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CHEMEXCIL

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


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Europe | India | South Korea | Eurasia | Turkey | UK | Taiwan | Australia | Ireland

# Speaker Profile

## Mr. Mirac Mert Pelister

Miraç is a chemical engineer with 4+ regulatory experiences in various sectors such as pharmaceuticals, ceramics, and detergents. Audit experience in ISO 9001. Mirac has a Master's degree in biotechnology from Lund University, Sweden. He joined GPC in 2020 and his area of expertise at GPC focuses on Turkey's REACH-like regulation, aka the KKDIK.

# Outline

- KKDIK in a nutshell
- Timeline
- Updates
- Current Situation
- Roles & Responsibilities
- Joint Submission, SIEFs & Consortia
- Registration Process & Requirements
- Your Obligations
- Our Role

# KKDIK In a Nutshell

Kimyasalların
Kaydı
Değerlendirilmesi
İzni
Kısıtlanması
Hakkında yönetmelik

Bylaw on
Registration
Evaluation
Authorization &
Restriction of
Chemicals

# KKDIK In a Nutshell

- Came into force on June 23rd, 2017
- EU Adaptation policy
- Competent authority: Ministry of Environment, Urbanization and Climate Change
- 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

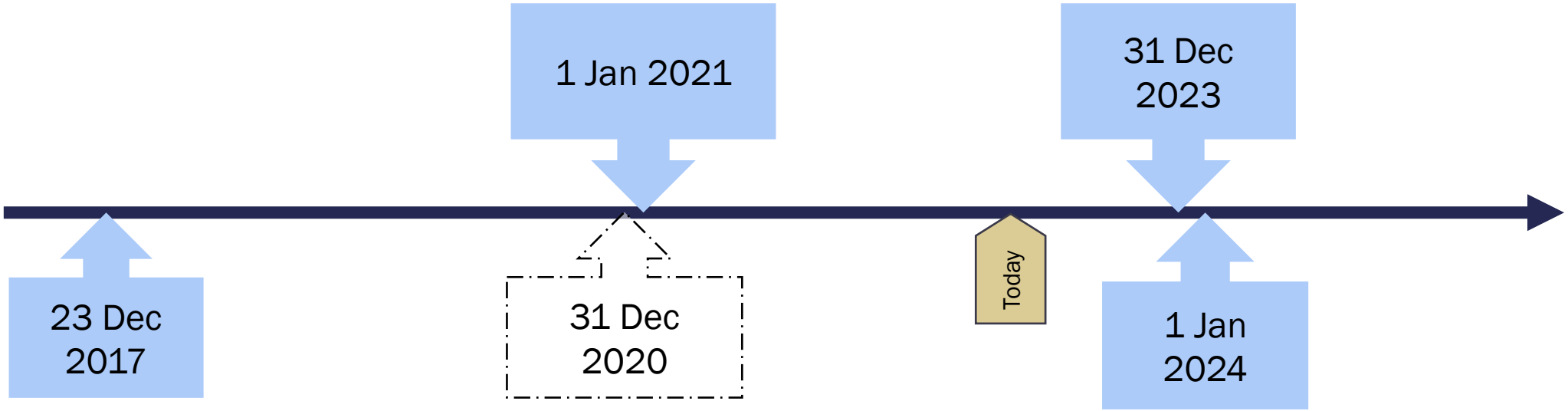
Article 1

*“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.”*

# Timeline

- Submission of registration dossier
  - Chemical safety assessment
  - SDS
  - Test proposals

} if needed




- Notification of substances
- CLP notification for local manufacturers & importers

- Notification of substances
- CLP notification for local manufacturers & importers

- Keeping all information up-to-date
- Evaluation communication
- Permit application if needed

# Frequently Used Abbreviations

- SIEF: Substance Information Exchange Forum (MBDF)
- LR: Lead Registrant
- OR: Only Representative
- SME: Small or Medium Size Enterprise
- LoA: Letter of Access
- LPR: Late Pre-registration
- CLP: Classification, Labeling and Packaging (SEA)

# Updates

- Ministry held a meeting with LRs and ORs on 11th of October
- Registrations are ongoing where there is an LR
- Update on TCC on KKS, got more detailed
- Importer information is required by the Ministry in case of non-Turkish manufacturers

# Current Situation

- New circular will be published
  - New criteria for OR
  - Regulating LoA costs
  - New (earlier) deadline for Lead Registrants
  - If no LR, Ministry will appoint one
- 504 registrations as of October 2022
- Deadline **will not** be postponed
- Authorization list will be available in 2024
- Monitoring of restricted substances already began

# Joint Submission, SIEFs & Consortia

# Joint Submission

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 Submission

- 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

# Joint Submission

- 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!**

# Consortia

- Not mandatory
- Can be agreed on by all or partial SIEF members
- Has to be transparent on joining conditions and members
- Cannot be anti-competitive
- Can last longer than SIEF

# SIEF

- Mandatory
- Formed by companies who has pre-registered same substance
- Valid until 2026
- Purpose: Preventing repetitive tests on animals & reducing costs by sharing
- Purpose: Data sharing

# Registration Process & Requirements

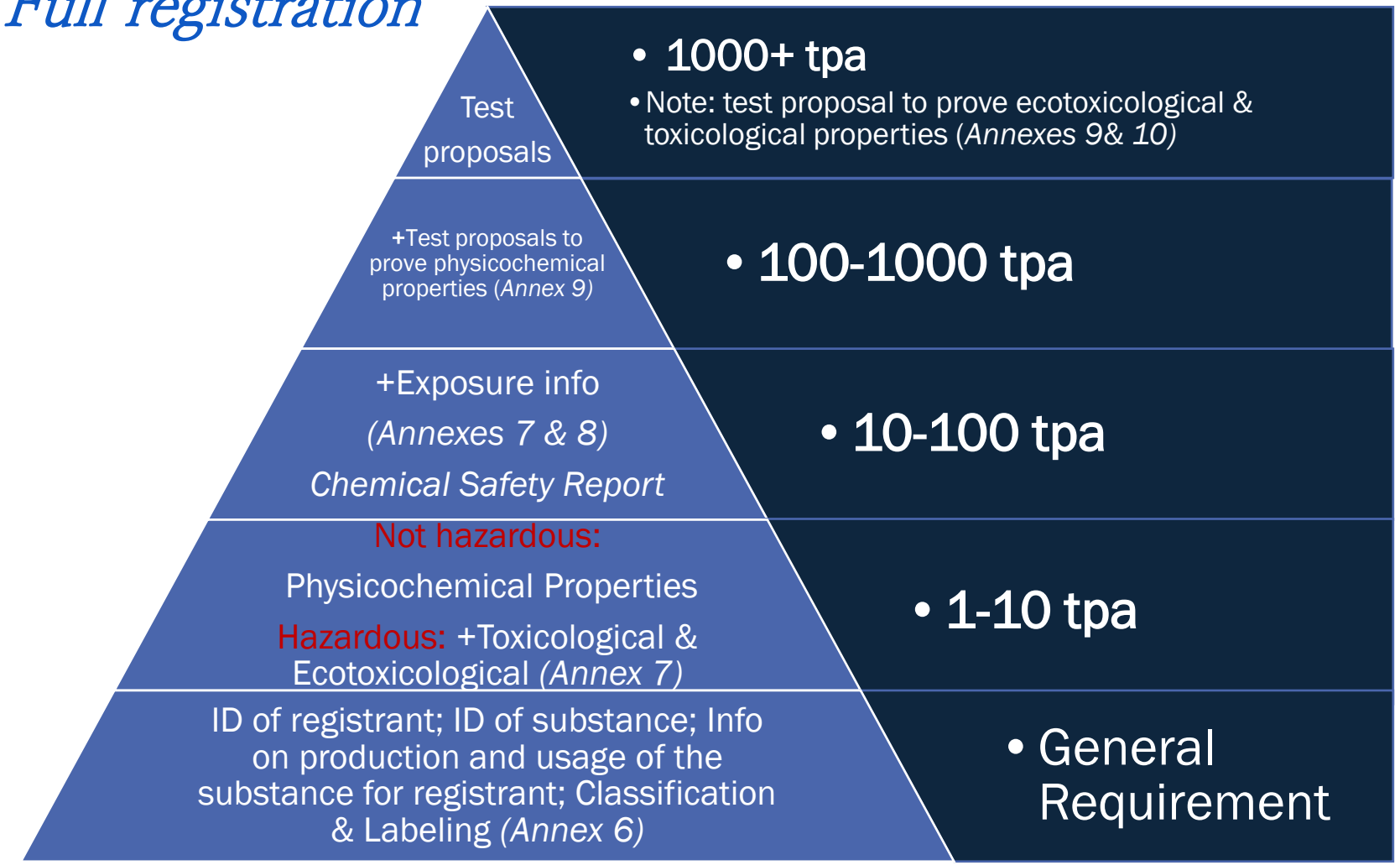
# Registration (Exemptions)

- 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

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

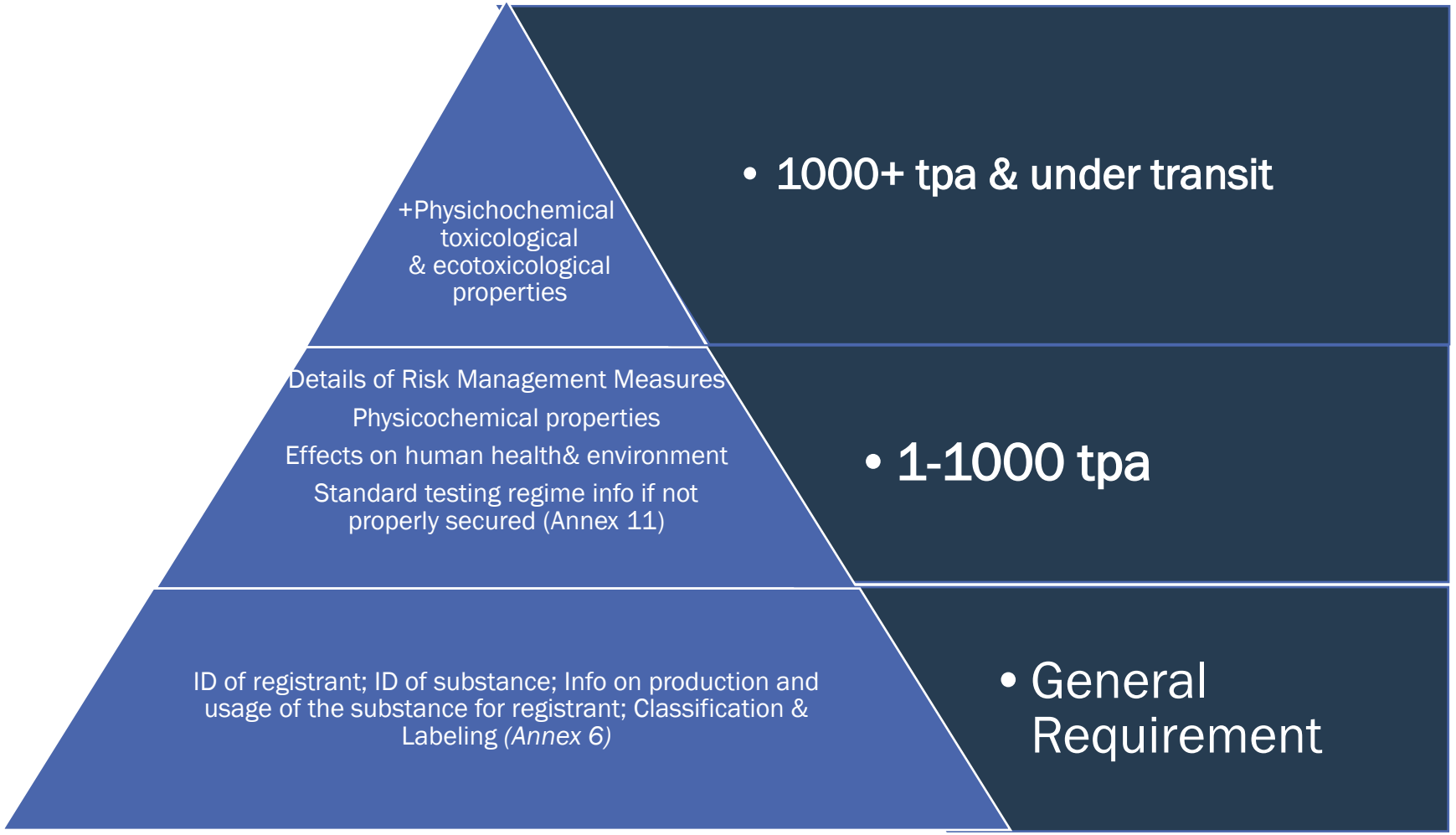
# Registration Data Requirements

## *Full registration*



# Registration Data Requirements

*Isolated intermediate registration*





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# Standard Data Requirements (1)

- Annex 6 information
  - Registrant info
  - Substance Identification
    - Name
    - Identifiers (CAS, EC etc.)
    - Molecular Structure
      - SMILES
      - InChI
      - Optical activity
      - Molecular Weight

# Standard Data Requirements (2)

- Annex 6 Information
  - Composition
    - Degree of purity
    - Impurities
    - Additives
    - Spectral data
      - UV, IR, NMR, MS
    - Chromatogram
      - HPLC
      - GC

# Standard Data Requirements (3)

- Annex 6 Information
  - Uses & Manufacture
    - Tonnage info
    - Process Info (PROC)
    - Form (subtance, mixture etc.)
    - Product categories (PC)
    - Technical function of substance
    - Industrial, professional and end-user uses (SU)
    - Service life
    - Uses advised against
  - C&L
  - First-aid measures

# 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

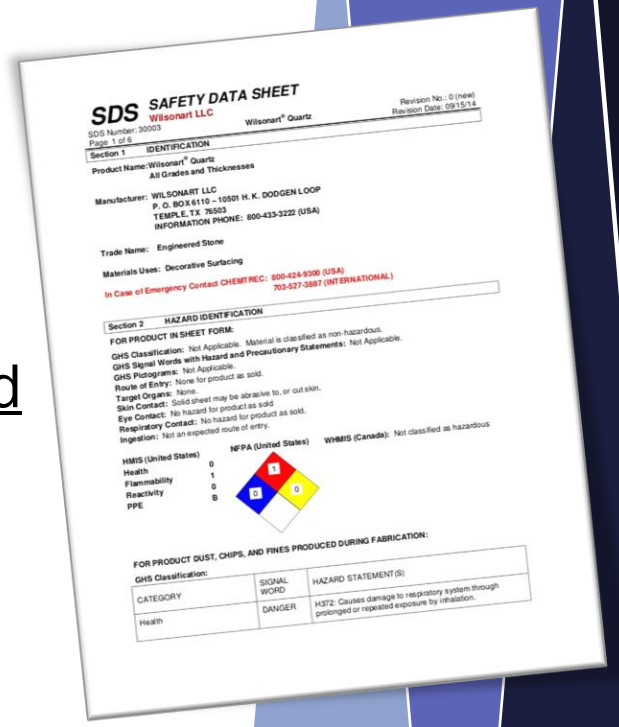
➢ Only prepared by a certified Chemical Safety Assessment Expert

# Registration

## 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


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. |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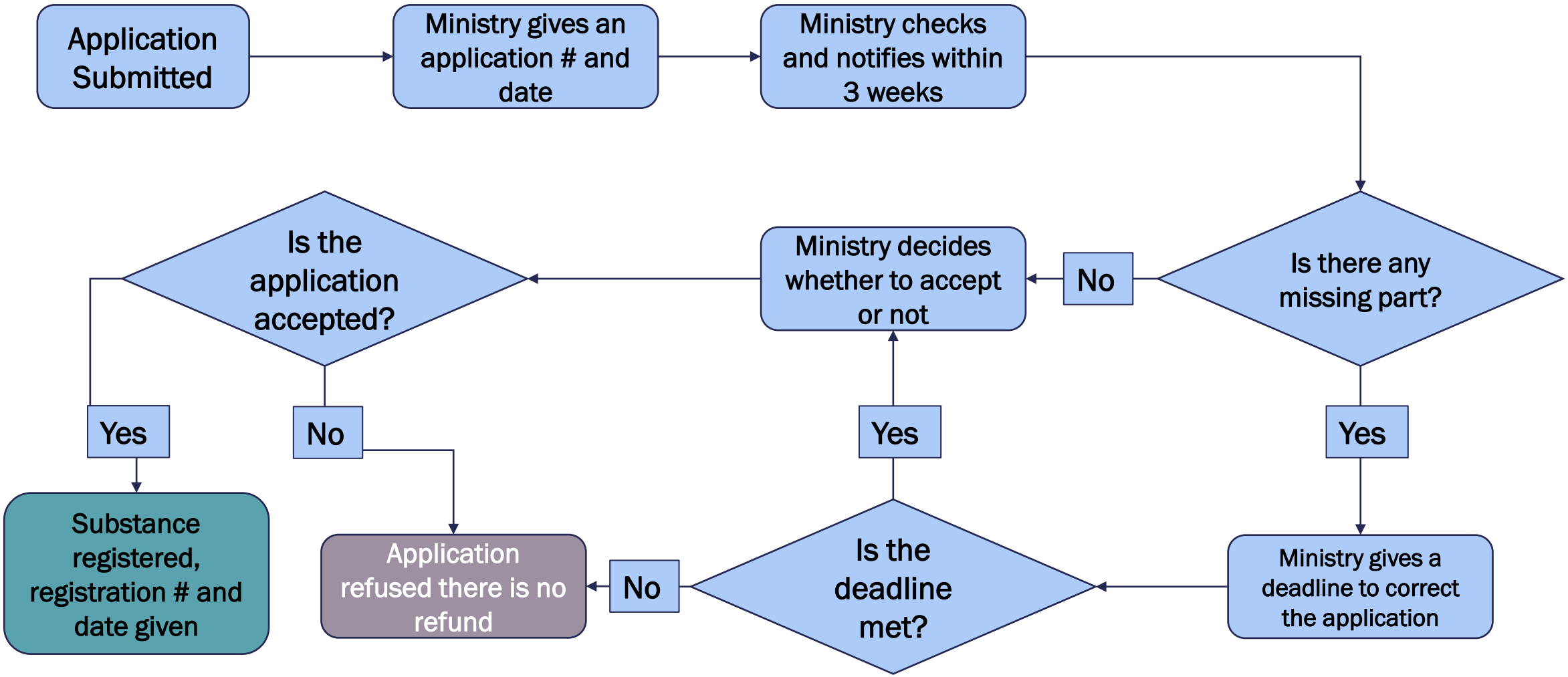
| | Large | Medium | Small | Micro |
|---|---|---|---|---|
| 1-10 tpa | € 101 | € 40 | € 20 | € 13 |
| 10-100 tpa | € 232 | € 121 | € 60 | € 25 |
| 100-1000 tpa | € 670 | € 267 | € 131 | € 50 |
| 1000+ tpa | € 1 613 | € 670 | € 403 | € 131 |

# Official Fees

# After Submission



# Responsibilities (1)

## 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
- Declare SME status on KKS
- Identify tonnage band

## Lead Registrant (LR)

- Prepare the dossier in time
- Be transparent of the costs and the process
- Collect information from the SIEF for the dossier
- Consult SIEF opinions
- Share substance identification as well as C&L with potential registrants
- Use the highest tonnage band among the SIEF members for the joint dossier

# Responsibilities (2)

## 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
  Decide what to register
- Decide on which role to take

## Only Representative (OR)

- Start and participate in
  SIEF communications
- Define the most cost-
  effective strategy to protect client
  interest
- Reflect client intention
  and represent in SIEFs
- Collect importer information

# Your Obligations

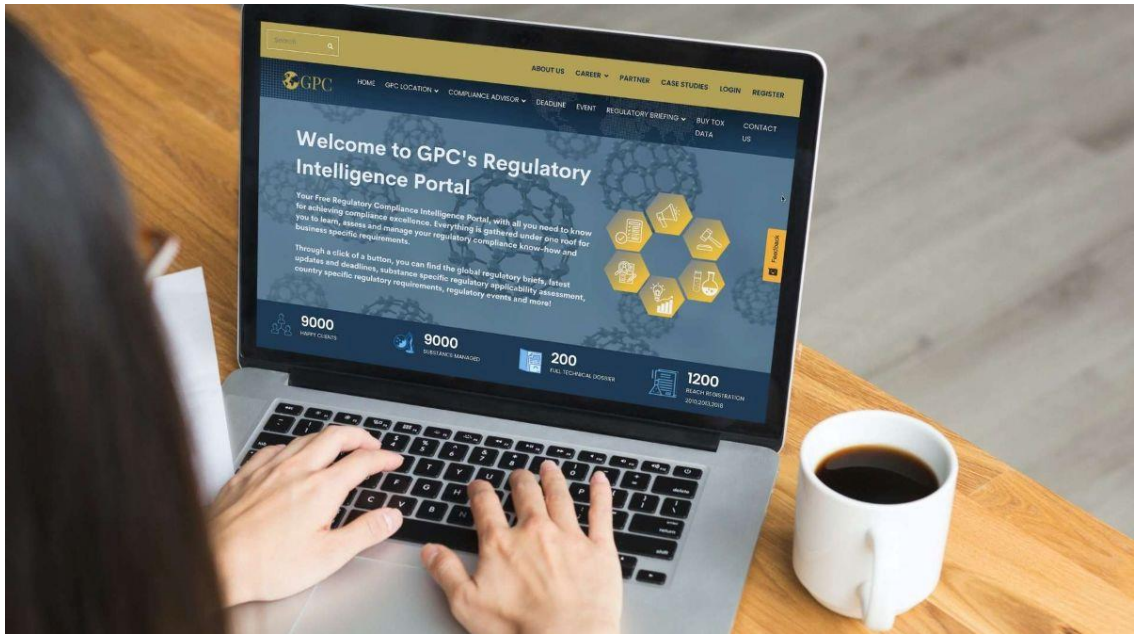
- Make a list of substances where you want to register
  - Don’t forget to decide on your SIEF role
- Be proactive if there is no LR and still the SIEF is silent!
- Answer as quickly as possible to surveys from LR, your consultant or your OR
- If there is a change in your intention, inform relevant contacts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

# 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

As GPC Turkey we have

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

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**1000+ Regulatory Briefings**

GPCgateway.com

*Gpcgateway remains the most updated source of info on the Rules and other regulations and is available for free to all users.*

# Thank You!

*“Your Seamless Extension in Global Regulatory Compliance.”*


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