How to submit a harmonised classification and labelling dossier - Part II
Questions and answers

ECHA organised an information session on how to submit a harmonised classification and labelling dossier - part II on 9 December 2021. It was a follow-up of our previous webinar on how to submit harmonised classification and labelling dossiers that took place on 26 May 2021.

It focussed on:

- Results of the survey on the challenges dossier submitters face in preparing harmonised classification and labelling dossiers
- Feedback on the practical guide that was collected after the previous webinar

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 will 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. Please see ECHA website for information on personal data: Personal data protection - ECHA (europa.eu). 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 relevant 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' names 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

Question	Answer
	the accordance check. Please see ECHA website: Personal data protection - ECHA (europa.eu).
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 greater time interval is needed, (e.g. for rare tumours, and if it can be demonstrated that a greater interval is still relevant and appropriate), a greater 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 (GLC) or specific concentration limits (SCL) 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.
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	You should first carefully check the generic (GCL) or specific concentration limits (SCL) for ensuring if the impurity has an impact on

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the test material classification. , but, this impurity by itself, in a concentration of 100% is deemed as either CMR or a respiratory sensitizer.	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. The 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 harmonised 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 the harmonsied classification(new or revised) would not be referred to, however at the new=xt renewal of the PPP substance this would be addressed. The "correct" classification that is legally binding is the harmonsied classification from the CLP 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, in that CLH is hazard based and the PPP process also includes risk assessment and so the use of the data may also be different. The PPP process includes the possibility to request the generation of new/further data/studies to conclude on its evaluation; however, in the CLH process, there is no possibility to request further/new data and the RAC opinion is based on the available data, which may be of lower quality 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 or the other way around. 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 harmonised 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 DS 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 stakeholder (up to half the number of RAC members) can participate and can bring one expert per agenda item.
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

Question	Answer
	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 (Restrictions. Authorisations. CLH) and not thematic as with the BPC. Their purpose is to discuss and recommend scientific and 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, and is not used for CLH due to no data. Yes, no classification due ti lack of data 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 occurs 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. Please see ECHA website for information on personal data: Personal data protection - ECHA (europa.eu).
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 authors' names must be anonymised in the non confidential version of

Question	Answer
	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 addressed by RAC during the opinion development process.
Concerning PPP substances, in the combined template RAC has also access to the updated RAR, including sections 8 and 9 for the environmental fate and ecotoxicity. Does it has any added value to copy the summaries from the RAR to Annex I? Or should reference be made to the RAR for full summaries	Vol.s 3 of DAR/RAR can be submitted as annexes to Vol.1, so in that case no need to copy/paste extended summaries in a different Annex, as long you refer to the respective sections. A further Annex can be submitted in case of further information not reported in the DAR\RAR.
How will it be ensured that also information requested during the 'Additional information request' submitted to the RMS/EFSA at a later timepoint than the closing of the commenting/consultation will also be taken into account by ECHA's RAC in case it relates to C&L?	After the closure of the consultation and during the proceedings of RAC, if important data becomes available that is considered to affect the classification, in principle a targeted ad hoc consultation with this new information can be launched. This requires case-by-case consideration as the RAC work and delivering the opinion in the legal deadline should not be disturbed.
Unless I missed it, how is other non-public data besides that of the PPP applicant, e.g. from the REACH registration dossiers ensured to be considered and reported in the combined document?	Non-public data can be either anonymised or included in a confidential annex to the CLH report.
CLH dossier for PPP - IUCLID and the CLP (CLH dossier) working context, specific manual	Since 27 March 2021 Pesticide application shall be submitted via the central submission system using the IUCLID software package. The reference EFSA webpage repository all of relevant information on the IUCLID software and PPP submissions is the EFSA toolkit webpage: https://www.efsa.europa.eu/en/applications/toolkit

Question	Answer
	At the same webpage, it is possible to access the ECHA Cloud Services, the secure online platform for submitting applications on pesticides. ▪ IUCLID 6.6 released in October 2021: details about enhancements/new features: https://www.efsa.europa.eu/sites/default/files/2021-10/iuclid-release-6.6.pdf ▪ IUCLID PPP active substance User Manual: https://doi.org/10.5281/zenodo.5091464 ▪ IUCLID 6.5 crosswalks: EU PPP Active substance application (product) to KCA&KCP Data set: https://doi.org/10.5281/zenodo.4946663 ▪ IUCLID training for regulators + range of supporting materials such as animated tutorials, recorded webinars and training sessions can be found on the EFSA website. ▪ Detailed instructions and pertinent templates for presentation of results in tabular format are available in the IUCLID user manual IUCLID templates for PPP Risk Assessment - Template 5.1 - Template for presentation of results in tabular format for mammalian toxicology studies
An active substance that appears in a plant protection product formulation is evaluated at the PRAS expert's meeting by EFSA and their conclusion by example is a proposed classification as Carc.Cat2; H351. ECHA through RAC eliminates this classification by applying the requirements of the CLP Regulation. The evaluator is the same person who is in relation to both EFSA and ECHA, for fulfilling the DRAR and the CLP report. Question: How can the RMS evaluator answer in front of the internal authorities for changes on classification? Evaluator is considered as guilty of negligence or lack of toxicological knowledge, considering that the time taken to prepare a DRAR is quite long, the evaluator requests additional studies to the Applicant and tries to evaluate as accurately as possible the toxicological data in the report, and the Applicant is in permanent contact with the competent authority from the RMS, having an office in the respective Member State. How would is possible to harmonize the outcomes from EFSA with ECHA,	As noted in EFSA peer review documents, the classification conclusions included in the EFSA opinions which preceed a RAC opinion are accompanied by a disclaimer stating that the definitive conclusion on classification was that from RAC. Harmonised classification is decided by ECHA's experts from RAC. As part of the alignment of EFSA pesticides peer review and ECHA CLH processes, EFSA and ECHA have identified relevant stages/phases in particular those requiring close collaboration between the two Agencies and MSCAs (both Member State Competent Authorities (MSCAs) under the CLH process and the Rapporteur Member States (RMS) under the EFSA peer review process), responsible for the planning, preparation and/or assessment of the same substances in the two different processes. Collaboration and good internal coordination between MSCAs to align their internal processes (in particular where the national authority dealing with CLP and peer review process is not the same) are considered key elements for a successful alignment. To allow a full alignment with common public consultation, MSCAs are strongly advised to use the combined template which has been noted by the SCoPAFF and published on the EC website. The combined template should be used for

Question	Answer
or maybe would will be better that the EFSA to cover the reference values and operator exposure and let the classification to ECHA's experts from RAC. Thank you.	preparation of joint DAR/RAR and CLH reports for active substances covered by Commission Regulation (EU) No 844/2012 and for active substances for which an application for approval has been submitted since 6 October 2017; this should be submitted in parallel to both ECHA and EFSA. With the use of the combined template the same level of information is made available to both EFSA and ECHA, ensuring consolidated views, transparency and consistency in the data set for the two processes. MSCAs are therefore advised to use the combined template for all new DAR/RARs, even in cases if the MSCA does not plan a submission to ECHA. According to the new the implementing act on renewals the RMS should submit the CLH report to ECHA at the latest at the same time when submitting the RAR to EFSA and with mandatory inclusion of information on classification or its confirmation / reclassification in dRAR for at least the hazard classes specified in Art 11(9). According to Article 13(1) of the implementing act on renewals EFSA will take account of the RAC opinion in the Conclusion which is established within 5 months + clock stop from end of the public consultation or 2 weeks after adoption of RAC opinion, if any (whichever occurs later). According to Art 11(10) the Committee for Risk Assessment 'shall endeavour' to adopt the opinion…within 13 months…' from submission of CLH report (indicative timeline defined to ensure that the RAC opinion is available to EFSA prior to the adoption of its conclusion). Therefore there is strong endeavour from both sides to align the process and it is confirmed that RAC opinion should be available to EFSA prior to EFSA's conclusion of the evaluation of the a.s. Therefore the harmonization of the outcomes from EFSA and ECHA is already in place and the situation reported by the requester is highly unlikely to occur.
If there are plans for using IUCLID to submit CLH dossiers and if so the timeframe that this is being looked at coming into force.	It is worth to note that as for the preparation of the combined EU-AR/CLH report, the aim in the medium/long term, with further IUCLID developments, is to use the Report Generator. In such a way it will be possible to create the AR/CLH, i.e. the combined EU AR-CLH report aimed to cover both processes to be generated directly from IUCLID dossier once the report generator could fit with the lay-out of the template. Work is ongoing in collaboration with ECHA, with the goal of adopting the report generator format for the CLH report, for use for both EFSA and ECHA regulatory purposes.

Question	Answer
CLH document for micro-organism: it is requested by Authorities but no really appropriate. Is it mandatory?	According to Article 3(1)(c) of Regulation (EU) No 528/2012 (BPR) 'active substance' means a substance or micro-organism that has an action on or against harmful organisms. According to Vol V of the Guidance on the BPR "provisions of the CLP Regulation cannot be used for the micro-organisms and thus they cannot be classified or labelled under the current classification and labelling system". However, the Guidance quoted above continues " the chemical constituents in a biocidal product, containing the microorganisms, may trigger classification and labelling according to the CLP Regulation and other specific labelling requirements can apply" The reference to sensitising potential is consistent with this Guidance. Regulation (EC) No 1272/2008 and Directive 67/548/EEC are not applicable to micro-organisms. However, microorganisms should be regarded as potential sensitizers and the following hazard statement has to be applied: 'Micro-organisms may have the potential to provoke sensitizing reactions'. However this seems not triggering classification with H317. Safety considerations are limited to the sensitizing potential relevant to all microorganisms. However further considerations may be provided by ECHA.

Question	Answer
Further instructions how to prepare a good PPP classification proposal in EFSA/ECHA new combined DAR/RAR template. What information is essential and how it should be performed in Vol 1. Can certain information be included as Annexies to Vol 1 (what B.CA parts or something else)? Or should the whole RAR that is submitted to EFSA to be submitted also to ECHA. It would be useful if this information was added to the ECHA guidance document "How to submit a harmonised C&L dossier" and a reference of ECHA's GD to EFSA Administrative GD, so that PPP evaluators can find the correct information easily.	For PPP active substances, as part of the alignment of EFSA pesticides peer review and ECHA CLH processes, MSs are strongly advised to use the combined template for preparation of joint DAR/RAR and CLH reports to be submitted in parallel to both ECHA and EFSA. The common template incorporating the CLH proposal and Volume 1 of the Assessment Report is available under EC website -> guidelines webpage (SANCO/12592/2012): • Same level of information is made available to both EFSA and ECHA, ensuring consolidated views, transparency and consistency in the data set for the two processes • Avoid duplication of work resulting from the need to present the same information based on the same hazard assessment in two different formats • Joint format is aimed to fit for both PPP and CLH processes, i.e. the information needed for both processes to be in one document. This facilitates the alignment of the active substance approval process

Question	Answer
Classification of active substances in plant protection products: Proposal for classification of an active substance will be sent in the same document to EFSA and ECHA. The document is the summary document of the whole risk assessment of the active substance. Therefore would it be possible to only include summary data in this shared document and provide documents with detailed evaluation of the original studies needed for classification as attachments? That would decrease the work load of MS evaluators and would maintain the shared document as a summary document for EFSA and MS i.e., as it was originally developed.	undertaken by EFSA in the framework of Regulation (EC) No 1107/2009 with the CLH procedure undertaken by ECHA under Regulation (EC) No 1272/2008. All information specific for classification is included in level 2 of Vol 1. • Overall summaries and overview of the conclusions reached in relation to the risk posed by the a.s. / representative product and uses and the proposal for CLH. - In level 2 the standard summaries with the effects data should be presented, as required for the exposure and risk assessment in the approval/renewal process, with the C&L sections to be added additionally. - For the CLH process, Vol 1 is equivalent to the CLH dossier and as such it should be as much as possible a stand-alone document => all information for the assessment of the studies should be included in Vol 1 => Vol 3 includes additional data to allow in depth assessment or clarification. - Tabular overviews for each section - Robust summary of studies on the hazard class in question (including overall relevance, uncertainty or controversy of the provided data, significance of any deviations from the guideline);=> all effects should be discussed - Comparison of results with the CLP classification criteria - Conclusion on C&L for the hazard class in question according to the CLP criteria - Additional recommendations - Information should cover effects observed at all dose levels to address both setting of NOAEL/LOAEL and need for classification - Study summaries should contain enough information to assess their acceptability and the reliability of results - It is recommended to indicate magnitude and direction of change, statistical significance - Cross references can be applied to Volume 3, - More detailed (extended) results and study summaries are presented in Vol 3 => all the endpoints should be described with a sufficient level of detail to allow a proper and transparent assessment both by peer review and by RAC

Question	Answer
How to submit the following parts of assessment: identity and properties of the active substances (including impurities and metabolites); analytical methods for data generation/risk assessment	Identity and properties of the active substances (including impurities and metabolites) and analytical methods for data generation/risk assessment is presented in the Vol. 1, Level 2. Specific instructions can be found in the combined AR/CLH template https://ec.europa.eu/food/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection_en
GROUP OF SUBSTANCES	
How to handle groups of substances in CLH proposals in the most efficient way	This is a very broad question, but to give a short general answer. For proposing a CLH entry, it depends on the characteristic of the substances in the group and substances to be included in the group would need to have a proposal leading to the same classification for all members of the group. If support is needed for a group entry, please submit the intention to prepare a CLH dossier for the group via the registry of intention to start a discussion with ECHA.
Currently group CLH dossiers are proposed in ARNs. Do you already have some reflections on format for such a (big) group dossier? e.g pres of data for many substances vs substances with no data, how to build a read across with more or less similar subst., how to tackle diff potency (e.g. resp sens)	There is no separate CLH report template for a group of substances. The DS may decide to put all data in one dossier or in separate ones, depending on the case. It is notable that a group entry can be made in the Annex VI of CLP, but only if all the proposed hazard classes are exactly the same for all the substances. If there is difference on how the substances, that are assessed in a group, should be classified, then individual entries to the Annex VI should be proposed. It is notable that ARN (Assessment of Regulatory Needs) is based on screening and does not necessarily mean that the read across would always "hold" in that sense that all those substances identified for the screening will actually form a group entry under CLP.
PHYSICAL HAZARDS	
Physical hazards	This is a very broad question: please check ECHA "Guidance on the Application of the CLP Criteria" and the Practical guide on "How to submit a CLH dossier".
CONFIDENTIALITY	
Anonymisation of the references - how to keep the balance between protection of the study authors and transparency of reporting in the CLP dossier, e.g. by means of use of the laboratory names instead of the authors` names as reference identifiers.	It is possible to replace the study authors' names by "anonymous", or by the laboratory names, reference number, etc. as long as the reference is unique (e.g. using Anonymous, 2020a,b etc) and a confidential annex is submitted containing the original confidential reference and their correspondent corresponding non-confidential version.

Question	Answer
In the combined AR/CLH report, once the accordance check had been finalised, who sanitizes/anonymizes the studies from Vol1/CLH	Sanitisation of the CLH dossier is in the first instance the responsibility of the Dossier Submitter. Please see ECHA website for information on personal data: Personal data protection - ECHA (europa.eu). In case of a combined template, if a sanitised dossier for PPP process is already available and published on EFSA website for consultation, it can be used also in the CLH process. In case of parallel consultation for CLH and PPP processes, ECHA and EFSA can use the same document(s), in that case sanitisation is performed by EFSA.
MISCELLANEOUS	
Brining a CLH dossier for a substance that already has a harmonised classification to RAC for a second time to refine a hazard endpoint.	Only MSCAs can submit a dossier to update an existing classification for a hazard class. MSCAs, manufacturers, importers, downstream users can submit a classification proposal for a hazard class not currently included in an existing entry. For more information see CLP Regulation Art. 37 and ECHA "Guidance on the preparation of dossiers for harmonised classification and labelling" section 3.2.
NEW HAZARD CLASSES	
New hazard classes being planned. If we become aware of relevant data generated by another company/party late in the process (e.g. post commenting phase), what would be the options for including these data?	After the closure of the consultation and during the proceedings of RAC, if important data becomes available that is considered to affect the classification, in principle a targeted ad hoc consultation with this new information can be launched. This requires case-by-case consideration as any ongoing development of a RAC opinion and delivering the opinion within the legal deadline need to be taken into account. Alternatively, if you are the DS and consider these data fundamental, you could withdraw the dossier, update it and restart the process.