

From the Ministry of Environment, Urbanisation and Climate Change:

PROCEDURES AND PRINCIPLES REGARDING THE IMPLEMENTATION OF THE REGULATION ON THE REGISTRATION,
EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (KKDİK)

SECTION ONE
Preliminary Provisions

Purpose

ARTICLE 1 – These Procedures and Principles have been prepared to set out matters related to ensuring the effective implementation of the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (KKDİK-Türkiye REACH).

Scope

ARTICLE 2 – (1) These Procedures and Principles cover matters related to the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (KKDİK-Türkiye REACH) and integrated chemicals management.

Basis

ARTICLE 3 – (1) These Procedures and Principles are based on the Environmental Law No. 2872 dated 09/08/1983, and the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (KKDİK-Türkiye REACH) published in the Official Gazette No. 30105 (repeated) dated 23/06/2017.

Definitions

ARTICLE 4 – (1) For the purposes of these Procedures and Principles:

- a) *Ministry*: The Ministry of Environment, Urbanisation and Climate Change of the Republic of Türkiye,
- b) *Potential registrant*: The manufacturer or importer of a substance, or the producer or importer of an article, who has not yet registered but intends to do so,
- c) *Agreement*: The comprehensive agreement to be concluded between the lead company and the potential registrants, covering all matters related to fulfilling joint registration obligations,
- d) *Regulation*: The Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (KKDİK-Türkiye REACH).

SECTION TWO
General Rules

Registration

ARTICLE 5 – (1) A manufacturer or importer who manufactures or imports a substance on its own or in a mixture in quantities of one tonne or more per year shall submit a registration application to the Ministry by providing the information set out in Article 11 of the Regulation via the Chemical Registration System, one of the applications of the Ministry's Integrated Environmental Information System.

(2) Each potential registrant of a substance manufactured or imported in quantities of one tonne or more per year shall submit a “Pre-Substance Information Exchange Forum” (pre-SIEF) in order to continue manufacturing or importing. This process allows potential registrants to contact each other for data sharing via the SIEF and to submit the registration application referred to in the first paragraph. All potential registrants of the same substance shall be participants in the SIEF.

Substance Information Exchange Forum

ARTICLE 6 – (1) All potential registrants shall submit their pre-SIEF regarding their substances to the Ministry via the Chemical Registration System (KKS) by 31/10/2025 and become participants in the SIEF.

(2) For substances to be manufactured and/or imported for the first time after 31/10/2025, the pre-SIEF created by potential registrants shall be submitted to the Ministry via the KKS within 30 days following their placement on the market, and potential registrants shall become SIEF participants.

One Substance – One Registration Principle

ARTICLE 7 – (1) Registrants shall, unless valid reasons as defined in the Regulation exist, be part of the same registration. For this purpose, potential registrants can obtain information about the registration status of the same substance by making a SIEF inquiry through the KKS.

(2) Companies that will submit the registration dossier separately from the joint registration group with a valid reason within the scope of the third paragraph of Article 12 of the Regulation shall notify the Ministry in writing of their reasons and all information and documents proving this reason.

(3) The lead registrant shall communicate in writing with previous registrants and potential registrants in necessary situations such as the obligation to update.

Determination of Lead Registrants

ARTICLE 8 – (1) For substances placed on the market before the date of the publication of these Procedures and Principles, lead registrants shall be determined no later than 31/12/2025. For substances placed on the market for the first time after the date of publication of these Procedures and Principles, the lead registrants shall be determined within six months following their placement on the market.

(2) The determination of lead companies shall primarily be based on voluntary participation. In the absence of a volunteer, taking into account criteria such as tonnage band, available data, and company size, the Ministry, with the opinion of the Union of Chambers and Commodity Exchanges of Türkiye (TOBB), shall initiate work to determine a manufacturer/importer of the substance to be registered as the lead registrant.

(3) A lead candidate company shall notify its request to be the lead, along with its justifications, to all SIEF members via the KKS and carry out the necessary correspondence. Following the notification by the lead candidate, all SIEF members must send their positive or negative opinions, with justifications, to the lead candidate within 30 days at the latest. Companies that do not respond within the specified period shall be deemed to have given a positive opinion, and all correspondence related to this shall be kept on record. The designated candidate:

a) If accepted by an absolute majority of SIEF members, shall be appointed as the lead company.

b) If not accepted by the absolute majority stated in subparagraph (a), the candidate shall inform all SIEF members of this situation and withdraw from lead candidacy. In this case, the process for electing a new lead registrant from among the SIEF members shall restart.

(4) The lead for a substance for which no registration dossier has yet been submitted shall carry out SIEF communication, including tonnage bands, data gap analysis, and other relevant matters. The matters foreseen to be

included in the Agreement shall be communicated in writing in full detail to the SIEF members. If these matters are approved by an absolute majority of the SIEF members, actions shall be taken within the framework of the Agreement to be concluded between the lead company and member companies. After this stage, the lead company may commence the registration process.

(5) If the majority specified in paragraph four cannot be achieved, the process for electing a new lead registrant shall restart.

(6) If the lead company of a registered substance is unable to continue in this role, the lead company shall inform all members of the existing SIEF of this request and subsequently submit it in writing to the Ministry along with the necessary information and documents. Following the Ministry's assessment, permission shall be granted through the system to initiate the process for selecting a new lead registrant. The existing lead shall be obliged to transfer all necessary information and documents to the new lead within 30 days following the Ministry's written approval, in accordance with the lead registrant's sharing rights and the confidentiality and data ownership principles of the Regulation.

(7) In joint registration groups where a lead company was determined before the date of publication of these Procedures and Principles but no registration dossier has been submitted, the lead registrant selection shall, if necessary, be repeated within the framework of these Procedures and Principles.

Joint Registration Group

ARTICLE 9 – (1) A Joint Registration Group shall consist of the registrants of the same substance. It shall work to ensure coordination within the SIEF for the preparation of the registration dossier to be submitted to the Ministry. Each joint registration group shall be responsible for determining its own registration and working procedures.

(2) TOBB shall work in coordination with organisations representing sectors engaged in chemical-related activities and the Ministry on processes such as the effective functioning of joint registration groups and the preparation of joint registration group-type agreements.

(3) The activities carried out within the scope of paragraph two of this article shall be reported by TOBB to the Ministry every December.

(4) The activities carried out shall be discussed in the Chemicals Advisory Group meetings.

Transitional Registration

ARTICLE 10 – (1) Where the lead company cannot fulfil its obligations regarding full registration, it shall make a transitional registration by submitting to the Ministry, via the KKS, the data set out in Annex-1 of these Procedures and Principles by 31/03/2026. Following the Transitional Registration by the lead company, member companies shall submit their member registration entries to the Ministry via the KKS by 30/09/2026.

(2) Companies that are not part of the joint registration group for a substance and will submit their registration dossier separately under paragraph two of Article 6, but cannot fulfil their obligations regarding full registration, shall make a transitional registration by submitting to the Ministry via the KKS, by 31/03/2026, the data set out in Annex-1 of these Procedures and Principles.

(3) The data set out in Annex-1 of these Procedures and Principles shall be entered into the KKS by a Chemical Assessment Expert (CAE), and the qualification certificate of the relevant CAE shall be attached.

(4) The provisions of the Regulation regarding registration fees, as set out in the Ministry's Revolving Fund Unit Price List, shall apply during the transitional registration process.

(5) For companies that will submit a full registration dossier by 31/03/2026, the provisions set out in paragraphs one, two, three, and four of this article shall not apply.

Completion of the Registration Process

ARTICLE 11 – (1) The following shall be deemed to have completed their registration if they fulfil, by the deadlines set out in the provisional Article 2 of the Regulation, the tonnage-dependent information requirements set out in the Regulation for the full registration dossier:

- a) Companies that submit their registration dossier separately under paragraph two of Article 7,
- b) Lead companies submitting a joint registration,
- c) Member companies of joint registration groups whose lead has submitted the full registration dossier.

(2) If potential registrants are unable to obtain the necessary data for the full registration dossier or cannot access such data from publicly available, copyright-free global data sources, the lead registrant in the case of joint registration, or the company itself in the case of a separate submission of the registration dossier under paragraph two of Article 7, shall submit to the Ministry via the KKS a request for an extension of time together with a detailed justification explaining the situation.

(3) The Ministry shall evaluate the justification specified in paragraph two and notify the relevant party of its decision regarding the extension request.

(4) If the Ministry requests additional information during the granted extension period, such requests shall be fulfilled within the period set by the Ministry. If the additional information cannot be provided within this period, an extension request shall be submitted to the Ministry together with its justification.

(5) The extension period to be granted by the Ministry under paragraph three shall not exceed two years after the final registration deadline set for the relevant tonnage band of the substance. If the data cannot be obtained by the end of the extension period, the justifications provided shall be evaluated by the Chemicals Advisory Group, and the Ministry shall approve or reject the registration for the specific substance accordingly.

Chemicals Science Group

ARTICLE 12 – (1) The Chemicals Science Group established under the coordination of the Ministry shall:

- a) Provide information and evaluation on current questions and issues related to work and activities under chemicals management,
- b) Carry out work related to training processes on chemicals,
- c) Evaluate matters identified in the Chemicals Advisory Group that could not be resolved.

(2) The Chemicals Science Group shall consist of academic staff from universities working on chemicals and their effects on human health and the environment.

(3) The group shall consist of at least seven members, convene with an absolute majority of the full number of members, and take advisory decisions by an absolute majority of the members present at the meeting.

(4) The Director General of Environmental Management shall chair the group, or, in cases where the Director General cannot attend, the Deputy Director General shall chair.

(5) The group shall meet twice a year upon the Ministry's invitation. Additional meetings may be held upon the Ministry's invitation when deemed necessary.

(6) The secretariat services of the group shall be carried out by the Ministry's Directorate General of Environmental Management.

(7) Sub-working groups may be formed when deemed necessary.

Chemicals Advisory Group

ARTICLE 13 – (1) The Chemicals Advisory Group established under the coordination of the Ministry shall:

- a) Hold consultations on the current situation, planned activities, and international developments under chemicals management,
- b) Make recommendations in studies to determine, monitor, and evaluate plans, policies, strategies, and actions related to chemicals management,
- c) Evaluate matters identified in the Chemicals Science Group that could not be resolved.

(2) The Chemicals Advisory Group shall include representatives from the Ministry of Health, the Ministry of Agriculture and Forestry, the Ministry of Trade, the Ministry of Industry and Technology, the Ministry of Interior, the Ministry of Labour and Social Security, TOBB, other relevant institutions and organisations as needed, and members of the Chemicals Science Group.

(3) The group shall consist of at least seven members, convene with an absolute majority of the full number of members, and take advisory decisions by an absolute majority of the members present at the meeting.

(4) The Director General of Environmental Management shall chair the group, or, in cases where the Director General cannot attend, the Deputy Director General shall chair.

(5) The group shall meet twice a year upon the Ministry's invitation. Additional meetings may be held upon the Ministry's invitation when deemed necessary.

(6) The secretariat services of the group shall be carried out by the Ministry's Directorate General of Environmental Management.

(7) Sub-working groups may be formed when deemed necessary.

Implementation Provisions

ARTICLE 14 – (1) In the implementation of the Regulation and these Procedures and Principles, the guidelines published by the Ministry shall be taken into account.

Updating of Registration Dossiers

ARTICLE 15 – (1) Where it becomes necessary to update existing registrations under paragraph one of Article 22 of the Regulation, such updates shall be made within three months from the date the update requirement arises. If there is an impediment to carrying out the update within this period, the situation shall be notified to the Ministry in writing together with a detailed justification, and an extension request shall be submitted.

(2) If the Ministry has taken a decision for an update under paragraph two of Article 22 of the Regulation, the registrant shall carry out the registration update containing the information required by the decision within the period specified in the decision.

(3) Updates to registrations made prior to the publication of these Procedures and Principles may be made until the final registration deadlines set out in the Regulation.

Safety Data Sheets

ARTICLE 16 – (1) Safety Data Sheets prepared under paragraph one of Article 27 of the Regulation shall be uploaded by the supplier to the Ministry’s dedicated package software for safety data sheets.

(2) In the Safety Data Sheets to be prepared under the Regulation and within the scope of the headings in Annex-2, under heading 16, the contact information of the Chemical Assessment Expert (CAE) who prepared the SDS, together with the date and number of the qualification certificate, shall be provided.

(3) CAE training and certification processes shall be carried out under the coordination of the Ministry.

SECTION THREE

Miscellaneous and Final Provisions

Inspection and Administrative Sanction

ARTICLE 17 – (1) In cases of non-compliance with the conditions specified in these Procedures and Principles, sanctions shall be applied pursuant to Law No. 2872.

Entry into Force

ARTICLE 18 – (1) These Procedures and Principles shall enter into force on the date of their publication.

Enforcement

ARTICLE 19 – (1) The provisions of these Procedures and Principles shall be enforced by the Minister of Environment, Urbanisation and Climate Change.

ANNEX-1

TRANSITIONAL REGISTRATION INFORMATION REQUIREMENTS

Information requirements to be provided for transitional registration by lead companies and companies that will make individual registrations, and section numbers in the Chemical Registration System (KKS):

1. Identification (KKS Section 1.1)
 - 1.1 Composition (KKS Section 1.2)
 - 1.2 Analytical Information (KKS Section 1.4)
 - 1.3 Suppliers: In this section, companies shall enter the names of their downstream users and keep this information up to date. This update is free of charge. (KKS Section 1.7)
 - 1.4 Joint Submission (KKS Section 1.5)
2. Globally Harmonised System (KKS Section 2.1)
3. Manufacture, Use and Exposure (KKS Section 3)
 - 3.1 Estimated Quantities (KKS Section 3.2)
 - 3.2 Sites (KKS Section 3.3)
 - 3.3 Information on Mixtures (KKS Section 3.4)
 - 3.4 Use and Exposure Information (KKS Section 3.5)
 - 3.5 Uses Advised Against (KKS Section 3.6)
4. Physical and Chemical Properties (KKS Section 4)
5. Guidance on Safe Use (KKS Section 11)

Note: Member companies shall enter the information requirements numbered 1 and 3 above into the relevant sections of the KKS.

ANNEX-2

SAFETY DATA SHEET FORMAT

1. Identification of the substance/mixture and of the company/undertaking,
2. Hazards identification,
3. Composition/information on ingredients,
4. First-aid measures,
5. Fire-fighting measures,
6. Accidental release measures,
7. Handling and storage,
8. Exposure controls/personal protection,
9. Physical and chemical properties,
10. Stability and reactivity,
11. Toxicological information,
12. Ecological information,
13. Disposal considerations,
14. Transport information,
15. Regulatory information,
16. Other information.