Eurometaux
European Association of Metals

June 2025

Guide for compliance with EU REACH Article 22(1) - Dossier Updating

Document updates

Version	Comment	Date
Version 1	First edition	October 2021
Version 2	Additional text on Chapter 3: • Cease of manufacture and import BoA-009-2020. • Decrease of tonnage band based on BoA-A-006-2020 and A-007-2020.	November 2023
Version 3	Note on "update reasons" in IUCLID Updated Chapter 3 • Decrease of tonnage band based on BoA-A-001-2023 and BoA-001-2024: clarified need for individual assessment and rejection of calendar year only approach Updated Chapter 12 • Updates involving co-registrants potentially subject to Russia sanctions	June 2025

Introduction

This guidance document compiles best practices from different chemical sectors for updating the REACH dossier. The aim is not to replicate the information on the current version of the ECHA REACH Guidance on Registration, but to provide feedback on how the chemical industry updates IUCLID dossiers based on the different scenarios provided in the Implementing Regulation (EU) 2020/1435.

Under the REACH Regulation (EC 1907/2006), manufacturers, importers, and only representatives of non-EU companies must submit a registration dossier to the European Chemical Agency (ECHA) for the substances they produce and import. Companies must

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update the REACH dossier with any relevant new information according to REACH Art. 22 without delay.

In 2017 and 2018, when the phase-in period was coming to a close, Member States and ECHA focused on updates of already registered dossiers. A concern was raised about whether the update frequency ensured timely updating of the dossiers. In addition, measures to provide clear and specific requirements and timelines to the registrants were discussed. As a result, it was suggested that ECHA provide clear criteria and explanations about:

1. What needs to be updated?
2. Who is responsible for the updates?
3. Why are the updates important?
4. Implementing Act to clarify the update requirements of Article 22 of REACH

Thus, on 12 October 2020, the European Commission published an Implementing Regulation (EU) 2020/1435 in the Official Journal of the European Union, which clarifies the meaning of "without undue delay" related to registration updates under the REACH Regulation.

The Implementing Regulation included deadlines for different scenarios, which triggered the need for the registrant to update their dossiers.

The Commission's Implementing Regulation states that "*a deadline of three months should be specified for updates of a more administrative nature and deadlines of six or twelve months for more complex updates, such as those requiring the generation of data or changes to the safety assessment.*"

The deadlines identified in the Commission Implementing Regulation (EU) 2020/1435 are to be counted from the specific trigger event described by each article of the Implementing Regulation. These defined deadlines are not to be confused with those communicated by ECHA or the Commission in their opinions and decisions to registrants; in such cases, the registrant must update the dossier following the deadlines specified by ECHA/ the Commission in the decision.

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Note on "update reasons" in IUCLID

When companies update their dossiers following the scenarios described in this guidance, they must select the appropriate reason(s) for update using the IUCLID drop-down list. These reasons serve an important signalling function to ECHA and to co-registrants in joint submissions. Selecting the correct reason ensures transparency and can trigger necessary actions, such as updates by other members of the joint submission or deadline calculations.

The use of "Other" should not be used unless the reason is not included in the IUCLID drop-down list, and even then, it should be clearly justified. IUCLID allows multiple update reasons to be selected via a repeatable block, which should be used where applicable. Lead registrants are especially encouraged to use the update reasons, as these are visible to co-registrants in REACH-IT and help ensure coordinated compliance with REACH obligations.

Disclaimer

The information contained in this paper is intended for guidance only. It is based on best understanding of the information currently available and is used by the reader at their own risk. Users are reminded that the REACH Regulation text is the only authentic legal reference and that the information in this paper cannot serve as a substitute for legal advice, and each company must decide upon the strategy to follow. No representations or warranties are made with regard to its completeness or accuracy, and no liability will be accepted by Cefic or Eurometaux or by any of their member companies or associations for damages of any nature whatsoever resulting from the use of or reliance on the information.

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Table of Contents

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EU Transparency Register n° 64879142323-90

Chapter 1

Changes in a registrant's status or its identity

Responsibility to update: Registrant

Deadline to submit the update: 3 months

Following article 22(1)(a) of the REACH Regulation, the registrant must inform ECHA of any change in their role in the supply chain by updating the registration dossier. These changes include:

- Changes in the company name and address should be reported directly in the ECHA business account, which provides access to ECHA IT tools: REACH-IT, R4BP, and ECHA cloud (there is no need to update the IUCLID dossier).
- Changes in the company size are to be reported directly in REACH-IT.
- Any change in the legal entity due to a split/merger/change of only representative should be reported directly in REACH-IT.
- Any change in the registrant's role within the supply chain should be recorded in section 1.1 of the IUCLID dossier. Additional information should also be included in sections 1.7 and 3.3 of the IUCLID dossier when it is relevant.

In all the cases indicated above, registrants have a maximum of three months to provide ECHA with the update, starting from the date when the specific change takes effect. If, in any case, the above triggers a change in the CSR, please refer to Chapter 11.

Any changes of Legal Entity by co-registrants should be updated in REACH-IT and communicated to the lead Registrant/consortia to keep track of changes and meet the obligations laid down in the Implementing Regulation on joint submission and data-sharing.

Further information on how to report changes in the identity of legal entities can be found in the Practical Guide:

"How to report changes in identity under REACH and CLP" is available at https://echa.europa.eu/practical-guides

Chapter 2

Changes in the composition of the substance

Responsibility to update: Registrant

Deadline to submit the updated dossier: 3 months

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Following article 22(1)(b) of the REACH Regulation, any significant changes to the relative composition of the substance currently submitted (section 1.2 of the IUCLID dossier) must be reported to ECHA by updating the registration dossier no later than three months from the date when the manufacturer or import begins with the change in the substance composition. If new analytical data shows that the typical concentration and/or concentration ranges reported in the dossier change, the registrant needs to check if the new composition remains within the boundary composition of the lead registrant dossier.

If the boundary composition indicated in the lead registrant's dossier already covers the new composition from the co-registrant, the co-registrant can modify its typical concentration and ranges of the constituents in its dossier. The analytical information should be included in section 1.4 of the IUCLID dossier. If the substance is a UVCB, the manufacturing process description should be reported and incorporated under the description in section 1.2 of the IUCLID dossier. A form for describing the manufacturing process of UVCB substances is provided on the ECHA page.

On the contrary, if the new composition does not fit within the Lead Registrant's boundary composition, this should be notified to the lead registrant, who may or may not decide to update the boundary composition of the joint submission because changes in the boundary composition may trigger a change in the hazard assessment, risk assessment, and classification reported in the joint submission. This may trigger the need to generate additional information and develop the related action plan to materialise this into an update of the joint submission.

If the lead registrant changes the boundary composition, all co-registrants must be informed of the change.

If the substance is a UVCB and the manufacturing process/starting materials change, a potential new registration could be envisaged since any significant change to the raw materials or the process would likely lead to a different substance that could require registration as a separate substance. Thus, it is recommended that the analytical data of raw materials and final products be regularly controlled. Also, the production processes should be reviewed regularly.

Further guidance on the degree of purity and UVCB substances can be found in the ***Guidance for identification and naming of substances under REACH and CLP,*** available at https://echa.europa.eu/guidance-documents/guidance-on-reach

Chapter 3

Changes in tonnage band

Responsibility to update: Registrant

Deadline to submit the updated dossier: 3 months/ 6 months (in case of a testing proposal)

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Following article 22(1)(c) of the REACH Regulation, any changes leading to a tonnage band change must be reported to ECHA by updating the registration dossier. The dossier update should be performed by each individual registrant (registrants covering their own tonnage band or lead registrants covering the tonnage of the jointly submitted data).

Based on the Implementing Regulation (EU) 2020/1435, no deadline is specified for a change in estimated annual quantity unless the registrant ceases manufacturing or the estimated annual quantity triggers a higher tonnage band. If the registrant finds that its tonnage band has changed, an updated dossier should be submitted without undue delay. Therefore, it is essential that total substance volumes (per legal entity) be tracked by automated routines, *e.g.*, the so-called substance volume tracking (SVT) in SAP systems. As a minimum, an assessment of the volume band for each registration should occur on an annual basis.

Cease of manufacture or import.

If manufacturing or importing of the substance, on its own, in mixtures, or articles, has ceased, it should be communicated to ECHA via REACH-IT.

Based on the Implementing Regulation (EU) 2020/1435, the registrant has a maximum of 3 months to communicate to ECHA from the date of the actual cease of manufacture or import. The date of ceasing manufacture or import refers to the moment the registrant takes a formal internal decision to permanently stop manufacturing or importing the substance. This date is not necessarily the same as the last day of actual production or import activity, as the decision to cease may occur before or after the final production or import batch.

Ceasing the manufacture has legal consequences depending on whether ECHA is notified of the cease of manufacturing/importing while ECHA processes an evaluation decision (Cases 2 and 3) or outside of that period (Case 1).

- CASE 1: If a company voluntarily decides to cease manufacturing or importing, then the registrant needs to inform ECHA through REACH-IT, after which the Agency will not request further information in the context of an upcoming evaluation process concerning that substance. Then the registration number is marked as "Inactive," and if the company in the future intends to restart the manufacturing or importing of the substance, then in REACH-IT, the submission number can be re-activated with no additional cost by clicking on "*Restart manufacture or import*" in the "*Reference number page*."
- CASE 2: After receiving a Draft Decision and before the decision is adopted, the registrant can notify ECHA about the cease of manufacture or import. If the registrant ceases manufacturing or importing before the adopted decision, then the registrant has no obligation to fulfil the requirements in the ECHA decision once it is final. The registrant is aware of the legal consequences as the registration number is no longer valid (Article 50(3)), and its status is marked as 'invalid' in REACH-IT. Registrations

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marked as 'Invalid' in REACH-IT cannot be re-activated or updated. Thus, if a company intends to manufacture or import again, they will need to submit an inquiry and subsequently submit a new registration dossier. Additionally, a new registration fee will need to be paid.

- CASE 3: If the registrant informs ECHA of the cease of manufacture or import after the adoption of an ECHA/Member State evaluation decision, the registrant remain obliged to fulfil the request in the decision and share costs incurred in that fulfillment process. Cease of manufacture or import after a decision is adopted falls under Article 50(2) of the REACH Regulation; the registration stays valid but becomes "*inactive*" in REACH-IT. If a company intends to restart manufacturing, then proceed as in Case 1.

In any of the cases mentioned above, the dossier information is kept for 10 years after the last manufacture or import and made available on request, as is mentioned in the legal text, Article 36(1).

However, if the substance is under restriction, and the competent authority concludes there is a potential long-term risk to human health or the environment, the registrant will still have obligations, which may include providing additional information to ECHA or MSCAs. Further information on the cease of manufacturing is available on the factsheet ***Cease and restart of manufacture or import under the REACH Regulation*** available at https://echa.europa.eu/publications/fact-sheets

Case 3 is also in line with the BoA-009-2020. Here, the registrant ceased manufacturing after receiving an adopted decision. The Board of Appeal (BoA) ruled that the company is bound to provide the information requested in the initial Compliance Check (CCH) decision, regardless of the fact that it ceased manufacturing the substance after receiving the decision. **The cease of manufacturing in REACH-IT only prevents the appellant from being subject to a new request concerning other information not requested in the initial CCH decision.** Thus, the reason for the cease of manufacturing (force majeure or any other circumstance) does not relieve the company from the obligation to provide the information requested in the initial CCH decision.

Decrease in tonnage band.

Based on the Implementing Regulation (EU) 2020/1435, no deadline is specified for this update, but the registrant is advised to submit a dossier that reflects the current volume manufactured/imported.

Companies are advised to review the Dossier Evaluation status from the ECHA page or REACH-IT to determine if their registered substances are under dossier evaluation. This acts as an indicator for companies to downgrade their tonnage band if they have manufactured/imported less than the registered tonnage band in the past year.

The BoA has clarified key procedural principles regarding tonnage downgrades:

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BoA-006-2020 and BoA-007-2020, it was established that ECHA must treat a tonnage downgrade submitted after a draft CCH decision but before the final decision as substantial new information. ECHA cannot presume that a registrant is using the downgrade to avoid obligations and must assess each case individually.

- BoA-001-2023 clarified that ECHA must not rely on the calendar year preceding the downgrade to reject its validity. Instead, ECHA must consider all relevant information and justification provided by the registrant, including changes in customer demand, production forecasts and other supporting evidence. These justifications should not be ignored as they constitute a breach of the registrant's right to good administration under Article 41 of the Charter of Fundamental Rights.
- In BoA-001-2024, the BoA further reinforced that past exposure to the substance at higher volumes is not a valid reason to impose higher tier information requirements under Article 41. ECHA must base its CCH on the dossier as it exists at the time of the adopted decision, not on historical data. The BoA ruled that a tonnage downgrade submitted after a draft decision but before the final decision is new and substantial information that must be considered, unless ECHA can demonstrate abuse of procedure.

According to these rules, ECHA must conduct a full, case-specific assessment of the downgrade, examining past volumes and additional elements, considering market developments, contracts, control mechanisms, or supply chain disruptions. The burden of proof lies with ECHA to demonstrate abuse of procedure, not with the registrant to prove good faith.

Therefore, companies should document the reasons for the downgrade clearly and maintain evidence (*e.g.,* customer orders, production planning) to support it in case of a CCH. Thus, ECHA should review all documentation and justify its position if a downgrade is not accepted.

After the adopted decision has been received, companies will need to fulfil the request in the decision; no new information, *e.g.* the downgrade of the volume manufactured/ imported, will be taken into account related to that decision.

If applicable, the member may cease manufacturing before receiving the adopted decision based on Article 50 (3), with the legal consequences that the registration is marked as "*invalid*" in REACH-IT, as stated in Case 2 in cease of manufacture.

Increase in tonnage band.

If changes in estimated annual quantities trigger a higher tonnage band (above the highest tonnage band already registered), the registrant must inform ECHA of its intentions to update the dossier. The deadline starts from the date when the higher tonnage band has been reached.

Under Article12(2) of the REACH Regulation, as soon as the quantity of a registered substance reaches the next tonnage band, the registrant must inform ECHA, via the inquiry process, of the additional information needed from the date when the higher tonnage band is

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EU Transparency Register n° 64879142323-90

reached. The inquiry procedure is described in Article 26 of REACH (referred to as "inquiry Type 4" in IUCLID). Based on the inquiry, the registrant may receive information from ECHA that no new data needs to be generated or that new data will need to be provided.

i. No new data needs to be generated.

If ECHA informs the registrant that no new data needs to be generated, the registrant has 3 months to submit an updated dossier.

In situations where the registrant is part of a Joint Submission, and there is an agreement in place on sharing additional data within the joint submission; then, the member of the joint submission might contact the lead registrant directly without submitting an inquiry for the increase in tonnage band if the information is available. The registrant must pay the LoA fee to grant the right to refer to the data requirements of the new tonnage band.

The inquiry is a necessary formal step for the registrant to start the data-sharing negotiations with the existing registrant at a higher tonnage band. In case the negotiations to share this data with the Lead Registrant fail, the inquiry is a pre-condition for submitting a data-sharing dispute.

While the registrant should do its best to obtain the LoA and update the dossier within the timeline provided, a delay in closing the LoA contractual negotiation may happen. The registrant is encouraged to discuss with the Lead Registrant/Consortium and finalise the process to update the dossier within 3 months.

ii. New data needs to be generated.

If ECHA informs the registrant that new data needs to be generated to fulfil the requirements on the tonnage update, the registrant has 3 months from the date when the higher tonnage band is reached to initiate the negotiations with the testing laboratory if the requirements concern Annex VII and VIII of the REACH Regulation.

If the data requirements concern those identified in Annex IX and X of the REACH Regulation, the registrant must update their dossier with testing proposals (or adaptations where appropriate) for the relevant endpoints within 6 months from the date they identify the need to perform one or more of the tests listed in Annex IX or X of the REACH regulation.

For the cases mentioned above, the registrant has another 3 months to update the registration from the date they have received all the final test results needed for the update. This is counted from the date when all required data for the new tonnage band is available.

The registrant may continue manufacturing/ importing the substance at the higher tonnage while waiting for the acceptance of the registration update.

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EU Transparency Register n° 64879142323-90

Note: in the text above, 'registrant' duties refer to the specific registrant or the 'joint submission' effort as appropriate for the registration dossier under evaluation.

Chapter 4

New identified uses and new uses advised against

Responsibility to update: registrant

Deadline to submit the updated dossier: 3 months

Following article 22(1)(d) of the REACH Regulation, any changes to sections 3.5 and 3.6 of the IUCLID dossier must be reported to ECHA by updating the registration dossier. The dossier update should be performed by the registrant (whether it is an individual, lead, or co-registrant). In case of a jointly submitted Chemical Safety Report (CSR), the lead registrant needs to update the CSR and, thus, the lead dossier to include the newly identified use of the co-registrant.

Registrants need to ask their downstream users which uses need to be covered in the registration dossier and verify that the proposed uses are covered by their registration dossier.

If a downstream user informs the registrant of a new use that is not covered by the joint submission and if the dossier has been registered in a tonnage band of less than 10 tonnes per year, the lead registrant should then update the IUCLID dossier and submit it to ECHA by no later than 3 months from the date the registrant receives all the information needed to add the new use[1] to IUCLID chapter 3.5.

On the contrary, if the lead registrant decides not to assess the new use because they consider that the assessment of the use is not technically possible or costly, then the member should discuss with the lead registrant and find a consensus to include the use.

In the case whereby the substance has been registered in a tonnage band of 10 tonnes or more per year, and the new use is not covered by the lead registrant dossier, the lead registrant must assess the chemical safety of this use and include it in the CSR if the results from the chemical safety assessment indicate that the risk to human health and the environment is controlled.

[1] According to Art. 37, the registrant must include the new use into the eSDS within 1 month or before the next delivery to the customer; the 3 months are only for informing the ECHA through a dossier update.

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EU Transparency Register n° 64879142323-90

If the Lead Registrant submits a joint CSR on behalf of the co-registrant, no further action from the co-registrant is needed in relation to the CSR, but the co-registrant may still need to update their own dossier. The Lead Registrant should ensure that sections 3.5, 3.6, and 13.1 of the IUCLID lead dossier are updated to comply with the REACH obligations.

In the situation where the Lead Registrant prepares a joint CSR but submits it separately, then the co-registrants should ensure that sections 3.5, 3.6, and 13.1 of their dossiers comply with the REACH obligations.

Further information on updates involving CSR is included in chapter 7 of this guide. In addition, the Implementing Regulation (EU) 2020/1435 modifies the deadlines for multiple updates in the CSR "deadline can be extended beyond the 3 months" see Chapter 11.

In the case that the chemical safety assessment indicates that the new use identifies a risk to humans or the environment and it cannot be controlled, the registrants must inform the Agency without delay by submitting an update of the dossier and indicating the new use as a use advised against.

In certain situations, the registrant shall submit new uses, *e.g.*, if the Lead Registrant does not support a specific use or if it is a unique or confidential use not to be shared with co-registrants.

The registrant (whether it is lead or co-registrant) is advised to keep the registered dossier up to date with information on how the substance is used in the supply chain since ECHA will not consider any dossier update after sending a draft decision to the registrant. The Agency will evaluate the dossier based on the uses indicated and available data submitted at the time the draft decision was issued. Thus, the registrant will not be able to update the dossier after the draft decision, *e.g.,* to remove uses of the substance, to have these considered during the evaluation process.

Companies are advised to review the Dossier Evaluation status from the ECHA page to assess if their registered substances are under dossier evaluation. This should be an indicator for companies to update their dossier and potentially remove the uses of the dossier.

Chapter 5

New knowledge of the risk to human health and/or the environment

Responsibility to update: Lead registrant

Deadline to submit the updated dossier: 6 months

The lead registrant must update and submit to ECHA by no later than 6 months from the date when the registrant becomes aware of information that could lead to other or different

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EU Transparency Register n° 64879142323-90

risks for human health or the environment caused by the substance they manufacture or import.

It is recommended that regular literature searches should be performed by Lead Registrant/consortia to identify relevant information in the context of REACH, *e.g.*, change of PNEC/DNEL, classification. The new knowledge can also come from within the company, *e.g.*, biomonitoring or own environment observations.

When the result of the literature search or new knowledge leads to a newly identified hazard, the risk assessment of certain uses must be revised. In those cases, updating the joint submission is required.

When a new risk is identified and leads to a change in the CSR, the initial CSR should be updated, and the CSA must be re-evaluated, and an update of the IUCLID dossier is needed. The changes in the risks of specific uses should be communicated in the SDS.

Chapter 6

Changes in the classification and labelling of the registered substance

Responsibility to update: Registrant

Deadline to submit the updated dossier: from the date when the harmonised classification applies/ 6 months for self-classification.

Following article 22(1)(f) of the REACH Regulation, any changes to section 2.1 of the IUCLID dossier must be reported to ECHA by updating the registration dossier when the decision was made.

In case of changes in the classification and labelling of the registered substance, the REACH registration dossier should be updated by the registrant (Lead Registrant if there is a joint submission or the co-registrant as an opt-out). This includes the CSR update and the re-evaluation of the CSA. The changes in the classification and labelling of the registered substance should be communicated in the SDS.

In the case of an addition, modification, or deletion of the harmonised classification and labelling, the IUCLID dossier should be updated no later than the date as of which the change is to apply. Note that the date at which the classification applies is specified in the relevant ATP.

In the case of a new or modified self-classification due to an adaptation in the classification of a substance resulting from a new evaluation in accordance with Article 15 of the CLP Regulation, the registrant will have 6 months from the date when the decision to change the substance's classification and labelling was taken.

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EU Transparency Register n° 64879142323-90

Chapter 7

Updates or amendments of the CSR or the guidance on safe use

Responsibility to update: registrant

Deadline to submit the updated dossier: 12 months

Following article 22(1)(g) of the REACH Regulation, if there are any updates or amendments to the chemical safety report or the guidance on safe use (GSU), the registration dossier must be updated and submitted to ECHA by no later than 12 months from the date when the need to update has been identified.

If there is a need to amend the CSR, the updated information should be included in section 13.1 of the IUCLID dossier. If there is any new information on Guidance on Safe Use (GSU), this should be included in section 11 of the IUCLID dossier.

In the case of a joint submission and a joint CSR, the Lead Registrant should update the CSR. Co-registrants with an opt-out dossier within the joint submission should update their CSR. In the case where the lead registrant does not provide a joint CSR, each member of the joint submission will need to update its own CSR, considering its uses.

Chapter 8

Testing proposal prior to conducting a test listed in Annex IX or X

Responsibility to update: Lead registrant or co-registrant in case of opt-out

Deadline to submit the updated dossier: 6 months/12 months

The registration must be updated to include the testing proposal and submitted to ECHA by no later than 6 months from the date as of which the lead registrant or co-registrant, in case of opt-out, identifies the need to perform one or more of the tests listed in Annex IX or X of the REACH Regulation.

In the case of a testing proposal developed as part of a testing strategy addressing a group of substances, the dossiers must be updated and submitted to ECHA by no later than 12 months from the date when the registrant identifies the need to perform one or more of the tests listed in Annex IX or X of the REACH Regulation.

As an example, a testing proposal could arise from a new interpretation of data by ECHA. A testing proposal may need to be reviewed based on newly generated data.

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EU Transparency Register n° 64879142323-90

Chapter 9

Changes in the access granted to information in the registration.

Responsibility to update: Registrant / Lead Registrant

Deadline to submit the updated dossier: 3 months

If there is a need to change the confidentiality claim in either the lead registrant or co-registrant registration dossier, *i.e.*, by introducing or removing a confidentiality claim, an update of the IUCLID dossier should be submitted to ECHA. The registration dossier must be updated and submitted to the Agency by no later than 3 months from the date when the change occurred.

If the lead registrant makes the change to the confidentiality claim, the data-sharing agreement should be updated according to the costs of the new changes and, consequently, update the lead dossier accordingly.

Further information on what can be claimed as confidential can be found at the ***Dissemination and Confidentiality under the REACH Regulation*** manual, available at https://echa.europa.eu/manuals

Chapter 10

Updates involving further testing

The deadlines indicated in Articles 1, 2, 4, 5, and 6 of the Implementing Regulation (EU) 2020/1435 and described in this guide should not be applied if new information needs to be generated following the update triggered by the aforementioned articles. This only applies to generating new data satisfying the data requirements of Annex VII and VIII.

The registrant should initiate the contract negotiations with the testing laboratory by no later than 3 months from the date they acknowledged the need to conduct further tests.

The registration dossier must be updated within 3 months from the date the registrant has received all the test results to carry on with the IUCLID update.

Chapter 11

Other combined updates

For any update related to article 22 (1) points (a) to (f) and (i) of the REACH Regulation or as chapters 1 to 6 and chapter 9 of this guide, whereby the registrant needs to modify GSU or CSR in endpoints 11 or 13.1 of the IUCLID dossier, an extended deadline to 12 months

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EU Transparency Register n° 64879142323-90

for submitting both updates apply after the registrant received the final test report needed to conduct the IUCLID dossier update.

In the case where the registrant would need to undertake several combined updates linked to those identified in article 22 (1) points (a) to (i) of the REACH Regulation or in chapters 1 to 9 of this guide, they will be able to update the dossier using the longest of the deadlines as applicable on the respective updates. The deadline is to be counted from the date when the first need to update the registration has been identified.

Chapter 12

Updates within the joint submission

When a member of the joint submission needs to update its dossiers and its dossier update depends on the lead registrant's dossier update, the member registrant should update its own dossier after ECHA's decision that the lead dossier has been submitted and accepted.

Once the lead dossier is accepted, the member registrant can update its own dossier according to the following deadlines:

1. No later than 3 months when the member registrant requires an update in the case of change in a registrant's status or in its identity, changes in the composition of the substance, changes in tonnage band, newly identified uses and new uses advised against, new knowledge of the risks to human health and/or the environment, changes in the classification and labelling of the registered substance or changes in the access granted to information in the registration.
2. No later than 9 months after the member registrant requires an update or amendment of the CSR or GSU.
3. No later than 9 months after the member registrant requires an update in any of the updates indicated in point 1 that would trigger the update or amendment of the existing CSR or GSU.

These deadlines shall apply from the date when ECHA informs the lead registrant and members of the joint submission that the updated lead dossier is complete.

Consortia/lead registrants should inform members after acceptance of the lead dossier update by ECHA on the reason for the dossier update and share the relevant files, *e.g.*, IU file and CSR, with the co-registrants.

When an update of the co-registrant's dossier in the joint submission does not depend on the lead registrant, the deadlines specified in Articles 1 to 11 of the Implementing Regulation (EU) 2020/1435 and in chapters 1 to 11 of this guide shall apply.

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EU Transparency Register n° 64879142323-90

From the perspective of a co-registrant, when the lead registrant updates a dossier, it is recommended that the co-registrants recognise this as a trigger to review their own registration dossier. Prior to commencing the review, it will be useful to have at hand the LR-updated Chemical Safety Report (CSR), and any IUCLID dossier template, and CHESAR template information that the LR/Consortium may provide to registrants containing, for example, updated Uses data.

The following 11-point check-list provided focuses on key dossier aspects for co-registrants to review:

1. **Are you still active in this substance?**

If you are no longer active in the substance, de-activate the registration via your REACH-IT account, using the "cease manufacturing" function.

2. **Is your tonnage band still the correct one?**

Check if your registered tonnage band is still up to date. The tonnage to be considered is the quantity manufactured/imported for the previous calendar year (*i.e.,* no longer the average of 3 previous years). You would need to update your dossier if your imported or manufactured tonnages have decreased/are likely to decrease or have exceeded/are likely to exceed your currently registered tonnage band.

3. **Are your contact details still current?**

Update if necessary.

4. **Have there been changes in Substance Composition that impact on your "co-registration" dossier?**

There may have been changes in the Lead Registrant (LR) dossier on substance composition. Check the Boundary Composition in the LR dossier. This Boundary Composition represents the Substance Identify Profile (SIP) that all registrants have/should have agreed upon. Each registrant needs to report its own "legal entity composition" in its co-registration dossier in section 1.2, which should be specific to the substance manufactured/imported by that registrant and must fit within the parameters established in the Boundary Composition. Check as well that your own substance composition still falls within the boundaries of the composition reported by the LR.

Technical details on how to report a composition have changed in recent years. If you have not updated your registrations recently, your information on composition may not be up-to-date with current requirements. The Boundary Composition for the Joint Submission is

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EU Transparency Register n° 64879142323-90

provided by the LR or the Consortium and can be used as a basis to prepare your legal entity composition data.

As a co-registrant, your dossier must contain analytical data in section 1.4 (spectra, analysis…) for the substance that you place on the EU market. The analytical data must be generated from samples of your own substance that you place on the EU market, and it must unequivocally characterise your substance, and demonstrate that your substance described in your legal entity composition falls within the Boundary Composition (SIP).

5. Are your substance Uses covered in the LR Dossier?

For all substances (*i.e.*, non-hazardous and hazardous), co-registrants should check that all their uses are covered in the joint submission Lead Dossier (IUCLID Section 3.5). For a hazardous substance, also check that there is an Exposure Scenario for your specific use(s) (see point 7 of this checklist). Check, to the extent possible, that the use(s) of your customers are included in the joint CSR and ES.
This likewise applies to non-EU manufacturers with an OR; check that the use(s) of your EU-based customers are covered. If there is any use that is not covered, the co-registrant can either:

i. Report that back to the LR/Consortium/Association with a request to include it, meaning that, for a hazardous substance, an exposure assessment and then generating a new Exposure Scenario for that use will be necessary, or
ii. The user can choose to conduct and document their own exposure assessment (i.e., CSR + ES) instead. This is, for example, for cases where uses are confidential or where registrants disagree to include the use in the joint CSR/ES.

The use of your substance to manufacture a product or article is an industrial use and should be reported as such. Refer to the ECHA R12: Use Description Guidance (on Information Requirements and Chemical Safety Assessment) to check that your substance has been allocated to the correct Life Cycle Stages. If you identify any mismatches, contact your LR or Consortium.

6. Do the Uses in your co-registrant dossier reflect only your Uses?

It is very important that, as a co-registrant, you only report your Uses in your co-registration dossier. If you include Uses that are not your Uses, ECHA may include you in a CCH about a Use that is not relevant to you. Manufacturing information contained in section 3.5 should also be checked.

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EU Transparency Register n° 64879142323-90

7. All OK with Exposure Scenarios (ES)?

If the substance is hazardous and registered above 10T/year, it requires an extended Safety Data Sheet (eSDS). Exposure scenarios shall describe safe use conditions, taking full consideration of human health, environment, and Man via the Environment or indirect exposure assessments. Check that each Use relevant to you (and your clients) has an ES and that you are working within its parameters to ensure safe use and handling.

8. eSDS appropriately disseminated?

If there are changes to the ES, ensure that you disseminate the revised eSDS (that includes the ES) along your supply chain to notify all parties.

9. All OK with Hazard Classification Communication?

Check that any hazard classification is appropriately reflected in your safety data sheet, product labels, and substance documentation (*e.g.*, for transport and product handling purposes) that you disseminate into the supply chain.

10. All OK with Guidance on Safe Use?

Review the Guidance on Safe Use to see if it has been submitted as part of the Joint Submission on behalf of all co-registrants in case the guidance changes. If submitted individually, check that it is consistent with the registration dossier.

11. Have you paid all your referral rights to the latest version of the LR dossier?

Registering substances under REACH is not a one-stop activity. Registration dossiers must be kept up-to-date with evolving scientific and administrative information. Co-registrants have the duty to contribute to the dossier registration updating process. This includes data and cost-sharing obligations. Failing to pay for dossier updates (*i.e.,* the fee payable to consortia or lead registrant for new studies, etc.) may involve losing the right to refer to the joint-submission LR dossier, subsequently followed by the risk of losing your registration number and market access. Unless you have already received a communication or invoice for this from the LR or Consortium, make sure you contact your LR or the Consortium to verify that you comply with all applicable data-sharing and cost-sharing obligations under REACH.

Updates involving co-registrants potentially subject to Russia sanctions

Following extensive discussions between industry, the European Commission, and ECHA, specific guidance has been clarified for situations in which one or more co-registrants in a joint submission may be subject to Russia-related sanctions.

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EU Transparency Register n° 64879142323-90

Before proceeding with any update to a joint registration dossier, the consortium or lead registrant must perform due diligence to identify whether any co-registrants are, or are reasonably suspected to be 'designated persons' under EU sanctions.

The dossier update may proceed if the steps outlined in FAQ 16 of the European Commission's Sanctions FAQs (Chapter 11: Chemicals[2] are followed. Key elements include:

- Screening co-registrant lists in REACH-IT to identify any sanctioned co-registrants, and encouraging them by a given deadline, to cease manufacture/import.
- Notifying ECHA in accordance with REACH Articles 22(1)(c) and 50.
- Communicating relevant information to the respective National Competent Authorities (NCAs), i.e.. The sanctions authority / REACH authority in the Member States (MS) of the lead registrant and the potentially sanctioned registrant must be informed.

It is essential to be able to demonstrate, with auditable evidence, that all actions are taken in good faith. Provided that duly diligent screening is conducted and can be demonstrated, and there is no criminal intent, the lead registrant should not be held liable for any inadvertent breach of Russia Sanctions.

While the European Commission FAQs recommend dissemination of relevant information to the supply chain "as appropriate," this is not mandatory. Care must be taken to avoid any behaviour that could be construed as anti-competitive or defamatory. However, it is considered courteous to inform the affected co-registrant(s).

Chapter 13

Updates as a consequence of an update to the Annexes of REACH

In the case where there is an amendment to one or more annexes of the REACH Regulation according to Article 131, which changes the data requirements of the registration, the registrant should submit a dossier update at the latest by the date from which that amendment is to apply.

If the update requirement generates additional needs for an update for any scenario in article 22 (1) points (a) to (i) of the REACH Regulation or as chapters 1 to 9 of this guide, the deadline applicable from entry into force of the new amendment should apply unless otherwise specified in that amendment.

[2] European Commission consolidated FAQs on sanctions against Russia and Belarus. https://finance.ec.europa.eu/document/download/66e8fd7d-8057-4b9b-96c2-5e54bf573cd1_en?filename=faqs-sanctions-russia-consolidated_en.pdf

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