

17th October 2023

Reasons and Comments Regarding The Need for Deadline Extension for KKDİK Registrations

Author: Melih Babayigit / CAE- Principal Regulatory Consultant

The lack of local resources and laboratory capacity to obtain registration data 17th requirements raises the need to use of data compiled under the REACH regulation.

Using the data compiled within the scope of REACH is the most reasonable way in terms of time, both because it is more cost effective, and the time required to conduct some analysis is longer than the registration periods of the legislation.

However, despite the fact that there are 70 days left until the deadline for registration, despite all the efforts of all stake holders (local manufacturers, global suppliers as well the OR and consultants) who are trying to comply with the legislation, Lead Registrants that are able to obtain data and submit the Lead registration dossier is only around 10% of all substances for which pre-registration is submitted That is mostly due to the issues such as intellectual property rights, global political sanctions and cost sharing regarding data sharing.

In the light of this information, for many of the substances, the issues of data sharing has not been yet settled and no Lead Registrant candidate has emerged, thus a registration dossier has not been prepared despite all good faith efforts.

Most of the REACH data owners or right holders are EU-based industry associations, consortia or companies and these organisations are subject to EU laws and the sanctions that they are operated under them. For this reason, these data owner organisations do not want to share data with Russian, Belarusian and related companies, which are subject to sanctions under EU law. When it is considered specifically for our country, it is seen that a significant portion of the inputs of some industries are supplied from these countries.

In this framework, the disruption of competitive supply chains in terms of the current foreign trade balance conditions for this reason may cause serious and difficult-to-repair problems in imports and, as a result will affect domestic production, and exports. In this framework, it is critical to postpone the registration date until a solution or policy is determined by the Competent authority for supplies via EU and UN sanctioned countries.

Despite all efforts, it is an inevitable fact that domestic manufacturers & producers will have to cease or suspend production due to the fact that data sources for some substances cannot be found or data owners have not yet reached an agreement on sharing conditions.

The time remaining until 31.12.2023 is not sufficient for many global companies to make supply and logistic planning for 2024 and to finance and pay the expenses required for regulatory compliance. Even if the registration conditions and data source of a substance is determined today, it is not possible to invite co-registrants to register and to execute the numerous data sharing

contracts and fee payments of these institutions. This factual reality leads companies to panic and uncertainty for 2024 manufacturing and supply.

For both domestic producers and global suppliers to make their 2024 plans without disrupting Turkey's domestic production and foreign trade, it is of vital importance that if a registration date revision is to be made due to the reasons presented above, it should be carried out within the current October at the latest. Because an extension to be made later carries the risk of not being able to prevent supply disruptions and negative commercial consequences due to the inability to make some planning.

In line with the objectives of the KKDİK regulation, it is only possible for the authorities to make decisions to protect human and environmental health more effectively within the scope of robust and up-to-date data if all stakeholders work in cooperation and take initiative and responsibility. Therefore, it is our hope and expectation from the competent authority for a reasonable time extension in line with the above reasons for a successful enforcement, and a transparent, open to dialogue cooperation in good faith from other stakeholders (Data Owners, Producers, Suppliers, Consortiums, Single representative institution and KDU individuals).

We wish successful works in compliance with the legislation and sensitive to human and environmental health.

Melih Babayigit

CRAD Çevre Risk An. Den A.Ş.