Turkey's KKDIK: Is it time for lead registrants to step up their game?

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Olesia Pochapska, global accounts lead and legal advisor at REACHLaw, investigates registration requirements at a crucial period in the run up to 'Turkey REACH's' December deadline

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On 23 December 2017, Turkey adopted a REACH-like national regulation related to chemicals registration, evaluation, authorisation and restriction. The KKDIK, or Turkey REACH, is almost identical to EU REACH with a few additional requirements. Article 65 of the KKDIK makes this clear when it says that it was prepared "taking into account" the EU regulation. The main differences between the two are related to:

- the transitional provisions for the pre-registration and registration deadlines; and
- the use of specially certified chemical assessment experts (KDU) who are mandatorily required to sign off Turkish safety data sheets and lead registration dossiers.

It is fair to say that if you know the EU regulation, you will also understand the KKDIK.

Turkey's competent authority for KKDIK-related matters is the Ministry of Environment, Urbanisation and Climate Change (MoEUCC).

This article will focus on the registration requirements and related developments. Other regulatory requirements under KKDIK will not be addressed here.

KKDIK's registration requirements

The basic KKDIK requirement coming from the regulation's Article 6 "no data, no market" rule means that all substances manufactured in or imported into Turkey at or above 1 tonne/year (t/y) must be first pre-registered and later registered according to the applicable deadlines. The pre-registration process is still ongoing in Turkey. If your company is placing any substances on the Turkish market at 1t/y or more that are in the KKDIK's scope, they must have valid pre-registrations in place. The registration deadline for all tonnages bands is 31 December 2023. After this date, only KKDIK-registered substances can be manufactured in or imported into Turkey.

Non-Turkish manufacturers may appoint only representatives (ORs) to take care of their KKDIK pre-registrations and registrations (KKDIK Article 9). When appointing an OR, it is important to remember that the KKDIK, in the same way as EU REACH, requires them to "have sufficient background in the practical handling of substances and the information related to them". In practice, a professional OR must have competences in several areas, including in:

- chemicals;
- legal matters; and
- data handling.

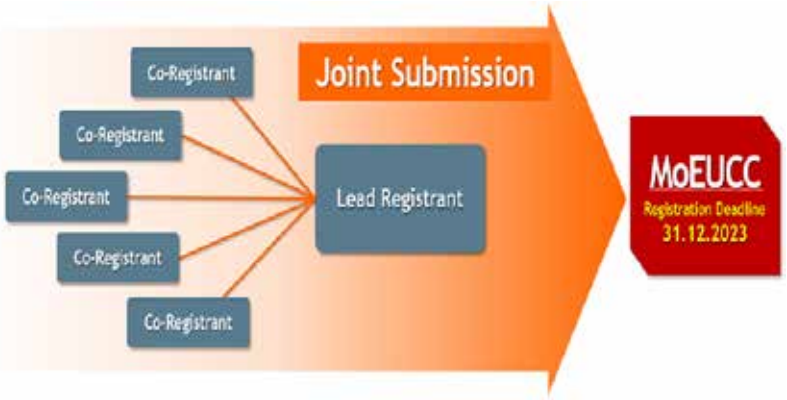
The legal aspect of an OR's competencies is absolutely necessary now that many will have to deal with the complex matters surrounding global chemicals data sharing requirements.

Pre-registrations and registrations in Turkey are submitted

via an online chemical registration system called the Kimyasal Kayıt Sistemi (KKS). This is in Turkish and only Turkish residents can log into the system.

In the same way as in EU REACH, when a substance is intended to be registered by more than one company, the KKDIK requires a joint submission of the "core data" of a substance in a registration dossier. In practice, this means that a substance will have a lead registrant submitting the lead registration dossier and co-registrants joining the joint submission and submitting their co-registration dossiers relying on the core data from the lead dossier. Registrants of the same substance form a substance information exchange forum (Sief), or MBDF in Turkish, where the core data for the substance needs to be shared and eventually jointly submitted in a joint submission on behalf of the registrants (see Figure 1).

Figure 1: Joint Submission under KKDIK



Therefore, a joint submission is not possible without one company taking a leading role and becoming a lead registrant for a specific substance. The co-registrations can only be compiled and submitted to the MoEUCC after the lead dossier has been approved by the authority. To enter a joint submission, a co-registrant must acquire all necessary rights to the core data, pay all related lead registration project costs, and receive a so-called letter of access (LoA).

If a substance is not KKDIK registered by 31 December 2023, then from 1 January 2024, if placed on the Turkish market at ≥ 1 t/a, it must first go through the inquiry procedure in the same way as in EU REACH and then the registration. If the result of the inquiry is that this substance has not been KKDIK registered, the company submitting an inquiry will have to submit a lead registration dossier before this substance can be placed on the market. Only once the registration is completed can this substance be placed on the Turkish market. To avoid any supply interruptions, the registration deadline must be met.

Current status of KKDIK lead and co-registrations

There is no official data on the number of lead and co-registrations submitted so far or intended for submission by 31 December. However, by working in the KKS, REACHLaw Turkey was able to estimate and extract the following numbers:

- more than 250,000 KKDIK pre-registrations submitted by companies;
- KKDIK lead registrant nominations for about 2,800 different substances; and
- more than1,100 lead registrations submitted to the MoEUCC.

Based on REACHLaw's analysis, most of the lead registrants so far are those nominated and submitted by the ORs of non-Turkish companies. Some of these represent the EU REACH lead registrants that took the same role via their ORs in Turkey.

According to the current estimates, the MoEUCC expects about 15,000 unique substances to be KKDIK registered by the deadline, which means that a little less than 20% (2,800) of this amount are on the right track towards the deadline. This leaves more than 80% of substances currently without nominated lead registrants and potentially being cut out of the Turkish market from 2024 on the basis of "no data, no market".

The co-registrations are directly dependent on the submission of the lead registrations. The lead registrant can provide access in the KKS for co-registrants to join the joint submission only after the lead dossier is checked and approved by the MoEUCC. At this stage, we estimate there are about 50,000 or more co-registrations for the dossiers the authorities expect to be submitted. However, this seems like a very unrealistic scenario given that industry has only seven months until the deadline.

Recent KKDIK registration developments

Therefore the biggest question is whether the MoEUCC will provide some kind of extension for the registration deadline to allow companies more time to work on their registrations, specifically lead registrations. So far, the authorities have indicated multiple times that no registration extension will be granted. In addition, over the past few months, the ministry has introduced a number of simplifications to the process of registering dossiers to help both lead- and co-registrants to proceed in an easier and less demanding way and to expedite the submission process.

Among these simplifications, the ministry has annulled the requirement of mandatory inclusion of the importers in section 1.7 "Suppliers" of the registration dossier when the dossier is submitted by the OR of a non-Turkish manufacturer or formulator. ORs are still required to keep up-to-date information on the importers in Turkey,

substances and tonnages for the companies that they represent. This means that non-Turkish manufacturers and formulators are nonetheless required to provide this information to their ORs, but it is no longer required to include this information in the registration dossier.

Additionally, the MoEUCC is now temporarily allowing the submission of the KKDIK chemical safety report (CSR) in English. Registrants have been given time until end of 2024 to translate the CSR into Turkish and submit the update. The information on robust study summaries and study summaries must be submitted in Turkish language via the KKS.

The ministry is constantly working on the KKS's functionalities where it relates to confidential business information (CBI) claims. A few months ago, it announced that registrants are now able to claim CBI in their registration dossiers for both the registrant's identity and its registration number. Such developments seem to be in line with CBI claim functionalities in the EU's REACH dossier compilation system, Iuclid.

Therefore, at this stage and taking into account the above, it seems more likely that the MoEUCC would rather provide some kind of temporary registration simplification with a requirement of mandatory update within a certain timeframe, rather than a deadline extension. For this reason, we do not recommend postponing any pending KKDIK registration activities in Turkey and concentrate all possible efforts on meeting the current 31 December registration deadline.

Lead registrations progress and hurdles along the way

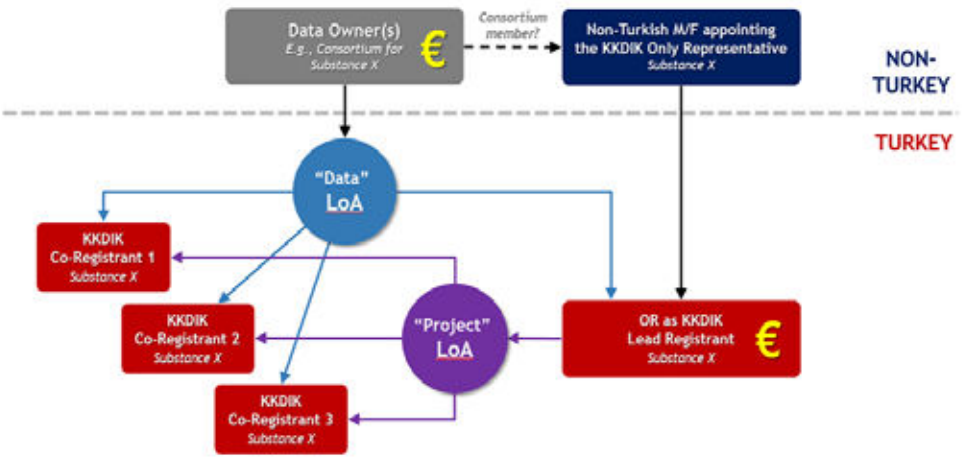
Lead registration nominations and lead dossier submissions have been climbing slowly. However, more than 80% of the estimated lead registrations amount still have no even had a lead registrant nominated. About 10% of the expected estimated lead registrations have been submitted to the MoEUCC and letters of access to the joint registration dossier are slowly becoming available, meaning that co-registrants are now able to submit their co-registration dossiers for those substances.

In some cases, the lead registrants do not own the core data for a substance, nor do they have rights to sublicence the data to the co-registrants. The lead registrant may, for example, be a member of an EU consortium and via a consortium agreement have acquired rights to use the data even outside the EU, but not the sublicensing rights. This means that such lead registrants can submit the lead registration dossier but they are not allowed to provide the right to refer to the data in the dossier to the co-registrants unless these co-registrants settle the data rights directly with the data owners. So instead of obtaining the sublicencing rights, the lead registrant will direct the co-registrants to the data owner, and in some cases multiple data owners, where the co-registrant will have to acquire legitimate access to the data for the substance via separate data sharing agreements and sometimes multiple agreements in case of multiple data owners. Such data sharing agreement(s) will be outside of scope of a Sief governing agreement between the lead registrant and the co-registrants.

From a contractual perspective, in such cases a co-registrant will have to sign a Sief governing agreement, a so-called joint registration agreement and an additional data sharing agreement with the data owner to acquire the rights to refer to the core data in its KKDIK co-registration dossier. In the best-case scenario, there is only one data owner or one data holder – such as a consortium, for example – having the rights to sublicence the data to the co-registrants. In more difficult cases, where there are multiple data owners, the co-registrant might have to enter into data sharing agreements with all of them to obtain all necessary rights to refer and use the data in its co-registration dossier. The obligation of the lead registrant is to provide the data owners' details and to confirm with the data owners that the required data compensation has been duly settled before allowing the co-registrant into the joint submission.

Figure 2 below represents graphically what kind of steps the co-registrant has to undertake in relation to the data in its registration dossier, where both access to the data, so-called "Data Letter of Access" or "Data LoA", and access to the lead dossier, including project costs, "Project LoA", have to be acquired separately.

Figure 2: Complex Data Ownership and Access to the KKDIK data



Co-registration status

The co-registrations are dependent on the lead registrations. Without an approved lead registration, there is no way for a co-registrant to submit its KKDIK registration – except becoming the lead registrant itself.

Due to the extremely low number of lead submissions so far, it is difficult for co-registrants to budget their co-registration since letter of access costs may not be available. In fact, LoAs are currently not available for more than 80% of the substances estimated for KKDIK registration.

For more experienced co-registrants, for example from EU REACH or other jurisdictions, it may be a good idea to consider becoming lead registrants themselves if there is no lead registrant activity in the Siefs for the substances of strategic importance to those co-registrants.

Conclusions

The KKDIK registration deadline currently set at 31 December is approaching fast and companies intending to register their substances for the Turkish market must focus on the registration process as much as possible, especially those that are in the process of lead registering or considering lead registering their chemical substances. In some cases, securing the required data access may not be easy as there are multiple data owners involved. The lead registrants need to act fast and not hesitate any longer to be able to compile and submit their lead dossiers and allow the co-registrants to join the joint submission and submit their co-registration dossiers. In the case of multiple data owners, co-registrants will have to spend more time obtaining data rights and this must be considered when budgeting and planning co-registration work.

Although there are many ongoing discussions in the industry related to the potential registration deadline extension, there are no clear indications that the authorities will be going in that direction. Instead, the authorities have repeatedly indicated that the KKDIK registration deadline will not be extended. The MoEUCC has already provided several registration simplifications to help industry comply with KKDIK registration requirements and might streamline the process even further. However, a registration deadline extension does not seem a realistic possibility, at least at the moment.

We have less than eight months until the registration deadline and thousands of registrations are still to be submitted. Now is the time for the lead registrants to step up their game and accelerate their efforts to ensure compliance and facilitate co-registration under the KKDIK regulation.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch.