Factsheet
REACH & ceasing manufacture

Index

1. What needs to be done when a registrant ceases to manufacture/import a registered substance or intermediate? 1
2. What are the costs associated with a Registration dossier update to put the tonnage to zero? 2
3. When to notify ECHA on the cessation of the manufacture and/or import? 2
4. What are the consequences of claiming 'cease manufacture'? 2
5. What if a Lead Registrant claims 'cease manufacture'? 3
6. What if a registrant of an intermediate received a letter from ECHA questioning the intermediate/SCC status and this registrant decides to cease manufacture? Does he still have to update his Registration dossier? 3
7. If a registrant decides to cease manufacture and the Registration dossier is disseminated, will the registrant still be included in the dossier? 4

1. What needs to be done when a registrant ceases to manufacture/import a registered substance or intermediate?

Every change in the quantities manufactured and/or imported resulting in a change of tonnage band requires an **update of the Registration dossier**. The cessation of manufacture and/or import[1] is also considered as a change of tonnage band.

The information on how to proceed can be found in the *ECHA Guidance on Registration (version 2.0, May 2012)*, *chapter 7.2 (Required update on registrant's own initiative)*. According to this guidance, if a registrant has ceased the manufacture or import of the substance, or the production or import of an article, he needs to inform ECHA of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero (Article 50(2)). He must keep the relevant information for 10 years after last manufacture or import and make it available on request (Article 36(1)). In the case where he restarts the manufacture or import of the substance or he restarts the production or import of the article he has to notify ECHA accordingly.

As indicated in the *REACH-IT Industry User Manual Part 6 (Dossier Submission)*, the registrant shall inform ECHA of cease of manufacture through the **REACH-IT 'cease manufacture' functionality**. The use of this functionality will update the registered volume to zero.

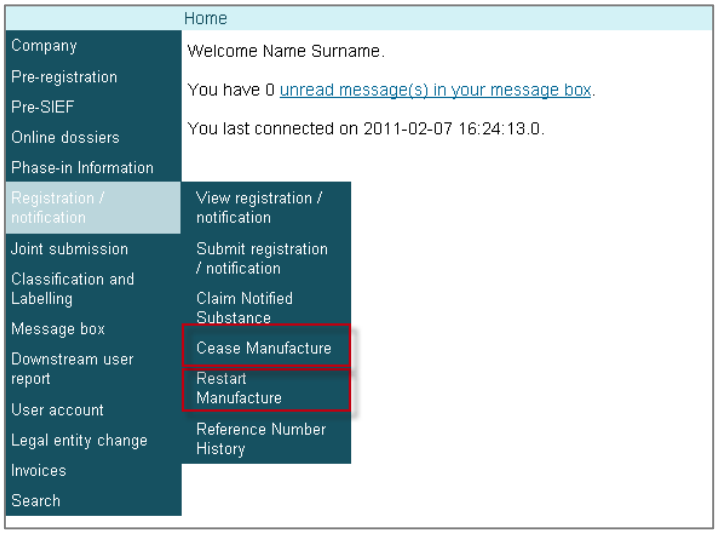

Figure 1: Cease and restart manufacture menu items in REACH-IT main menu.

[1] It is important to note that the 'cease manufacture' functionality should only be used when the cessation of manufacture and/or import results in a total registered volume of zero (i.e. when a registrant ceases to import a substance, but still manufactures it, or vice versa, the 'cease manufacture' functionality should not be used).

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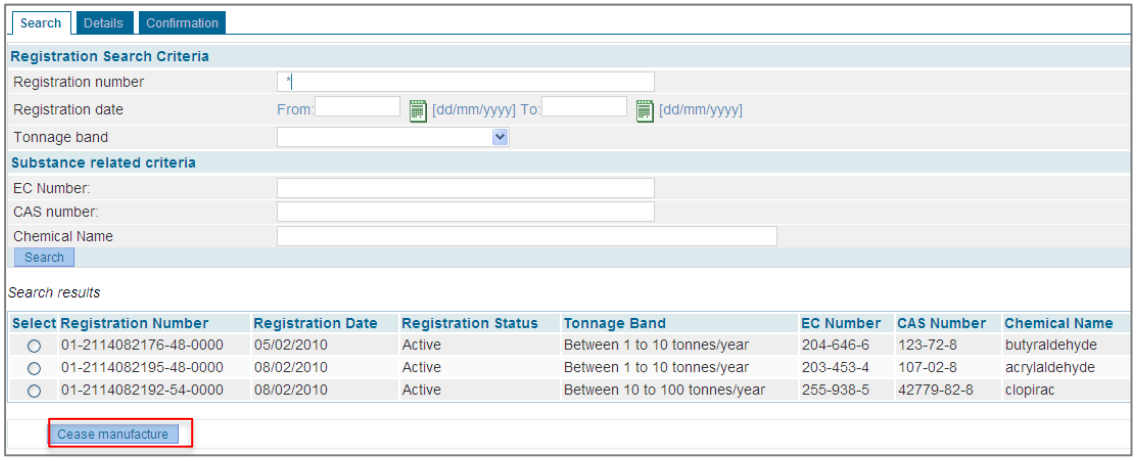

Figure 2: Cease manufacture search tab with 'cease manufacture' button in REACH-IT.

2. What are the costs associated with a Registration dossier update to put the tonnage to zero?

Following Article 5 of the Regulation on REACH fees, no fee shall be charged for a change from a higher to a lower tonnage band, thus a dossier update to notify cessation of manufacture or import does not entail any fees.

3. When to notify ECHA on the cessation of the manufacture and/or import?

This 'cease manufacture' functionality should be used in the following cases:

1) A registrant ceases manufacture/import of a registered substance for commercial reasons (e.g. no longer profitable or competitive, alternatives available, etc.) -> registration status is changed to 'inactive'.
2) A registrant ceases manufacture/import of a registered substance upon receipt of a draft decision (e.g. requesting further information on the substance after a compliance check or decision on authorisation/restriction regime) -> registration status is changed to 'revoked'.
3) A registrant decides that the registered substance is exempted from REACH registration obligations -> registration status is changed to 'inactive'. If this is the case, registrants have an obligation to justify that their decisions are made in accordance with the REACH Regulation in case contacted by enforcement authorities.

4. What are the consequences of claiming 'cease manufacture'?

The consequences of claiming cessation of manufacture depend on the context in which 'cease manufacture' is claimed by the registrant.

4.1. Cease manufacture for commercial reasons or because of exemption from REACH registration obligations

Pursuant to REACH Regulation Article 50(2), if a registrant has ceased the manufacture (e.g. for commercial reasons), he shall inform ECHA of this fact with the following consequences:

- The registered volume is updated to zero, the registration's status is marked inactive but it remains a valid registration.
- The registrant will not be requested to provide further information regarding the registered substance.
- The registrant may continue acting as the Lead Registrant for a joint submission if he so chooses.
- The registrant may restart manufacture of the substance by simply notifying the Agency of this (no additional fee will be charged unless the tonnage band manufactured or imported increases compared to original registration).
- The Agency shall inform the relevant MSCA.

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4.2. Cease manufacture upon receipt of a draft decision

Pursuant to REACH Regulation Article 50(3), if a registrant decides to cease manufacture upon the receipt of a draft decision, he shall inform ECHA of this fact with the following consequences:

- The registration will no longer be valid and its status will be marked as revoked.
- The registrant will not be requested to provide further information regarding the registered substance.
- If the registrant is the Lead Registrant of a joint submission, he will have to give up this Lead Registrant role using the 'Assign new lead' functionality as explained in the *Industry User Manual Part 7 (Joint Submission)* before ceasing manufacture.



Figure 3: 'Assign new lead' functionality in REACH-IT.

- The registrant may only restart manufacture of the substance by submitting a new registration.
- The Agency shall inform the relevant MSCA.

5. What if a Lead Registrant claims 'cease manufacture'?

A Lead Registrant may continue acting as a lead on behalf of his joint submission even though he decides to cease manufacture under REACH Regulation Article 50(2). However, in the event that he wants to give up this role he may do so by using the 'Assign new lead' functionality. If no other members have confirmed their membership to the joint submission, the Lead Registrant may cease manufacture but cannot give up his role as Lead Registrant until he can transfer his role to a new member. If any member would be interested in continuing the registration of such substance in the future, the role as Lead Registrant in REACH-IT will need to be transferred. In this scenario, the new Lead Registrant will not be considered legally as the new Lead until he has confirmed its role as Lead in REACH-IT and a new Lead Registration dossier has been successfully submitted.

The system will not allow cease manufacture for a Lead Registrant who has received a draft decision; the Lead Registrant should indeed address the impact of the draft decision and/or assign a new Lead Registrant first. Hence, before being able to cease manufacture in this situation, the Lead Registrant must relieve himself of this lead role using the 'Assign new lead' functionality.

6. What if a registrant of an intermediate received a letter from ECHA questioning the intermediate/SCC status and this registrant decides to cease manufacture? Does he still have to update his Registration dossier?

The registrant will not be requested to provide further information regarding the registered substance if he ceases manufacture. This also means that the registrant does not have to update the Registration dossier to prove intermediate/SCC status as ECHA requested (but would need to submit an updated Registration dossier with a tonnage of zero as explained in question 1 above).

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7. If a registrant decides to cease manufacture and the Registration dossier is disseminated, will the registrant still be included in the dossier?

Unless ECHA is informed on the confidential nature of specific portions of a registrant's dossier, information on the registration already disseminated by ECHA will remain on the dissemination portal. If some information should not appear on the dissemination portal (e.g. registrant details[2]), an updated dossier for the registered substance including the relevant confidentiality flags and claims has to be submitted to ECHA without delay. Upon payment of the relevant confidentiality claim fees, ECHA will update the content of the dissemination portal to remove information having been claimed to be confidential.

If the dossier was updated before 1 November 2012, it will be "re-disseminated" soon after that. If the dossier is updated later, the re-dissemination may take longer. Indeed, ECHA disseminates dossiers in groups every quarter and so forecasting precisely when an updated dossier will be disseminated is impossible.

[2] If there is a third party representative (TPR), the legal entity name and contact details of the registrant will be displayed in the dissemination portal, not the TPR information. On the inquiry – co-registrants page (which ECHA will launch mid November with the new version of REACH-IT), the TPR will be displayed. On this page in REACH-IT which will be accessible to registrants and inquirers which have received an inquiry number, you will find two tabs, one with the co-registrants and one with the potential registrants (inquirers). Here the TPR info will be given if one was appointed by a co-registrant.

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