

From the Ministry of Environment, Urbanization and Climate Change

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

PART ONE

Introductory Provisions

Purpose

Article 1 – These Procedures and Principles have been prepared to determine the issues necessary to ensure the effective implementation of the Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals.

Scope

Article 2 – (1) These Procedures and Principles cover matters related to the Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals and integrated chemicals management.

Legal Basis

Article 3 – (1) These Procedures and Principles are prepared on the basis of the Environmental Law No. 2872 dated 09/08/1983 and the Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals published in the Official Gazette dated 23/06/2017 and numbered 30105 (duplicate issue).

Definitions

Article 4 – (1) In these Procedures and Principles:

- a) **Ministry**: the Ministry of Environment, Urbanization and Climate Change,
- 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 register,
- 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,
- ç) **Regulation**: the Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (KKDİK),

are meant.

PART 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 a quantity of one tonne or more per year shall submit the information specified in Article 11 of the Regulation to the Ministry through the Chemical Registration

System (a module of the Ministry's Integrated Environmental Information System) and apply for registration.

(2) For each substance manufactured or imported at 1 tonne/year or above, every potential registrant must submit a **Pre–Substance Information Exchange Forum (Pre-MBDF)** to continue manufacturing or importing. This process enables potential registrants to make contact for data sharing through the MBDF and to be able to submit the registration application referred to in paragraph one. All potential registrants of the same substance shall be participants of the MBDF.

Substance Information Exchange Forum

Article 6 – (1) All potential registrants shall, by **31/10/2025**, submit their Pre-MBDF for their substances to the Ministry via the Chemical Registration System (CRS/KKS) and become MBDF participants.

(2) For substances that will be manufactured and/or imported for the first time after **31/10/2025**: Pre-MBDFs created by potential registrants shall be submitted to the Ministry via KKS within **30 days** following the placing on the market, and the potential registrants become MBDF participants.

One substance, one registration principle

Article 7 – (1) Unless registrants have valid reasons specified under the Regulation, they must be part of the same registration. For this purpose, potential registrants may inquire through KKS about the registration status of the same substance by conducting an MBDF search.

(2) Companies that will submit their registration dossier separately from the joint-registration group with a valid justification within the scope of Article 12(3) of the Regulation shall notify the Ministry in writing of their justification and all information and documents proving this justification.

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

Determination of lead companies

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

(2) Volunteering has priority in determining lead companies. In the absence of a volunteer, considering criteria such as tonnage band, existing data, and company size, the Ministry—taking the opinion of the Union of Chambers and Commodity Exchanges of Türkiye (TOBB)—initiates work to designate one of the manufacturers/importers of the substance as the lead company.

(3) The lead-candidate company notifies all MBDF members via KKS of its request to be lead together with its justifications and conducts the necessary correspondence. Within **30 days**

following the lead candidate's notification, all MBDF members must convey their positive or negative opinions with justifications to the lead candidate. Companies that do not respond within the specified time are deemed to have given a positive opinion, and all correspondence regarding this is retained. The candidate:

- a) If accepted by an absolute majority of MBDF members, is designated as the lead company.
- b) If not accepted by the absolute majority stated in subparagraph (a), all MBDF members are informed of the situation by the candidate, and the candidate withdraws from leadership. In this case, the process for a new lead selection among MBDF members restarts.

(4) For a substance whose registration dossier has not yet been submitted, the leader carries out MBDF communications, including issues such as tonnage bands and data-gap analysis. The leader communicates in writing to MBDF members all the details foreseen to be included in the Agreement. If these are accepted by an absolute majority of MBDF members, actions proceed within the framework of the Agreement to be concluded between the lead company and member companies. From this stage, the lead company may start registration procedures.

(5) If the majority specified in paragraph four cannot be achieved, the process for a new lead selection restarts.

(6) If the lead company of a substance for which a registration dossier has been submitted cannot continue leadership, the lead company notifies all current MBDF members of this request and subsequently submits its request together with the necessary information and documents to the Ministry in writing. Following the Ministry's evaluation, permission is given in the system to carry out the procedures for selecting a new leader. The existing leader is obliged to transfer to the new leader, within **30 days** after the Ministry's written approval, all necessary information and documents within the framework of leader-sharing rights and in accordance with the confidentiality and data-ownership principles of the Regulation.

(7) In joint-registration groups for substances whose lead has been determined before the publication date of these Procedures and Principles but whose registration dossier has not been submitted, the leadership selection shall, where necessary, be redone within the framework of these Procedures and Principles.

Joint-registration group

Article 9 – (1) The Joint-Registration Group consists of the registrants of the same substance. It undertakes coordination within the MBDF for preparing the registration dossier to be submitted to the Ministry. Each joint-registration group is responsible for determining its own registration and working procedures.

(2) TOBB carries out work, in coordination with the Ministry and sectoral organizations operating in the field of chemicals, on processes such as the effective functioning of joint-registration groups and the preparation of model joint-registration group agreements.

(3) The work carried out within the scope of paragraph two is reported by TOBB to the Ministry every year in December.

(4) The work performed is discussed in the meetings of the Chemicals Advisory Group.

Temporary registration

Article 10 – (1) If the lead company cannot fulfill the obligations related to full registration, it shall submit to the Ministry, by **31/03/2026**, the data listed in **Annex-1** of these Procedures and Principles and perform a **temporary registration**. Following the lead company's temporary registration, member companies shall submit their member-registration entries to the Ministry via KKS by **30/09/2026**.

(2) Companies that will submit their registration dossier separately under Article 6(2) without joining the joint-registration group for their substance, and cannot fulfill the obligations related to full registration, shall submit to the Ministry via KKS, by **31/03/2026**, the data listed in **Annex-1** and perform a temporary registration.

(3) The data listed in **Annex-1** of these Procedures and Principles are entered into KKS by a **Chemical Assessment Expert (KDU)**, and the qualification certificate of the relevant KDU is attached.

(4) Provisions of the Regulation regarding registration fees set out in the Ministry's Revolving Fund Unit Price List shall apply during the temporary registration process.

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

Completion of the registration process

Article 11 – (1) By the deadlines in Provisional Article 2 of the Regulation, those who complete the tonnage-dependent information requirements stipulated in the Regulation and necessary for the full registration dossier are deemed to have completed their registration:

a) Companies that submit their registration dossier separately within the scope of Article 7(2),
b) Lead companies that submit a joint-registration application,
c) Member companies of joint-registration groups whose leader has submitted the full registration dossier.

(2) If potential registrants cannot obtain the data required for the full registration dossier or cannot access the data from public, copyright-free global data sources, an extension request together with a detailed justification for this situation shall be submitted to the Ministry by filling in the relevant sections in KKS—by the leader registrant in a joint registration for that substance, or by the company itself if the dossier is submitted separately under Article 7(2).

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

(4) If the Ministry requests additional information within the extension period granted, such requests shall be met within the period determined by the Ministry. If the additional information cannot be provided within the period, an additional extension shall be requested from the Ministry by stating the justification.

(5) The extension to be granted by the Ministry within the scope of paragraph three shall be at most **two years** after the final registration date set for the relevant tonnage band of the

substance. If the data still cannot be obtained at the end of the extensions, the Ministry shall approve or reject the registration for the relevant substance after the Chemicals Advisory Group evaluates the submitted justifications.

Chemicals Science Group

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

- a) Provide information and evaluations on current questions and issues related to work and activities within the scope of chemicals management,
- b) Carry out work related to training processes on chemicals,
- c) Evaluate the matters identified and unresolved in the Chemicals Advisory Group.

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

(3) The Group consists of at least **7** members, convenes with an absolute majority of the full number of members, and adopts advisory decisions by the absolute majority of the members attending the meeting.

(4) The Group is chaired by the Director General of Environmental Management, or, where the Director General cannot attend, by a Deputy Director General.

(5) The Group meets **twice a year** upon the Ministry's call. Additional meetings are organized upon the Ministry's call when deemed necessary.

(6) The Group's secretariat services are carried out by the Ministry's Directorate General of Environmental Management.

(7) Sub-working groups are 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 work, and international developments within the scope of Chemicals Management,
- b) Make recommendations in the work of determining, monitoring, and evaluating plans, policies, strategies, and actions related to chemicals management,
- c) Evaluate the matters identified and unresolved in the Chemicals Science Group.

(2) The Chemicals Advisory Group comprises 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; and, when needed, other relevant institutions and organizations, together with members of the Chemicals Science Group.

(3) The Group consists of at least **7** members, convenes with an absolute majority of the full number of members, and adopts advisory decisions by the absolute majority of the members attending the meeting.

(4) The Group is chaired by the Director General of Environmental Management, or, where the Director General cannot attend, by a Deputy Director General.

(5) The Group meets **twice a year** upon the Ministry's call. Additional meetings are organized upon the Ministry's call when deemed necessary.

(6) The Group's secretariat services are carried out by the Ministry's Directorate General of Environmental Management.

(7) Sub-working groups are 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 the registration dossier

Article 15 – (1) Where it is necessary to update registrations within the scope of Article 22(1) of the Regulation, existing registrations shall be updated within **3 months** from the date the need for update arises. If there is a situation preventing the update within this period, this situation shall be notified to the Ministry in writing together with a detailed justification, and an additional period shall be requested from the Ministry.

(2) If there is a decision by the Ministry to update within the scope of Article 22(2) of the Regulation, the registrant shall make the update containing the information required by the decision within the period specified in the decision.

(3) Updates to registrations made before the publication of these Procedures and Principles may be carried out until the final registration dates specified in the Regulation.

Safety Data Sheets

Article 16 – (1) Safety Data Sheets (SDS) prepared within the scope of Article 27(1) of the Regulation shall be uploaded by the supplier to the Ministry's dedicated software for Safety Data Sheets.

(2) Under the Regulation and within the headings in **Annex-2**, the following shall be written under Section 16 of the SDS to be prepared: the contact information of the KDU (Chemical Assessment Expert) who prepared the SDS and the date and number of the qualification certificate.

(3) KDU training and certification processes are carried out under the coordination of the Ministry.

PART THREE

Miscellaneous and Final Provisions

Inspection and administrative sanctions

Article 17 – (1) In cases of non-compliance with the matters 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 enter into force on the date of their publication.

Enforcement

Article 19 – (1) The provisions of these Procedures and Principles are executed by the Minister of Environment, Urbanization and Climate Change.

ANNEX-1

REQUIREMENTS FOR TEMPORARY REGISTRATION

Information requirements that Lead Companies and Companies to Register Individually must submit for Temporary Registration and the section numbers in the Chemical Registration System (KKS):

1. **Substance Identification** (KKS Section 1.1)
 - 1.1 **Substance Composition** (KKS Section 1.2)
 - 1.2 **Analytical Information** (KKS Section 1.4)
 - 1.3 **Suppliers**: In this section, companies enter the names of their own company's downstream users and keep this information up to date. This update is not subject to a fee. (KKS Section 1.7)
 - 1.4 **Joint submission** (KKS Section 1.5)
2. **Globally Harmonized System (GHS)** (KKS Section 2.1)
3. **Manufacture, use, exposure information** (KKS Section 3)
 - 3.1 **Estimated Quantities** (KKS Section 3.2)
 - 3.2 **Sites/Facilities** (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. **Safe Use Guide** (KKS Section 11)

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

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