

21 October 2021

Questions and answers from the Helpdesk stand at ECHA Safer Chemicals Conference, 6 October 2021

Question	Response
<p>Hello, I would like to know is who is responsible for checking SIPs for chemical sameness under REACH legislation. Thank you for your help in advance.</p>	<p>Hello, under REACH it is foreseen that all members of a joint submission would discuss substance sameness and, consequently, agree on the substance identity profile (SIP) for the joint registration. It is important that the parameters defining the boundaries of the substance identity covered by the joint submission are agreed by all the joint registrants and are clearly documented in the SIP.</p> <p>Q&As on SIP: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Substance+identity+profile</p> <p>Practical Guide on SIP: https://echa.europa.eu/documents/10162/17250/practical_guide_how_to_develop_prepare_sip_en.pdf</p>
<p>Is it possible for same legal EU entity to register substances under REACH as EU manufacturer, EU importer and an OR at the same time?</p>	<p>The same LE can be importer and manufacturer. However, if you are acting as an OR you will need to create a different LE account.</p> <p>Please see the Q&A: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0349</p>
<p>We registered substance as co-registrant in 1-10t, and would now like to upgrade to 10-100tpa involving CSR preparation. Can import to EEA continue above 10-100tpa during this period until 12 months?</p>	<p>You have 12 months to submit an update or amendment of the CSR or the Guidance on safe use from the date when the need for the update arises, i.e. in your case when the TB exceeded 10 tonnes.</p> <p>See Section 7 of the Guidance on registration at: https://echa.europa.eu/documents/10162/23036412/registration_en.pdf/</p>
<p>After the substance is listed in SVHC list and has potential for an entry to authorization list also? Is 36 months fair to consider for substitution project as a minimum timeline until sunset date?</p>	<p>Hello, The identification of a substance as an SVHC (Article 57, REACH) and its inclusion in the Candidate List (Article 59, REACH) is the first step of the authorisation process under REACH. The European Commission decides using the comitology procedure which of the recommended substances are to be included in Annex XIV and specifies the transitional arrangements (sunset dates, etc).</p>

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	<p>The Authorisation process under REACH aims to progressively replace substances of very high concern (SVHCs) with suitable alternatives, as soon as they are technically and economically feasible. In addition, via consultations during each step on the authorisation process, ECHA encourages interested parties to get involved and provide their views including information on available substitution. You can find a wealth of information and useful links on our dedicated substitution web pages: https://echa.europa.eu/substitution-to-safer-chemicals</p> <p>Finally, for the 36 months the deadline is set by the legislator, Art. 58 (1) (c) REACH. We hope the above helps.</p>
<p>We plan to register monomer as polymer exported to EEA is exempted under REACH. This monomer is on authorization list, is there any regulatory requirement for this monomer in addition to registration?</p>	<p>Monomers are by definition intermediates. Therefore, they cannot be subject to authorisation under REACH for the use as monomers in polymerisation reactions -even if the substance is on the list.</p>
<p>Is there a plan for the future to have the ability to delete incorrectly submitted PCN dossier? Since at the moment from my knowledge this is not possible.</p>	<p>It is indeed not possible to delete a submission at the moment. Later this year it will be possible to e.g. cease market or disable; please see the PCN presentation at 3.30 pm Helsinki time.</p>
<p>When monomers in polymers are registered, how will that affect the future demands of registration of polymers?</p>	<p>Polymers meeting the criteria of Article 3(5) of REACH are exempted from the registration obligation (Article 2(9)).</p> <p>The manufacturer or importer of a polymer must submit instead a registration for the monomer substances or any other substances that meet all criteria mentioned in Article 6(3) of REACH. So far there have not been any legislative changes regarding the registration of polymers under REACH. While there are ongoing discussions, the Commission, industry and relevant stakeholders on the possible registration of polymers in the future, these are still at the discussion/development phase.</p>