Webinar:
Questions and answers

ECHA organised a webinar on 16 November 2021 on **Completeness checks of chemical safety reports: practical advice.** It gave targeted advice on the most common reasons for incompleteness and our observations and useful tips on how to avoid failing the check.

This document compiles the questions and answers from the webinar. 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, contact us or refer to our support material.

Question	Answer
General	
Would it be possible to have access to the individual powerpoints as reference material?	The presentations are published on the webinar page: https://echa.europa.eu/-/webinar-completeness-checks-of-csr-20211116
How long is the timeline for the completeness check?	The legal deadline for the completeness check is within three weeks of the submission date. The completeness check cycle has two attempts for any submission of a registration dossier. If you fail the first time you get a deadline of 4 months to correct the failures.
IUCLID Validation assistant	
Are IUCLID quality warnings in the Article service life assessment to be taken as indications of CSR-failures?	We advise you to address the quality warnings as much as possible. They may indicate an issue that is connected to the completeness of the CSR.

There are remaining warnings despite splitting the consumer and prof workers uses of articles according to your recommendations (both are allocated ERC 10a & 11a and same ACs, and workers are assigned PROC21). Is this normal?	Your question requires further consultation and cannot be answered during the webinar. Send us your question using our contact form: echa.europa.eu/contact. Could you please indicate in your request the IUCLID version, submission type (working context), validation scenario (on top of VA report, e.g. SC0001), rule ID (e.g. QLT200) and screenshots, if possible. Any confidential information can be replaced.
When is a CSR required?	
Do I need to prepare and submit a CSR for non-hazardous substances (no GHS classification) with volumes of more than 10 tons / year?	Yes, a CSR is required when the volumes are 10 tons/year or more, but it does not need to contain exposure assessment and risk characterisarion if the substance does not meet any of the classification criteria and is not PBT or vPvB.
If a substance is being registered between 1-10 tpa and it is a (self) classified PBT, is a Chemical Safety Report required?	No, a CSR is not required if the substance is registered between 1-10 tpa.
In case substance is used in mixture above 10 ton and is hazardous, is CSR required?	Yes, a CSR is required when the substance is registered for a volume of 10 tons/year or more. It must contain an exposure assessment and risk characterisation if the substance meets the classification criteria or is PBT/vPvB, and it must cover the uses of the substance on its own, in mixtures, and in articles.
When is an exposure assessment and risk characterisation required?	
If a substance is only classified for environmental hazards, but DNELs as well as PNECs are derived based on effects observed in studies, does the CSR require for an exposure assessment on the human health endpoints too?	Yes, in this case an exposure assessment is required also for human health.
A substance registered above 10 tn/y is classified for a physical or a health hazard but not for environmental hazard. However, a PNEC is derived. We need to include exposure assessment / Risk characterization of the contributing scenarios for the environment, for the relevant ERCs. Please confirm.	Yes, this is correct. Exposure assessment and risk characterisation for the environment are required because PNECs are derived.

If our substance is classified only for human health hazards but not for the environment, do we have to derive PNECs and perform an environmental risk assessment?	PNECs are derived if an effect is observed in the required studies. If PNECs are derived then an environmental exposure assessment is required.
Is a CSA needed for substances classified for Physchem hazards only?	Yes, if the substance is registered for 10t/y or more.
What about the degradation products hazard classification? if it is below the cut off limits do we still need to assess and report it in CSR?	If the concentration of the degradation product is below the cut-off limits you could waive the exposure assessment by providing an explanation on the concentration of the degradation product in the use. If the concentration is below 0.1%, no further reasoning is expected at TCC (exceptions: specific concentration limit for mixture classification and 'Aquatic Acute 1', 'Aquatic Chronic 1'). If the concentration is above 0.1%, you have to provide the hazard category(ies) and class(es) of the degradation products and corresponding cut-off(s) from CLP
Derivation of hazard assessment conclusions	
Can we conclude "no hazard" for the general population in the DNEL section of IUCLID if there are no uses by the general population (and substance not meeting criteria for assessment for man via the environment)	No. DNELs are to be derived corresponding to the effects observed in the required studies. However in the situation you describe, the DNEL does not trigger an exposure assessment for humans via environment or for consumers (no uses).
In some cases, effects are observed in a study, however they are not sufficient for requiring a classification of the substance. Do I understand correctly that in this case as well, no DNEL derivation or exposure scenario is required?	Based on current ECHA guidance, DNELs are to be derived based on effects observed in the study, independent of whether the effects qualify for triggering a classification.
Concerning the need to derive a DNEL: It was stated that: if no effect was observed up to or at the limit dose. Is it correct that there has to be a NOEL at the limit dose or is it also feasible to not derive DNEL´s if there is no ADVERSE effect (NO(A)EL) at the limit does???	If there is no advserse effect observed up to limit concentration in the guideline-test, it can be concluded that no hazard has been identified, and hence no DNEL is to be derived.

Thank you for this very useful webinar. If a substance is poorly soluble in water to reach the limit dose set in the guidance and if no adverse effects were observed at the solubility limit, do we have to derive a PNEC?	Your question requires further consultation and cannot be answered during the webinar. Send us your question using our contact form: echa.europa.eu/contact Thank you.
CSR submitted by a member registrant	
If a member registrant reports in IUCLID section3.5 own uses and uses down the supply chain, but attaches a jointly prepared CSR containing also other uses, will the CSR pass the completeness check? Sometimes the jointly prepared CSR is a pdf so we cannot modify it.	Having a CSR that is covering a wider range of uses (than those reported in IUCLID section 3.5) is not an issue for the completeness check but you need to make sure that the CSR covers all the uses that you report in your own dossier.
If a LR has a created a joint CSR and we need to add only one CS for one of the ES, how do we need to complete the related assessment in 3.5?	If the lead submits a joint CSR on your behalf, but it does not completely cover one of your uses, we advise you to provide the full exposure scenario corresponding to your not covered use in your own additional CSR. In IUCLID section 3.5 you should report all your own uses (onsite or downstream). When the uses are assessed in different CSRs, it is essential to specify which use is assessed in which CSR. In each use record under IUCLID section 3.5, there is the field 'Related assessment' to indicate in which CSR (own or joint) each use is assessed.
We receive the LR's IUCLID dataset with the hazard data (min. the endpoint summaries) to run the exposure assessment for our uses in CHESAR. Should the member dossier contain the hazard information (as used in CHESAR) or should this be removed before submission (as it is already submitted by the LR? Do we need to keep two IUCLID datasets, one for running CHESAR and one for submission?	You only need one dataset as a source of information for input to Chesar and to your registration dossier. It is not necessary to remove the hazard data manually before submission as this will be done automatically during the dossier creation step.
In cases where we (member registrant) receive the CSR from Lead Registrant, how can we ensure that information provided in it (DNEL/PNEC values, exposure estimates etc) are complete or correct? Do we just trust the	If you submit the CSR yourself, you are responsible for checking its completeness/correctness by confirming that your composition matches the boundary composition, all your uses (and the related contributing activities) reported in IUCLID section 3.5 have a corresponding exposure (contributing) scenario in the provided CSR and that the conditions of use reported are not conflict with what you know about your customers

information provided by the Lead so we just fill the company specific parts?	
Reporting of uses and exposure scenarios	
Is it necessary to report PROCs if no DNELs are derived but a CSR is triggered based on environmental hazard/classification? Or can we omit use description for worker+prof.+consumer with a general justification?	No, you cannot omit it. Use description for both human health and the environment is to be provided, independent of whether or not an exposure assessment for the environment and/or human health is required.
Based on the suggested workflow on slide 48 I understand that the "use as intermediate under SCC" needs to be displayed in IUCLID Section 3.5 but this use does not have to mentioned in Section 9 of the CSR. Is my understanding correct?	Yes, you need to report such uses in IUCLID section 3.5. They don't have to be mentioned in section 9 of the CSR, if you have properly reported them as being covered by article 17/18 in IUCLID section 3.5 under 'Registration/ Notification status for the use'. For uses reported under article 17/18, the conditions of use ensuring strict controls are to be described in the dedicated fields in the use record as explained in section 8.5.4.6 of the manual How to prepare registration and PPORD dossiers: https://echa.europa.eu/documents/10162/1804633/manual_regis_and_ppord_en.pdf
Can sections 9 and 10 be combined?	We acknowledge that combining sections 9 and 10 will improve the readability of the CSR. It is accepted.
What are ECHA's expectations regarding aggregate exposure assessment?	REACH requires that exposure of humans simultaneously occurring through different routes are combined with each other for risk characterisation. For environment it is expected that the releases from the various sources are aggregated for assessment.
As a follow up tom my first question: What is the difference between "aggregating" and "combining" exposures?	Unfortunately there is no fully harmonised terminology, so best always to make the context clear, for example: i) Estimating human exposure through various routes from a given source and "combining" the exposure for systemic risk characterisation. ii) "Aggregating" (summing up) exposure to a substance released from different sources
Can we put several ERC in one exposure scenario?	Yes, one exposure scenario could have more than one environmental contributing scenarios covering different ERCs. However, you need to ensure that all these environmental contributing scenarios can be assessed within one use (i.e. compatible ERCs).
If we put 2 ERC in the 3.5 as for example indoor and outdoor, can we do only one assessment for the worst case in chapter 9 and put a justification?	You may cover your two ERCs within the same contributing scenario (provided that there is a reference to both ERCs), but you need to ensure that you can specify a worst case as the conditions of use are likely to be different for an indoor and outdoor use

CSR for monomers in imported polymers	
If we register a monomer that is manufactured outside of EU and is only imported to EU as a polymer, is CSR for the monomer required in the registration dossier? Can we put our justification in section 3.5.0?	It may be possible to justify the absence of the CSR if you are registering a monomer imported in a polymer. The justification must contain specific elements that are explained on p. 12-13 of the document 'Information on manual verification at completeness check': https://echa.europa.eu/documents/10162/17246/manual_completeness_check_en.pdf. The justification (i.e. the summary of arguments) for not providing a CSR must be entered in the field 'Discussion' of the section 13.1 record.
CHESAR	
As i understand, Chesar is not able to calculate local PECs for agricultural soil. How should we address this issue?	You may report manually exposure estimates obtained via other tools into Chesar.
When assessing a service life use in CHESAR, some PROCs are not applicable according to the physical state of the substance. For example, PROCs 21 & 24 are not applicable to liquid substances. Does this mean worker assessment for the liquid substance in article is not necessary?	In this case, you can perform the worker assessment in Chesar using an external tool
Should we add a PROC 28 even if we can't assess it by Chesar?	You could find a workaround to assess PROC 28 in Chesar in here https://chesar.echa.europa.eu/support/frequently-asked-questions