

ECHA Urges Companies to Get Ready for New REACH Requirements for Nanomaterials



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The European Chemicals Agency (ECHA) issued a [press release](#) on October 8, 2019, reminding companies that by **January 1, 2020**, companies must provide more information on nanomaterials on the European Union (EU) market under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. The new information requirements concern companies that manufacture or import nanoforms of substances that are subject to registration under REACH. As reported in our December 4, 2018, [blog item](#), the European Commission (EC) amended several REACH Annexes to introduce clarifications and new provisions for:

- Characterization of nanoforms or sets of nanoforms covered by the registration (Annex VI);

- The chemical safety assessment (Annex I);
- Registration information requirements (Annexes III and VII-XI); and
- Downstream user obligations (Annex XII).

ECHA states that the purpose is to ensure that companies provide enough information to demonstrate the safe use of their nanoforms for human health and the environment. The amendments apply to all the new and existing registrations covering nanoforms. ECHA states that it expects registrants to update their existing dossiers with nanoform-specific information by **January 1, 2020**.

ECHA notes that its new nano-specific guidance is intended to help companies comply with the changes in Annex VI. In addition, ECHA is updating the guidance on read-across between nanoforms or sets of nanoforms to reflect the changes. ECHA intends to have both documents ready by the **end of 2019**. ECHA is also updating the 2017 ECHA guidance for human health and the environment. According to ECHA, the Organization for Economic Cooperation and Development (OECD) is revising some of its existing test guidelines used under REACH to ensure that data generated on nanoforms is reliable and meets regulatory standards. An overview of the revised REACH Annexes and the available test methods is [available on the EU Observatory for Nanomaterials \(EUON\) website](#).

On **October 30, 2019**, the International Uniform Chemical Information Database (IUCLID) will be updated with new data fields for reporting the characteristics of nanoforms and sets of nanoforms. Beginning **October 30, 2019**, registrants who intend to submit registrations covering substances in nanoform must provide complete characterization information on their nanoforms or sets of nanoforms.

According to ECHA, the completeness check will include a verification that the sets of nanoforms are accompanied by a justification for creating the set. As before, the IUCLID tool will include the means to link these nanoforms or sets of nanoforms with the relevant data on their properties and hazards in the other parts of the dossier. ECHA states that companies submitting information on nanoforms must use the new version of IUCLID because it is not possible to prepare a successful submission with previous versions.

As reported in our September 27, 2019, [blog item](#), ECHA is [hosting a webinar](#) on **November 12, 2019**, to introduce the guidance on identifying and reporting nanoforms and sets of nanoforms. During the webinar, companies will have the opportunity to get advice directly from ECHA's experts. ECHA notes that its help desk is available to assist companies prepare for the new requirements.

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