GPC
Global Product Compliance

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

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

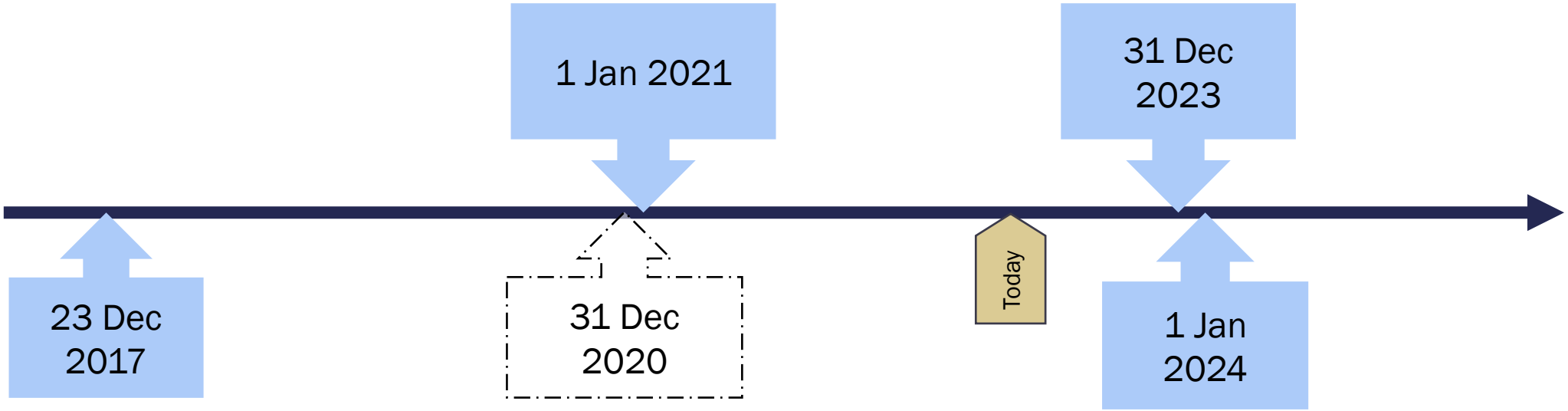
Article 1

“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

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- 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
- A circular was supposed to be published by December 2022
- 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*
- CSR Turkish requirement temporarily lifted*

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

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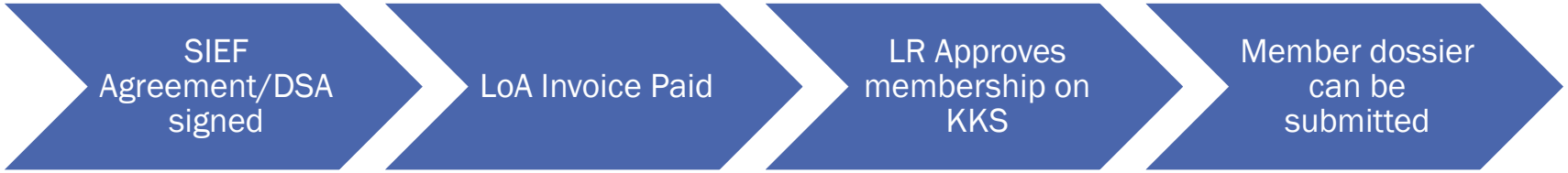
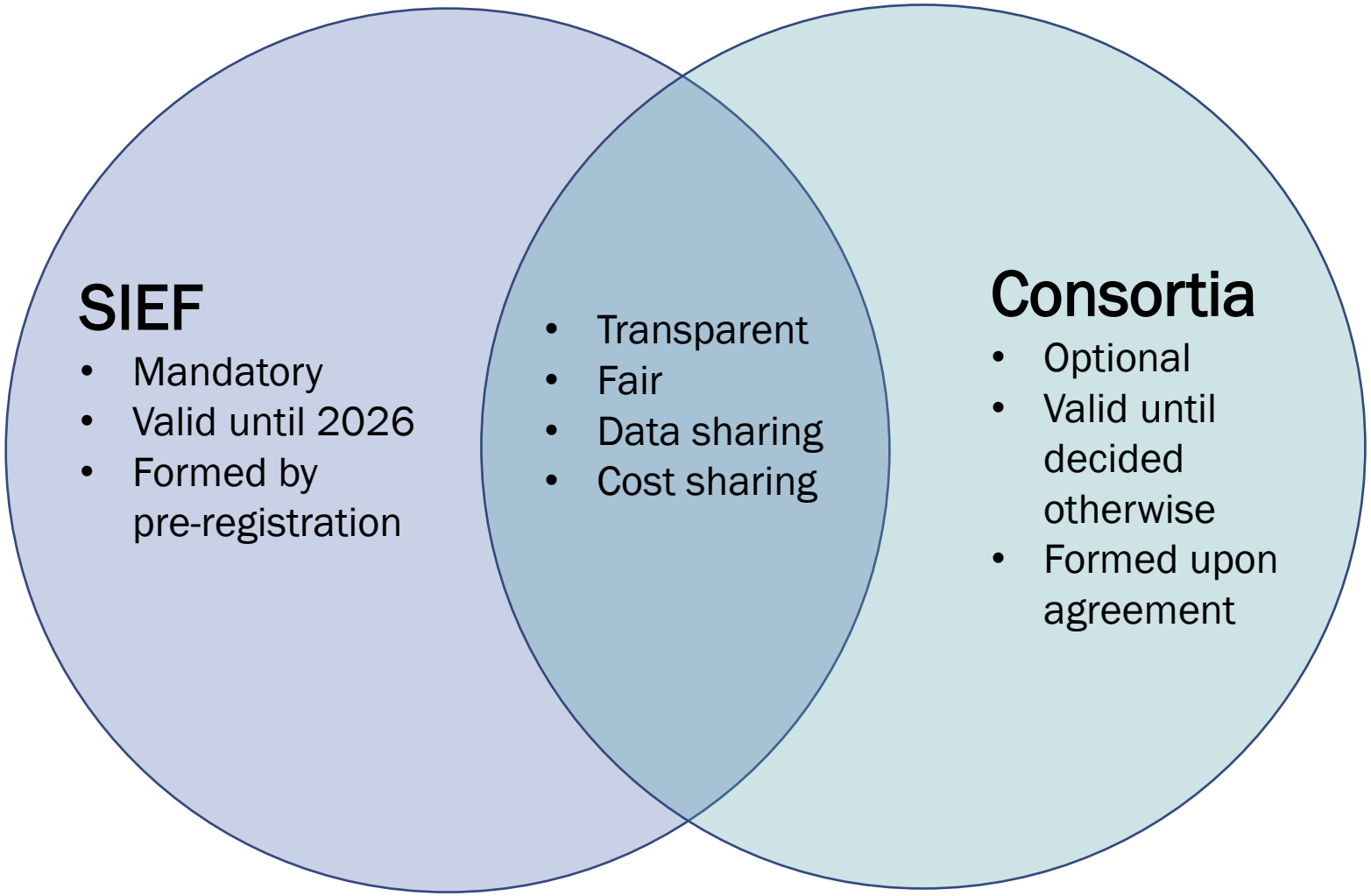
Joining as a Member



SIEFs & Consortia



Registration Process & Requirements

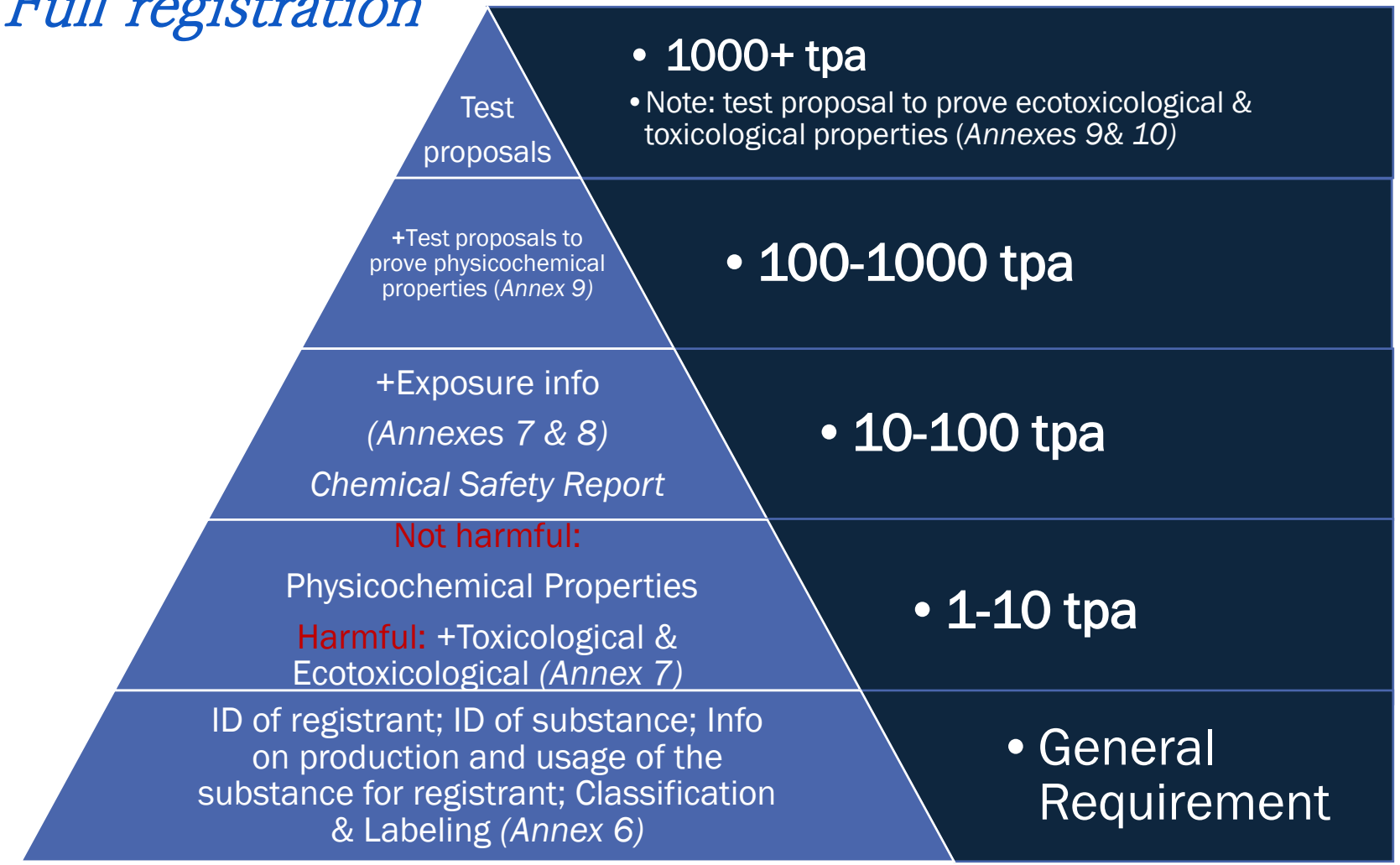
Registration (Exemptions)

- Recycled that is registered before in Turkey
- 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 biocides & 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)

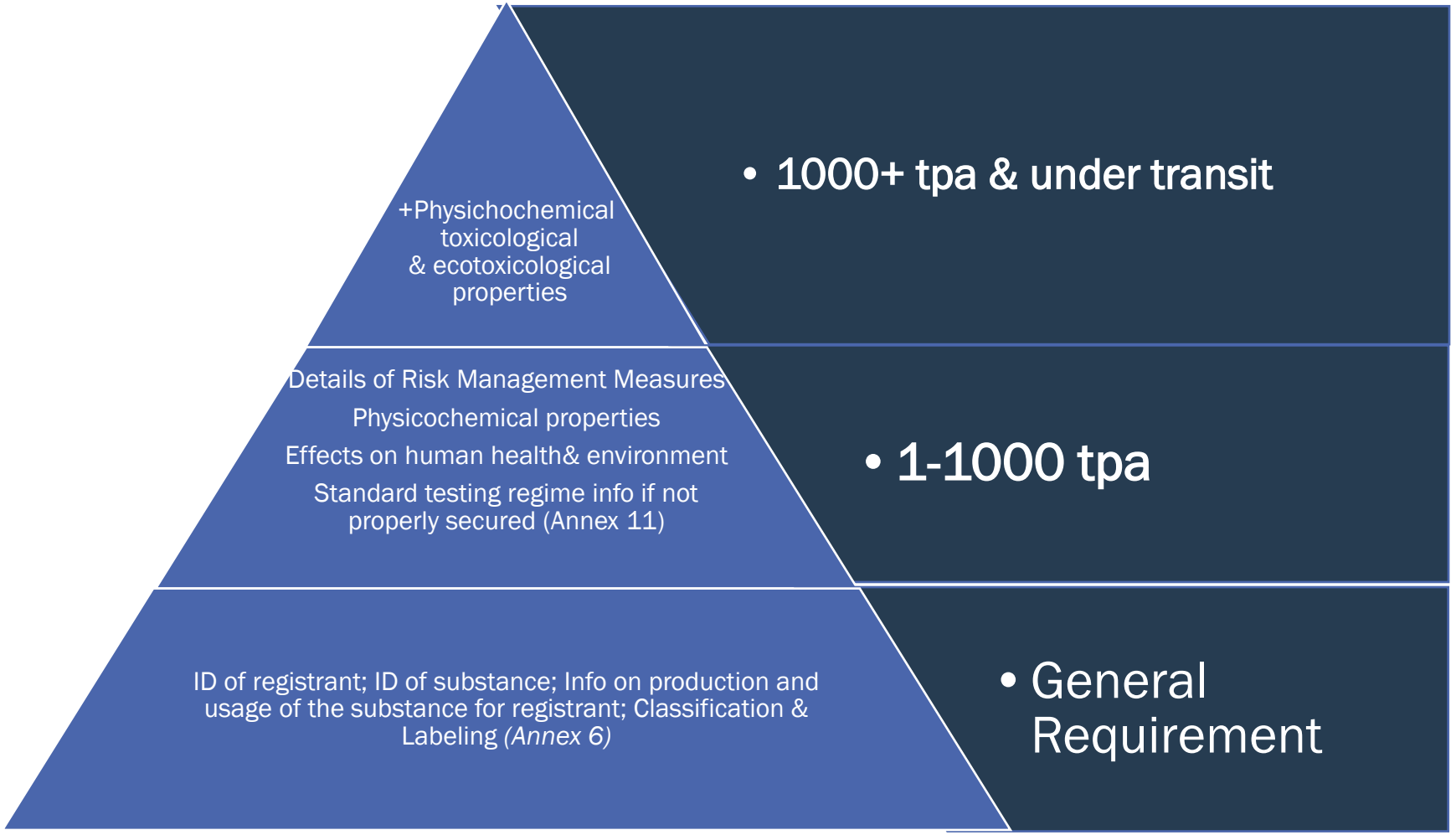
Registration Data Requirements

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
  - Substance is in mixture & less than defined threshold in *Annex 1* of CLP
  - PBT/vPvB & <0.1w% of mixture/formulation
- Includes
  - Human health hazards
  - Physicochemical hazards
  - Environmental impact & hazards
  - PBT and vPvB evalutation

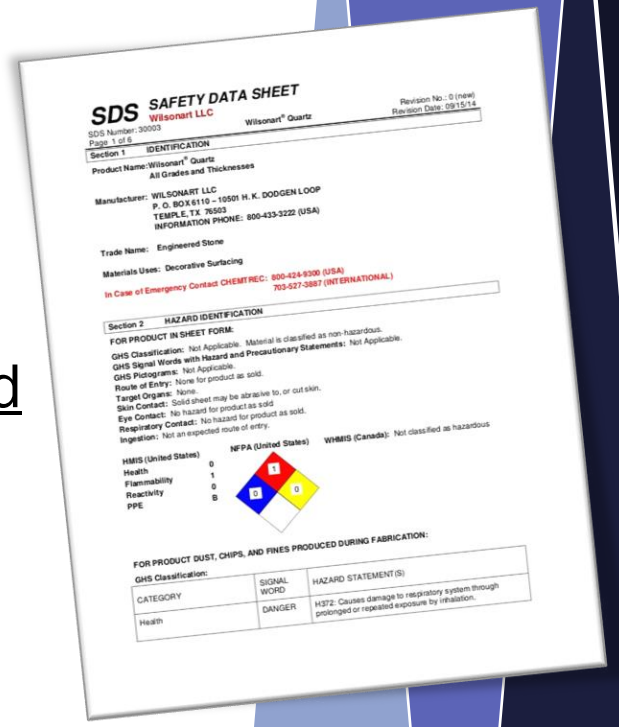
➢ Only prepared by a certified Chemical Safety Assessment Expert, in Turkish*

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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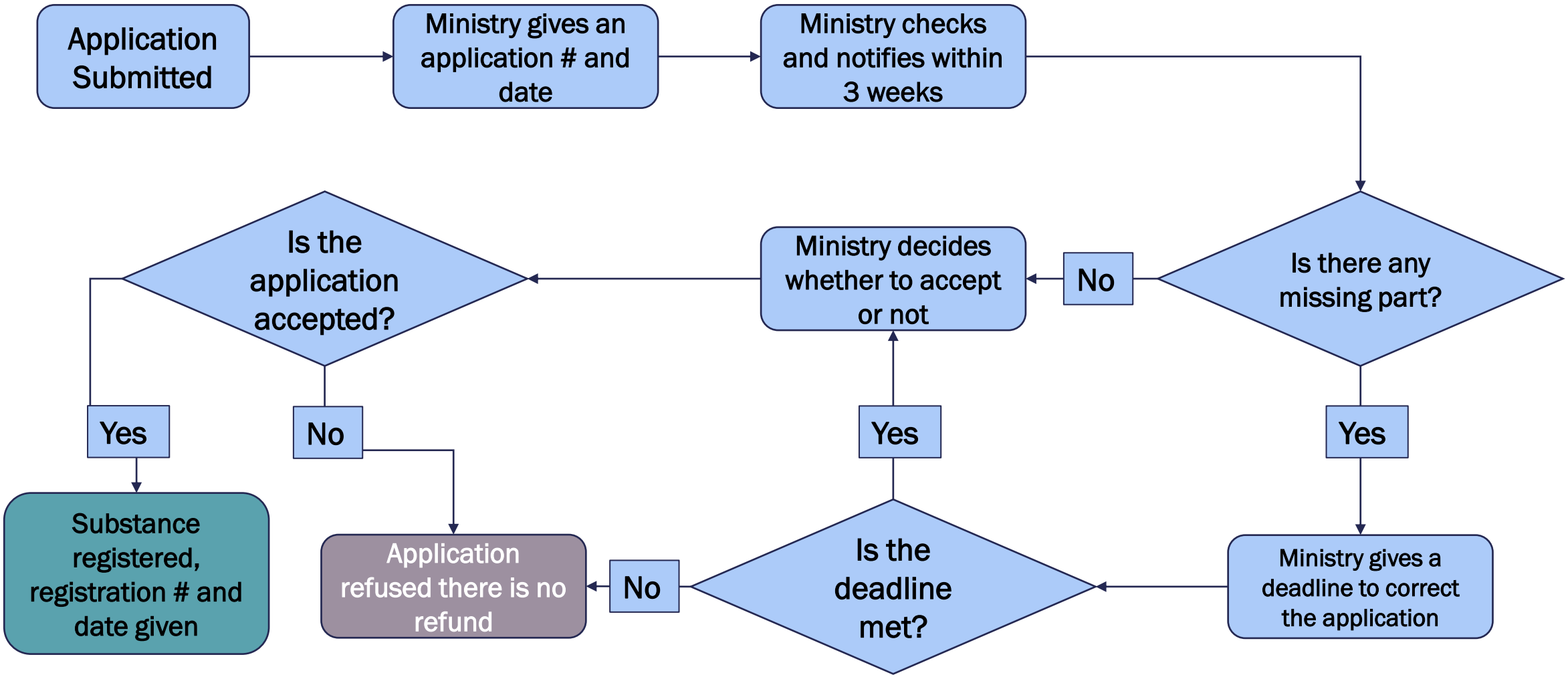
	Large	Medium	Small	Micro
1-10 tpa	€ 97	€ 39	€ 19	€ 12
10-100 tpa	€ 222	€ 116	€ 58	€ 24
100-1000 tpa	€ 642	€ 256	€ 126	€ 48
1000+ tpa	€ 1 545	€ 642	€ 386	€ 126

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

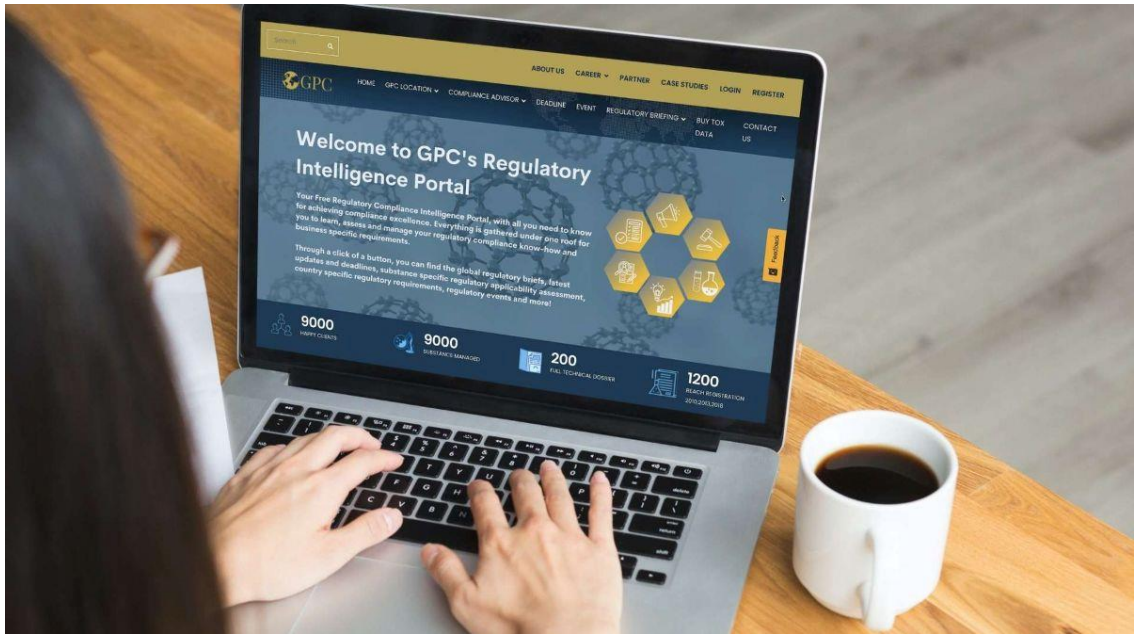
- Make a list of substances where you want to register
  - Don’t forget to decide on your SIEF role
- Be proactive if there is no LR and still the SIEF is silent!
- Answer as quickly as possible to surveys from LR, your consultant or your OR
- If there is a change in your intention, inform relevant contacts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



Regulatory Intelligence

You can explore regulatory information and intelligence related to:

- **15+** regions across **5** continents
- **40+** regulations
- Over **100,000** chemicals
- **100+** regulatory events
- **50+** regulatory summaries
- **100+** regulatory briefings since 2021, and **50+** added each month from across the globe, and much more!

15+ Regions | 5 Continents | 40+ Regulations |

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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