HelpNet CLP workshop: summary of discussions

Time Wednesday 23 September 2015, 11:00 – 17:30
Place European Chemicals Agency
Annankatu 18, 00120 Helsinki, Finland

The HelpNet CLP workshop, organised for the HelpNet CLP correspondents and observers (see Annex I for list of participants), took place the day before the Forum's "Train the trainers" event. HelpNet correspondents could participate in both events. The workshop was moderated by Outi Tunnela (ECHA). This document summarises the ideas discussed and agreed conclusions. Please note that 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.

1. Opening of the workshop

The Chair of the HelpNet Steering Group, Andreas Herdina (ECHA), welcomed the participants giving his appreciation for their work. He made a point of multilingual labels, which are helpful in ensuring the safe use of products by immigrant workers or even tourists in a given country. In relation to the event to follow, he highlighted the potential of the flow of information between Industry, national helpdesks and inspectors.

2. Update on discussions in CASG-LP. Items to be included in the Guidance

Outi Tunnela (ECHA) briefed the participants on the ongoing discussions at the Competent Authorities Sub-Group (CASG) on Labelling and Packaging (LP) in relation to the update of the Labelling and Packaging Guidance. The Commission (COM) had committed to circulate excerpts of the draft to the participants of CASG-LP. Some specific topics were discussed.

Fold-out labels: COM is gathering opinions on practical implementation. CASG-LP was positive on the proposal by BE to place certain label elements on the front page and develop the text in different languages inside. ECHA informed that this discussion is also taking place at United Nations (UN) level and that this material could be a good source of inspiration. For example, the UN Sub-Committee of Experts on GHS is considering an example including five languages in labels. Another aspect discussed was the font size: e.g. Food legislation has a minimum of 1.2 mm, however the font should be in proportion to the label size.

Consolidated packaging: ECHA proposed to work on an example of an over-pack. Again, there is a related discussion taking place at UN level, which could be expected to become part of the Globally Harmonised System (GHS).

Chemical names: The discussion considered the actual usefulness of the names, beyond what the legislation stipulates. Consumers would benefit from more common names (in their own language). Also professionals (doctors, emergency workers, etc.) could find INCI names more useful. INCI names are not translated, however. It was commented that this would be in contradiction to the language requirements of Art. 17(2) and section 4.2 of the current Guidance on labelling and packaging. The topic will still be discussed at CASG-LP. COM informed about their work on translating the Annex VI names.

3. Labelling of difficult-to-label products (pens and markers (HelpEx 12660), candles, air fresheners, matchboxes)

Pens and markers

The discussion turned around the concept of container, inner and outer package, and article. Clarifying these concepts would allow deciding what would need to be labelled. An example was labelling the box containing the ink cartridges, which are too small to be labelled. In addition, it was pointed out by some participants that in some cases the cartridge could also be considered as not fulfilling the criteria of packaging and thus would always require further packaging. It was also discussed if a pen as such is an article, not a package.

The actual enforceability of the labelling obligation of small ballpoint cartridges was also discussed. An observer suggested that other legislation (consumer safety) could be used to skip labelling obligations yet ensuring the safe use of the pen. COM thought that Industry has already been inventive in the past and could also find a practical solution for labelling of very small packaging in this case. It was remarked that there is no value in labelling the ink cartridge/refill inside a pen, since it cannot be seen.

It was suggested that exemptions on labelling for very small packaging also outside research and development activities could be considered in the future.

Matches

The match head is a mixture, which is both flammable and toxic. The stick is considered a carrier and is not taken into account for volume calculations. It was noted also that the friction strip of the matchbox could contain sensitisers. CLP only allows exemptions for packages under 10 ml when intended for research and development. The old Dangerous Preparations Directive allowed Member States to decide if they would allow exceptions from labelling for small packages or small volumes which did not pose a risk. Widening the scope of the current CLP exemption could be a solution.

Toilet blocks and air fresheners

The discussion started with the concept of container: both products are sold in different types of containers. One type of 'container' for air fresheners has holes and therefore cannot be considered a real container, and is usually packed in plastic; another type has a removable sticker that is removed before use. It has already earlier been agreed that the first type must either be inside an outer packaging or attached to e.g. cardboard which is properly labelled. However simply attaching to a piece of cardboard might not fulfil the containment function according to Art. 35. The second type should have labelling on the side which is not removed when taken to use. In addition to the first type above, some toilet blocks use re-fill cartridges. These cartridges must be properly labelled. Labelling should in principle be indelible, but it should be noted that once a toilet block is in place, it will not be looked at anymore. The use of three dimensional labelling (embossing directly on the plastic container) can always be considered by the manufacturer.

Candles

There was a general understanding that due to the use of the candle, a label permanently fixed to the side of the candle would burn. Furthermore, if the candle is a hazardous mixture it would need to be packaged. Some ways forward were discussed:

- It was noted that if the candle wax is considered a mixture, this means that when the mixture fulfils the criteria for the application of CLP, the mixture must also be packaged. So if the candle needs a label, then it needs a proper package which in turn

should include any necessary label elements.

- Labelling the bottom of the candle, better than not labelling at all (e.g. when the packaging has been removed) (however this would be in contradiction to Art. 31(1)).
- Where the candle and the candle holder are sold together, the holder could act as packaging and bear the label. However, a candle holder does not fulfil the packaging definition and containment function.
- In this context there was a mention of the "sausages" used in construction work, where the label elements are repeated on the package. The package disappears during use, and this way there is always visible at least one repetition of the label elements. However this might not be a practical solution for candles.
- The participants agreed that the aluminium foil of the "tea candles" is not packaging.

COM thanked for the ideas provided and mentioned that although the mandate of the CASG-LP working group is until the end of 2015, if new questions arrive it could be prolonged.

4. Classification of aerosols: How should the propellant be considered, when classifying the aerosol form of the mixture?

The starting point for the discussion was setting out the two routes for classification. The first one was using the calculating method (used also for CMR) where indeed the propellant is used to "dilute" the aerosol form. The second one, also discussed at the Biocides CA meeting, is the approach in which the propellant is not included as it is expected to disappear when the mixture is sprayed and exposure takes place. The European Aerosols Federation had provided an opinion and a decision tree.

The correspondents agreed that the relevant mixture to be considered for classification purposes is not the whole content of the aerosol container (propellant plus the substance/mixture = aerosolised form) but the non-aerosolised form (provided that the added propellant does not affect the hazardous properties of the mixture upon spraying and that the aerosolised form is not more hazardous than the non-aerosolised form). The MS could raise the issue at UN-GHS level, requesting for clearer rules. The next revision of the "Guidance on the application of the CLP criteria" should also take this topic into consideration.

The correspondents agreed on creating an FAQ on the topic. Germany promised to draft the FAQ, with input from the aerosol experts in the Commission. The European Aerosols Federation has also expressed their wish to be involved in the discussion.

5. The meaning of Article 48 CLP on advertising – is there a need to modify the existing FAQ 273?

Several questions were raised during the discussion:

- What does "type of hazard" really mean (this is used only in Article 48(2), while Article 48(1) mentions hazard classes and categories)? The old Dangerous Preparations Directive (DPD) could cast some light over the original intention of the legislator regarding the meaning of "type of hazard", which is not commonly used in the CLP. Some correspondents pointed out that the indications of danger (names of the symbols) under the DPD were very useful.
- Would consumers need a different type or amount of information to ensure the safe use of a chemical? Article 48.1 (substances) is more directed to professional users while Article 48.2 (mixtures) covers specifically consumers.
- What exactly is advertising? There are many media where advertisements are placed. It

was discussed when the potential buyer makes the decision and where this information is thus needed. Art. 48(2) explicitly only applies to an advertisement which allows a consumer to conclude a contract for purchase. The matter of enforcement was also treated at this point: how to control advertising? Which authority would be better placed to effectively enforce?

- Some correspondents indicated that the FAQ goes beyond the legal text and could be revised. On the other hand some correspondents regarded the FAQ as helpful, providing guidance what can be considered as good practice when advertising hazardous mixtures for consumers. As a minimum the word "shall" needs to be exchanged for "could be".

6. Possible FAQ updates

The moderator explained that several FAQ refer to the 1 June 2015 deadline. Now that the deadline has passed, these FAQs need to be updated. ECHA asked the correspondents to agree to the HelpNet Secretariat making the necessary editorial changes. The correspondents will be informed on the outcome. The formal FAQ update procedure will thus be skipped.

A correspondent highlighted that some of the FAQ are obsolete. Another correspondent pointed out some FAQs (271, 241 and 246) that need update due to outdated legal references. The correspondents agreed on the proposed action.

Regarding FAQ 234 on the definition of 'placing on the market', COM explained that this issue will be discussed at the next CARACAL meeting in November. There will be a proposal to follow a two-track approach in defining the concept of 'placing on the market': (1) for the purpose of the transitional period (when mixtures placed on the market before 1 June 2015 and packaged and labelled according to the Dangerous Preparations Directive do not need to be relabelled and repackaged until 1 June 2017), and (2) more generally.

7. Discussion in smaller groups on current issues

7.1. Cut-off values when classifying mixtures for corrosion: clarification on where there can be a presumption of effects below cut-off value.

Outi Tunnela (ECHA) presented the topic. Classification for skin corrosion using the 1% cut-off value for relevant substances is based on the assumption that this value is generally applicable. However, certain substances can be presumed to be corrosive below 1%, and they must be taken into account at any concentration. The identification of such substances sometimes causes problems and further guidance has been asked for. However, it could be difficult to create such guidelines. Some specific examples explaining why a certain substance below the threshold can be considered as relevant would be helpful in the guidance.

7.2. Classification of mixtures containing a UVCB: state of play. Clarification for applying the mixture-rules on hazardous components of an UVCB when classifying the whole mixture is needed.

Andreas Fleischer (DE) presented the topic based on following scenario:

A UVCB listed in Annex VI is classified e.g. as carcinogen due to a known concentration of a hazardous component. This UVCB is contained in a mixture with a concentration above 0.1%. The concentration of the hazardous component in the mixture is below 0.1%.

There is a clear legal issue when a UVCB substance appears in Annex VI and thus needs to be considered as such.

In this case from a legal perspective it would be questionable to use the mixture-rules by comparing the concentration of the hazardous component of the UVCB in the whole mixture with the relevant generic concentration limit. Participants indicated that from a legal point of view only the concentration of the whole UVCB is relevant for the classification of the mixture. This is true, even if the hazardous components of the UVCB and their concentration in the mixture are known.

This is considered a conservative approach prone to lead to over-classification. Only in cases where there is enough knowledge on the composition of the UVCB substance the mixture-rule could be applied where the critical constituent of the UVCB is responsible for the classification. By the definition of the UVCB it is understood that these cases are few. There may be cases where the supplier of a mixture (e.g. an importer) has no information on the (UVCB) origin of a hazardous substance in the mixture. He might only have available analytical data of the concentration of the substance. In this case he needs to base the classification on the concentration of the hazardous substance in the mixture.

Concerning the legal basis of classifying mixtures due to a known component of a UVCB, ideas of further notes in Annex VI section 1.1.3.2 relating to certain mixtures were raised. New notes could eventually refer to specific cases where critical components of a UVCB are well known. However participants mentioned that similar notes assigned to specific substances already exist (e.g. entries for certain complex coal- and oil-derived substances containing benzene, with the Note J "The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene […]"). In these specific cases scientific evidence should be available showing that the component benzene is the sole trigger for the classification as a carcinogen or mutagen of the UVCB. This could support the approach to base the classification of the mixture on the concentration of benzene in the whole mixture.

Finally, considering the questions raised in the discussion and the need for further clarification, as a preliminary answer the participants indicated they would not advise companies to base the classification of a mixture on e.g. a low concentration of a critical component of a UVCB listed in Annex VI.

Gunilla Ericsson (ECHA) informed about discussions at UN-GHS level concerning the definition of UVCB, component substances and others.

7.3. Ecotoxicological testing of mixtures: classification of e.g. a PPP mixture. Is testing on different trophic levels unnecessary, if the outcome can be predicted? Examples from Cefic.

Blanca Serrano (Cefic) presented the topic. After the discussion she agreed that this was not the correct forum to discuss Plant Protection Product (PPP) cases.

8. Sharing the outcomes of the group discussions

8.1. Cut-off values

Points to consider when analysing whether a substance can be relevant for skin corrosion below the cut-off value of 1%:

- Look for read-across: certain structural features are known to irritate and corrode skin (organic acids and bases, aldehydes, halogenated esters and chemicals with reactive groups),
- Certain relevant chemical groups are already listed in point 3.2.3.3.2 of Annex I to CLP,
- If a substance is shown to be corrosive at 1% concentration, it is reasonable to think it

will be corrosive also below that concentration.

- If there is data, it is advisable to set specific concentration limits (SCL),
- Problem: Downstream users of mixtures and inspectors can often only refer to the safety data sheet (SDS) and the label, and may thus not know about the presence of a substance.

The participants agreed that a way forward could be producing a fact sheet or extensive Q&A advising how to use similar structure features and providing a real life example, so it would not be too simplistic. The factsheet/Q&A would be specifically meant for the use of NHD and inspectors.

7.2 Classification of mixtures containing a UVCB

There is further need for clarification, how to classify mixtures containing UVCBs when critical components are known.

7.3 Ecotoxical testing of mixtures

Some useful hints were gathered in the discussion:

- Unnecessary testing should be avoided.
- The discussion should take place with the PPP authorities and not in the CLP group.
- The proposal does not take in account changes in bioavailability in other trophic levels once the active substance is combined with the solvent.
- Examples would help the case.

After sharing the outcomes the moderator thanked all correspondents, observers and presenters for their participation.

Annex I List of participants

Members of HelpNet

Belgium	CLAES Kristof
Bulgaria	ZIDAROVA Elena
Croatia	JEZIC VIDOVIC Irena Zorica
Cyprus	PALEOMYLITOU Maria
Denmark	ANDERSEN Trine Thorup
Estonia	LAHE Aigi
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Germany	FLEISCHER Andreas
Greece	SKAFIDA Panagiota
Hungary	BURAI Erika
Italy	IZZO Paolo
Latvia	RUBENE Liga
Lithuania	JANONYTE Agne
Luxembourg	CHOCHOIS Laurene
Malta	GIORDMAINA Wayne
Norway	LARSEN Ann Kirstin

Poland	DOMANSKI Krzysztof
Romania	CAROLE Nicoleta
Slovakia	PORUBIAK Michal
Slovenia	MENARD SRPČIČ Anja
Spain	SANCHEZ DIAZ Maria Elena
Sweden	FALCK Carl Olof Jonas
Sweden	NORRTHON RISBERG Eva Ulrika Susanna
The Netherlands	WOUTERS Margaretha
UK	PEPPIN-HUGUES Lindsay

Representatives of the European Commission

DG ENV:	VAN RAEMDONCK Fabienne
DG GROW:	Absent

Candidate country observers

Serbia	GRUJIC Jelena
Serbia	RASOVIC Aleksandra
Turkey	OZGUN Pinar

Observers

CEFIC	SERRANO RAMON Blanca
CEPE	ROBINSON Janice

ECHA staff

Representing the Units: A2, B2, D2