ECHA webinars

EUROPEAN CHEMICALS AGENCY

Information session:
Questions and answers

ECHA organised an information session on How to submit a CLH dossier on 26 May 2021. The session presented the practical guide that gives advice to dossier submitters on what to check before submitting the CLH dossier with the aim of reducing the number of dossiers for which an update is needed.

This document compiles the questions and answers from the information session. Minor editorial changes have been made to correct spelling mistakes and similar questions have been combined into one. The document will not be updated.

For the most up-to-date advice on this topic, contact us or refer to our support material.

Question	Answer
ANNEX	
What is the use of the annex to the CLH report in ECHA? If the CLH report is a stand-alone document, is it really necessary?	The annex 1 was developed to facilitate using extracts from DARs, CARs and similar. If sufficient information is available in the report itself the annex is not needed.
APPLICATION FORM	
It is mandatory to fill the application form of “Submission of an intention or a proposal for harmonized classification and labelling (CLH) of a substance, in accordance with the CLP Regulation (EC) 1272/2008” via ECHA?	It is not mandatory to submit an intention, but it is highly appreciated and informative for Stakeholders and Interested Parties.

Question	Answer
BIOCIDES	
The template to be used when submitting at the same time a biocidal active substance AR and a CLH is the same as for the AR?	The template is the combined CAR-CLH report template. For the CLH, a second cover page of the template must be used, and non-relevant parts deleted. The template guides the user through which sections and parts are not relevant for a CLH dossier and should be deleted. This means that from one template, two separate reports can be created, a biocides draft assessment report/CAR and a CLH report.
DATA PROTECTION	
I would like to ask how to handle the data protection, if there are more applicants for the same active substance CLH dossier. It should be combined report prepared and so data from both applicants to be used. How should be data protection kept between those applicants for the same report?	The MSCA submitting the CLH dossier can insert information considered confidential by the applicants in the specific confidential Annex. The confidential Annex shall not be shared with the applicants.
In case of unpublished report that is important to classify for an hazard class how can we report the data? The data are considered protected or we can use them as Competent Authority?	We understand you refer to the study results and study summaries to be reported in the CLH dossier. These are to be considered separately from the names of authors of the study, which constitute personal data under the GDPR and Regulation (EU) 2018/1725, and should be anonymised in the non confidential version of the CLH report, but included in the confidential version of the CLH report, unless the study is published. The CLH report should contain sufficient amount of details on all studies (both negative and positive results) to allow their independent assessment by RAC for the hazard class. Confidential studies can be submitted in a separate confidential annex. The MSCA shall carry out an assessment of the confidentiality of the information reported in light of the criteria established in Article 119 of the REACH Regulation. This is without prejudice to the specific protection periods applicable to the data submitted for the purpose of registration (see Article 10 and Article 25(3) of the REACH Regulation) or the Biocidal Product Regulation (see Article 59 and 60 of the BPR).
In the combined DAR/RAR-CLH template V1, EFSA does not anonymized the name of authors of vertebrate studies, how it should be proceed if V1 will be send to ECHA?	EFSA anonymises the authors' name of non-publicly available studies in the first instance upon request from the Applicant(s) of PPP approval. If the Applicant(s) do not require this, it's up to the CLH dossier DS (usually the RMS of PPP dossier) to anonymise authors' name. This is checked at the accordance check.

Question	Answer
Must references be named as (Unnamed, year) in the CLH dossier when they are not given in the ECHA dissemination site and only available in the Chemical Safety Reports in the REACH registrations? Or is it OK to give the name? This relates to unpublished references.	The name of the author of unpublished studies must be anonymised in the non confidential version of the CLH report, but included in the confidential version of the CLH report. The year of the study does not constitute personal data and therefore should be made publicly available.
EFSA DAR/RAR	
Due to an EFSA DAR/RAR is done, and a new harmonized classification will be proposed, is necessary to perform a CLH with the proper template or it is enough with the V1 of the EFSA DAR/RAR?	For the submission of a CLH report, it is mandatory to use one of the templates available, which are CLH , CLH-PPP (combined Volume 1) or CLH-BPR (combined).
HCD (Historical control data)	
Does ECHA request HCD for ai renewals, for studies previously peer reviewed at initial approval, where the HCD were not requested before?	ECHA does not request HCD , however classification is based on all available data and HCD are part of it.
How strictly should the 5 year interval be interpreted. 2.5 years on each side of the study or more flexible?	For new studies, the 5 years can only be prior to the study, while for older studies the interval could be interpreted as 2.5 years before and after.
Would you please indicates how the nominal 5y period relates to the number of study carried out at a facility in that interval vs the rarity of incidence ? i.e. For rare tumours there could not be sufficient power to be able to assess using a 5y only period.	The CLP guidance states that HCD should be considered on a case by case and with assessment of relevance and appropriateness. Therefore if a larger time interval is needed, e.g. for rare tumours, and if it can be demonstrated that a larger interval is still relevant and appropriate, a larger interval may be accepted. It is necessary to provide sufficient information to allow RAC to come to an independent conclusion about the appropriateness and relevance of the HCD.
IMPURITY	
It should be included all the available information about the impurity in the CLH or in the Vol. 1 DAR/RAR.	You should first carefully check the generic or specific concentration limits for ensuring if the impurity has an impact on the classification of the substance. If you conclude that the impurity has no impact you can report information on its identity and concentration level in a confidential annex to the report.
If an impurity affects the classification and the DS claims for confidentiality, is it enough to place this information in the confidential version of the CLH dossier?	If the impurity affects the classification of a substance, the impurity cannot be kept confidential.

Question	Answer
If there is an impurity that is less than 10% in the substance/PPP, and this impurity in not in current Annex VI of CLP and does not influence in the test material classification. , but, this impurity by itself, in a concentration of 100% is deemed as either CMR or a respiratory sensitizer.	You should first carefully check the generic or specific concentration limits for ensuring if the impurity has an impact on the classification of the substance. If you conclude that the impurity has no impact you can report information on its identity and concentration level in a confidential annex to the report.
OECD toolbox	
Do you consider it necessary to use the information from searches in the OECD toolbox for retrieving information not available in the registration? This can add to the info in sources as Pubmed etc. but is not usually used	All relevant information for the assessment of the substance can and should be used in the dossier preparation. OECD Toolbox can provide alerts for hazard classes that can be relevant for the assessment.
PPP	
Data on classification from RAR's on pesticides and RAC adopted opinions are not correlated. Example: metiram, metalaxyl-M, dithianon, famoxadone. The new classifications are not included in these Reports, in favour of the Applicants. Case of those which have an updated renewal data time.	PPP approval and Classification of chemicals are two distinct processes (under two different pieces of legislation) with different timelines. It could happen that the approval/renewal of a PPP ends before the classification process, and that the classification of the substance in the two are different. However, the classification legally binding is the one coming out from the CLH process.
Do you find many incidences where papers are discounted in an assessment according to EFSA public literature guidance for PPP that the RAC later include and deem relevant?	It should be noted that the PPP and CLH processes differ in their assessments and so the use of the data may also be different. lit. The PPP process includes the possibility to request the generation of new/further data/studies . However, in the CLH process, there is no possibility to request further/new data. Thus the CLH process has to work with the available data even if the quality is lower than would be desired. It is also the case that the needs are different: for instance a study may be good enough to conclude that there is a hazard, but not sufficient for risk assessment. In addition, "no classification based on lacking/inconclusive data" is not a desired outcome for PPPs. We do not regularly assess if studies in a CLH dossier are in accordance with the EFSA guidance, so we cannot answer how many cases.
For PPP substances, can you confirm that it will be ensured that the combined volume 1 will either set up such that no redaction of personal data will be required or that redaction will be done after potentially required amendments (as result of the accordance check) by the submitting MS CA?	EFSA will do the sanitisation of the whole dossier, including the CLH part. We are not in a position to be more specific on that process in the Q&A session. More information is available on the EFSA website https://www.efsa.europa.eu/en/applications/pesticides.

Question	Answer
For PPPs, the joint assessment report (DAR/RAR-CLH) template is for the evaluation and submission by the CA to EFSA and ECHA. But is there guidance/ templates available for applicants submitting PPP dossiers and how to present the CLH data in the dossier?	There is guidance for the CLH process on the ECHA website (links in the Practical Guide); in particular the "Guidance on the Application on CLP criteria" should be considered in drafting Volume 1 of DAR/RAR including all required information and comparison with classification criteria. Guidance for the PPP process is available on the EU Commission https://ec.europa.eu/food/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection_en
For PPPs, the joint assessment report (DAR/RAR-CLH) template is for the evaluation and submission by the CA to EFSA and ECHA. But is there guidance/ templates available for applicants submitting PPP dossiers and how to present the CLH data in the dossier?	Link to the template is included in the Practical Guide under discussion.
PPP AIR Submission with IUCLID: is there a specific place/section for the CLH dossier?	In the template for both PPP approval and CLH, Volume 1 is the document used for both processes.
With regard to PPP it appears that a combined AR-CLH report can include information and study requests to be discussed and concluded by EFSA. Is RAC asked for an opinion before all requested information, which is also relevant for classification, is submitted?	PPP approval/renewal and Classification of chemicals are two distinct processes, (under two different pieces of legislation) with different timelines, running independently. The RAC opinion is the product of the CLH process, and is based on all available data at the time of submission; if the CLH process ends before the PPP approval/renewal process, the resulting classification is reported in the corresponding DAR/RAR.
Would presubmission dossier questions and answers be possible in any way as we do already with PPP? Even if it's written procedure only?	As dossier submitter you are most welcome to discuss the dossier with ECHA prior to submission. However, sending such questions to RAC is not foreseen.
In addition to my previous question: Is there already an agreed process between MS and ECHA for the setup or redaction of the combined volume 1?	Please see response to previous question.
RAC	
By when will the rapporteur be nominated to participate to working group?	The rapporteur(s) for a CLH dossier is nominated in RAC Plenary (closed session) usually up to 1 year in advance. The names are disclosed to Stakeholders when the first draft opinion is uploaded to S-CIRCABC and are available publicly after the RAC opinion is published.
Can you please confirm that how many people from Industry can attend plenary and working groups meeting ? Could it be with someone from regulatory affairs plus one toxicologist expert ? thank you	As per the rule of participation, one person per accredited stakeholders (up to half the number of RAC members) can participate and can bring one expert per agenda item.

Question	Answer
How do you deal with confidential information in open RAC meetings?	All participants in RAC have signed a confidentiality agreement, however, as RAC discusses only the study results that have been made available on the ECHA website during the consultation, it is unlikely that confidential information is discussed.
Will the working groups be similar in nature to BPC working groups providing technical input prior to plenary debate? If so, who will make up the WG? Members of RAC with particular expertise or all members can participate?	The RAC working groups are process based (Restr. Auth. CLP) and not thematic as with the BPC. Their tole is indeed to discuss and recommend technical input to plenary. The working groups are run under the RAC rules of procedure with the same participation opportunities for stakeholders. The members are entitled to attend, also with their advisors or, they may be represented by an advisor.
"No classification due to lack of data" How is the precautionary principle applied here? No classification will it mean that a chemical may go to market without the classification?	RAC classifies a substance based on scientific evidence. Precautionary principle is more relevant for risk assessment. Yes, no classification means exactly that the substance will go to the market without classification.
Could no classification due to conclusive data happen and why is that not taken up in the CLH for those endpoints?	No classification due to conclusive data happens often and it is reflected in the opinion. The term 'no classification' does not appear on Annex VI of CLP.
REDACTIONS	
What is the process, will there be the possibility for industry to verify redactions? To whom do missing redactions need to be addressed, especially if the CLH or combined volume 1 is already published for general consultation?	For the PPP process and use of a combined template (so an aligned process) the sanitisation is done mainly by EFSA: the process includes consulting with the applicant. For more information please consult the EFSA website: https://www.efsa.europa.eu/en/calls/consultations. For all other dossiers, the Dosser Submitter is responsible for this task before submitting the CLH dossier. The checking of CLH reports for confidential names is done before the reports are launched for consultation.

Question	Answer
STUDY REFERENCES	
What is the preferred approach for referencing studies in the body CLH dossier? Particularly for studies that the dossier submitter does not have the study report. Referencing ECHA's dissemination site and the year accessed rather than fully referencing the study report which is usually not available.	The preferred approach is to sufficiently report details of the study in the body of the CLH report, as guided by the CLH report template. The evaluation of the findings relevant for classification for each hazard class is based on the effects (incidence, severity, stat. sign. etc.). To enable an independent assessment by RAC, the observed effects, and their details for each dose in numeric values should be included in the tables and/or the text instead of a qualitative assessment (such as limited, slightly, moderate). An alternative way to report these details is to include them in an annex to the CLH report. The reference for a study in question must be included, but in a case it is a “unpublished” toxicological study, the author names must be anonymised in the non confidential version of the CLH report, but included in the confidential version of the CLH report (e.g. Anonymous, 2010). MSCAs have normally the access to the REACH registration dossiers in IUCLID which include study summaries.
If in the tables of the CLH dossier the dossier submitter references studies as: 'ECHA dissemination site, 2021' this is not considered acceptable? Is the following considered acceptable 'ECHA dissemination site, 2021. Study year: 1999'?	We would suggest a following option: 'ECHA dissemination site, 2021. Anonymous 1999a', and in a confidential report include the author name(s) to be able to identify the study.
WEIGHTING OF DATA	
Is weighting of the data a requisite going forward with dossiers (part of conformity check)? I see very little weighting in dossiers to date (Klimisch scores often missing, balanced discussion of multiple data sources often not included etc)	The CLH dossier should include a summary of data relevant for classification for each endpoint and a comparison with the criteria. As classification is based on a weight of evidence of all available relevant data, weighting of the data is required to allow a conclusion on classification. Klimisch scoring and highlighting key studies helps in weight of evidence, but is not a legal requirement. RAC discusses and agrees on harmonised classification by weighting the data, so if this is not clearly done in the CLH dossier, it will be after all done by RAC during the opinion development process.