20 February 2018

Questions and answers - REACH 2018 Stakeholders' Day

At the REACH 2018 Stakeholders' Day held 31 January 2018, we were not able to answer all questions received online due to limited time. We collected 50 unanswered questions and provide answers in this document. For any additional clarification, please contact us at https://echa.europa.eu/contact.

If we are a manufacturer of a substance that has been pre-registered but will not be registered for the deadline 31.05.2018, can we produce this substance up to that deadline date, storage it and after that deadline only sell this substance from our storage simply as a distributor?

The last registration deadline (31 May 2018) for the phase-in regime substances concerns companies that have pre-registered their substances and manufacture or import the substances in low volumes, between 1-100 tonnes a year. A company that imports or manufactures a substance at quantities of 100 tonnes or more in 2018 must submit a registration before placing the substance on the market. Q&A 40 explains that a substance can still be used/supplied after the registration deadline by suppliers and downstream users down the supply chain. A manufacturer/importer that has ceased manufacture or import before the registration deadline can thus become only a supplier and keep supplying those quantities of the substance that they manufactured or imported before the registration deadline.

When registering a full Annex VII Dossier (including tests, RSS) how to calculate the joint submission costs for members who only want to join for Intermediate use? Do you recommend a fixed rate? If yes, what should it cover? If no, how else to calculate the costs?

In case of a normal joint submission, registrants of intermediates (with the exception of transported isolated intermediates in volumes above 1 000 tonnes per year) which are largely exempt from the obligation to submit the standard information specified in Annexes VII to XI, cannot be forced to share in the joint submission costs related to the data they don't need (registrants of intermediates are only required to submit any information available to them for free). Intermediate registrants are obliged to share administrative fees of the joint submission, which should be in proportion to their reduced information requirements.

What is your advice for downstream users if a supplier does not register a pre-registered substance, which has not be pre-registered by ourselves?

In case a supplier has no intention to register, a downstream user may consider taking up the role of an importer and submitting a registration, or engaging another importer to do so on their behalf. If the dossier cannot be totally compliant with the REACH requirements due to unexpected circumstances, companies should contact ECHA as soon as they become aware of the situation. See our news here: https://echa.europa.eu/-/helping-registrants-in-exceptional-cases.

After the registration deadline 31.05.2018, the company first time coming to the EU market - is the registration dossier needed immediately before coming to the EU market if tonnage is above 1 t/y? How to calculate the tonnage for registration dossier?

Any potential registrant aiming to enter the EU market after 31 May 2018, has to inquire from ECHA whether a registration has already been made for the same substance (Article 26 of the REACH Regulation). The volume of the substance you manufacture or import needs to be determined in tonnes per calendar year. The calendar year is from 1 January to 31 December. A volume at or above one tonne per calendar year triggers the registration obligation. For more information, you can consult: https://echa.europa.eu/reach-2018

What measures ECHA will take to improve the communication with lead registrant (or other party in charge of letter of access issues)? As a sales director I am really struggling to find out the LoA fees which are essential factors when compiling a quotation for customer.

Data sharing and related negotiations are in the responsibility of the registrants. ECHA has prepared advice to help companies negotiate. Under REACH, the parties need to make every effort to come to an agreement. If the negotiations fail, the dispute procedure is foreseen as a last resort. For more information: https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations

There is a lot of discussion when buying letter of access for transported isolated intermediates < 1.000 tpa. If you do the registration yourself, you only provide data available to you. However, there are companies asking for >10k EUR to join. Is it possible that ECHA grants an opt out by default?

ECHA cannot grant a token to join a joint submission by default for a company who wants to opt-out. You can discuss the conditions of joining the joint submission with the lead registrant of the joint submission you need to join. In case of opt out, you still need to share administrative fees of the joint submission, which should be in proportion to reduced information requirements. As an alternative for joining the full joint submission, you can create a parallel joint submission for intermediates only. Registrants of intermediates (less than 1000 tonnes per year) cannot be forced to share in the costs related to data they don't need. Registrants of intermediates are only required to submit any information available to them for free.

Can you please explain the formulator legal obligation to ensure that mixtures they are using are fully REACH registered? How can formulators be 100% sure on 1st June 2018 that they are using fully registered mixtures if so many manufacturers/importers are still working on obtaining registrations?

In case a supplier has no intention to register, a downstream user may consider taking up the role of an importer and submitting a registration, or engaging another importer to do so on their behalf. If the dossier cannot be totally compliant with the REACH requirements due to unexpected circumstances, companies should contact ECHA as soon as they become aware of the situation. See our news here: https://echa.europa.eu/-/helping-registrants-in-exceptional-cases.

A company is importing between 1-100 tonnes and decides not to register and stops all import before May 2018 (similar to Example Guidance document 6a). When can the company restart their imports in volumes below one tonne per year without having the requirement of submitting a registration?

No full reply available due to the pending decision from the European Commission about the transitional period. What is clear is, if you restart import after 1 June 2018 and your overall tonnage for the calendar year 2018 (January to December) is above 1 tonne, you have registration obligations.

Will ECHA officially communicate a temporary waiver option - aligned with 2010 & 2013 deadlines - that a company will be given a registration number even if some data would be still missing, subject to providing prove that testing had been placed with a lab?

Yes, this and other DCG solutions for companies in exceptional situations were communicated by ECHA on 31 January. See our news here: https://echa.europa.eu/-/helping-registrants-in-exceptional-cases.

Since the pre-registration is not possible any more, will the inquiry always be the path to register a substance in the future, also in cases where the substance is already registered by other companies? We find the process relatively time consuming.

The inquiry process is the "normal" way to get to the EU market. This is to ensure that data is shared by all registrants of the same substance, and that the joint submission obligation can be met. For more information, consult the following link: https://echa.europa.eu/reach-2018.

Christel Musset said there is no fee for updating registration dossier except for a bigger tonnage band. So what is it table 3 "Fees for other updates", annex III of regulation 2015/864 ?

Table 3, Fees for other updates are to be considered when informing the Agency about changes, e.g. merger, split or only representative change. A spontaneous update within the same tonnage band, where the registrant would include new/updated information is free of charge.

What happens if we don't match the SIP that has been submitted, but only slightly different. The lead agrees we have same substance but will not update the dossier due to their work on other dossiers. Will our joint submission be rejected or can we put in an explanation?

As you state that both you and the lead registrant agree that you have the same substance then indeed you should be part of the same joint registration. The boundary composition in the lead registrant dossier will need to be amended to include your composition, and we understand from your question that the lead registrant has agreed to do this but not until after you have submitted your registration dossier. In such a case it would be wise to include an explanation in your registration dossier and attach any documentation, confirming that the lead registrant has agreed to do this. IUCLID Section 1.2 in the description field would be a good place to include/attach such an explanation. Your registration will not be rejected on this basis.

Tonnages that have been pre-registered and manufactured or imported before May 31st stay compliant in the market if the import and manufacture is completely ceased. Is this right?

Yes. In case you cease manufacturing or importing of pre-registered substances before the relevant registration deadline and simply act as a supplier after that, you may continue to use and/or supply these quantities of the substance. For more information, read Q&A 40 at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0040

The manufacturer before the 31.05.2015 ceases the manufacturing of the pre-registered substance and changes his legal entity status as a distributor. Is it possible that this "distributor" sells from storage the substances produced by him

without the registration after the deadline?

Yes, although this aim can be achieved without changing your legal entity status. REACH does not impose registration obligations on downstream users, distributors or suppliers of substances. In case you cease manufacturing of pre-registered substances before the relevant registration deadline and simply act as a distributor after that, you may continue to use and/or supply these quantities of the substance. Nevertheless, technically it is possible to change your legal entity status from manufacturer to distributor. For more information, you can read Q&A 40 at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0040

If we purchase a raw material and the supplier is REACH registered under our use, are we covered by their registration?

Assuming that you are an EU-based company and you buy substances from a company based in the EU, then you are a downstream user and do not have a registration obligation. If you import substances from outside the EU, you are an importer and are subject to the registration obligation unless your non-EU supplier has appointed an only representative to fulfil all the REACH obligations related to the import of the substance.

Can we submit a REACH dossier when not all test reports are received yet?

Your case might be covered by the so called DCG solution 10.3. Please have a look at the notice on the use of the DCG issues to get an overview of what documentation is needed to benefit from the solution and what are the expected consequences. It is available here: https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues. There you also find instructions how to proceed if you think the solution applies to you.

Is there any kind of inspection on importers of end products? Most of them are for consumer use and substances are not registered.

Registration obligations apply to all substances unless the substance or its use is specifically exempted. Consumer products are not exempted from REACH obligations. Enforcement actions can equally be taken against incompliant consumer products.

ECHA has a statement that SIEFs no longer exist as of 0.06.19. However, all of the discussions rely on a SIEF in principle being present. Can ECHA change the statement to 'SIEFs should continue to exist for as long as the registration remains valid?' This would be a clearer message for industry.

The issue of SIEF functions after the last registration deadline is under discussion with the European Commission. In any case, there will be a need for the co-registrants to cooperate after the deadline, e.g. for compliance check or substance evaluation, but also to accommodate newcomers. Therefore, the co-registrants will need to have an agreement in place for the cooperation after the deadline.

How can we get better predictability regarding the length of the 'reasonable deadline' that ECHA will set under REACH Article 20(2) to complete the dossier after 31.5.2018?

The reasonable deadline set under Article 20(2) refers to the deadline given to update a dossier after failing completeness check. The deadline given by ECHA in these cases is of 4 months after the issue of the first decision. More information on completeness check at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Completeness+check and

https://echa.europa.eu/-/completeness-check-preparing-a-registration-dossier-that-can-be-successfully-submitted-to-echa

How to decide if the letter of access is transparent - since there are many lead registrants or consortia that can give long complicated excel for cost justification. And for SME it's difficult to decide if the cost is fair or not?

The potential and existing registrants need to make every effort in the negotiations. As a potential registrant, this means to challenge everything you disagree with and to ask for clarification in case of unclarity. In turn, the other party needs to give you understandable information. This is part of their obligation to make every effort. If you cannot come to an agreement, as a last resort, you can file a dispute to ECHA. For more information, see: https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations.

If required, the use of a DCG exemption will result in a lead registrant not receiving a registration number until dossier acceptance. However, co-registrants within the same SIEF can be granted a registration number before the lead registrant, correct? If correct, how is that a fair solution?

No, the member registrants will not get a registration number either. What will happen is that the LR gets a submission number upon submission, and, after passing the completeness check they will get a registration number. In a similar manner, the members will get a submission number upon submission (which they can do right after the lead dossier has passed the business rule check), and the registration number only after the joint part of the dossier (submitted by the lead) and their member registration dossier both have passed the completeness check.

As a formulator / downstream user we have been trying to get clarity from our supplier about registration intentions. Can we stockpile substances before 31 May to ensure some level of business continuity and allow for reformulation if needed after 31 May?

The use of a substance manufactured or imported before the registration deadline can continue after the deadline. Q&A 40 explains that a substance can still be used/supplied after the registration deadline by suppliers and downstream users down the supply chain. A manufacturer/importer that has ceased manufacture or import before the registration deadline can become only a distributor and keep supplying those quantities of the substance that they manufactured or imported before the registration deadline.

If a confidentiality claim is rejected, is the respective fee refunded?

No, the fee covers the work done on the assessment of the confidentiality claim.

If the dossier submitted by a lead registrant will fail at the manual completeness check, will the co-registrants be able in any case to submit their dossier?

Co-registrants can start submitting their member dossiers as soon as the lead dossier has passed business rules.

It is quite common not to receive answers on time from lead registrants lately, how can we address this issue?

If the lead registrant continues not to reply, you can file a data sharing / joint submission dispute.

Capacities of EU laboratories are already very limited since late spring/early summer 2017. Commissioning of tests is thus - even if done early - not ensuring a timely availability of test reports delaying consequently the entire registration process and risking the deadline in quite a no. of cases.

This is a known issue, addressed by the DCG solution 10.3. Please have a look at the notice on the use of the DCG issues to get an overview of what documentation is needed to benefit from the solution and what are the expected consequences. It is available here: https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues.

LoA fees: most of the time, very high costs; reliability of data is low. As co-registrant (SME) I do not have the power to do my own registration and at the end I agree to pay the LoA fee. I'll have to pay for next endpoints required after dossier evaluation. More control on consortium activities?

The potential and existing registrants need to make every effort in the negotiations. As a potential registrant, this means to challenge everything you disagree with and to ask for clarification in case of unclarities. In turn, the other party needs to give you understandable information. This is part of their obligation to make every effort. If you cannot come to an agreement, as a last resort, you can file a dispute to ECHA.

The joint dossier is a common responsibility of all co-registrants. If you disagree with the selection of the data (e.g. because of low reliability), you need to discuss this with your co-registrants. If you cannot agree to jointly submit better data, you may consider to opt-out in accordance with Article 11(3). For more information, see: https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations.

We're buying several letters of access. Are there any studies on the variation of LoA cost after June, i.e. is there an average percentage of refund we can take in account due to the number of companies which will buy LoA for this deadline?

The price of the Letter of Access (LoA) depends on a number of factors, e.g. the number of members in the joint submission, their tonnage band, the cost of the actual data, etc., and are dependent on e.g. earlier reimbursements and other contractual arrangements. Therefore, potential reimbursements are expected to differ very widely. ECHA is not aware of any study on the expected ranges for reimbursements.

What restriction process and which conditions are meant by the European Commission in footnote 50 of the EU Plastic Strategy?

You may find more information on the request of the Commission from this page: https://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance-rev/18301/term

The restriction process in REACH is described on ECHA's website: https://echa.europa.eu/regulations/reach/restrictions/restriction-procedure.

How important is it to submit the 'sameness test report' along with the dossier? Is there an option to submit the dossier first, followed by test report?

We cannot be certain what you mean by a "sameness test report". What is important is that sameness is agreed amongst all potential and existing registrants for the same substance. If there is a study report available to explain this then it can be included in the registration dossier, preferably that of the lead registrant. Such a report can be included subsequent to

registration by a spontaneous update.

In the event that a dossier is incomplete and ECHA assigns a submission number to grant additional time to allow the tests to be completed - would this submission number allow continued trade, i.e. can the substance still be placed on the market without a registration number?

Yes, for a phase-in-substance for which a registration dossier has been submitted before the relevant registration deadline, a company can continue to place the substance on the market until they get the result of their completeness check. Even if they fail the completeness check first time, they can continue to place the substance on the market.

If there is a blending of substances that have the same EC number, is the final product considered as a mixture? The substances are the same (they are identified with one EC number), however, they have different viscosity and other phys chem parameters.

If you refer to blending of petroleum substances, then it is possible this could be considered a substance rather than a mixture. In such a case, we recommend you refer to the following link https://www.concawe.eu/wp-content/uploads/2017/02/Response_from_ECHA_May_2008-2008-01415-01-E.pdf for further information.

Will it be compulsory to register ethanol as a chemical substance in REACH when it is sold as a biocidal product? Or is it necessary to wait until ethanol is approved/rejected as biocidal active substance?

The answer is in article 15(2) of REACH: they are exempted from registration.

When registering a substance, is it possible to sell our product with the customer label? If so, is it necessary to register all customers in the dossier?

The registrant must provide the registration number in the SDS to downstream users. The registration number does not need to be on the label. A 'customer label' is possible. The SDS of the customer's product must also contain the registration number they received from their supplier. A registration dossier does not include information on the identity of customers.

When as an importer and agreed with the manufacturer you will be the lead and there are no other registrants involved, do you have to send a formal SIEF communication that confirms testing is underway but will not be completed by the deadline to meet the criteria for use of the contact form?

Please have a look at the Notice on the use of the DCG issues on this web page to get an overview of what documentation is needed to benefit from the DCG solution 10.3 and what are the expected consequences. It is available here: https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues.

Can you confirm that a co-registrant can submit his individual dossier in the event the Lead Registrant (LR) submits his dossier before the 31 May 2018 deadline but the LR has not yet been assigned his registration number?

Co-registrants can start submitting their member dossiers as soon as the lead dossier has passed business rules. The answer to above is 'yes'.

Is it possible to highlight (mark) substances at Dissemination Portal that have been evaluated by ECHA? The reason is that we will see in portal the substances with fully

reliable data. In other words: we will see dossiers that have passed successfully the evaluation step.

The substances which have been, or are planned to be, evaluated can be found in the CoRAP list: https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table. The registered substances for which dossiers(s) have been evaluated, and the related evaluation decisions, can be found here also: https://echa.europa.eu/information-on-chemicals/dossier-evaluation-decisions. Note that we hope to improve the evaluation life-cycle visibility and extend the amount of information shown in this list. We are working on this now and aim to have the improvement in place by the end of the year. Once in place, this improvement will show more granularly the positive and negative evaluation outcomes.

On the info card for each substance, the full regulatory context is shown, which indicates in which regulatory list(s) the substance participates. This shows at the substance level whether the substance itself, or some registration dossiers relating to the substance, have been evaluated. Please note however that, as always, the responsibility for data quality lies with the registrants, as clearly stated in the Legal notice on the ECHA website.

Main aim of the REACH is communication of safe uses and that is done via dossiers and safety data sheets. Why is it not possible to generate automatic SDS from the IUCLID dataset as it is with CSR? All the needed information is there.

Although (some of) the information required to generate a Safety Data Sheet (SDS) for a substance can be extracted from a IUCLID dossier, it is the responsibility of industry to generate SDSs and ECHA is not mandated to provide tools for this process.

Is the same deadline (May 2018) applicable for substances in articles?

Yes. The same deadline 31 May 2018 applies as well to substances in articles. Please note that the registration requirement for substances in articles applies only if all conditions of Article 7(1) of REACH are fulfilled (see Q&As 73, 77).

Question for Flying Tiger Copenhagen - for which kind of "products" do you have registration duties (I guess most of the "products" are articles)?

The Guidance on requirements for substances in articles provides information on how to determine if an object is an article. In relation to this question, the registration duties of the company apply to substances in mixtures (e.g. in cosmetic products) and possibly to substances intended to be released from articles.

Is it permitted to register a single biocidal product when 2 or more different manufacturers produce the product that we sell under the same commercial brand?

Yes but the authorisation of the product needs to cover both manufacturers and the technical equivalence between the two sources of the active substance contained in the product must be proven.

A new comer on the EU market will need to have his registration finalised before being able to put his substance in the market. How can he manage to do so?

If a registrant wishes to put a substance on the market in the volume of above one tone per year, a REACH registration is required. As of 1 June 2018, it is the requirement for all newcomers.

In 2010, the Director's contact group allowed companies to register even though

tests are pending as long as there was a good excuse. Will the same process be allowed this year?

This situation is addressed by the DCG solution 10.3. Please have a look at the notice on the use of the DCG issues to get an overview of what documentation is needed to benefit from the solution and what are the expected consequences. It is available here: https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues.

If SMEs will be asked to pay a lump sum, based on "pragmatic" grounds, as recommended by the DGG, and this lump sum represents less than a fair share of the costs, who is going to suffer the loss?

The reasoning behind the recommendation is that by this approach the parties would reduce the administrative burden (including setting up a reimbursement scheme) and reduce the risk of a data sharing dispute. It is acknowledged that the recommendation may not be feasible for very small SIEFS, and that each SIEF has to consider individually whether the recommendation would work for them. The whole recommendation can be read at: https://echa.europa.eu/documents/10162/23556156/171219_dcg_recommendation_low_volume_sme_en.pdf.

Regarding the answer from Christel Musset on updating registration dossiers if only volumes have changed but not passing different tonnage bands, does the dossier still need to be updated with the exact volumes of a particular year?

Yes, the exact tonnages are required.

What kind of information is needed to apply for the exceptional case that studies will not be available in time?

Have a look at the notice on the use of the DCG issues on this web page to get an overview of what documentation is needed to benefit from the DCG solution 10.3 and what are the expected consequences. It is available here https://echa.europa.eu/about-us/partners-and-networks/directors-contact-group/dcg-issues.

Disclaimer

This is a compilation of questions submitted online during the questions and answers sessions at ECHA's REACH 2018 Stakeholders' Day Conference held on 31 January 2018. The answers are collected here with the aim to assist companies in complying with their obligations under the REACH Regulation. However, you are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.