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

Mr. Mirac Mert Pelister
Turkey Business Coordinator and Regulatory Researcher
Global Product Compliance (GPC) Turkey
Email: mirac@tr.gpcregulatory.com

1

Outline

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

2

2

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 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

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.*"

5

5

Timeline

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

  } if needed

1 Jan 2021

31 Dec 2023

Registration

2017

23 Dec 2017

Pre-registration

31 Dec 2020

Today

1 Jan 2024

Post-registration

- 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

6

6

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)

7

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 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

8

8

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

9

9

Registration (Exemptions)

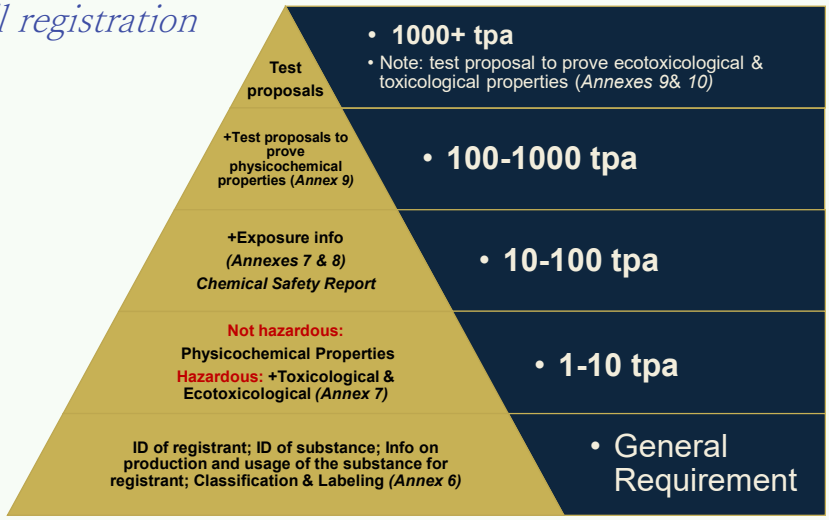
- Imported only to be used in biocidals & plant protection
- Human or veterinary medicines
- Substances in *Annexes 4&5*
- Polymers
- Non-isolated intermediates
- On-site and transported isolated intermediates (only from full registration)
- Recycled in Turkey that is registered before
- Exported from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

10

10

Registration Data Requirements

Full registration

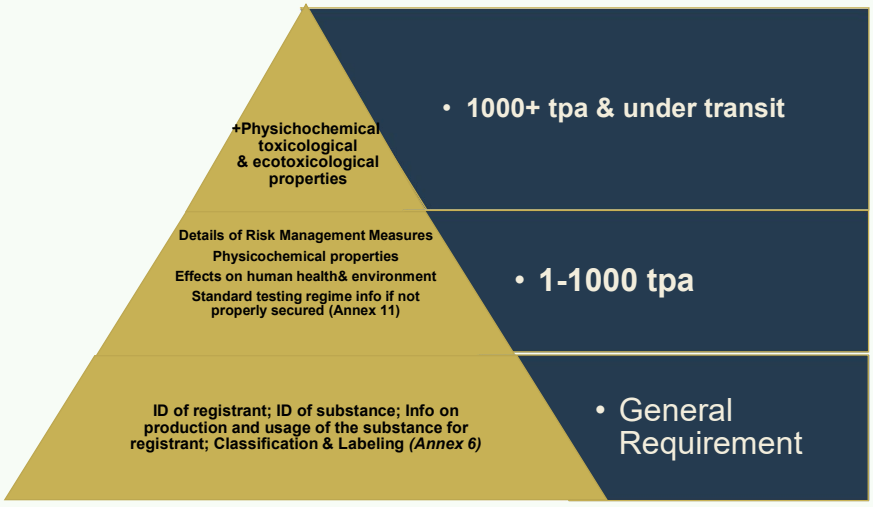


11

11

Registration Data Requirements

Isolated intermediate registration



12

12

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

13

13

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

14

14

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

15

Joint Registration

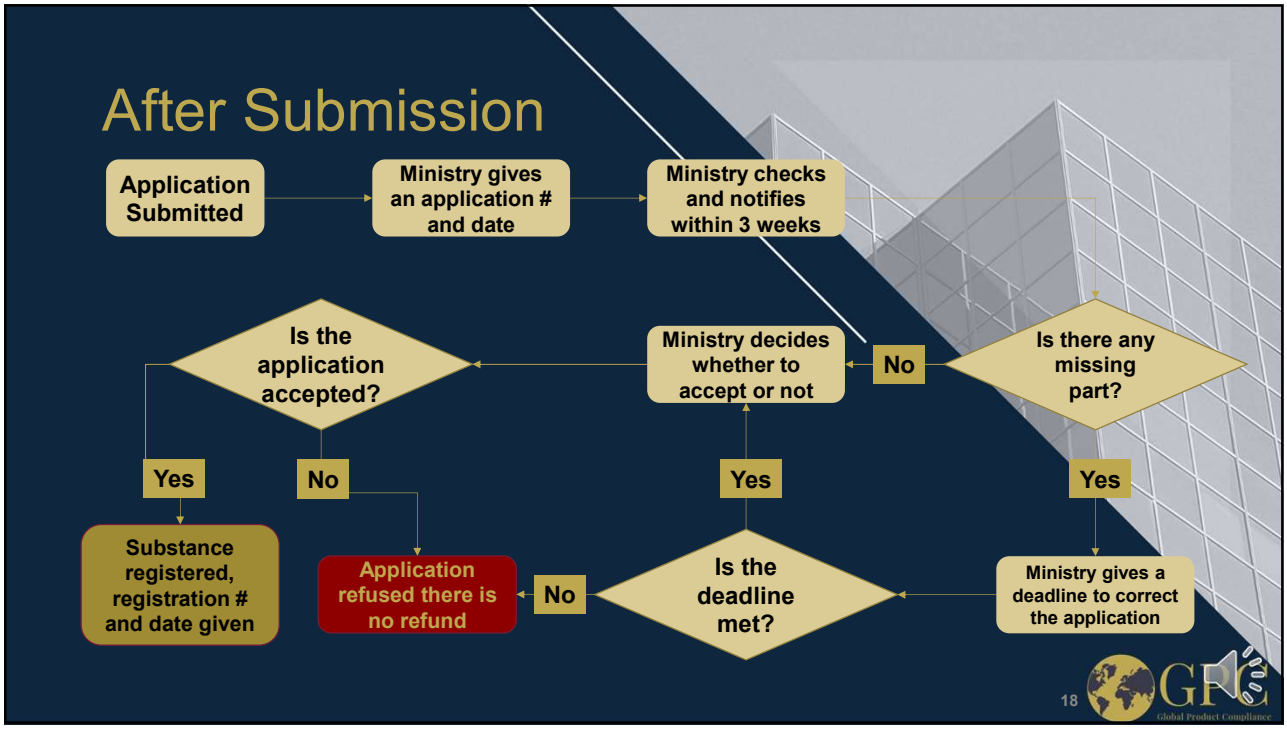
- Purchasing of LoA & Cost Sharing
  - After LR submits the registration and includes the members, LoA and other dossier related cost are shared among members
  - Costs are calculated per usage & tonnage band
- According to KKDIK members are not discriminated in cost sharing

16

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!**

17



18

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

19

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

20

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

21

21

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

22

22


GPC
Global Product Compliance
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
23

23


Thank You.
Contact us for global regulatory services
https://gpcgateway.com/
Global Product Compliance (GPC)
compliance@gpcregulatory.com
+46 46 2114615
IDEON, Beta 5, Scheelevägen 17, 22363
LUND, SWEDEN

24