February 2020

Webinar on revised completeness check of REACH registrations – questions and answers

The revised completeness check enters into force at the end of April 2020. It extends the manual completeness check to the chemical safety report and strengthens the automated checks on key hazard endpoints.

ECHA organised a webinar on 29 January 2020 on the revised completeness check and how you can prepare. The first part of the webinar gave an overview of the changes to the checks done on Annex VII-X information requirements. The second part focussed on the manual checks that will be done on the chemical safety report and gave practical advice on how to ensure the completeness of this information.

Participants had the chance to ask questions from our experts. This document compiles and groups questions and answers reveived during the webinar. It has been complimented with more elaborated advice that was not possible to give in the webinar.

This document will not be updated. For the most up-to-date advice on completeness check, please refer to our manuals.

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1. SUPPORT DOCUMENTATION

1.1. ECHA contact form

If your question was not answered during the webinar you can send us your question using our contact form: echa.europa.eu/contact

1.2. Where do I find the manual on registration?

The document is available on the ECHA website, under Support > Manuals. The direct link to the document is here:
https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf

1.3. Where do I find the document that explains what areas are subject to manual verification during completeness check?

The document is available on the ECHA website, under Support > Manuals. The direct link to the document is here:
https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf

1.4. Where do I find information on Chesar?

The Chesar website provides information on the Chesar tool: https://chesar.echa.europa.eu

An overall description of the tool is available here:
https://chesar.echa.europa.eu/documents/2326902/2424432/Chesar+in+a+nutshell

For those who would like to better understand the principles of the tool, we suggest to read the Chesar user manual available at:
https://chesar.echa.europa.eu/documents/2326902/28587435/Chesar3-5_user_MAN_en.pdf

2. TCC PROCESS

2.1. When does the revised TCC start to apply?

The revised completeness check enters into force with the IUCLID release on 29 of April 2020.

2.2. Does the revised TCC apply also to joint submission member registrants?

Every registration dossier submitted to ECHA undergoes the completeness check as per REACH Article 20(2). The completeness of a registration dossier is done against the information expected in that dossier; this will depend on the registrant's role in the joint submission, the information that is agreed to be submitted jointly, the tonnage band of the registration and whether the dossier is for an Article 10 or 17/18 registration.

2.3. If a dossier submission or update is rejected due to the outcome of the manual completeness check of the CSR, how much time does the submitter have to correct the CSR? Extensive discussion with other registrants may be required.

As for any completeness check failure, you are given a deadline of 4 months to resubmit the dossier with the missing or incomplete information. We encourage you to get familiar with the expectations of a complete CSR as outlined in this webinar and, if necessary, contact the co-registrants already in advance of the submission to avoid failures.

2.4. If a submission for a tonnage band increase is rejected due to incompleteness of the CSR, is it correct that the submitter only has two chances to submit? A manual check cannot be simulated with the IUCLID Validation assistant.

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. The failure letter will list all the missing elements. Also, you can always contact us if the reason for failure is not clear.

If the second submission is also found incomplete, then the submission is rejected. For a submission to obtain the registration number, this means that a registration number is not assigned. For an update of an existing registration, it means that the registration number is kept but the updated information is not accepted into ECHA's database.

In both cases it is possible to submit a new dossier once the rejection process is finalised.

2.5. Are all failures identified during the first completeness check or is it possible that new additional failures can be added after the re-submission after the first failure?

If your submission fails the first completeness check, you will receive a letter with all the failures detected in this submission. You should ensure to address all the failures listed in the letter when preparing your re-submission.

The completeness check on the re-submission will be performed on the whole dossier and not only the part that failed the first completeness check. Therefore you are recommended at this point not to amend any other parts of your dossier than those requested in order not to

generate any new failures. You should also ensure to run the IUCLID Validation assistant on every dossier to reduce the possibility of failures.

2.6. When will the IUCLID Validation assistant plug in be updated with the new completeness check rules?

The updated completeness check rules will be part of the Validation assistant included in the next IUCLID release which will take place on April 29, 2020. It can be downloaded from the official IUCLID 6 webpage at https://iuclid6.echa.europa.eu

3. ANNEX VII-X INFORMATION REQUIREMENTS

3.1. Can the information requirement for the screening study for reproductive toxicity be waived?

An information requirement can be waived if it falls under column 2 of the relevant REACH Annex VII-X, or under Annex XI sections 2 or 3. For the reproduction toxicity information requirements the screening study must be addressed at Annex VIII with either a key study or weight of evidence approach, or with a valid data waiving.

At Annex IX and X, if the information requirements for the extended one-generation reproductive toxicity study and the pre-natal developmental toxicity study are both waived, you must always address the screening study with a key study, weight of evidence approach or data waiving.

If study summaries are provided for at least one of the higher tier reproductive toxicity information requirements (i.e. pre-natal developmental toxicity and/or extended one-generation reproductive toxicity studies), the screening study may not be necessary. As a consequence, the completeness check does not require the screening study to be addressed whenever the higher tier studies are provided. However, depending on the nature of the substance and the registration, approach used (e.g. read-across), you may need to perform the screening study to complement the information from the higher tier studies for the dossier to be compliant.

3.2. ECHA acknowledges that REACH requires "all available information" be gathered in registrations, yet many contain zero published toxicity findings. In the webinar it was said that ECHA is still only requiring "one study per endpoint". When will ECHA begin to check for compliance with the provision of all available information? I can envisage that ECHA would believe this would make a difference to the conclusions of a CSR.

The REACH Article 20(2) completeness check, which is in scope of this webinar, ascertains that the elements to fulfil the REACH information requirements are present in a dossier submitted to ECHA. For Annex VII-X information requirements, one study may be sufficient to fulfil the requirement, if it is of the appropriate adequacy, and therefore the completeness check requires that a minimum of one study is provided.

The quality and adequacy of the information are then checked at compliance check and as a consequence it may be concluded that further information is necessary for the information requirement to be fulfilled.

4. REPORTING IN IUCLID OF USE AND EXPOSURE INFORMATION

4.1. As a member registrant I have some uses that are covered by the lead registrant in the joint CSR and some that are my own uses. Should my own CSR cover all uses i.e. copy/paste those that also the lead registrant has submitted, as well as my own?

There is no need to copy/paste the uses and exposure assessment from the joint CSR to your own additional CSR. However, you should report all your own uses in IUCLID in section 3.5, regardless of whether they have been assessed in your own CSR or the joint CSR submitted by the lead registrant. When your uses are assessed in different CSRs, it is essential to specify which use is assessed in which CSR. In each use section under IUCLID section 3.5, there is the field 'Related assessment' to indicate where each use is assessed. The options that are relevant for a member registrant are: "use not assessed", "use assessed in an own CSR", "use assessed in a joint CSR".

4.2. If I am using the CSR from the SIEF and submit it as part of my member registration, I would need to add all uses from the CSR to the dossier, even though not all apply?

If you are a member registrant, you need to report all your own uses in IUCLID in section 3.5. You should not report uses that are covered by the joint CSR if they are not relevant to you.

4.3. If a lead registrant submits the joint CSR on behalf of all co-registrants and includes all uses in IUCLID, does it also need to include in IUCLID uses that are relevant only for a member co-registrant at below 10 tpa or uses under strictly controlled conditions for which an exposure scenario would not be required?

No. Only the member uses that require exposure assessment and are covered in the joint CSR must be reported in the lead dossier.

4.4. In the dossier header of joint submission registration dossiers there is the need to indicate who has submitted the CSR. In the case that some uses are covered by the joint CSR submitted by the lead registrant and some uses are covered in my own member registrant dossier, what should I indicate?

If you rely on the joint CSR for the assessment of some of your uses, you should indicate that the CSR is provided by the lead registrant on your behalf. This does not prevent you from providing your own CSR with your own assessment for some of the uses. It is however 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 where each use is assessed. The options that are relevant for a member registrant are: "use not assessed", "use assessed in an own CSR", "use assessed in a joint CSR".

4.5. Some substances are formulated into mixtures at concentrations below the thresholds specified in REACH Article 14(2). Will it now be a requirement to list the uses of these formulations in the CSR, even though exposure scenarios are not required?

The use description of the substance in the registration dossier should cover all uses. This includes uses where the substance delivers its function in low concentrations in mixtures. The Article 14(2) cut-offs are not related to the use description.

5. TCC OF USE AND EXPOSURE INFORMATION

5.1. Is it a problem for the completeness check if a use is assessed in the CSR but is not included in section 3.5 in IUCLID?

This will not lead to a completeness check failure. We are aware of that such situations may occur when there is a chemical safety report developed at the joint submission level, but submitted separately by each registrant. However, we remind you of that only the uses reported in IUCLID section 3.5 of each registrant are considered to be covered by that registration. For completeness, we will check that all uses reported in IUCLID section 3.5 are assessed in the CSR.

5.2. Is my understanding correct that only CSRs of classified substances that are manufactured/imported at above 10 tpa will be checked in the revised completeness check?

Yes this is correct. We will perform the manual completeness check on the CSR when the registration is for a tonnage band above 10 tpa and the substance is classified according to Article 14(4) of REACH, which means that an exposure assessment and risk characterisation must be part of the CSR. For substances not meeting the criteria for classification or PBT/vPvB an exposure assessment is not needed, and in these cases the CSR will not be manually checked at completeness check.

5.3. If the CSR is produced using Chesar, would that be indicative that the manual checks would probably be considered complete as the level of information checked is that contained in Chesar?

Using a CSA tool (like Chesar) for preparing the CSR is not a guarantee that the completeness check will pass, but it reduces the likelihood of failure. Following the standard workflow of Chesar will ensure that the registrant prepares a CSR consistent with the information available in the technical dossier and which addresses all reported uses and compartments/routes of exposure, in line with the outcome of the hazard assessment.

5.4. Will it be enough to include a complete CSR document in the dossier or are you expecting that all information from the CSR are included in Chapter 3 of IUCLID for the completeness check?

The use description must also be provided in IUCLID section 3.5. For the other CSR information (exposure scenarios, exposure estimates, risk characterisation), inclusion in IUCLID section 3.5 is possible but not mandatory.

5.5. In cases where no exposure scenarios are needed as per article 14 (not classified or below classification threshold): is it still required to provide detailed use information in the form of use descriptors (PROC, ERC…) for all the subsequent life cycle stages?

Yes, use names and the relevant use descriptors (PROC, ERC, PC, AC) for all the life cycle stages need to be reported in IUCLID section 3.5., even if no exposure scenarios are needed as per article 14. The use descriptors must be reported in the fields 'Contributing activity/technique for the environment', 'Contributing activity/technique for workers' and/or 'Contributing activity/technique for consumers'.

5.6. Many times, lead registrants provide only the generic CSR. In this case, will the CSR of joint submission member registrants for section 9 & 10 be checked?

As a member registrant, you have to make sure that all your own uses are covered either in the joint CSR submitted by the lead or in your own CSR. Uses indicated to be covered in the joint CSR must be fully assessed there (i.e. the member is not expected to provide further information on the assessment). If the joint CSR does not cover all your uses, you will need to assess the remaining ones in an own CSR.

When a member registrant indicates that it relies on a joint CSR provided by the lead registrant, we will not during the submission process check the content of a potential additional CSR in the member dossier. However, this does not remove the registrant's responsibility to ensure that all their uses are assessed. We may decide to open a completeness check on the whole joint submission at a later stage, to verify that all reported uses are indeed assessed.

5.7. In case the lead registrant does not submit a joint CSR on behalf of members of the joint submission, will each CSR submitted by the members be manually checked? How long does the completeness check of the CSR take?

If lead registrant does not submit a joint CSR, each CSR submitted by the members will be manually checked during the submission process. As stipulated in REACH Article 20, the completeness check is performed within 3 weeks of the submission date.

5.8. In the case of a joint submission member registrant, is it sufficient for the lead registrant to submit a CSR with required improvements, or should the member registrant also submit an updated dossier with reference to the corrected CSR?

If the member registrant fully relies on a joint CSR submitted by the lead and has indicated this in his own dossier, then it is sufficient that the lead submits an improved CSR. However, the member registrant needs to ensure that the updated CSR and the use description in his own dossier are still synchronised with each other, and if not, the member registrant has to submit a spontaneous update of his registration.

If the lead registration dossier fails the completeness check then only the lead must submit an update to amend the failures by the completeness check deadline.

5.9. Could you clarify the requirement for the lead registrant of the joint submission to submit in their dossier all uses covered by the joint CSR. According REACH Article 11 the lead registrant does not have to submit the information under Article 10(1iii) on behalf of the co-registrants.

The lead registrant is always responsible for submitting his own uses under IUCLID section 3.5. In addition, the lead registrant is responsible for including in the dossier all the jointly submitted information. If the joint submission registrants have agreed that the CSR is done jointly, then the lead must report the joint uses in the lead dossier, as these are the basis for the joint CSR.

When the lead registrant dossier contains uses that are not relevant for the lead registrant, it is advisable to indicate this via the field 'Related assessment' in each use record in IUCLID section 3.5. The relevant option would be: "use assessed in a joint CSR but not a lead's own use".

5.10. Consider the following case: a substance is registered for the tonnage band 10-100 tpa; however all uses corresponding to Article 10 are below 10 tpa. Uses at higher yearly tonnages are Article 17/18 uses. It is necessary to include a CSR in the registration dossier?

The answer depends on how the registration has been performed.

- If it is a full Article 10 registration for the tonnage band 10-100 tpa, then all uses that are not explicitly indicated as Article 17/18 uses in section 3.5.1 – 3.5.3 of IUCLID must be assessed in a CSR, regardless of their yearly tonnage.
- If it is a full Article 10 registration for the tonnage band 1-10 tpa which is coupled with a registration under Article 17/18 for higher tonnages, then a CSR is not needed.

Whenever different types of uses are included in a registration, it is highly recommendable to document this in the field 'Registration/Notification status for the use'. This clarifies the uses that are expected to be assessed in the CSR and may also improve the correct prioritisation of the substance in ECHA's regulatory processes.

6. CHEMICAL SAFETY ASSESSMENT

6.1. If a substance is only classified for health hazards, but not for environmental hazards, is it necessary to perform an environmental assessment?

Yes, there is need to perform a full chemical safety assessment, including the environmental assessment. The environmental exposure assessment needs to address all environmental compartments where adverse effects have been observed in testing, and hence PNECs have been derived. It also applied if substances meet the criteria to be considered PBT or vPvB.

6.2. What is needed in terms of exposure assessment when no PNEC or DNEL for any compartment or route is derived, but still the substance meets the classification criteria for at least one endpoint?

If no PNECs or DNELs are derived in the hazard assessment, and the substance is not classified

for high human hazards without threshold (i.e. CMR or sensitiser) and is not considered PBT/vPvB, then no release/exposure quantification is expected.

6.3. If a substance is only classified as skin irrit. 2 but DNEL/PNEC values are available due to long term studies, does a full assessment for all uses need to be conducted and provided in the CSR?

Yes. An assessment is required for all uses for all exposure routes with DNEL and all environmental compartments with PNEC. Note that DNELs/PNECs should only be derived if effects have been seen in the study – you should not derive "hypothetical" DNEL/PNEC values based on the highest dose tested if no effect was observed.

6.4. If a substance is only classified for health hazards, but not for environmental hazards, and addition, there are no effects in the eco-toxicological studies observed – is there still the need to perform an environmental assessment?

An environmental assessment may be required in order to address exposure of humans via the environment (i.e. via food-chain, drinking water or local ambient air). However, if the assessment of humans via the environment is not required (please refer to the webinar presentation for criteria), then in the above situation also the environmental assessment can be omitted.

6.5. Do you need a full risk assessment if the substance is only classified for physical and chemical hazards?

Yes, you do if the physical and chemical classification corresponds to the endpoints referred to in REACH Article 14, and other human health hazards or environmental hazards have been identified in the hazard assessment.

6.6. You said that "human via the environment" assessment requires oral and inhalation assessments. However, if no adverse effect is noted for one of these routes, the assessment is normally not required. Can you clarify?

Correct, it covers oral exposure via food-chain and drinking water, and inhalation exposure via local air. However, if no systemic hazards for human health (oral or inhalation) or respiratory effects have been identified (i.e. no adverse effects seen), no exposure assessment for "human via environment" is required.

6.7. How is the "Speed of reaction" defined? Is it one day, one hour or less?

Usually you express it as half-life. You can also choose other ways of expressing, e.g. time until 99% of substance reacted, % of substance reacted after 1 min. It depends on what you want to demonstrate.

6.8. If some environmental compartments have PNECs but others are NHI (no hazard identified), will environmental exposure for every compartment need to be quantified in the CSR? And similarly for different worker/consumer exposure routes if some have DNELs but others NHI?

No exposure assessment and risk characterisation is required for environmental compartments/exposure routes for which the hazard conclusion is "no hazard identified".

However, if hazards have been identified in aquatic testing you usually also derive PNECs for soil and sediment via extrapolation.

6.9. A substance causes adverse effects in a repeated dose toxicity study at below the limit dose (i.e. there is a LOAEL), but the effects are not severe enough to meet the CLP hazard classification criteria. Do you have to derive a DNEL and do you have to conduct an exposure assessment? The substance is not classified for any other endpoint.

If the substance does not meet any classification for any endpoint, according to REACH, no exposure assessment is required. However, if an adverse effect relevant for humans has been observed a DNEL still has to be derived.

6.10. When a PNEC is calculated, does it make mandatory the exposure assessment and the risk characterization for the environment?

The need to include the exposure assessment and risk characterisation in the CSR is based on the hazard classification and PBT assessment of the substance, as per REACH Article 14(4). If this requirement is triggered, the derivation of PNECs will mean that the exposure assessment and risk characterisation for the environment has to be performed.

6.11. How should we handle a PNEC (e.g. for freshwater or marine water) that is above the substance's water solubility?

For substances with low water solubility it is important that the substance is tested for chronic toxicity at the level of water solubility. With appropriate testing, a PNEC above water solubility should not occur.

6.12. Is a PNEC required when effect was seen above the limit of classification (>100 mg/L for example)?

If no effect has been seen up to limit concentration in the test (100 mg/l), it can be concluded that no hazard has been identified, and hence no PNEC is to be derived.

6.13. If the test was performed above the "regulatory limit" of 100 mg/L (often in literature data) and an effect was seen for example above 1000 mg/L, does this require a PNEC to be derived?

ECHA suggests in its guidance to apply the limit dose in the standard test protocols to determine whether a hazard has been identified or not. Thus effects at 1000 mg/l would not trigger the derivation of a PNEC.

6.14. Is a PNEC required when, for example, effect was seen below 100 mg/L, but the substance is not classified for the environment because it is readily biodegradable?

If an acute effect is seen below 100 mg/l, a PNEC should be derived, even though no environmental classification is required.

6.15. If no hazard is seen at the saturated concentrations, does this waive the exposure assessment and the risk characterization for this specific hazard?

In case no effects have been observed at the saturated concentrations (in both short-term and long-term tests), the hazard conclusion should be set to "no hazard identified" for that compartment and therefore no exposure assessment and risk characterisation will be required for that compartment.

6.16. Can an example be given for how to justify that a CSR is not needed for monomers imported in polymers?

First determine the hazard of the monomer. Then select the applicable cut-off value from the CLP Regulation (e.g. 0.1; 1%, ...) and provide analytical evidence that (i) the free monomer concentration is lower than this value, and (ii) the monomer cannot re-occur during the life cycle of the polymer at a higher concentration than this, due to bonding type and no reaction with e.g. heat/water/UV expected that could break the bonding.

7. CHESAR

7.1. Will ECHA be running further Chesar training to support the increased focus on the CSR? Previously basic training has been provided but will advanced training be available?

At the moment we do not have plans to organise advanced Chesar training session. However, we are open to feedback and suggestions from our stakeholders. Keep an eye on the Chesar website; if new sessions will be organised, we will publish the information there.

7.2. Chesar delivers the exposure scenario that has to be shared with the downstream users. However, according to the regulation this has to be delivered in the relevant EU languages. How do we have to solve the translation issue?

Chesar offers the possibility to select any EU language in which you would like to generate the exposure scenarios for communication, and consequently Chesar provides translated template headings and sub-headings. To obtain fully translated exposure scenarios, you would need to import translations of the standard phrases which have been used in the exposure scenarios. At present however, we are not aware of any freely available translations of the standard phrase catalogue.