

KKDIK DRAFT REGULATION AND KKDIK CURRENT REGULATION COMPARISON TABLE.

CURRENT REGULATION	NEW DRAFT REGULATION
SECOND PART Registration of Substances	
FIRST SECTION Information Requirements and General Obligation to Register	
<p>Joint submission of data by multiple registrants</p> <p>ARTICLE 12 – (1) When a substance is intended to be manufactured by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 8, the following shall apply:</p> <p style="padding-left: 40px;">.....</p>	<p><i>The following paragraph has been added to Article 12 of the Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals.</i></p> <p>Joint submission of data by multiple registrants</p> <p>ARTICLE 12- (5) As a result of the studies to be carried out together with the sector and the Union of Chambers and Commodity Exchanges of Turkiye (TOBB), the issues related to the joint registration process, including the selection of leaders and data and cost sharing, are carried out within the framework of the procedures and principles to be published by the Ministry.</p>
SECOND SECTION Sharing of Existing Data	
<p>Sharing existing data for registered articles</p> <p>ARTICLE 24 – Every potential registrant of a substance shall inquire from the Ministry through Chemicals Registration System in the website of Ministry from 31/12/2023 whether a registration has already been submitted for the same substance</p>	<p>Sharing existing data for registered articles</p> <p>ARTICLE 24 – (1) Potential registrants send the following information to the Ministry through the Chemical Registration System on the Ministry's website to inquire about the registration status of the same substance as of 31/12/2030:</p>
THIRD SECTION Rules for the Substances	
<p>Article information exchange forums</p> <p>ARTICLE 25 – (1) All potential registrants, downstream users and third parties who have sent a pre-Article Information Exchange Forum (pre-SIEF) to the Ministry regarding the substance, or registrants who have applied for a registration before the specified date of 31/12/2023 regarding the substance, become participants of the Article Information Exchange Forum (SIEF).</p>	<p>Article information exchange forums</p> <p>ARTICLE 25 – (1) All potential registrants, downstream users and third parties who have sent a pre-Article Information Exchange Forum (pre-SIEF) to the Ministry regarding the substance, or registrants who have applied for a registration before the specified date of 31/12/2030 regarding the substance, become participants of the Article Information Exchange Forum (SIEF).</p>

<p>(3) SIEF participants shall provide existing studies to other registrants, respond to other registrants' requests for information, jointly define the needs for future studies, and arrange for the conduct of such studies to be carried out for the purposes specified in subparagraph (a) of the second paragraph. Each SIEF <u>continues to operate until 31/12/2025</u>.</p>	<p>(3) SIEF participants shall provide existing studies to other registrants, respond to other registrants' requests for information, jointly define the needs for future studies, and arrange for the conduct of such studies to be carried out for the purposes specified in subparagraph (a) of the second paragraph. Each SIEF continues to operate until 31/12/2032.</p>
<p>SIXTH PART Evaluation</p>	
<p>FIRST SECTION Dossier Evaluation</p>	
<p>Procedure and time periods for examination of testing proposals</p> <p>ARTICLE 39 – (1) The Ministry shall prepare the draft decisions in accordance with the Article 36 (3) in order to fulfil the information requirements in Annexes 9 and 10 by 31/12/2025 for the proposals received by 31/12/2023 including the testing proposals.</p>	<p>Procedure and time periods for examination of testing proposals</p> <p><i>In the first paragraph of Article 39 of the same Regulation, "... It has been changed to "for all proposals received until the deadlines determined depending on the amount of tonnage within the scope of the first paragraph of the transitional article 2 of the regulation, within 2 years after the expiry of the periods specified in the same paragraph."</i></p> <p>ARTICLE 39 – (1) The Ministry shall prepare the draft decisions in accordance with the Article 36 (3) in order to fulfil the information requirements in Annexes 9 and 10 within 2 years after the expiry of the periods specified in the same paragraph for all proposals that include test offers and are received until the deadlines determined depending on the tonnage amount within the scope of the first paragraph of the Provisional Article 2 of the regulation.</p>
<p>TWELVETH PART Miscellaneous and Final Provisions</p>	
<p>FIRST SECTION Miscellaneous Provisions</p>	
<p>Transitional provision TRANSITIONAL ARTICLE 1 – (1) All registrants, shall send a pre-SIEF including below mentioned information to the Ministry through Chemicals Registration System in the website of Ministry until 31/12/2020:</p>	<p>Transitional provision TRANSITIONAL ARTICLE 1 – (1) All registrants, shall send a pre-SIEF including below mentioned information to the Ministry through Chemicals Registration System in the website of Ministry until the "periods specified in the procedures and principles to be published by the Ministry":</p>

<p>Entry into Force ARTICLE 66- (1) Of this Bylaw; a) Articles 6, 40-56 will enter into force on 31/12/2023, b) Article 57(1); (1) Entries 28, 29, 30, 31, 32, 34, 35, 36, 37, 38, 40, 41, 45, 48,49, 54, 55,57, 58, 60 of Annex 17 will enter into force on 31/12/2018, (2) Entry 62 of Annex 17 will enter into force on 31/12/2019 (3) Entries 46a, paragraphs 1 to 4 of 47 and 65 of Annex 17 will enter into force on 31/12/2021 (4) Enty 66 of Annex 17 will enter into force on 31/12/2022 (5) All other entries of Annex 17 will enter into force 6 months later the date of its publication on the Official Gazette. c) Article 64(1)(a) will enter into force on 31/12/2023, Article 64(1)(b) will enter into force on the published day, ç) All other provisions will enter into force 6 months later the date of its publication on the Official Gazette.</p>	<p><i>Subparagraph (a) of the first paragraph of Article 66 of the same Regulation has been amended as follows, the following <u>subparaqraph (b) has been added and the other subparagraphs have been amended accordingly.</u></i></p> <p>Entry into Force ARTICLE 66 – (1) Of this Bylaw; a) Article 6 of this Regulation, on the <u>last dates of the tonnage-related periods specified in the first paragraph of the second transitional article"</u> b) Articles 40 to 44 and Articles 47 to 49 on 31/12/2026, Articles 45 and 46 and Articles 50 to 56 on 31/12/2028</p>
<p>TRANSITIONAL ARTICLE 2- (1) If substances on their own or in a mixture are manufactured or imported before 31/12/2023 and equal to or more than 1tonne/year, Articles 7 and/or 8 or 17 or 18 are executed between dates 31/12/2020 and 31/12/2023. (2) Safety Data Sheets shall be prepared according to the Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures until 31/12/2023. (3) Safety Data Sheets can be prepared according to this Bylaw from the execution date of Article 27 until 31/12/2023. In these cases, provisions of Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures will not be applied. (4) Chemicals Assessment Specialist can prepare a safety data sheet also according to the Bylaw on Safety Data Sheets Concerning Hazardous Substances and Mixtures.</p>	<p>Transitional provision TRANSITIONAL ARTICLE 2 – (1) The provisions of Articles 7 and/or 8 or 17 or 18 of this Regulation a) Until 31/12/2026 for substances that meet the following conditions, 1) Substances manufactured or imported in an annual amount of 1000 tons or more in their own form or in a mixture or in goods, 2) Substances that are manufactured or imported in an annual amount of 100 tons or more in their own form or in a mixture or in goods and are in the category of Aquatic Acute 1 and Aquatic Chronic 1 (H400, H410) in accordance with the Regulation on the Classification, Labeling and Packaging of Substances and Mixtures published in the first Repetitive Official Gazette dated 11.12.2013 and numbered 28848, 3) Substances manufactured and imported in an annual quantity of 1 ton or more in their own form or in a mixture or</p>

	<p>in goods and in the category of carcinogenic, mutagenic and toxic to the reproductive system in accordance with the Regulation on the Classification, Labeling and Packaging of Substances and Mixtures in the category of Category 1A and 1B hazards</p> <p>b) Without prejudice to the period given in subparagraph (a) of this paragraph, until 31/12/2028 for substances manufactured or imported in an annual quantity of 100 tons or more, either in their own form or in a mixture or in goods,,</p> <p>c) Without prejudice to the periods given in subparagraphs (a) and (b) of this paragraph, it is applied until 31/12/2030 for substances manufactured or imported in an annual amount of 1 ton or more in their own form or in a mixture or in goods.</p> <p>(2) The procedures and principles regarding the registrations to be made within the scope of the Regulation and the provision of data are determined by the Ministry.</p>
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Deadline Summary		
Tonnage Bands	Characteristic	Registration deadline
1000 tons and above per year	-	31/12/2026
100 tons and above per year	Aquatic Acute 1 and Aquatic Chronic 1	
1 ton and above per year	carcinogenic, mutagenic and toxic to the reproductive system Category 1A and 1B	
100 tons and above per year	-	31/12/2028
1 ton and above per year	-	31/12/2030