

From the Ministry of Environment, Urbanization and Climate Change of Republic of Türkiye

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

PART 1

Preliminary Provisions

Purpose

Article 1 – These Procedures and Principles have been prepared to set forth the provisions ensuring the effective implementation of the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

Scope

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

Legal Basis

Article 3 – (1) These Procedures and Principles are based on the Environment Law No. 2872 dated 09/08/1983, and on the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals 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**: Refers to the Ministry of Environment, Urbanization and Climate Change,
- b) **Potential registrant**: A manufacturer or importer of a substance, or a producer or importer of an article, who has not yet completed registration but intends to do so,
- c) **Agreement**: The comprehensive agreement to be concluded between the Lead Registrant and the potential registrants, covering all matters related to fulfilling the obligations of joint registration,
- ç) **Regulation**: Refers to the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

PART 2

General Rules

Registration

Article 5 –

(1) A manufacturer or importer who manufactures or imports a substance, either on its own or in a mixture, in a quantity of one tonne or more per year, shall submit a registration to the Ministry through the KKS (Chemical Registration System), which is part of the Integrated Environmental Information System applications, by providing the information specified in Article 11 of the Regulation.

(2) Each potential registrant of a substance manufactured or imported in a quantity of 1 tonne or more per year shall submit a “Pre-registration” in order to continue manufacturing or importing. This process enables potential registrants to establish contact via the SIEF for the purposes of data sharing and to proceed with the registration application specified in paragraph one of this Article. All potential registrants of the same substance shall be participants in the SIEF.

Substance Information Exchange Forum

Article 6

1. All potential registrants of substances manufactured or imported in quantities above 1 tonne per year (t/y) before 31.10.2025 shall submit a pre-registration by no later than 31.10.2025.
 2. For any substances manufactured or imported in quantities above 1 t/y after 31.10.2025, pre-registration shall be submitted within 30 calendar days from the first date of placing the substance on the market.
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One Substance One Registration Principle

Article 7 - (1) Unless there are valid reasons specified in the Regulation, registrants must be part of the same registration. For this purpose, potential registrants can obtain information about the registration status of the same substance by querying the SIEF via the KKS.

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

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

Determination of Lead Registrants

Article 8 –

1. For substances placed on the market before the publication date of these Procedures and Principles, the Lead Registrant shall be determined by 31.12.2025. For substances placed on the market after the publication date, the Lead Registrant shall be determined within six (6) months from the date of placing the substance on the market.
2. The primary method for determining the Lead Registrant is through voluntary initiative among SIEF members. If no SIEF member volunteers, the Ministry, in consultation with the Union of Chambers and Commodity Exchanges of Türkiye (TOBB), shall initiate the determination process based on criteria such as tonnage band, company size, and data ownership.

3. A Lead Registrant candidate shall notify SIEF members of its intention, including justification, via the KKS. All SIEF members shall respond within 30 calendar days, either accepting or objecting. Members not responding within this period shall be deemed to have accepted. All records shall be retained. If the Lead Registrant candidate secures an absolute majority (including non-responses counted as acceptance), they shall be appointed as Lead Registrant. If an absolute majority is not achieved, the candidate shall inform the SIEF and withdraw, and the procedure shall restart.
4. For substances where the registration dossier has not yet been submitted, the Lead Registrant shall communicate within the SIEF the tonnage band, data gap status, and proposed conditions of the SIEF agreement. If these are accepted by an absolute majority, the Lead Registrant may proceed with registration.
5. If the Lead Registrant fails to secure an absolute majority, the procedure to determine a new Lead Registrant shall commence.
6. If the Lead Registrant of a submitted registration dossier is unable to continue, they shall notify the SIEF members and formally apply to the Competent Authority. Following the Authority's assessment, a new vote shall be conducted within the SIEF. The former Lead Registrant shall transfer the relevant data, without prejudice to confidentiality, data ownership, and cost sharing principles, within 30 calendar days after the new Lead Registrant is approved.
7. For substances where the registration dossier has not yet been submitted but a Lead Registrant has already been appointed before the publication of these Procedures and Principles, re-determination shall only be conducted if necessary.

Joint Registration Group

Article 9 –

1. A Joint Registration Group consists of registrants of the same substance. It operates within the SIEF to ensure coordination in the preparation of the registration dossier to be submitted to the Ministry. Each Joint Registration Group is responsible for establishing its own registration and working procedures.
2. The Union of Chambers and Commodity Exchanges of Türkiye (TOBB) shall work in coordination with sectoral organisations representing industries involved in chemical activities and with the Ministry on processes such as ensuring the effective functioning of Joint Registration Groups and preparing model agreements for such groups.
3. The activities carried out under the scope of paragraph 2 of this Article shall be reported by TOBB to the Ministry each December.
4. The activities undertaken shall be discussed at the meetings of the Chemicals Advisory Group.

Article 10 – Temporary Registration

1. If the Lead Registrant is unable to fulfil its obligations for complete registration, it shall submit a Temporary Registration by providing the information specified in Annex-1 of these Procedures and Principles to the Ministry via the KKS by 31.03.2026. Following the Lead Registrant's Temporary Registration, other members of the joint submission shall submit their registration to the Ministry via the KKS by 30.09.2026.
2. Companies outside the co-registration groups referred to in Article 2, submitting individual registration dossiers in accordance with Article 6(2), and unable to complete a full registration, shall submit the data specified in Annex-1 of these Procedures and Principles to the Ministry via the KKS by 31.03.2026.
3. Entry of the Annex-1 data into the KKS shall be carried out by a Certified Chemical Assessment Specialist (KDU), and the KDU's qualification certificate date and number shall be attached.
4. The provisions of the Regulation on registration fees, as listed in the Ministry's Official Fee Schedule, shall apply to the Temporary Registration process.
5. Paragraphs (1)–(4) of this Article shall not apply to companies able to submit a complete registration dossier by 31.03.2026.

Article 11 – Completion of the Registration Process

1. Companies fulfilling the tonnage band-based information requirements specified in the KKDİK Regulation and necessary for a complete registration dossier by the deadlines set in Provisional Article 2 of the Regulation (as amended in December 2023) shall be deemed to have completed their registration if they are:
 - a) Individual registrants submitting under Article 7(2),
 - b) Lead Registrants who have submitted a complete registration dossier,
 - c) Co-registrants whose Lead Registrant has submitted a complete registration dossier.
2. If potential registrants cannot obtain the necessary data for a complete registration dossier or access such data from publicly available, non-copyrighted global sources, the Lead Registrant shall notify the Ministry via the KKS with detailed justification and request an extension. Individual registrants under Article 7(2) shall notify the Ministry in the same manner.
3. The Ministry shall evaluate the justification and notify the registrant of its decision regarding the extension request.
4. If the Ministry requests additional information during the extension period, such information shall be provided within the specified timeframe. If this is not possible, a further extension request, with justification, shall be submitted.
5. The total extension period granted under paragraph (3) shall not exceed two years from the final registration deadline for the relevant tonnage band. If data are still unavailable at the end of this period, the Ministry shall approve or reject the registration following assessment by the Chemical Advisory Group, considering the registrant's justification.

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 activities and operations within the scope of chemicals management,
 - b) Carry out activities related to the training processes concerning chemicals,
 - c) Evaluate matters identified but unresolved in the Chemicals Advisory Group.
 2. The Chemicals Science Group shall consist of academic staff from universities who work on chemicals and their effects on human health and the environment.
 3. The Group shall be composed of at least seven (7) members, shall convene with an absolute majority of its full membership, and shall adopt recommendations by an absolute majority of those present.
 4. The Group shall be chaired by the Director General for Environmental Management, or, in the absence of the Director General, by the Deputy Director General.
 5. The Group shall convene twice a year upon the Ministry's invitation. Additional meetings may be held if deemed necessary, upon the Ministry's invitation.
 6. The secretariat services of the Group shall be carried out by the Directorate General for Environmental Management of the Ministry.
 7. Sub-working groups may be established if deemed necessary.
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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 in the field of chemicals management,
 - b) Provide recommendations for the determination, monitoring, and evaluation of plans, policies, strategies, and actions related to chemicals management,
 - c) Evaluate matters identified but unresolved in the Chemicals Science Group.
2. The Chemicals Advisory Group shall include representatives from the Ministry of Health, Ministry of Agriculture and Forestry, Ministry of Trade, Ministry of Industry and Technology, Ministry of Interior, Ministry of Labour and Social Security, TOBB, and, where necessary, other relevant institutions and organisations, along with members of the Chemicals Science Group.
3. The Group shall be composed of at least seven (7) members, shall convene with an absolute majority of its full membership, and shall adopt recommendations by an absolute majority of those present.
4. The Group shall be chaired by the Director General for Environmental Management, or, in the absence of the Director General, by the Deputy Director General.

5. The Group shall convene twice a year upon the Ministry's invitation. Additional meetings may be held if deemed necessary, upon the Ministry's invitation.
6. The secretariat services of the Group shall be carried out by the Directorate General for Environmental Management of the Ministry.
7. Sub-working groups may be established if deemed necessary.

Implementation Provisions

Article 14 –

(1) In the implementation of the Regulation and these Procedures and Principles, the guidance published by the Ministry shall be taken into consideration.

Updating the Registration Dossier

Article 15 –

1. In cases where registrations made under the Regulation are required to be updated in accordance with Article 22(1) of the Regulation, the existing registrations shall be updated within three (3) months from the date on which the need for update arises. If there is a circumstance preventing the update within this period, the situation shall be notified to the Ministry in writing with detailed justification, and an extension request shall be submitted to the Ministry.
2. Where the Ministry has taken a decision to update, in accordance with Article 22(2) of the Regulation, the registrant shall carry out the update including 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 carried out until the final registration deadlines specified in the Regulation.

Article 16 – Safety Data Sheets

1. Safety Data Sheets prepared in accordance with Article 27(1) of the KKDİK Regulation shall be uploaded by the supplier to the Ministry's dedicated SDS portal within ECBS.
2. In accordance with the Regulation and Annex-2, under Section 16 of the SDS, the contact details of the Certified Chemical Assessment Specialist (KDU) and the date and number of the KDU qualification certificate shall be provided.
3. Training and certification processes for KDUs shall be carried out under the coordination of the Ministry.

Part Three – Miscellaneous and Final Provisions

Article 17 – Administrative Sanctions

(1) In case of non-compliance with these Procedures and Principles, sanctions shall be imposed pursuant to Law No. 2872.

Article 18 – Entry into Force

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

Article 19 – Enforcement

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

ANNEX-1

INFORMATION REQUIREMENTS FOR TEMPORARY REGISTRATION

The information requirements to be submitted for Temporary Registration by Lead Registrants and individual registrants, along with the section numbers in the KKS (Chemical Registration System) are as follows:

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 shall enter the names of their own downstream users and keep this information up to date. This update is not subject to any 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 and Exposure Information (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 co-registrants shall enter the information requirements specified under items 1 and 3 above to the relevant sections of the KKS.

ANNEX-2

SAFETY DATA SHEET FORMAT

1. **Identification of the substance/mixture and of the company/undertaking**
2. **Hazard identification**
3. **Composition/information on ingredients**
4. **First-aid measures**
5. **Firefighting 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**