

## Turkey Updates KKDIK Registration Requirements

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On February 3, 2023, the Turkish Ministry of Environment, Urbanization and Climate Change (MoEUCC) released new guidance on the registration requirements under the KKDIK regulation (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kontrolü). As a result of this new guidance, providing importer information for the registration of a substance is now optional instead of mandatory, the chemical safety report (CSR) may be submitted in English, and there is additional time after the registration deadline to submit the Turkish translation. Additionally, the “Registrant Identity” and the “Registration Number” may now be claimed as confidential business information (CBI).

### Background

In effect since December 23, 2017, KKDIK is a hazard-based chemical regulatory framework that requires registration of chemicals manufactured or imported in quantities of one metric ton (mt) or more per year in Turkey. KKDIK is modeled after the European Union’s (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. While still allowing for substance pre-registrations, KKDIK has been in its registration phase since January 1, 2022, with the registration deadline set for **December 31, 2023**. The substances are registered online, through the KKS information technology (IT) platform, which resembles the European Chemicals Agency’s (ECHA)

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REACH IT and IUCLID platforms.

## Updates to the KKDIK Registration Requirements

Prior to this new guidance, registrants were required to identify at least one importer for every lead or co-registration dossier. Industry repeatedly expressed concern with this requirement, as it added additional burden with no apparent benefit and was not part of the EU construct.

Now, providing mandatory importer information is no longer a barrier to completing the registration. The Ministry encourages registrants or their Only Representatives (OR) to include importer information where possible but no longer includes it as a mandatory field in KKS. The OR must keep an up-to-date list of the importers and the tonnage covered for each of these importers, as well as the information on obtaining the latest update of the safety data sheet (SDS). All the relevant guidance documents will be updated to reflect these updates.

Industry also expressed concern about the requirement to submit a CSR translated into Turkish for every registration dossier at more than 10 mt per year. To many, this requirement would significantly delay the registration process. With the registration deadline rapidly approaching, the Ministry relented and announced that registrants now have the option of submitting the CSR in English. Registrants have up to an additional year after the **December 31, 2023**, deadline, to submit the Turkish translation. The Ministry does require that risk management measures be included in Turkish. The requirement to submit the information regarding robust study summaries in Turkish remains unchanged.

Registrants or their ORs may now also claim Registrant Identity and Registration Number as CBI in the KKS IT system. These options were not available prior to the Ministry's February 2023 announcement. The CBI claims must be substantiated in accordance with the template in

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KKS. Companies wishing to claim the Registrant Identity and/or Registration Number as CBI for the dossiers that are already submitted must initiate the KKDIK registration dossier update process. The CBI claims are subject to a fee.

## **Commentary**

These changes are a relief to stakeholders that were struggling to identify an importer and provide the level of detail the Ministry required well after the registration window opened. The requirement was delaying lead registration completion, as complex supply chains are seldom easily navigated.

The tight registration period of three years for all tonnage bands, laden with translation requirements, was also viewed as a significant roadblock to completing lead registrations. The elements of the CSR are often hundreds of pages, and translation of complex scientific details requires technical expertise and mastery of the Turkish language. Allowing an additional year should increase the volume of lead registration submissions.

The further alignment of KKS to include confidential fields that are common in EU tools was urged by technical experts in Turkey some time ago. The Ministry noted previously that it was considering many of the issues raised but took months to release the new guidance. With the deadline fast approaching and an estimate that only 25 percent of the lead registrations are complete, stakeholders welcome the changes but worry that the deadline may not be feasible. Failure to achieve the deadline could result in supply chain disruptions in a region that is implementing these complex regulations to further its bid for EU membership. In addition, supply chain disruption and adverse economic impacts are likely, due to ongoing domestic distress caused by the disruptions as the government deals with several tragic earthquakes and the impacts of upcoming elections.

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