

NEW PROVISIONS RELATED TO THE BELOW SECTIONS OF KKDİK REGISTRATION DOSSIERS:

• **1.7 IMPORTERS**

As known, Only Representatives (OR's) are obliged to add the Turkish importers of the non-Turkiye company they represent to the section 1.7 Importers to the registration dossiers.

As a result of the evaluation of the opinions and suggestions from industry associations, and various companies by our Ministry, it has been deemed appropriate to remove the aforementioned information from being obligatory part of the registration dossier.

Even though the obligation to submit the importers is removed from dossier Technical Completeness Check (TCC), we as the Competent Authority (CA) advise the OR's to submit this information where possible.

The Only Representative's registration dossier must contain all uses of the importers (who are then deemed as downstream users) covered by the registration. The Only Representative must keep an up-to-date list of the customers (importers) of the 'non-Turkiye manufacturer' in the same supply chain and the tonnage covered for each of these customers, as well as the information on obtaining the latest update of the Safety Data Sheet and keep this information ready for the purposes of enforcement audits carried out by our Ministry.

In this regard, the information in the already published guides such as "Registration Guide", "KKS User Guide" and in the "Frequently Asked Questions" field in the Chemicals Help Desk will be updated as soon as possible per the above-mentioned provisions.

Some issues that Only Representatives and importers should pay attention to regarding the registration of chemicals are as follows. Detailed information can be found in the "Registration Guide" on the Chemicals Help Desk website:

Importers should obtain confirmation from the 'non-Turkish manufacturer' whether an OR has been appointed. In addition, it is highly recommended that they obtain written confirmation from the OR that the tonnage and usage imported are indeed covered by the registration submitted by the Only Representative. This will provide the importer with a point of contact to report their use if they are considered as downstream users and will also give the importer clear documentation that their imports are covered by the registration of the OR. In addition, the importer is required to obtain sufficient information from the 'non-Turkish manufacturer' and/or the OR, to fulfil the obligation to compile the Safety Data Sheet, where relevant. The importer in Turkiye should be able to document which imports are covered with in the scope of the registration submitted by the Only Representative, when requested by the CA.

The OR's registration dossier must contain all uses of the importers covered by the registration. The Only Representative should maintain an up-to-date list of the 'non-Turkish manufacturer' customers (importers) within the same supply chain and the tonnage covered for each of these customers, as well as information on obtaining the latest update of the Safety Data Sheet and must submit that information during any audit conducted by CA.

- **13.1 Chemical Safety Report**

It has been stated that the compilation of the Chemical Safety Reports in Turkish, which are required to be submitted in the registration dossier of chemicals of 10 tons or more per year, is taking long time in the mean of translation and considering the registration period will end by the end of 2023. The option to upload the Chemical Safety Report in English initially has been introduced for companies who want to.

However, the registrants who prefer to upload the Chemical Safety Report in English initially to catch the deadline should add the Turkish translated version to the registration dossier, including exposure scenarios and risk management measures within 1 (one) year from the date 31 December 2023.

On the other hand, the requirement to fill in all the fields in the KKS system regarding the "Robust Study Summaries" and "Study Summaries" to be submitted in Turkish remains the same.

REGISTER YOUR CHEMICALS UNDER THE KKDIK REGULATION BEFORE 1.1.2024. THE MANUFACTURING AND/OR IMPORT OF SUBSTANCES THAT ARE NOT REGISTERED WILL NOT BE ALLOWED AFTER 1.1.2024.

- **Confidentiality demands on the Registrant Identity and Registration number:**

New fields/options have been added in the KKS for the purposes of confidentiality regarding the "Registrant's identity" and "Registration number" in their registration dossiers, in case a confidentiality claim is raised.

- The confidentiality request regarding the "Registrant's identity" should be determined in section 1.1 "Substance Identification" section of the registration dossier under the option "Confidentiality for the company name".
- The confidentiality request regarding the "registration number" should also be determined in section "1.3 Identifiers" section of the submission.

It is important that the information to be submitted in the text of the justification is submitted in accordance with the template in the KKS, for all confidentiality claims that companies want to raise.

Note 1: Companies wishing to request confidentiality regarding the " Registrant's identity" and/or "Registration number" for the dossiers that are already submitted should initiate registration dossier update process. This can be done by following the steps under the title "4.5.4.3 Registration Dossier Update Process:" of the KKS User Manual which can be found [at the link](#).

Since these confidentiality claims are subject to a fee; you can submit your registration dossier again after payment of the related fee for confidentiality claim.

Note 2: The confidentiality claims which are not specified with in the dossier per the above instructions will not be taken into consideration by the Competent Authority.