Webinar: Completeness check of REACH registration dossiers: what changes in 2023 and how you can prepare

Questions and answers

This document is based on the questions received during the webinar organised on 8 February 2023. Editorial changes have been made to improve clarity and similar questions have been combined.

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#	Question	Answer
	Completeness check process	
1	Hi. If I have a registration and it is not complete regarding the new rules, I now need to update it, but if I do not have the time to update it before the new rules come into force, what will happen? Is there a transition period?	There is no obligation to update your dossier after 1st of May just to satisfy the new rules. However, if you submit a dossier update after 1st of May, you need to have a complete dossier as per the new rules. If you plan to submit a registration update in Q2 of 2023, you may also consider submitting it before the 1st of May, when the new and amended completeness check rules are not yet in force.
2	If a dossier fails the first manual check, the problem is fixed, but then the dossier fails the second manual check on a different issue not raised in the first manual check, will the	The completeness check is always performed on the whole dossier and not only on the part that failed the first completeness check. Therefore, after the first completeness check, you are recommended not to amend

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	dossier update be rejected, or will that count as the first manual check fail?	any other parts of your dossier than those requested in order not to introduce any new failures. You should also ensure to run the IUCLID Validation assistant on every dossier to reduce the possibility of failures. To answer your question: if you introduce a new failure and your dossier is found to be incomplete the second time, this will lead to rejection of your dossier update.
3	If the registration (update or new registration) fails, what can we do as a next step? Can we make a new submission with updated information?	The completeness check cycle has two attempts to submit a complete 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. If the second submission is also found incomplete, then the submission is rejected. For a submission meant 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. After a rejection, you can submit a new dossier.
4	It was mentioned, that if the TCC is failed, there is only one more chance to correct the dossier. After that, the registration will be invalid. Is this correct? What will happen to failures in updates? Do we need to renew the registration and pay the registration fee again?	The completeness check cycle has two attempts to submit a complete dossier. If you fail the first time, you get a deadline of 4 months to correct the failures. If the second submission is also found incomplete, then the submission is rejected. 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 case your dossier update involved fees (e.g., for the increase in tonnage band or new confidentiality claims), ECHA will not reimburse these. Once you have received the rejection decision, you can submit a new update to your registration. If relevant, a new invoice is issued. However, you do not need to pay the registration fee again when updating your existing registration after a rejection.
5	What will be the situation in relation to dossier updates if for example new studies are required (Aquatic toxicity (long term) Degradation). These studies can take many months to complete, however there may be needs to update the dossier (e.g. C&L update) will the agency block all updates?	Information provided in the dossier must be complete at the time when submitted. If you have received an ECHA decision or draft decision requesting you to carry out a new test, then meanwhile you should provide a specific justification for waiving the data. In the field 'Justification for data waiving', select 'other:' and type the following sentence in the free text field: "This information will be submitted later

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		based on ECHA communication/decision number TPE/CCH/SEV-x-xxxxxxxxxx-xx xx", where you replace the "x"-characters with the decision/communication number issued to you by ECHA. Note that a communication number or decision number following a completeness check failure is not a valid justification to waive an information requirement.
6	Where can I find ECHA's criteria for which registration dossiers will go through a manual check and which dossiers will not go through manual check?	You will find more information on this in the document 'Information on manual verification at completeness check'.
7	Considering the invoice is sent by ECHA to co-registrant after completeness check has been done, in which cases the fees will not be reimbursed after failing completeness check?	The completeness check cycle has two attempts to submit a complete registration dossier. If you fail the first time you get a deadline of 4 months to correct the failures. If the second submission is also found incomplete, then the submission is rejected. If there was a paid fee related to the rejected submission, it will not be reimbursed.
8	To update a substance which is a member of a Category, should submit the entire category or only the substance of interest to pass TCC?	Completeness check is done on the registered substance. If your registered substance is part of a category, you can update just that substance. The relationship to the category is not directly checked in the completeness check, but it will be checked in an assessment of compliance. However, the presence of the category object is checked at the completeness check.
	IUCLID Validation assistant	
9	I believe that an XLS report will be available, in Validation assistant Tool (latest version) and could be used to analyse the actual content of the IUCLID databasis and allowed us to prepare the future modification before the official release april and avoid failure in May?	The updated Validation assistant can only be released in the next IUCLID update at the end of April. Until then, we recommend that you prepare for the changes by reviewing your existing dossiers with the help of the webinar material. If you are already in the process of preparing your dossier, you may also consider submitting it before 1st of May, when the new and amended completeness check rules are not yet in force.
10	Do you plan to review the QLT about SMILES in IUCLID? It is most of times present even if we use the suggested tool in the IUCLID validation assistant.	The SMILE validity check you are referring to is a quality reminder. If you follow the instructions provided in the Validation assistant message, you can ignore the check. It is there to alert you to double check but does not mean that there is an issue with your SMILE notation value. There is no review planned for this check.
11	I assume that the manual check is supported by a technical tool	There is no additional technical tool for the manual completeness check.

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	- which is not yet part of the validation assistant. Is it possible to make that - assumed - technical support for the manual check available as "inofficial tool"? This might help registrants to spot critical parts of the dossier.	To know the areas subject to manual checks, please consult the document 'Information on manual verification at completeness check'
12	It was pointed out that it is important to use the latest version of IUCLID when creating or updating existing dossiers. If you use IUCLID cloud I assume that you automatically are working in the latest version? Are there any disadvantages to use the cloud version compared to the download version?	You are correct! IUCLID Cloud is always the latest version. In relation to your question about disadvantages between IUCLID Cloud and desktop version, this we are not able to clarify during this webinar. Could you please send us your question using our contact form?
13	The current validation assistant is not capable to check dossiers with multiple assessment entities, which is particularly relevant for dossiers covering nano forms. Will this be possible in the future?	IUCLID Validation assistant can only detect that all information requirements have been addressed when the dossier is expected to contain one dataset of Annex VII-X data. Currently, there is no plan to further develop the validation assistant so that it could automatically validate data submitted in the dossiers covering multiple datasets.
14	the expected release minor (VERSION 6.27.4 AND 6.27.5) will be integrated with the validation assistant	Thank you for your question! The IUCLID minor version you refer to does not include the new checks described in this webinar. New rules apply as of new release of IUCLID 6 v7 scheduled for April 2023.
15	When justifications exists for a substance on category level with read-accross, would the new justification need to be entered on category level or would all end-points need to be filled at substance level as well to pass the new TCC ? Will a betta IUCLID be available to test dossiers before April?	The justification should be provided at the substance level prepared for the registration; category member substances, although linked to the registration dossier, are not subject to the completeness check. The information about IUCLID Beta version will be available at IUCLID website this month: https://iuclid6.echa.europa.eu/
	Boundary composition	
16	When adding the boundary composition details in a LR dossier, in section 1.2?, then should other entries also be made in this section?	For a lead registrant we would expect to find at least two records in section 1.2. A boundary composition which sets the limits for jointly submitted data. And a legal entity composition which covers the substance as produced/used by the registrant.
17	when the LR has successfully passed the Inquiry stage of a UVCB what is your recommendation for the boundary composition?	The Boundary composition should describe the collectively agreed data for other registrants in the same joint submission and set the limits for the jointly submitted data.
	Annexes VII-XI information requirements	
18	In June 2022, changes in testing strategy for in vitro genetic toxicity was published in an ECHA letter (in vitro MNT instead of choice between CAT and MNT). Is it still relevant here? Will it be	Section 8.4.2 of REACH annex VIII now mentions 'In vitro mammalian chromosomal aberration study or in vitro mammalian micronucleus study'. So, if reliable data are available for the in vitro chromosome

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	implemented in the regulation?	aberration study in mammalian cells (OECD TG 473) or for the in vitro micronucleus study in mammalian cells (OECD TG 487), then data from both of these tests are acceptable to be inserted in IUCLID dossier. Please note that ECHA recommends the in vitro MN test (487) because this test can detect both clastogenicity and aneugenicity (while the CA test/473 is optimised only for the detection of clastogenicity).
19	Are the new rules for mutagenicity studies applicable to all studies with all adequacies, i.e. are in vitro studies which are rated as "disregarded" and potentially also with reliability "not reliable" having a positive outcome expected to be followed-up with an in vivo study?	The logic applicable for the new completeness check rules will not change and is used across all IUCLID sections, not only for the Mutagenicity studies. This means that the rules are applicable for the IUCLID records for which the 'Adequacy of study' is indicated as 'key study' or 'weight of evidence'. A reduced number of rules is also applicable for the data waiving records. The field 'Reliability' is not a trigger for the completeness rules. Therefore, a positive result reported in a record/study with the adequacy 'disregarded due to major methodological deficiencies' will not trigger the need for a follow-up in-vivo record/study.
20	For the mutagenicity studies, when talking about Annex IX studies, the presenter said the you have to "propose or provide" the studies. Can you please confirm that any new study of Annex IX-X need to go trough TP before being run? Or it is only for animal testing? or only for vertebrates?	Indeed, for any new in vivo study for mutagenicity a testing proposal has to be submitted to ECHA and approved before the study can be performed. At the level of Annex IX and X, before conducting any new study, the registrant must submit a testing proposal. However, ECHA can also directly request an in vivo study for mutagenicity in a compliance check or substance evaluation decision and registrants will have to provide the study (or an adaptation).
21	Hello, thanks for the webinar. Regarding mutagenicity, if the classical in vitro studies are found positive under Annex VII or VIII, would you also accept additional alternative testing such as the 3D skin comet assay or the reconstructed skin micronucleus test? In order to avoid animal testing.	In cases where the 'in vitro studies are found positive', the provisions in Annex VII and VIII state that "… the registrant shall propose, or the Agency may require, an appropriate in vivo study referred to in Annex IX, point 8.4.4. The in vivo study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate". In such cases, Annex IX, point 8.4.4 says "An appropriate in vivo mammalian somatic cell genotoxicity study […] shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate." The ECHA guidance provides information on the nature of the 'appropriate in vivo mammalian somatic cell genotoxicity study': they are the comet assay (OECD TG 489), the transgenic rodent gene mutation test (OECD 488), the in vivo micronucleus test (OECD 474) and the

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		chromosomal aberration test (OECD 475). Data from alternative testing such as the 3D skin comet assay or the reconstructed skin micronucleus test can be used as additional supporting evidence. However, such data cannot replace the legal requirement to follow-up a positive reliable in vitro result with an appropriate in vivo mammalian somatic cell genotoxicity test.
22	section 8.4.2 In-vitro chromosome aberration study in mammalian cells/ in-vitro micronucleus study in mammalian cells: are both tests still accepted? was the in vitro MN not the preferred one? Same question for in vivo.	Section 8.4.2 of REACH annex VIII now mentions 'In vitro mammalian chromosomal aberration study or in vitro mammalian micronucleus study'. So indeed, if reliable data are available for the in vitro chromosome aberration study in mammalian cells (OECD TG 473) or for the in vitro micronucleus study in mammalian cells (OECD TG 487), then data from both these tests are acceptable to be inserted in IUCLID dossier. Please note that ECHA recommends the in vitro MN test (487) because this test can detect both clastogenicity and aneugenicity (while the CA test/473 is optimised only for the detection of clastogenicity). Similarly for in vivo tests: both in vivo CA test (OECD TG 475) and in vivo MN test (OECD TG 474) are acceptable to fulfil the data requirement for 8.4.4 to investigate the chromosomal aberration concern if the available data are reliable. Also for this test, the MN/474 is recommended. Please note that before performing any in vivo test, a registrant needs to submit a testing proposal and must wait for ECHA's decision before starting the test.
23	So, if you are under annex VII and you have a positive result for in vitro ames test (OECD 471), you must perform and in vitro chromosome aberration or micronucleus test and if you have also a positive result here, do you have to include a testing proposal for an in vivo and this level (annex VII)?	Indeed, for any new in vivo study for mutagenicity a testing proposal has to be submitted to ECHA and approved before the study can be performed, independently from the Annex at which it is required or triggered. But even if the in vivo study is triggered at Annex VII, the testing proposal will have to be included in IUCLID section 7.6.2 "Genetic toxicity in vivo".
24	What are the appropriate in vivo mutagenicity assays required?	The in-vivo genotoxicity study(es) will need to cover the observed concerns from the in-vitro studies, or the potential concerns which have not been addressed because of an in-vitro study(es) being inapplicable.
25	A WoE approach can be elaborate and therefore does not always fit in free-text fields in IUCLID. Is it acceptable to refer in the 'Justification for type of information' field to a WoE justification attached in the 'Attached justification' field?	The justification field takes 32000 characters, but in addition you can refer to an attached document.

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26	How to handle several READACROSS (RA) entries with "adequacy" WoE" for one endpoint? RA sources are to be linked with one, possibly more target summaries, and also as WoE-sources to different WoE-targets. This overlap sounds complex. Or do I misunderstand the technical operation to be undertaken?	Electronic cross-referencing aims to bring transparency as to which documents belong together. There must be a link to the respective RA source record from the RA target record. Suppose the RA target record contributes to a WoE approach according to Annex XI, 1.2. In this case, you need to make a link to it from the new WoE justification/conclusion document (introduced in this webinar). Note that read-across source documents are normally expected to be key studies which are on their own adequate and reliable enough to provide information on the concerned endpoint.
27	Q concerning WoE: if the WoE is built with read-across substances already structured as source (robust study summary) and target (read-across study summary) records in IUCLID - which endpoint study records (source or target records) have to be linked to the WoE endpoint created?	Electronic cross-referencing aims to bring transparency as to which documents belong together. There must be a link to the respective RA source record from the RA target record. Suppose the RA target record contributes to a WoE approach according to Annex XI, 1.2. In this case, you need to make a link to it from the new WoE justification/conclusion document (introduced in this webinar). Note that read-across source documents are normally expected to be key studies which are on their own adequate and reliable enough to provide information on the concerned endpoint.
28	If any new robust study documents flagged as weight-of - evidence are added to an existing dossier (to be re-submitted before May 2023) – will these then be regarded as "old" WoE documents (thus not necessarily requiring the new WoE structure)?	The WoE justification/conclusion record will be required when new documents with the 'adequacy of study' marked as 'weight of evidence' are added to the registration dossiers as of May 2023. For this, you will need the next IUCLID version, which will be released at the end of April. No action is required if the 'weight of evidence' documents were created before May 2023. However, we recommend adding a WoE justification/conclusion record for all the documents contributing to a WoE approach.
29	In the presentation it was shown that in the WoE record a value (e.g. NOAEL) has to be entered. Is this mandatory? When waiving acc. to Annex XI Sec. 1.2 WoE, sometimes it is not really possible to derive a NOAEL.	Yes, you need to provide something. You should provide a value, but if this is not possible, then you should provide a justification explaining why not. As background, WoE is meant to provide information which is (inter alia) adequate for risk management. To that extent, if the normal expectation is that you will get a NOAEL derived from the study, then the default expectation is that the WoE will also provide that NOAEL value.

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30	Waiving Annex XI Sec. 1.2 WoE: use data not generated for REACH purposes. If publications are used in the waiver, do we need to enter them as study records in IUCLID to be able to link them in the WoE record? Even if they were described in detail in a statement attached to the record?	If you are not substantially relying on the publication, and it is not an essential part of the WoE, you may be able to avoid making a study record. However, to the extent that you are relying upon the publication as an essential component of the WoE adaptation, you need to provide it as an endpoint study record so it can be assessed.
31	What is meant if WoE studies shall be of "good reliability"?	Overall, the WoE adaptation should provide reliable information. In order to use studies in a WoE, you need to have a view on their reliability. If they are all reliable, fine. If you don't know anything substantial about the study (e.g. an abstract), it is difficult to make a case that this can contribute because you cannot rely on it. Specific studies may have a particular reason why they are unreliable, and you may be able to directly address the cause of unreliability. To conclude, you need to make clear how the WoE adaptation is reliable. Note the background information, which is characterising the reliability of studies, e.g. Klimisch scores. See also Chapter R.4: Evaluation of available information of ECHA Guidance on Information Requirements and Chemical Safety Assessment - ECHA (europa.eu)
32	Is it MANDATORY to provide a Weight of evidence document using the Template file on ECHA website or is it used to strenghten the approach/strategy? Thank you.	The 'Weight of Evidence/Uncertainty' template available on the ECHA website is to guide you. It is not a mandatory document to be used. Similarly, the template text in IUCLID in the justification field is meant to help, but it is not a constraint.
33	As of May 2023, outcome of chemical safety assessment no longer considered as valid data waiving justification in IUCLID sections 5.2.2, 5.2.3, etc' However, will we still be able to use ANNEX XI. section 3. SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING for adapatation in testing requirements?	Yes. Suitable options to fullfill these REACH requirement(s) are: - Provide the standard required study; or - Provide a testing proposal; or - Provide an adaptation according to section 1 of Annex XI (use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across approach); or - Provide a data waiving based on column 2 of Annex IX, or on sections 2 or 3 of Annex XI (testing technically not possible, substance-tailored exposure-driven testing).

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34	How will justification for data waiving work if "other justification" is chosen and the standard phrases "(...) if the chemical safety assessment performed with Annex I indicates (...)" is not valid any longer?	If selection 'other' is chosen and the justification for data waiving is provided in the free text field, your justification must be in line with column 2 of the relevant REACH Annex or with sections 2 or 3 of Annex XI (testing technically not possible, substance-tailored exposure-driven testing). If none of these options is suitable you may need to consider which of the below options is suitable for your situation to fulfil any of this/these REACH requirement(s): • Provide the standard required study; or • Provide a testing proposal; or • Provide an adaptation according to section 1 of Annex XI (use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across approach)
35	If 'other' is used in a waiver, will the manual check reject the waiver if it is a non-standard waiver, or is it just to check information is provided?	When selection 'other' is used and a justification is provided in the free text field it will be manually verified. In order to pass the completeness check, your justification must be in line with column 2 of the relevant REACH Annex or with sections 2 or 3 of Annex XI (testing technically not possible, substance-tailored exposure-driven testing).
36	Q on the stand information/water solubility: indeed for metals we typically perform TDP testing and include them in the Wat Sol endpoint. Do you suggest to also include a waiving statement for 'regular way solubility' testing or is the TDP report enough? Thanks	The standard information requirement in REACH Annex VII section 7.7 is Water solubility. However, if your substance is a sparingly soluble metal compound, indeed, you need to waive the water solubility requirement, and at the same time, provide a record with the endpoint selection 'transformation / dissolution of metals and inorganic metal compounds'.
37	Surface tension is renamed "surface tension of an aqueous solution". What if the substance is not or poorly soluble in water ? A surface tension can also be measured versus air (chemical/air interface). Tx.	The REACH requirement in Annex VII section 7.6 refers to the "surface tension of an aqueous solution". Column 2 of this section 7.6 also mentions that "if the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted". If your substance falls under this solubility category but you still have data for a non aqueous solution, you can waive the requirement for the aqueous solution, but report other data in IUCLID section 4.10 under the Endpoint selection 'Surface tension, other'.
38	Thank you for the interesting webinar. Could you give one or two example of a valid long-term Fish weight of evidence justification, which might be enough to Waive the information requirment. Would a fast metabolization, low water solubility and low toxicity in chronic daphnia and alge be enough?	You are asking about the fish information requirements, and column 2 based adaptation, rather than Annex XI, 1.2 Weight of Evidence. You need to contact us via the ECHA helpdesk, and we will reply that way. Please send us your question using our contact form.

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39	Will manual check verify waiver conditions are fulfilled, or just it's in-line with column 2/Annex XI? i.e., if OECD 414 is waived based on column 2 waiver (low toxicological activity, it can be proven from toxicokinetic data...no exposure...) will the manual check look for TK data in the dossier?	At the completeness check level, ECHA only assess the completeness of the dossier and not the quality nor the compliance of the dossier. However, for a waiver to be considered complete, it must contain all the conditions that column 2 requires under one bullet point. For example, for OECD 414 at Annex IX, a complete waiver based on column 2 should contain references to (1) the substance having low toxicity, (2) no systemic absorption occurs and (3) there is no significant human exposure.
40	When you have an harmonised classication for an endpoint (e.g skin corrosion), will it be necesary to perfom an study and include it in the dossier?	Where a substance has a harmonised classification for an endpoint, the classification must be applied to the substance (and to mixtures containing it where applicable) and reported in the dossier, and no further study is necessary for the purpose of classification. However, performing the study can still be needed under REACH, for instance for risk assessment. Please also note that some of the provisions in REACH Annexes VII-X allow the adaptation or waiving of studies based on the classification of the substance for other endpoints. For instance, if the substance is classified as skin corrosion (Category 1), no skin sensitisation study needs to be conducted.
41	Follow-up Q on the harmonised classification: is this option (not perform a study when a harmonised classification is available) listed in any guidance document? Which source can be used as citation in such a waiver?	The conditions for adaptation of an information requirement are normally described in columns 1 and 2 of REACH Annexes VII-X. The possibility to waive a study based on classification and the conditions to fulfil for such an adaptation can differ between endpoints. As indicated in reply to the previous question, where a substance has a harmonised classification for an endpoint, this harmonised classification must be applied to the substance (and to mixtures containing it where applicable) and reported in the dossier, and no further study is necessary for the purpose of classification. However, performing the study can still be needed under REACH, for instance for risk assessment.
	Uses and exposure	
42	3.5.3 & 3.5.4 regarding polymers where the monomers are registred this is not necessary?	Uses of the monomer need to be reported only till polymerisation. The reporting of the uses of the polymer is nevertheless recommended for completeness of information. You are not expected to carry out an exposure assessment for the uses of the polymer.
43	Hello, you mentioned that Product Categories need to be added to Industrial and Professional uses. Do these Product Categories need to be included in the CSA?	Yes, consistency is needed between the use description in IUCLID and the exposure scenarios in the CSR. However, the dossier will not fail the Completeness Check if the PCs are not reported in the CSR for Industrial

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		and Professional uses.
44	Would a Product Category be required for the 'Formulation' exposure scenario included in IUCLID?	No, the field 'product category use' will become mandatory only for uses reported in sections: 3.5.3 Uses at industrial sites, and 3.5.4 Widespread uses by professional workers
45	If LR adds missing Product Category information for Industrial and Professional uses and submits an updated dossier to ECHA, will the co-registrant also have to submit the updated dossier?	Thank you for your question. Changes in use description impact all registrants (lead, members and individual). This means that both lead and member registrants need to add the missing product categories when they update their dossiers. However, the new requirements do not trigger automatic need for an update of a dossier.
46	How can the new iuclid validation requirements be met for ERC 8c, 8f or ERC 5 if a service life does not exist for the articles produced (e.g. if the substance is included in the article as such that no exposure can occur, the substance is fully converted or bound during inclusion into the matrix)? Follow-up question on service-life -> section 3.5 is relevant for identified uses only. So if no (service-life) use was identified by definiton due to the exemptions you stated above, there should be a technical option in IUCLID to not having to report a non-existing (service-life) use!	If you have selected ERC 5, ERC 8c or ERC 8f then you have to systematically report a Service life use. When you report one or more uses in Section 3.5.6: Service Life of IUCLID, and the substance you register meets the criteria of Article 14(4) of REACH for classification as hazardous (or considered PBT/vPvB), then your CSR must contain the corresponding exposure scenario(s). There are few exceptions to this rule, that you should justify preferably under the ES heading in the CSR: • Under certain conditions when a substance is contained in concentration in the article material below the cut-off values as laid down in Regulation 1272/2008 (CLP) in relation to the mixture classification • Under certain conditions when the substance reacts on use, and hence is not available for exposure anymore during service life. • For the use of polymers You will find more detailed information in the Q&A 1860: What is needed in the CSR when a service life use is reported in IUCLID?
47	In the registration of a monomer which is imported to EU only in reacted form, as a polymer, should section IUCLID 3.5 indicate "No identified uses for the substance"?	The reporting of the uses of a polymer is not mandatory but is recommended for the completeness of the information. An exposure assessment for the uses of the polymer is nevertheless not expected. If you do not report any use, you need to provide a justification in section 3.5.0, in the picklist 'Justification for no uses reported'. In your case you will have to select "other" and explain that it is an imported polymer. Nevertheless, if you have made an exposure-based adaptation for the information requirement, you should describe the uses of the polymer and

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		assess them.
48	Hello! For which substances that are present in a mixture is a chemical safety assessment needed? Thank you!	A chemical safety assessment / report is required in the registration of substances that are manufactured or imported in more than 10 tonnes per year. However, the exposure assessment of a specific use may be omitted if the substance is used in a mixture or article at a concentration level below the mixture classification thresholds as laid down Regulation 1272/2008 (CLP). For more details please check here (Q&A 1860). To add, a chemical safety assessment is only required if the substance fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 (Article 14 (4)).
49	If the registered substance react to a new substance and become part of the article. In the service life, should the new substance be assumed to be the registered substance (in terms of concentration present in the article)? can the registered substance's DNEL still be used even though it's acutalll	You can find more information on "What is needed in the CSR when a service life use is reported in IUCLID?" in the Q&A 1860 (in particular in section B) Justification related to reaction on use. When you cannot justify the absence of assessment for the transformations products of the substance you will need to carry out the assessment on the basis of the transformation product characteristics.
	Registration process - general	
50	when updating the registration due to the lead register updated the dossier, what extra updates needs to be performed? guide? is there a dead-line for updating the registration after the lead has updated?	The 'Implementing regulation on dossier updates' clarified the deadlines to submit a dossier update. This and other information on updating your dossier can be found here: https://echa.europa.eu/keeping-your-dossier-up-to-date. The implementing regulation is linked at the bottom of the page under 'related' or can be accessed directly here: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R1435
51	A follow up on the guidance for updating a joint registration. If there are no changes in my own part of the dossier, do I need to update the dossier? There are additions in the Lead dossier but they are submitted by LR.	If there are no changes required in your own dossier then there is no need to submit an update dossier. The lead registrant will be covering any jointly submitted data requirements.
52	Do I need to create the dossier for all ingredients in the finished products i manufacture, or all ingredients regardless if its used or not?	You have to register the substances you manufacture or import from outside EU in > 1 t/y. In case you are formulating mixture (you are a mixture producer), you have to register all ingredients of your mixture that you import >1t. For the ingredients you purchase in EU, you need to check that your uses and the uses of your supply chain is covered by the registration of your supplier. More information here.
53	Hello, are article manufacturers affected by the changes that	If you need to register according to article 7(1) of REACH, then you may

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	will take place in May 2023?	be impacted by the changes introduced, as any other registrants.
54	Hello! A substance not registered by exemptions from the obligation to register in accordance with Article 2(7)(b), but classified under CLP and placed on the market in several countries, is it necessary to make a PCN notification?	Thank you for your question, however we are only able to answer questions related to the content of the webinar. Please use our contact forms to submit your question: https://echa.europa.eu/contact
55	In case of a Substance without full Registration but with a Registration of intermediates isolated dossier, if the legal entity intends to do any scientific experimentation, analysis or chemical research in quantities above 1 tonne/year, must the company submit a PPORD notification to ECHA?	Yes, it is expected that the PPORD ACTIVITY is specifically covered by a PPORD notification in the absence of a full Registration that also includes among the identified uses the activity foreseen in the research programme. More specifically the type of uses 'scientific experimentation, analysis or chemical research' would reasonably differ from what can be covered in an isolated intermediate registration.
	Other	
56	For future webinars it would be very helpful if the presenters are using a "laserpointer" since it is difficult to follow what detail on the slide is currently explained - especially when several screenshots are shown on a page. Thanks in advance.	Thank you for your feedback. We will consider it for the future webinars.
57	Which type of academic research suitable for completeness check of Reach? Is Uni central or multi central research suitable for non Eu or candidate of EU countries?	We kindly ask you to submit this question via the contact form so it can be directed to the relevant experts.
58	How is it possible to get all Q+A as a file at the end of the session (e.g. as a download) since the information is/may be valuable for many companies?	The full Q&A transcript will be published shortly after the webinar. You will find it on the webinar page and it will be announced in our Weekly news bulletin. If you haven't already, you can subscribe to it here.