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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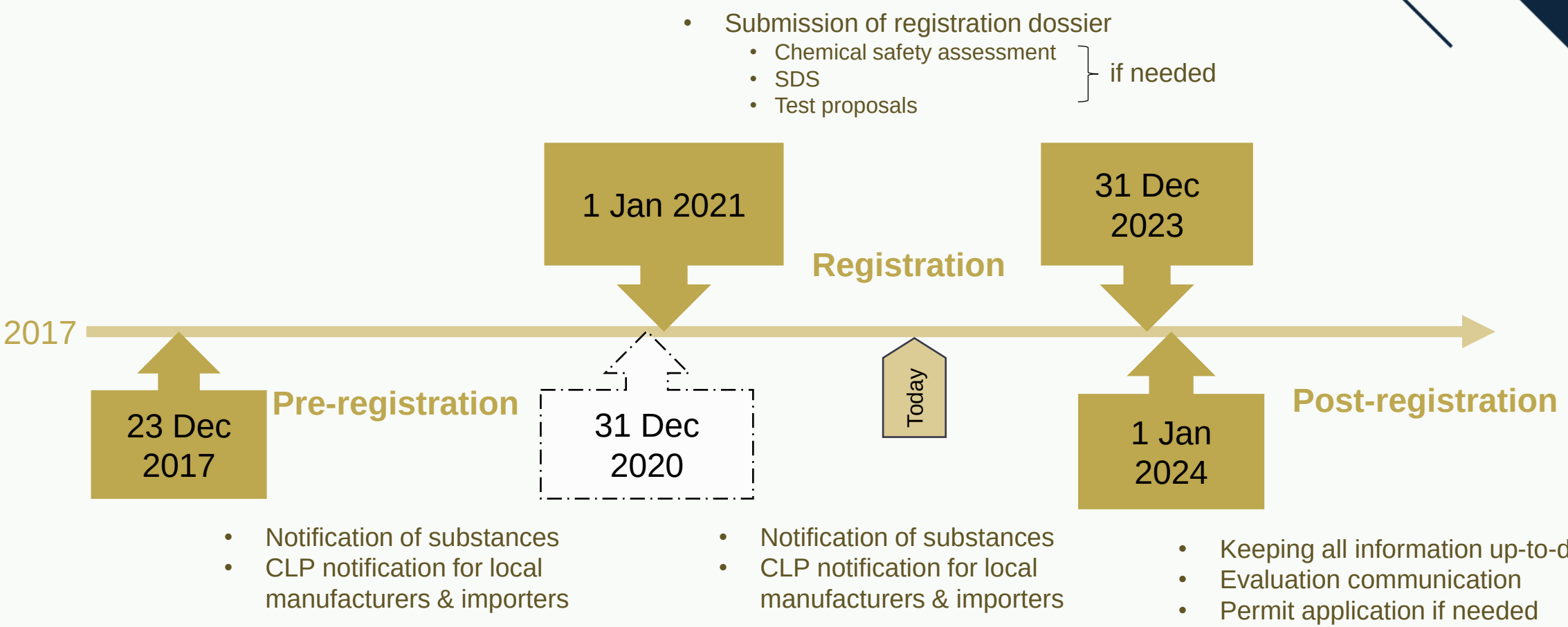
Timeline



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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

- Ministry: Deadline will not be postponed
- 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 KGDRS
- 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 LRs in some SIEFs in progress
- Joint submission is ongoing in SIEFs with submitted lead dossiers

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Registration(Exemptions)

- Imported only to be used in biocidals & plant protection
- Human or veterinary medicines
- Substances in *Annexes 4&5*
- Polymers
- Non-isolated intermediates
- On-site and transported isolated intermediates (only from full registration)

- 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

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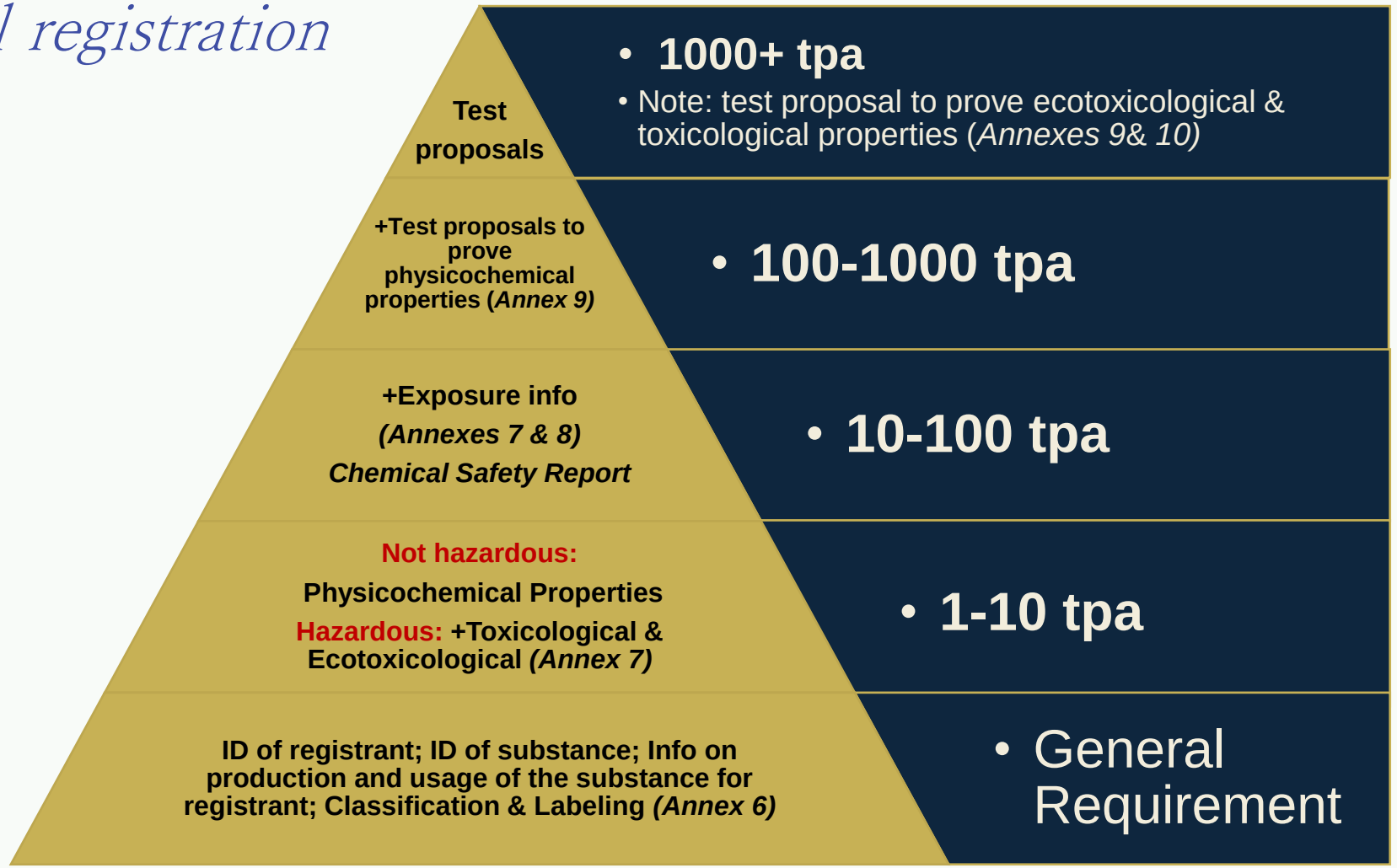
Registration Data Requirements

Full registration



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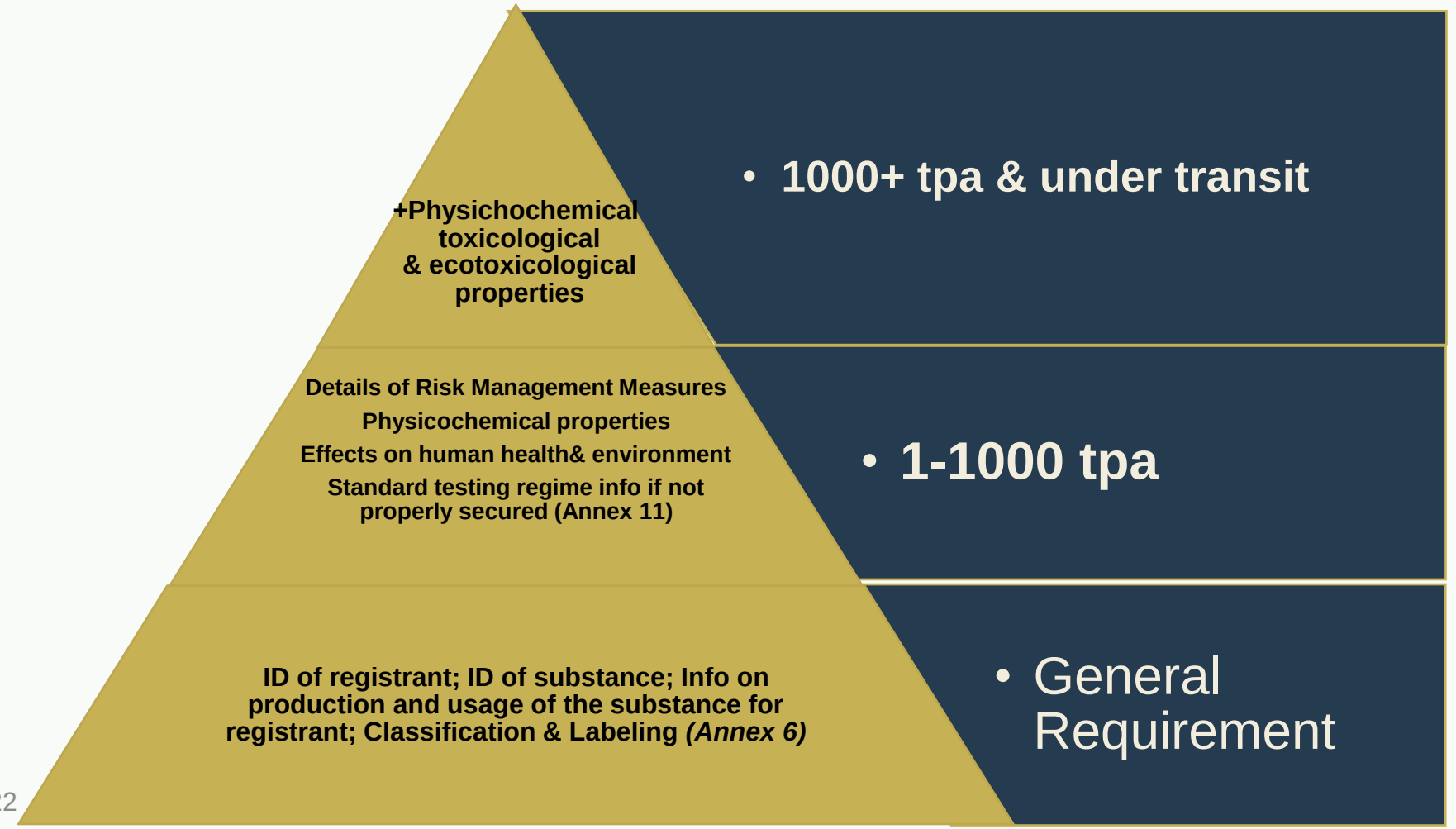
Registration Data Requirements

(Transported) isolated intermediate registration



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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 evalutation

➢ Only prepared by a certified Chemical Safety Assessment Expert

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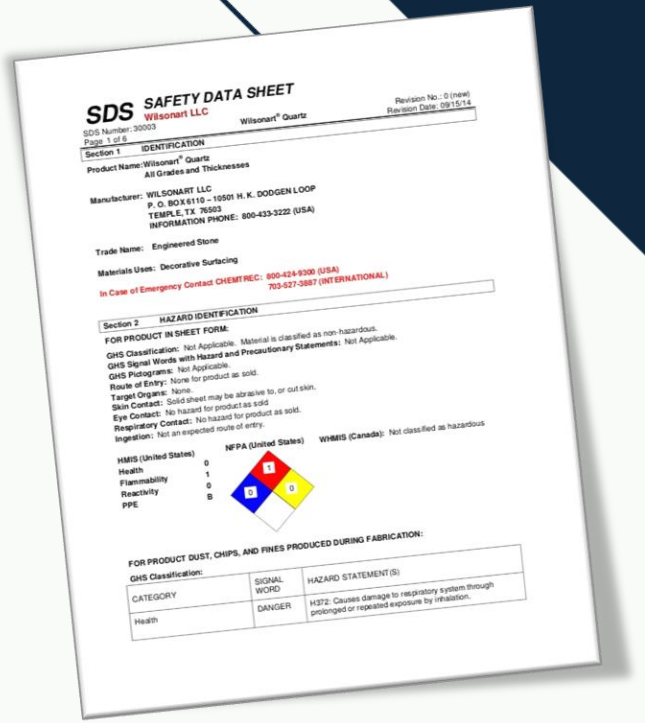
Registration


SDS SAFETY DATA SHEET
Wilsonart LLC
Wilsonart® Quartz
Section 1 IDENTIFICATION
Product Name: Wilsonart® Quartz
All Grades and Thicknesses
Manufacturer: WILSONART LLC
P. O. BOX 6110 – 10501 H. K. DODGEN LOOP
TEMPLE, TX 76503
INFORMATION PHONE: 800-433-3222 (USA)
Trade Name: Engineered Stone
Materials Uses: Decorative Surfacing
In Case of Emergency Contact CHEMTREC: 800-424-9300 (USA)
703-527-3887 (INTERNATIONAL)
Section 2 HAZARD IDENTIFICATION
FOR PRODUCT IN SHEET FORM:
GHS Classification: Not Applicable. Material is classified as non-hazardous.
GHS Signal Words with Hazard and Precautionary Statements: Not Applicable.
GHS Pictograms: Not Applicable.
Route of Entry: None for product as sold.
Target Organs: None.
Skin Contact: Solid sheet may be abrasive to, or cut skin.
Eye Contact: No hazard for product as sold.
Respiratory Contact: No hazard for product as sold.
Ingestion: Not an expected route of entry.
HMIS (United States)
Health 0
Flammability 1
Reactivity 0
PPE B
NFPA (United States)
WHMIS (Canada): Not classified as hazardous
FOR PRODUCT DUST, CHIPS, AND FINES PRODUCED DURING FABRICATION:
GHS Classification:
CATEGORY | SIGNAL WORD | HAZARD STATEMENT (S)
Health | DANGER | H372: Causes damage to respiratory system through prolonged or repeated exposure by inhalation.

Safety Data Sheet

- Prepared only by a Chemical Safety Assessment Expert* and only in Turkish
- Needed if:
  - Harmful 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 individiual 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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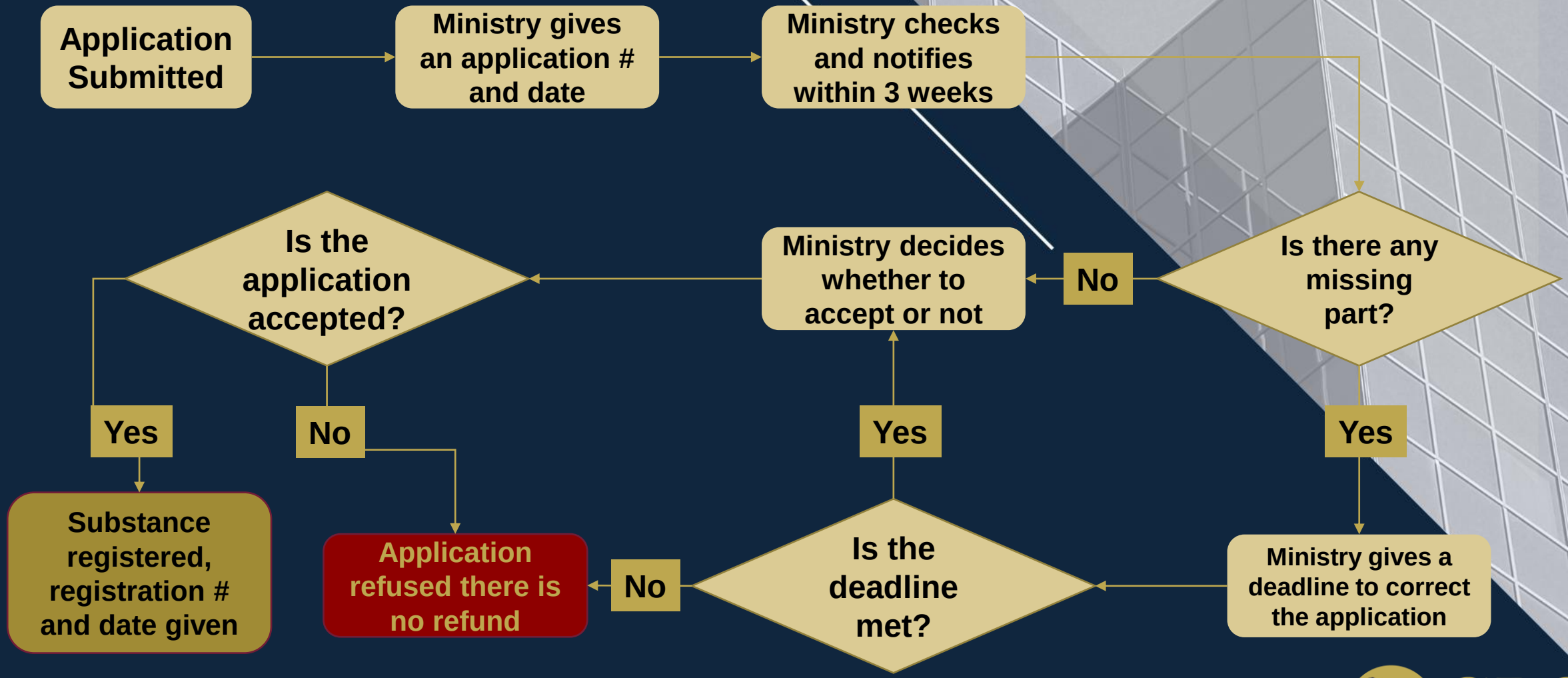
After Submission



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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
3500+ pre-registered substances
~300 happy clients
We are active in 1600+ SIEFs

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Thank You.

Contact us for global regulatory services

https://gpcgateway.com/

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