May 2021

CHECKLIST FOR CO-REGISTRANTS[1] AFTER LEAD REGISTRANT (LR) DOSSIER UPDATING[2]:

This document:

- *Is not intended to be more than a checklist. For formal/official information please refer to ECHA* guidance documents[3].
- *Is written for co-registrants who have some reasonable familiarity with REACH dossiers, not for absolute beginners.*
- *Addresses cases where all information is submitted jointly. It does not cover updates related to information submitted individually (e.g. opt-outs, confidential content, etc.).*

Important note – Your REACH co-registrant registration is not a one-stop activity. Registration dossiers must be kept up to date with evolving scientific and administrative information. All registrants, i.e. lead registrant (LR) and co-registrants[4], have the duty to contribute with data and financially to the dossier registration updating process. Keeping dossiers (and in particular tonnages and use information) updated may avoid unnecessary regulatory scrutiny[5]!

From the perspective of a co-registrant, when the LR updates a dossier it is recommended that the co-registrant recognizes this as a trigger to review his own registration dossier. Prior to commencing the review, it will be useful to have at hand the LR-updated Chemical Safety Report (CSR)[6], and any IUCLID dossier template information that the LR/Consortium may provide to registrants, containing for example, updated Uses data.

The 11-point check-list below 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If you are no longer active in the substance, de-activate the registration via your REACH-IT account, using the "cease manufacturing" function.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 average of 3 previous years). You

[1] In this document, the widely adopted term "co-registrant" is used as synonym of "Member Registrant", which is the legal terminology present in REACH legal text.
[2] Link to ECHA page "Keep your registration up-to-date"
[3] Link to ECHA guidance documents
[4] Extract from the Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations 2019: "The responsibility to update their registrations requires registrants to monitor and track all relevant information in order to ensure their registrations remain up-to-date at all times. In the case of joint submissions, **the responsibility to update the registration is, for information that was jointly submitted, the responsibility of all the registrants** in accordance with Article 11 of Regulation (EC) No 1907/2006 and is covered by the data-sharing and cost-sharing provisions laid down in Commission Implementing Regulation (EU) 2016/9.
[5] Link to European Commission Implementing Regulation 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations
[6] To be noted that CSR is not required in case of tonnage bands below 10 tpa

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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 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 your 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 characterize 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, check also 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 instead to conduct and document their own exposure assessment (i.e. CSR + ES). 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 your substance has been allocated to the correct Life Cycle Stages. If you identify any mis-matches 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 compliance check about a Use that is not relevant to you. Manufacturing information contained in section 3.5 should also be checked.

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 the 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 if it has been submitted as part of the Joint Submission on behalf of all co-registrants, in case the guidance has changed. If it is 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 a 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 already have 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.