards during the life-cycle of the product? It was pointed out that such later stages as e.g. scraping off the paint from the wall should not be taken into account during the classification of the paint, as this is no longer a use of the mixture.

It was expressed that reasonably expected use can depend on the form of the paint (spray, liquid), i.e. it can be reasonably expected that the customer cannot spray the paint if the paint is thick. The importance of proper information that needs to be passed to consumers was stressed.

Jonas pointed out that although there are some exemptions from the labelling of hazardous chemicals (section 1.3 of Annex I to CLP) there are no clear exemptions from classifying these chemicals. This implies that although there may be reasons not to immediately inform the user of the intrinsic hazardous properties, the information may still be important to pass on in, e.g.,

¹ The text of the CLP Regulation is the only authentic legal reference and that this workshop summary does not constitute legal advice. For further advice, contact your national CLP helpdesk.

² The names of the participants attending the CLP Workshop are listed in Annex I of this summary.

the safety data sheet. However, it is still not fully clear when one can go further than just the derogations from labelling and consider that the state and form of the chemical would also lead to no classification.

It was agreed that the topic must be further discussed and that there may be a need to check if there is a need to improve the current wording in the *Guidance on the CLP Criteria* on reasonably foreseeable use.

3. Application of the additivity principle for constituents with similar modes of action

COM briefed the participants on the proposal to expand the application of the additivity principle, which applies to some hazard classes mentioned in Annex I. The issue (originally raised for rodenticides by FR during 21-CARACAL) is whether this principle can be applied to other human health hazards classes. COM's conclusion is that it is possible, but there are two options depending on the availability of data on the substances in the mixture:

1. Following Article 12(c) which requires scientific evidence to be taken into account;
2. Applying weight of evidence (WoE) and expert judgement according to Annex I to CLP to determine the classification of a substance/mixture.

COM mentioned that ECHA will update the *Guidance on CLP Criteria*. The Partner Expert Group (PEG) meeting will take place on 8 November 2016. The proposal will be also discussed during the upcoming CARACAL.

Participants discussed the difficulties of using the WoE by national enforcement authorities. ECHA stressed the importance of involving experts, as the legal text often refers to expert judgement.

A NHD mentioned the importance of information on the mode of action and similar chemistry of substances for CLH. COM and NHDs mentioned that guidance is needed for WoE to help national authorities correctly interpret the synergistic/antagonistic aspects during classification.

COM concluded that practical examples would be needed and ECHA encouraged participants to provide such examples before the PEG meeting, as it is difficult to 'design' examples during PEG.

4. Classification and labelling of e-liquids

The moderator gave an overview regarding C&L for e-liquids for electronic cigarettes in the context of the newly implemented Tobacco Products Directive (TPD). The presentation was originally provided by the Danish helpdesk (DK HD).

It was clarified that e-liquids must be classified and labelled in accordance with CLP, despite such requirements not being spelled-out in the TPD. This approach is in line with the interpretation of COM, also at the drafting stage of the TPD.

The participants exchanged information on whether e-liquids are required to be classified and labelled in accordance with CLP in the different Member States (MSs). A NHD mentioned the need to check the internet market. The NHDs discussed the difficulties with enforcement of C&L requirements for e-liquids, as in many MSs it is not clear which authority should enforce and

what is the subject of enforcement: is it the container that should be labelled or the e-cigarette device?

COM informed about the 10th ATP in relation to the classification (including the ATE values) for nicotine. This change in the legal text should help inspectors. Following the new RAC opinion, the classification of the nicotine liquid is less severe.

ECHA reminded about other, different compounds in the composition of e-liquids. ECHA and COM concluded that the e-cigarette device itself (with or without liquid) cannot be labelled, as the contents can be changed with re-fills or self-made mixtures. FI added that in Finland the labelling provision applies to e-liquid containers and e-cigarettes (with liquids) as such, but not to their unit packets or any outside packaging.

The correspondents agreed on creating an FAQ on the topic. ECHA will prepare the first draft as soon as possible.

5. Classification and labelling of mixtures contained in soluble packaging

The Hungarian HD gave a presentation on the following questions, also discussed in HelpEx:

1. How to classify soluble packaging with several compartments?
2. Do the labelling exemptions for soluble packaging with multiple compartments only apply when the total volume of the mixture is below 25 ml?

COM clarified that, for practical reasons, the idea was to classify such packaging as one compartment. COM also confirmed that the exemption applies when the total volume is below 25 ml and mentioned the ongoing study with the Poison Centres, which also investigates whether the 25 ml exemption should be lifted.

Some arguments were against classifying the mixtures in the compartments as one compartment (this would not be in line with guidance on mixtures; in the case of an accident, there would be no accurate information on the classification of the mixture that e.g. leaked out from one of the compartments).

ECHA proposed to apply classification based on the leading (most severe) hazard. This was not seen as a good solution, because it would be difficult to decide which hazard should be considered as most severe. COM added that the whole 'entity' could be treated as if it were one mixture, taking into account the volume. COM also reminded that the CLP amendment on soluble packaging applies only to laundry detergents but in the future, it can be extended to dishwasher and even biocidal products packed in a similar way.

As a starting point for further discussion, it was concluded that each hazard class should be considered individually and the most severe category for each should be indicated on the packaging. It was agreed that ECHA will look into the possibilities given by the legal text and draft an FAQ proposal that will be consulted with HelpNet.

6. Labelling of articles acting as containers (e.g. pens) – continuing discussion from previous workshop

The Irish HD gave a presentation on the CLP classification and labelling requirements of articles acting as containers. The presentation focused on practical aspects and problems related to labelling of products such as pens, matches and candles.

One NHD mentioned the need for clear guidance, as the producers of such 'difficult-to-label' products are not sure of their legal obligations. Similarly, NHDs have problems with providing advice on this topic.

The questions raised were: can the container meet the definition of packaging under CLP and be labelled? Is it possible to enforce this? Possible solutions were discussed, for example: a new chapter in labelling and packaging guidance or even an exemption in the CLP legal text for objects that are very small and difficult to label.

The participants discussed the difficulties in the labelling of pens, as there are various types of pens (with and without replacement cartridge, i.e. re-filled and non-refilled packaging).

The NHDs in general agreed with COM's view that when a mixture is hazardous or contains hazardous substances so that CLP applies, it must be labelled and packaged in accordance with CLP. The (re-fillable) article that contains the container of the mixture (e.g. the pen that contains the cartridge) should not be labelled, as changing the cartridge could mean that the mixture inside is different and with different hazards. COM added that if they start receiving information that the labelling of specific products is not possible or there are problems with enforcement, COM may have the option of considering extending the existing exemptions.

The participants agreed on creating an FAQ on this topic.

7. Updated labelling guidance: label readability and other thoughts

ECHA presented three main topics included in the *Guidance on labelling and packaging* during the previous (version 2.0) and on-going (version 3.0) update.

1. Label readability

One NHD commented that in the future legal provisions for minimum font size in CLP would be appreciated. COM replied that this might be possible.

2. Fold-out label

COM informed on the intention to extend the scope of the fold-out labels with the 12th ATP to CLP and to justify a maximum number of languages on the fold-out label. COM added that for now it is good to have the current recommendations in the guidance.

3. Outer packaging

Draft guidance proposal was prepared by ECHA based on the CASG-LP document and further consulted with COM and CASG-LP experts. The new chapter will be shared with PEG members and discussed during the PEG meeting on 9 November.

COM briefed the participants on the Article 33(2) interpretation in the proposal and informed that the draft will be uploaded to the CARACAL CIRCABC and addressed during Wednesday's CARACAL meeting as a follow-up to the CARACAL-21 discussion.

The NHDs appreciated the initiative of including this topic in the *Guidance on labelling and packaging*.

8. Is there a need to develop criteria for setting an SCL that is higher than the GCL? Can there be definite criteria?

The discussion was started by ECHA regarding the possible need for guidance for the setting of an SCL (specific concentration limit) that is higher than the GCL (generic concentration limit).

Some MSs were of the opinion that this is not possible, as a higher SCL can only be set in exceptional cases, according to CLP. COM suggested that such guidance could be developed by industry.

One participant informed about a problem among companies that must apply the classification agreed in the SIEF for a particular substance. Submitting the C&L dossier is not possible until the new CLH proposal is accepted. This also causes problems for enforcement authorities.

ECHA reminded that the notifier must provide a scientific justification for setting an SCL. An NHD considered that it is not possible for the enforcement authorities to judge whether the justification is sound and that ECHA should evaluate such cases. ECHA, however, does not have the mandate to decide on such issues. Though, ECHA has promised to help where possible, on a case-by-case basis.

It was suggested that NHDs should report cases on HelpEx to keep track of whether such cases are frequent. All participants welcomed the suggestion. It was also suggested that it should be considered whether it would be possible to provide some guidance on when the higher SCLs would not be acceptable. This would be helpful especially to enforcement authorities.

9. Thoughts on the topics of the next day's workshop

A.I.S.E. gave a brief overview of the topics that were to be discussed at the next day's workshop. HelpNet CLP members were invited to attend the A.I.S.E workshop on the 'Classification and Labelling of detergents and cleaning products under CLP' on 18 October 2016, at The Hotel, Boulevard de Waterloo 38, Brussels.

10. End of the HelpNet CLP Workshop

The moderator informed the participants that next year, due to the upcoming 2018 registration deadline, there will only be one HelpNet meeting with regulatory workshops.

Annex I - List of participants

Members of HelpNet

Austria	PAPARELLA	Martin
Belgium	CLAES	Kristof
Bulgaria	ZIDAROVA	Elena
Croatia	JEZIC VIDOVIC	Irena Zorica
Cyprus	PALEOMYLITOU	Maria
Czech	KATRUŠÁKOVÁ	Adéla
Denmark	ANDERSEN	Trine Thorup
Estonia	AMELKINA	Anna
Finland	MÄKI	Markus
France	DUFFORT	Gaëlle
Germany	KNIETSCH	Anja
Greece	NAKOPOULOU	Chrysanthi
Hungary	HARSANYI	Eszter
Ireland	WALSH	Caroline
Italy	D'ILIO	Sonia
Latvia	JAUNKALNE	Natālija
Liechtenstein	RELLA	Maria Rosaria
Lithuania	JANONYTE	Agne
Luxembourg	CHOCHOIS	Laurene
Norway	LARSEN	Ann Kristin
Poland	DOMAŃSKI	Krzysztof
Portugal	LAGINHA	Isabel
Romania	CAROLE	Nicoleta
Slovakia	PORUBIAK	Michal
Slovenia	HUMAR JURIČ	Tatjana
Spain	SÁNCHEZ DÍAZ	María Elena
Sweden	FALCK	Jonas

Representatives of the European Commission

DG ENV:	BINTEIN	Sylvain
DG GROW:	PRINZ	Maurits-Jan
DG GROW:	JAMERS	An

Candidate country observers

Serbia	RASOVIC	Aleksandra
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Sylvain

Observers

A.I.S.E.	BERTEIN	Caroline
CEFIC	SERRANO RAMON	Blanca
CEPE	ROBINSON	Janice
IMA-Europe	DOOME	Roger

ECHA - Support, Forum & HelpNet Secretariat Unit (A2)

A2	TUNNELA	Outi
A2	SKOWRON	Ewa