Webinar:
Questions and answers

ECHA organised a webinar on 4 March 2021 on Reach-IT new functionalities. It explained the features implemented in the last version of REACH-IT (v3.9): new section on the co-registrants page with contact details of submitters of (robust) study summaries and new section on the joint submission page with information on ongoing and past dossier evaluations.

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 on REACH-IT functionalities, contact us or refer to our support material.

Question	Answer
Will the slides be made available (independent of the youtube video)? this would be highly appreciated. Thanks	Yes, we will publish the presentations in webinar's page in the coming days: https://echa.europa.eu/-/reach-it-new-functionalities
I have a question on slide 16 - deadline information. What kind of deadline does it refer to? Is there a legal deadline to submit a lead dossier when creating a new Joint Submission? Where can I find additional information? Thanks	Hi, the deadline introduced for the lead dossier submission is not one coming from the REACH regulation. We have implemented this to avoid cases, where a potential registrant creates a joint submission, but does not submit the lead dossier for a long time. With this, they could block any other new registrants to enter the market. This way the lead has 3 months to submit the lead dossier from the date of the creation of the joint submission. Following the end of the transitional regime (with the 3 registration deadlines), we do not see a need to use the creation of a

	joint submission as a communication method towards other registrants, to indicate that there is a lead. A joint submission should be created, when the lead is (close to) ready to submit the lead dossier.
Do you have a time frame for when will it be available to see the (Joint Submission) reasons for the updates. it would be an amazing step forward?	It is expected that this feature will go live with the new version of REACH-IT to be released during April.
Inside REACH-IT under "Joint submission - registration, Search and view", is there a limit to the number of substances that you can "Download member details" for in one go? I just tried to download 16 substances at once, which came up with an error page.	There is not a limit with the number of Joint Submissions to be exported. There might be a performance with large numbers, however it should not be the case for 16 substances. Please use our contact forms to submit your case (via echa.europa.eu/contact) and we can further investigate
There is currently a manual on creating C&L notifications that focuses on the manual process in IUCLID. For the companies interested in creating the IUCLID dossiers offline and then submitting via system-2-system: Will there be any further technical guidance or example files be provided?	We are preparing all the relevant documentation (e.g. System to System integration, C&L notification format, developers' guide to the IUCLID format and C&L data model, API specification etc.). The full support documentation will be available later this year together with the C&L S2S functionality going live in REACH-IT
For S2S C&L bulk notifications, is it possible to submit updates for existing C&L notifications? Thanks, is there a guidance document where we can find how this is done? If it is in Iuclid format, which systems are referred here then?	Thank you for your question. Just to clarify that with the S2S C&L notification functionality you will be able to submit a dossier in IUCLID format containing a single C&L notification (not one single file containing a bulk of notifications). Having said that, yes you will be able to submit updates of previous notifications. Yes, we are preparing all the relevant documentation (e.g. System to System integration, C&L notification format, developers' guide to the IUCLID format and C&L data model, API specification etc.). The full support documentation will be available later this year together with the C&L S2S functionality going live in REACH-IT
We have many registrations that have come to us via OR change. If ECHA has made dossier evaluation before the OR change, can the new OR see in their REACH-IT also decisions made before the registration has been transfered to them?	Yes the new OR can see the decisions, in the section "Key documents" of the reference number page.

At which point after dossier evaluation starten can the dossier not longer be updated?	You can update your registration dossier at anytime. However, ECHA will not consider the updates during the decision making. The updates submitted after the draft decision are considered when the deadline to provide the information (given in the adopted decision) has expired.
When ECHA has initiated a Dossier compliance Check, at what point of time does ECHA stop to consider dossier update? As soon as the CCH was initiated or as soon as the draft decision was issued?	ECHA takes the dossier updates into account until a draft decision is issued.
Does the REACH-IT message sent when CCH has started include EC number(s) of substances concerned?	Yes, it is planned to include the EC number in the REACH-IT message, but please take into consideration that this future is still under development.
Concerning the 12 year rule, this does only apply to the obligation to data sharing of the SAME substance covered in the Joint Submission, correct? If data is needed for read-across purposes (which is NOT legally mandatory under REACH!) data sharing negotiations must take place with the data owners.	Thank you for your question. The fact that read-across is not explicitly mandatory under REACH does not affect the scope of Article 25(3). This provision enables a manufacturer or importer to use, for the purpose of registration, any (robust) study summary submitted in the framework of a registration under REACH. This provision does not specify that this must be a registration on the same substance. Therefore, in order to achieve the objective of promoting alternative methods for the assessment of hazards (Recital 1 and Article 1), the right to use (robust) study summaries submitted at least 12 years previously must apply to data submitted on analogue substance for read-across purpose.
Are the RSS of studies submitted at least 12 years ago also free to use for the purpose of registrations under EU-BPR? Thanks for your answer. Does it mean that applicants for EU-BPR that are interested in EU-REACH studies submitted at least 12 years ago must pay for the RSS and the right to use while potential registrants under REACH must not? I understand that this is the case. The same rational should apply for read-across purposes under REACH.	The RSS studies submitted at least 12 years ago cannot be used for the purpose of applications under EU-BPR. Please consider that there is here is no cross data sharing obligations between the BPR and REACH. However, The fact that read-across is not explicitly mandatory under REACH does not affect the scope of Article 25(3). This provision enable a manufacture or importer to use for the purpose of registration any robust study summary submitted in the framework of a registration under REACH. This provision does not specify that this must be a registration on the same substance. Therefore, in order to achieve the objective of promoting alternative methods for the assessment of hazards (Recital 1 and Article 1), the right to use robust study summaries submitted at least 12 years previously must apply to data submitted on analogue substance

	for read-across purpose.
Are the RSS of studies submitted at least 12 years ago also free to use for the purpose of read across to another substance for REACH registration? No. This should not be the case. Data Access negotiations with the data owners (according to the ECHA Guidance Document on Data Sharing) MUST take place. Data sharing for read-across is not legally mandatory under REACH.	Thank you for your question. The fact that read-across is not explicitly mandatory under REACH does not affect the scope of Article 25(3). This provision enables a manufacturer or importer to use, for the purpose of registration, any (robust) study summary submitted in the framework of a registration under REACH. This provision does not specify that this must be a registration on the same substance. Therefore, in order to achieve the objective of promoting alternative methods for the assessment of hazards (Recital 1 and Article 1), the right to use (robust) study summaries submitted at least 12 years previously must apply to data submitted on analogue substance for read-across purpose. Please also note that, the previous registrants cannot claim compensation from you for the (robust) study summaries submitted more than 12 years ago, even though these robust study summaries are going to be used for read-across purposes.
In which format does ECHA provide the RSS of studies submitted at least 12 years ago for inquiries for NONS? Just in PDF-format or is it possible to receive it in i6z-format as well? Can this information be downloaded from within REACH-IT after successfull inquiry? How do we request the RSS?	In the cases when ECHA provides the RSS of NONS/REACH dossiers, the RSS are in PDF format. At this moment, ECHA does not provide the RSS in any other format. The RSSs cannot be downloaded from within REACH IT. You need to inquiry to have access to the co-registrants page. From the co-registrants page, in the studies section, you can see which registrant owns the data and request it from the registrant. An explained in the presentation today, ECHA will no longer provide the RSSs studies by default.
Just for a better understanding of the big picture. Regarding the 12 years period for data access: Why was this set to 12 years? Is there a historical background/reason? Yes, that was mentioned in the webinar. But any reason why it was set to 12?	The 12 year period stems from the REACH regulation. The reasoning will have to be found in the legislative documents leading to the adoption of the regulation. These documents are available in the Council registry of document on the Council's website and on the European Parliament website.
is it possible to have a separate contact details added in co-registrant page on ReachIT with Studies section? yes, I would like to add consortia email as contact Where in ReachIT or dossier I can select the consortia contact to be used only for studies and for other requests the company contact	Thank you for your question. Do you mean that you would want to have different contact details for your company shown under the 'studies' section in the co-registrants page for matters only relating to studies, and then you would have different company contact details for other matters? Currently the contact details in the 'studies' section on the co-registrants page can be accessed by clicking the respective 'Endpoint name' after

	which the contact details, available for us in REACH-IT, are displayed for both 'studies submitted less than 12 years ago' and 'Studies submitted at least 12 years ago', if available. Thank you for the clarification. At the moment the contact details shown in the 'studies' section on the co-registrants page are taken when the dossier is submitted to REACH-IT and when the submitter enters their contact details into REACH-IT. Therefore, should you wish to update the contact details for the studies, you can do this by submitting a new dossier and updating the relevant contact details in REACH-IT. Thank you for the question. Currently it is only possible to insert one set of contact details when you submit your dossier to REACH-IT and those contact details will be displayed in the 'studies' section on the co-registrants page. We will take note of your suggestion and will see if it would be possible to carry out it in the future.
Regarding the 12 years period for data access: should we take into account the date of submission of the data or the date of the study report? Thank you.	Thank you for your question. The submission date is the date that is taken into account not the date when the study was done. Further information can be found in the Guidance on data sharing, under The "12-year rule" `.
Is it possible to download (all) the details on dossier evaluation steps - for a single substance or for all substances/registration in the legal entity? I have the same question for the information on data sharing (e.g. test <>12 years...). thanks	No , so far it is not possible to download this information for the dossier dossier evaluation either for the data sharing. We take note about the request and we will evaluate it as further improvement.
There was a question and answer (copied in summary format) QUOTE which format does ECHA provide the RSS of studies submitted at least 12 years ago ? Moderator 9:32 AM ECHA provides the RSS in PDF. The RSSs can't be downloaded from REACH IT. UNQUOTE My question is: How do I request the RSS?	Thank you for your question. You need to inquiry to have access to the co-registrants page. From the co-registrants page, in the 'studies' section, you can see which registrant owns the (R)SS and you can also see the contact details. You need to request the (R)SS from the (R)SS submitter(s) directly. As explained in the presentation today, ECHA will no longer provide the (R)SSs studies by default.
In case you update an RSS for a same study report (eg with more details), will the clock then again start ticking for 12 years? Or will it be the original submission date which counts?	
Does the co-registrant page have a message board where the LR can share information with the existing or potential registrant regarding the substance (such as status of ongoing studies)?	Currently there is not such functionality. Thank you in any case for the suggestion.

Is an LoA needed to refer to study summaries submitted at least 12 years ago in any case?	REACH does not specify the mechanism for use of (robust) study summaries submitted more than 12 years earlier for registration purposes. The previous registrant should not in any case claim compensation for such (robust) study summaries if those study summaries are part of the data package the potential registrant purchases to fulfil the data requirement under REACH.
Will the RSS for studies > 12 years still be provided as pdf with the inquiry result?	The current practice is that ECHA provides pdfs of (Robust) Study Summaries (RSS) submitted more then 12 years previously (if any) ONLY in the case where the RSS are submitted under Directive 67/548/EEC for which NO contact details are known. In case the contact details of the data submitter are known and the study was submitted more then 12 years early, you will find on the "Co-Registrants" page the UUIDs of the corresponding RSS. Note that pursuant to Article 25(3) of the REACH Regulation, you can use any study summaries or robust study summaries hereof for registration purposes without compensation. You are advised to contact the previous registrant to obtain the RSS.
A substance dossier with a study summary has been submitted as read cross five years later than for the original tested substance and its study summary. Which date of study summary will be taken into account when considering the 12 year rule	The submission date of a (robust) study summary is determined by the submission date of the specific study summary, Thus the 'original' summary has the submission date 12 years ago and the summary 'for read-across purposes' has a submission date 5 years later.
Are REACH-IT able to distinguish between 12+ year old RSS and endpoints that have had an RSS for 12+ years, but have updated information incorporated?	Thank you for your question. Yes, each submission has it own time stamp and each (R)SS is treated as a (R)SS of its' own even if it is the same study.
RSS are often updated and sometimes replaced (e.g. if a service provider has improved the summary). Will this still be recognised as an RSS submitted in e.g. 2010? So, if the RSS has been updated within the 12 years for the same study behind it, the clock starts ticking again?	Thank you for your question. Yes, each submission has it own time stamp and each RSS is treated as a RSS of its' own, even though it is the same study. Each submission will have its own "clock ticking". Each RSS submitted in different submissions is a different RSS.
Is it allowed/possible that a TPR purchases a study/RSS from the study owner (competitor) on behalf of the registrant without naming this registrant (for reasons of confidentiality)?	Your question does not fall well in the scope of this Webinar. Please submit your question via ECHA contact form available at https://echa.europa.eu/contact
It is a good improvement that you can see per endpoint what studies are older than 12 years. Will functionality be to get a table of all studies that	Currently there is not such functionality. Thank you in any case for the

have expired for the 12 year rule?	suggestion.
Does this mean that for an endpoint needed if an additional study is submitted later, these two studies could be placed one as study submitted at least 12 years earlier and the other as less than 12 years.	Yes, this is correct.
Thanks, Eduardo and Tuomas, for the presentation. What about if our substance will read-across from other substances that have submitted studies for more than 12 years. How can we know that information, Can the LR from the other consortium claim compensation even if the data is old?. Thanks, where can I see if the data from other LR is more than 12 year. I can see some information from substance factsheet, but for some it is confidential. How can we really know that it is more than 12 years or not. Is it responsibility of the LR to check its own data that is old that 12 years?.	The previous registrants cannot claim compensation from you for the robust study summaries submitted more than 12 years ago, even though these robust study summaries are going to be used for read-across purposes. To learn whether the RSSs have been submitted more than 12 years ago for read-across you will have to contact ECHA through its contact form (echa.europa.eu/contact).
Is it possible to download (all) the details on dossier evaluation steps - for a single substance or for all substances/registration in the legal entity? I have the same question for the information on data sharing (e.g. test <>12 years...). thanks	No , so far it is not possible to download this information for the dossier dossier evaluation either for the data sharing. We take note about the request and we will evaluate it as further improvement.