

Moving forward in KKDIK: How should companies prepare for registration process



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Outline

- KKDIK in a nutshell
- Timeline
- Updates
- Current Situation
- Roles & Responsibilities
- Your Obligations
- Our Role

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KKDIK In a Nutshell

Kimyasalların
Kaydı
Değerlendirilmesi
İzni
Kısıtlanması
 Hakkında yönetmelik

Bylaw on
Registration
Evaluation
Authorization &
 Restriction of
Chemicals



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KKDIK In a Nutshell

- Came into force on June 23rd, 2017
- EU Adaptation policy
- Competent authority: Ministry of Environment and Urbanization
- Merges&Replaces:
 1. Bylaw on Safety Data Sheets of Hazardous Substances & Mixtures (Until 2024)
 2. Bylaw on Inventory and Control of Chemicals
 3. Bylaw on Restriction and Ban of Hazardous Substances & Mixtures



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KKDIK In a Nutshell

The Aim of KKDIK

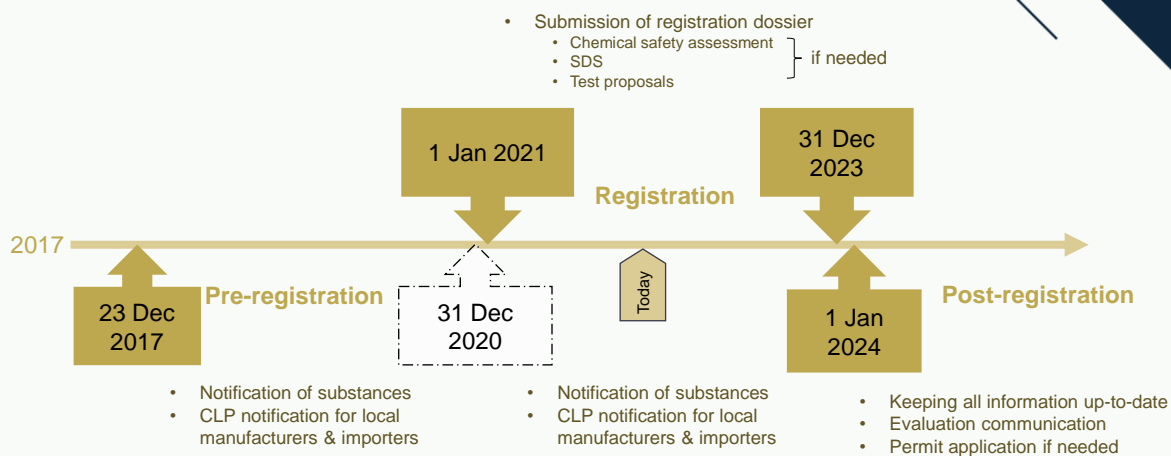
Article 1

“The purpose of this Bylaw is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances while enhancing competitiveness and innovation.”



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Timeline



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Frequently Used Abbreviations

- SIEF: **S**ubstance **I**nformation **E**xchange **F**orum (MBDF)
- LR: **L**ead **R**egistrant
- OR: **O**nly **R**epresentative
- SME: **S**mall or **M**edium Size **E**nterprise
- LoA: **L**etter **o**f **A**ccess
- LPR: **L**ate **P**re-**r**egistration
- CLP: **C**lassification, **L**abeling and **P**ackaging (SEA)



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Updates

- LR appointment started on March 2021
 - In relation to this, pre-registrations submitted after 15th of February cannot be deleted!
 - Voting system integrated into KKS
- SME fee calculator integrated into KKS
- CHESAR integrated with the name KDGRS
- Authority Fees updated
 - Not much change from Euro perspective
- Downstream User features supposed to be available by January 3rd 2022 on KKS, no announcement yet



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Current Situation

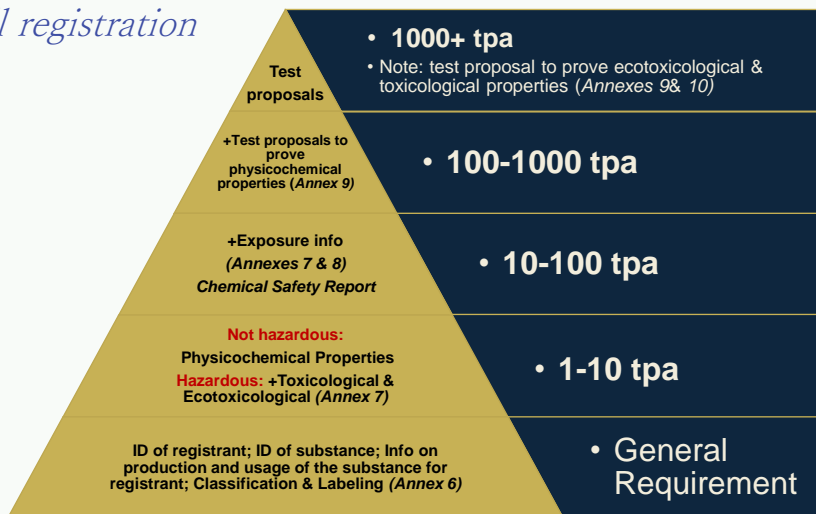
- LR nominations still going on
- Dossier submissions & preparations have started with SIEFs with LR
- Individual inventory formation by potential registrants
- Surveys sent by LR in some SIEFs in progress
- Joint submission is ongoing in SIEFs with submitted lead dossiers

Registration(Exemptions)

- Imported only to be used in biocidals & plant protection
- Human or veterinary medicines
- Substances in *Annexes 4&5*
- Polymers
- Re-isolated intermediates & transported intermediates
- Recycled in Turkey that is registered before
- Exported from a supply chain and reimported by the same supply chain
- Food and feedstock
- Less than 1 ton/year

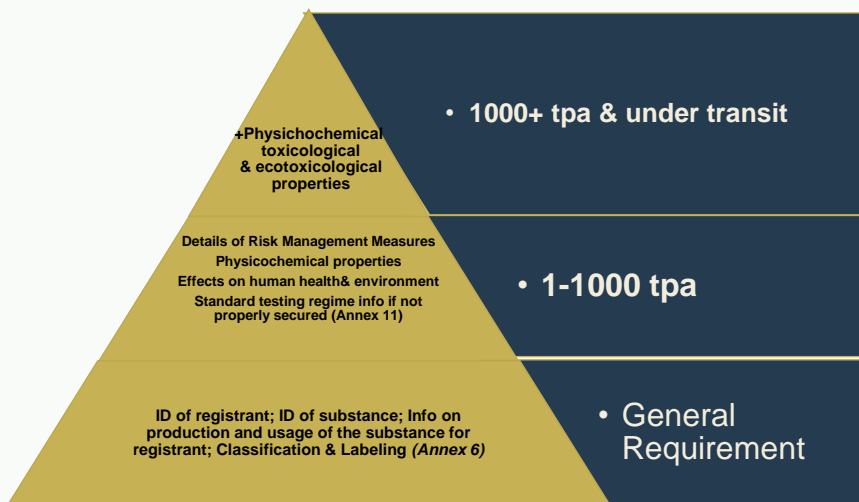
Registration Data Requirements

Full registration



Registration Data Requirements

Isolated intermediate registration



Registration

Chemical Safety Report (CSR)

- Prepared for 10+ tpa unless is less then:
 - Substance is in mixture => defined threshold in *Annex 1* of CLP
 - PBT/vPvB=> 0.1w% of chemical
- Includes
 - Human health hazards
 - Physicochemical hazards
 - Environmental impact & hazards
 - PBT and vPvB evaluation
- Only prepared by a certified Chemical Safety Assessment Expert



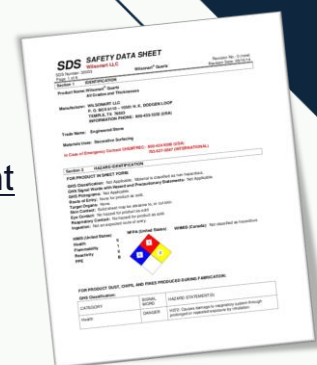
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Registration

Safety Data Sheet

- Prepared only by a Chemical Safety Assessment Expert* and only in Turkish
- Needed if:
 - Hazardous according to CLP
 - PBT/vPvB
 - Substance is SVHC and in *candidate for authorization* list
 - Includes standard 16 headings



*: Not necessarily until 2024



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Joint Registration

- 1) LR is elected
- 2) SIEF members who would like to join the dossier inform the LR
- 3) LR creates application, including members and their uses
 - In case an individual registration is necessary for a SIEF member, application to the Ministry is needed
- 4) Members complete their part of the dossier individually afterwards



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Joint Registration

- Purchasing of LoA & Cost Sharing
 - After LR submits the registration and includes the members, LoA and other dossier related cost are shared among members
 - Costs are calculated per usage & tonnage band
- According to KKDIK members are not discriminated in cost sharing



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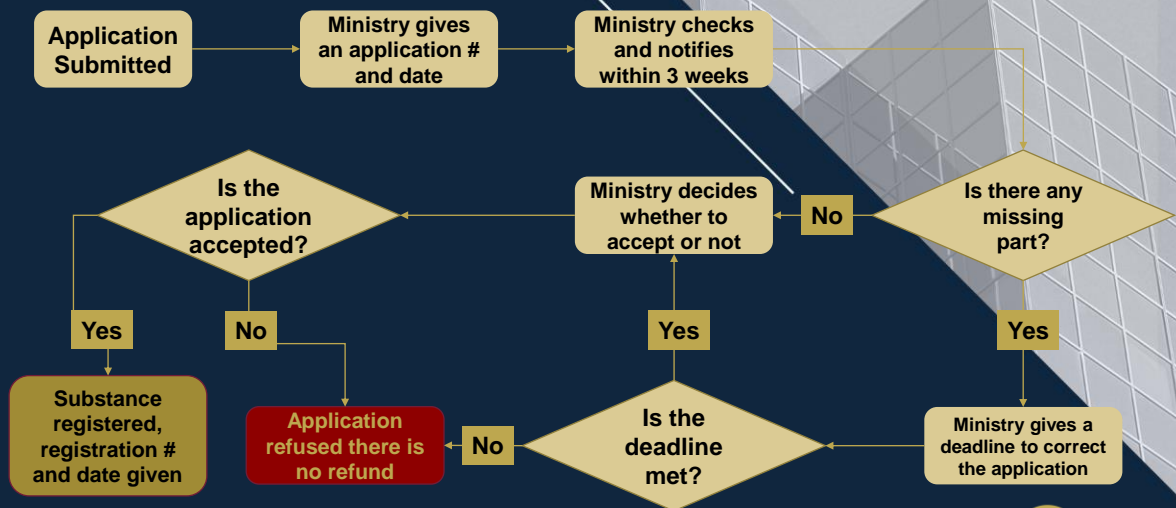
Joint Registration

- SIEF agreements should be signed well before
- Cost structure should be prepared and agreed on
- LR needs to inform members about SIP, uses, tonnage, SIEF agreement and cost sharing structure **BEFORE** moving forward
 - **Be proactive in your SIEF for registering in good time before the deadline!**



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After Submission



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Roles & Responsibilities

- SIEF Participants:
 - Vote among LR candidates or become a candidate
 - Gather necessary data to identify substance, required for sameness survey later on
 - Identify uses for their substance
- Downstream Users:
 - Register on ministry's environment portal if haven't yet and share environmental identity number with suppliers
- Non-Turkish Manufacturers:
 - If pre-registered via OR, share a list of substances
 - Including importer information as above
 - Decide what to register
 - Decide on which role to take
- OR
 - Start and participate in SIEF communications
 - Define the most cost-effective strategy to protect client interest
 - Reflect client intention and represent in SIEFs



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Roles & Responsibilities

SIEF Roles

- Active Member
 - Actively participating in deciding on SIP, uses, data requirement
 - LR is also an active member
- Passive Member
 - Not interested in preparation of the dossier but is willing to join
 - Only interested in registration but not the process
- Dormant Member
 - Not interested in registration unless stated otherwise but still part of the SIEF



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Your Obligations

- Make a list of substances where you want to register
 - Don't forget to decide on your SIEF role
- Be proactive if there is no LR and still the SIEF is silent!
- Answer as quickly as possible to surveys from LR, your consultant or your OR
- If there is a change in your intention, inform relevant contacts swiftly
- **Identify your substances & uses correctly**



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Our Role

- GPC is experienced with LR and consortia management for 400+ substances before Turkey
- Currently taking lead +250 SIEFs in Turkey
- We will:
 - Manage SIEF communication as well as legal & administrative aspects
 - Prepare technical dossier
 - Represent your best interests in the SIEF
 - Take LR position whenever possible & desired
 - Manage communication down the supply chain
 - Follow most economic strategies for your compliance



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Your seamless extension in global regulatory compliance

As GPC Turkey we have
3200+ pre-registered substances
~300 happy clients
We are active in 1600+ SIEFs



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Thank You.

Contact us for global regulatory services



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