25 - 26.10.2023 | DAY 2

Chemical Regulations and Sustainability Symposium 2023

100 YEARS 1923 - 2023 Chemical Business Association

REACHLAW COMPLIANCE. SUSTAINABILITY.

Turkey KKDIK

Registration Strategy

Turkey KKDIK Registration Strategy

Agenda

1. Turkey KKDIK in Brief
2. KKDIK Registrations
3. How to Register by the Registration Deadline
4. KKDIK Registration Action Plan
5. Some Case Examples *(If time permits – else, included FYI)*
6. Conclusions
7. Quick Q&A

Duration: 45 min

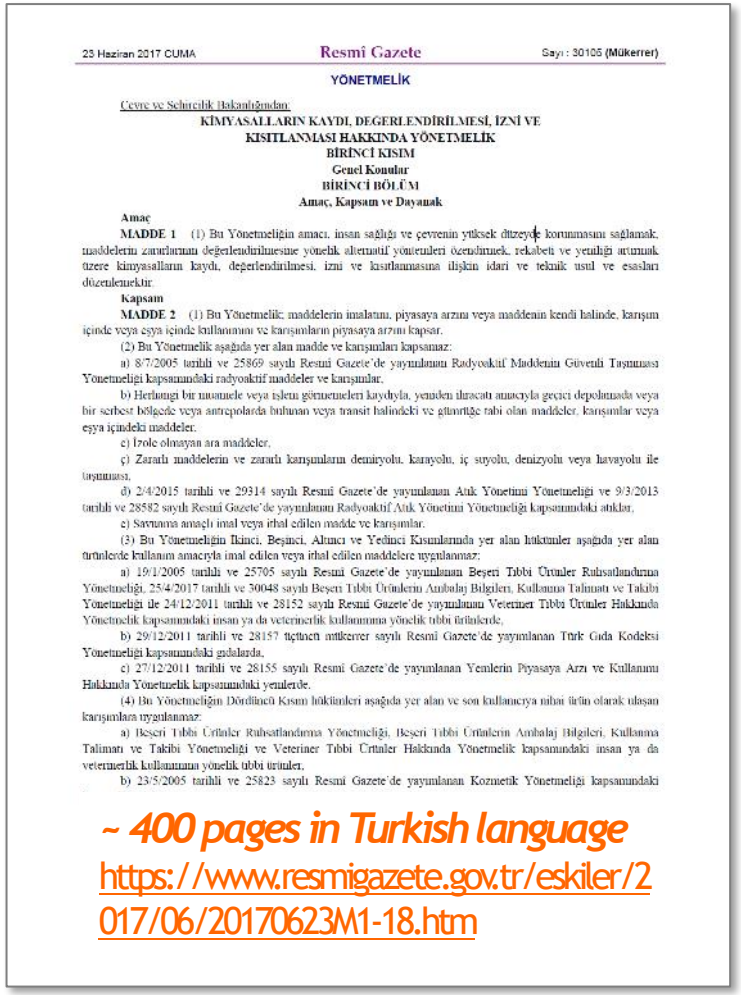
1. TURKEY KKDIK IN BRIEF
2. KKDIK REGISTRATIONS
3. HOW TO REGISTER BY THE DEADLINE
4. KKDIK REGISTRATION ACTION PLAN
5. SOME CASE EXAMPLES
6. CONCLUSIONS
7. QUICK Q&A

Turkey KKDIK In Brief

Overview

- The **Regulation on Chemicals Registration, Evaluation, Authorisation and Restriction (*Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması*) ("KKDIK")** (Regulation No. 30105) dated June 23rd, 2017, **came into force on December 23rd, 2017**
  - **Is VERY similar to the EU REACH Regulation**
  - **Transitional provisions apply,** such as for registration
- **Competent authority:**
  - ***M**inistry **o**f **E**nvironment, **U**rbanization and **C**limate **C**hange (MoEUCC)*

REPUBLIC OF TURKEY
MINISTRY OF ENVIRONMENT,
URBANIZATION AND CLIMATE CHANGE



23 Haziran 2017 CUMA — Resmi Gazete — Sayı : 30105 (Mükerrer)

YÖNETMELİK

Çevre ve Şehircilik Bakanlığından:

KİMYASALLARIN KAYDI, DEĞERLENDİRİLMESİ, İZNİ VE KISITLANMASI HAKKINDA YÖNETMELİK

BİRİNCİ KISIM

Genel Konular

BİRİNCİ BÖLÜM

Amaç, Kapsam ve Dayanak

Amaç

MADDE 1 – (1) Bu Yönetmeliğin amacı, insan sağlığı ve çevrenin yüksek düzeyde korunmasını sağlamak, maddelerin zararlarının değerlendirilmesine yönelik alternatif yöntemleri özendirmek, rekabeti ve yeniliği artırmak üzere kimyasalların kaydı, değerlendirilmesi, izni ve kısıtlanmasına ilişkin idari ve teknik usul ve esasları düzenlemektir.

Kapsam

MADDE 2 – (1) Bu Yönetmelik; maddelerin imalatını, piyasaya arzını veya maddenin kendi halinde, karışım içinde veya eşya içinde kullanımını ve karışımların piyasaya arzını kapsar.

(2) Bu Yönetmelik aşağıda yer alan madde ve karışımları kapsamaz:

a) 8/7/2005 tarihli ve 25869 sayılı Resmî Gazete'de yayımlanan Radyoaktif Maddenin Güvenli Taşınması Yönetmeliği kapsamındaki radyoaktif maddeler ve karışımlar.

b) Herhangi bir insandan veya işlem görmemeleri kaydıyla, yeniden ihracatı amacıyla geçici depolamada veya bir serbest bölgede veya antrepolarda bulunan veya transit halindeki ve gümrüğe tabi olan maddeler, karışımlar veya eşya içindeki maddeler.

c) İzole olmayan ara maddeler.

ç) Zararlı maddelerin ve zararlı karışımların demiryolu, karayolu, iç suyolu, denizyolu veya havayolu ile taşınması.

d) 2/4/2015 tarihli ve 29314 sayılı Resmî Gazete'de yayımlanan Atık Yönetimi Yönetmeliği ve 9/8/2013 tarihli ve 28582 sayılı Resmî Gazete'de yayımlanan Radyoaktif Atık Yönetimi Yönetmeliği kapsamındaki atıklar.

e) Savunma amaçlı imal veya ithal edilen madde ve karışımlar.

(3) Bu Yönetmeliğin İkinci, Beşinci, Altıncı ve Yedinci Kısımlarında yer alan hükümler aşağıda yer alan ürünlerde kullanım amacıyla imal edilen veya ithal edilen maddelere uygulanmaz:

a) 19/1/2005 tarihli ve 25705 sayılı Resmî Gazete'de yayımlanan Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği, 25/4/2017 tarihli ve 30048 sayılı Beşeri Tıbbi Ürünlerin Ambalaj Bilgileri, Kullanma Talimatı ve Takibi Yönetmeliği ile 24/12/2011 tarihli ve 28152 sayılı Resmî Gazete'de yayımlanan Veteriner Tıbbi Ürünler Hakkında Yönetmelik kapsamındaki insan ya da veterinerlik kullanımına yönelik tıbbi ürünlerde,

b) 29/12/2011 tarihli ve 28157 üçüncü mükerrer sayılı Resmî Gazete'de yayımlanan Türk Gıda Kodeksi Yönetmeliği kapsamındaki gıdalarda,

c) 27/12/2011 tarihli ve 28155 sayılı Resmî Gazete'de yayımlanan Yemlerin Piyasaya Arzı ve Kullanımı Hakkında Yönetmelik kapsamındaki yemlerde.

(4) Bu Yönetmeliğin Dördüncü Kısım hükümleri aşağıda yer alan ve son kullanıcıya nihai ürün olarak ulaşan karışımlara uygulanmaz:

a) Beşeri Tıbbi Ürünler Ruhsatlandırma Yönetmeliği, Beşeri Tıbbi Ürünlerin Ambalaj Bilgileri, Kullanma Talimatı ve Takibi Yönetmeliği ve Veteriner Tıbbi Ürünler Hakkında Yönetmelik kapsamındaki insan ya da veterinerlik kullanımına yönelik tıbbi ürünler,

b) 23/5/2005 tarihli ve 25823 sayılı Resmî Gazete'de yayımlanan Kozmetik Yönetmeliği kapsamındaki

~ 400 pages in Turkish language

https://www.resmigazete.gov.tr/eskiler/2017/06/20170623M1-18.htm

Turkey KKDIK In Brief
KKDIK Basic Requirements

- **Basic KKDIK market access requirements:**

Substances manufactured in or imported into Turkey at 1 t/a or more need to be Pre-registered and Registered by 31.12.2023*

- Same as the EU REACH Regulation → *"No Data, No Market"* (Art. 6)

* According to Current Legal Text

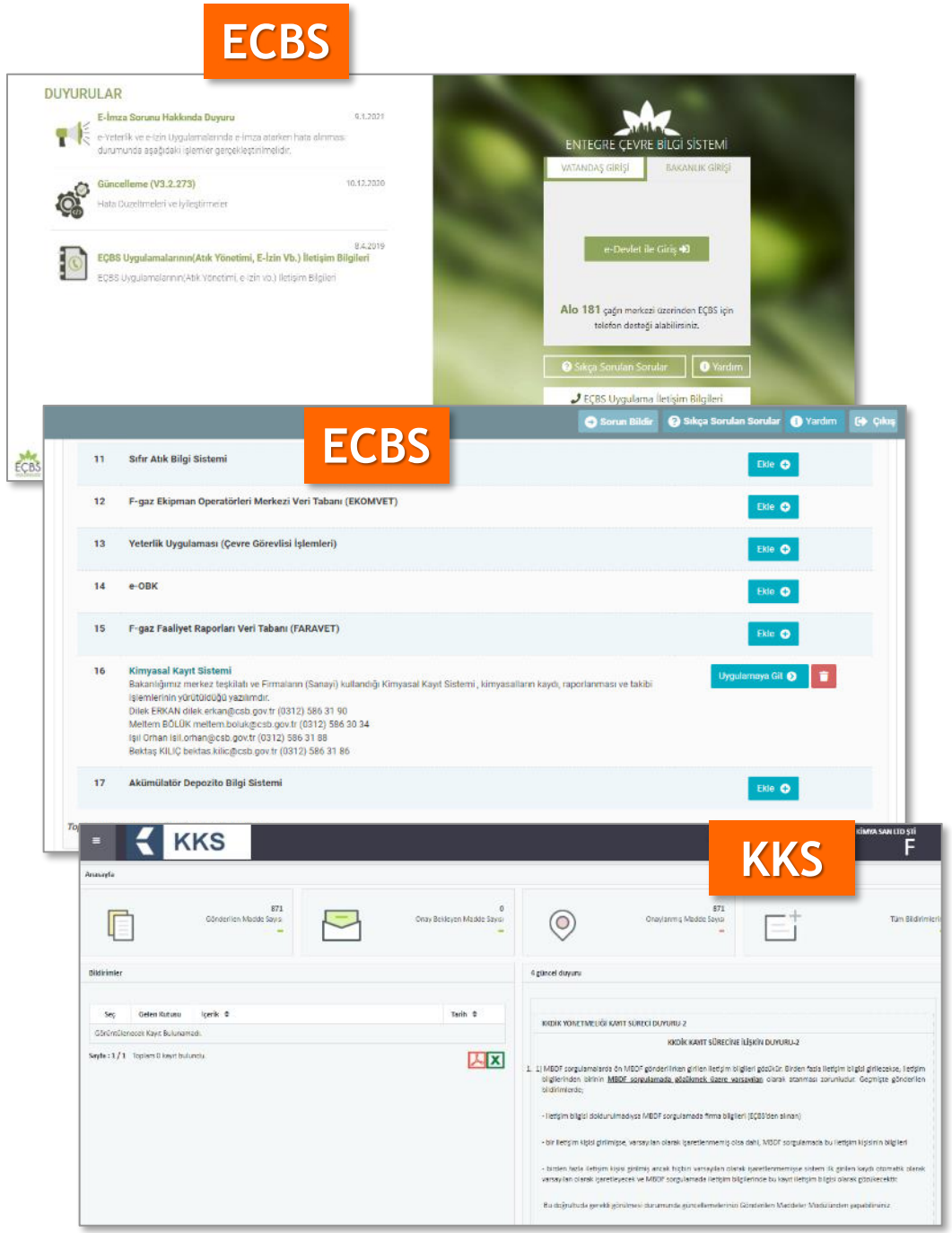
Turkey KKDIK In Brief

Substances Within Scope of KKDIK

All substances, unless specifically exempted, are within the scope of the KKDIK Regulation

Turkey KKDIK In Brief
KKS System – The Tools

- KKDIK regulatory dossiers *(pre-registrations, registrations, Inquiry, authorisation, PPORD, SEA notifications etc.)* are prepared and submitted using the **KKS System** (*Kimyasal Kayıt Sistemi* = "*Chemical Registration System*") **in the Turkish language**
- KKS is an ***online, hybrid system*** combining ***REACH-IT***, ***IUCLID 6*** and the ***CHESAR*** tool
- **Turkish citizenship** is required to ***create*** and ***access*** the KKS account
- Account activation takes **ca. 3 weeks** by the MoEUCC



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Turkey KKDIK In Brief

Comparison of EU REACH and the KKDIK Regulation

Task / Scope	EU REACH	Turkey KKDIK
Pre-registration	Yes, but no longer possible	Yes
Inquiry	Yes	Yes, from 1.1.2024
Registration	New and existing at ≥ 1 t/a	All chemicals at ≥1 t/a
Polymer	Exempted, but not monomers	Exempted, but not monomers
Data requirement	More volume, more data	More volume, more data
Joint Registration	Yes	Yes
Only Representative	Yes	Yes
R&D / PPORD Exemptions	Yes	Yes
Product notification	No	No
Safety Data Sheets	Yes	Yes, from 1.1.2024 according to KKDIK only
SDS Certification	No	**Yes**
Dossier review by certified person	No	**Yes**, by the Chemical Assessment Expert ("KDU")

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KKDIK Registrations
Overview

Registration Threshold = 1 t/a

- **All in Turkey manufactured substances or substances imported into Turkey as such or as part of mixtures at 1 t/a or more must be KKDIK registered by 31st of December 2023***
- **Registration tonnage bands:** *(Same as EU REACH)*

≥1 - <10 t/a	≥10 - <100 t/a	≥100 - <1000 t/a	≥1 000 t/a

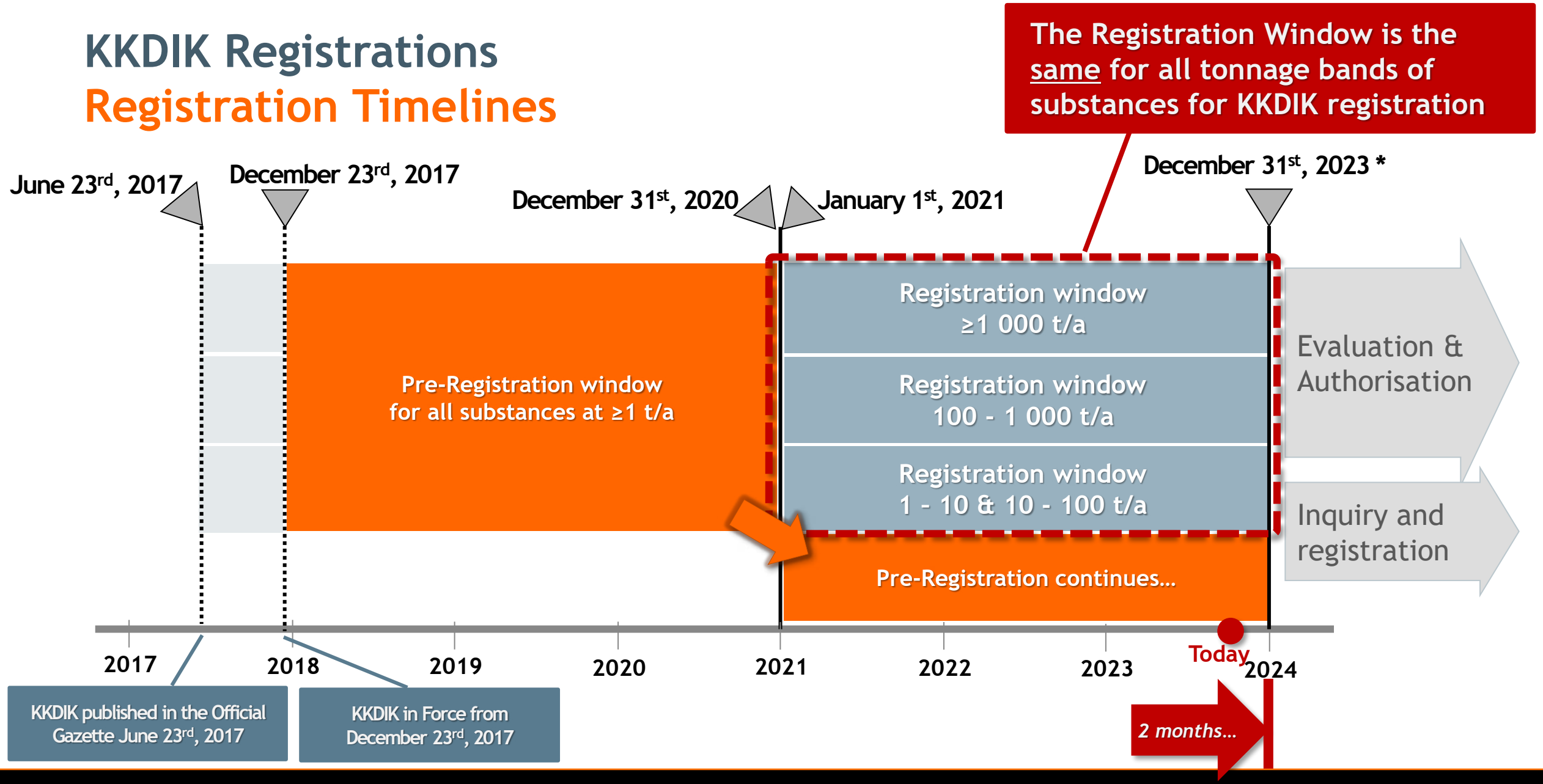
- **Registration types:** *(Same as EU REACH)*
  1. Full substance
  2. On-Site Isolated Intermediate > *Strictly Controlled Conditions ("SCC") must apply!*
  3. Transported isolated intermediate > *SCC must apply in the whole supply chain!*
- **Submissions** in **Turkish language** using the **KKS System**

*** Unless deadline is postponed**

The threshold for substances requiring a KKDIK Pre-Registration and Registration when manufactured in or imported into Turkey is:

≥ 1 tonne / year

KKDIK Registrations
Registration Timelines



* Unless deadline is postponed

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KKDIK Registrations
Joint Submission Concept

- **When a substance is intended to be KKDIK registered by one or more companies, a Joint Submission of "*core registration data*" is required**
  - Opt-Out is possible
  - Defined in *KKDIK Articles 12, 23 and 26*

* Unless deadline is postponed

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KKDIK Registrations

MoEUCC KKDIK Registration Fees *(Updated January 2023)*

- All updated KKDIK fees are published annually on the MoEUCC website.

Type	Tonnage band	Fee, Large Size Company	
KKDIK Registration Joint submission	**1 - 10 t/a + TII/OSII at ≥ 1 t/a**	**1 688 ₺**	(Ca. 50 GBP*)
	10 - 100 t/a	**3 946 ₺**	(Ca. 117 GBP*)
	100 - 1 000 t/a	**11 288 ₺**	(Ca. 335 GBP*)
	> 1 000 t/a	**27 051 ₺**	(Ca. 803 GBP*)

Discounts will apply to SME companies

* Exchange rates of **15.10.2023**

KKDIK Registrations
Some Registration Statistics

- Submitted **KKDIK Pre-registrations:** > 250 000
- Nominated **KKDIK Lead Registrants:** 3 200 (*different substances*)
- Submitted **Lead Registrations** to the MoEUCC: 2 500

- The MoEUCC expects **up to** 15 000 different substances **to be KKDIK Registered**
- Currently, most Lead Registrants are Only Representatives for non-Turkish companies (*many represent the EU REACH Lead Registrants*)

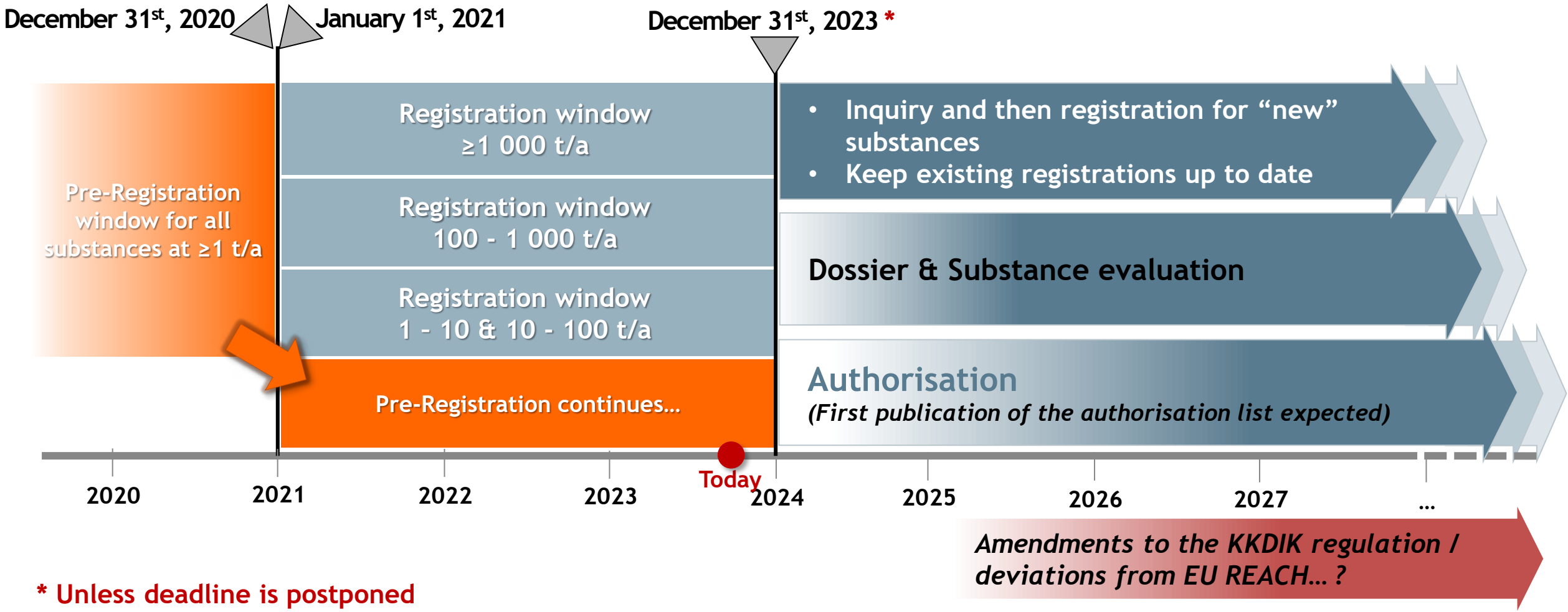
KKDIK Registrations

Only Representatives Overview – Same Requirements as for EU REACH

- **KKDIK provides the possibility for non-Turkish manufacturers and formulators to assign an Only Representative to take care of KKDIK importer obligations**
  - Pre-Registration
  - Registration
  - (*Authorisation - Later*)
- **Only Representation defined in KKDIK Article 9**
- **Only Representative can be a natural or legal person resident in Turkey**
  - Such as *REACHLaw Turkey*
- **The Only Representative *"shall have sufficient background in the practical handling of substances and the information related to them"***
  - Must have the competence to handle KKDIK compliance such as the required chemical, legal, data handling / IT, organisation & other skills and a compliance management system

KKDIK Registrations

KKDIK Timeline – Looking ahead



* Unless deadline is postponed

KKDIK Registrations

Extension of the Registration Deadlines

- Last Thursday **19 October 2023**, a meeting on **KKDIK** was held at the **MoEUCC**.
- It was announced that the **KKDIK registration deadlines will be revised based on a "*Tonnage Based Gradual Transition*" approach**.
  - This likely means a staggered approach, based on tonnage band (*and hazards*) of the substance, like under EU REACH / UK REACH
- Furthermore, it was announced that the **revision will be published asap in a circular** by the MoEUCC.
- **Once the circular is communicated, the deadline extensions will be official. However, for this presentation, the registration deadline will be as it is according to the current legal text, 31.12.2023**

Turkish Chemical Manufacturers Association (*TKSD*) communication

TÜRKİYE KİMYA SANAYİCİLERİ DERNEĞİ

20.10.2023

Değerli Üyelerimiz;
Çevre, Şehircilik ve İklim Değişikliği Bakanlığı,
Çevre Yönetimi Genel Müdürlüğü,
Kimyasallar Yönetimi Dairesi Başkanlığında
19 Ekim 2023 tarihinde
'Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması Hakkında Yönetmelik ***(KKDİK Yönetmeliği)"***
hakkında **Dernek başkanlarının katıldığı bir toplantı düzenlenmiştir.**

Toplantıya Dernek Başkanımız **Haluk ERCEBER** ve Genel sekreterimiz **Derya ERÇIKAN** Katılmıştır.

Toplantıda KKDİK Yönetmeliğinde belirtilen uygulama takvimi konusunda
"Tonaj Bazlı ve Kademeli Geçiş"
kapsamında revizyon yapılacağı bilgisi verilmiştir.
Revizyonun en kısa sürede Bakanlık tarafından bir genelge ile yayınlanacağı bilgisi ayrıca belirtilmiştir.
Üyelerimizin bilgisine sunulur.

Türkiye Kimya Sanayicileri Derneği

www.tksd.org.tr

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KKDIK Registrations

Expected New Registration Deadlines *(To Be Confirmed in Circular)*

Type of Substances	New Registration Deadlines
Substances at ≥1 000 t/a CMR substances (Category 1A and 1B) at ≥1 t/a Substances Very toxic to aquatic organisms *(acute or chronic)* at ≥100 t/a	31 December 2025
Substances at 100 – 1 000 t/a	31 December 2026
Substances at 1 - 100 t/a	31 December 2027

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How to Register by the Deadline
KKDIK Registration Process Overview (*Recap*)

- **Step 1**: **Pre-Registration** >> **Deadline 31.12.2023** *(unless extended)*
- **Step 2**: **Registration** as part of a Joint Submission >> **Deadline 31.12.2023** *(unless extended)*
  - Select the **Lead Registrant**
  - Everyone else is a **Co-registrant**
- **Step 3**: Manufacture / Import at pre-registered tonnage band allowed before the registration deadline and **after the deadline in the registered tonnage band.**

REPUBLIC OF TÜRKİYE
MINISTRY OF ENVIRONMENT,
URBANIZATION AND CLIMATE CHANGE

If you have not KKDIK Pre-Registered already, please do so a.s.a.p.!

How to Register by the Deadline
What is a Lead Registrant?

Pre-Submission

- **The Lead Registrant takes upon itself the responsibility in the SIEF to:**
  1. Manage / lead the SIEF work (*get organised*)
  2. Clarify substance identity
  3. Collect and assemble the required data to fulfil data requirements
  4. Share costs fairly, transparently and non-discriminatorily → Selling a ***"Letter of Access"***
  5. Manage and submit the Joint Registration dossier to the MoEUCC through KKS in good time **before** the registration **deadline**

Post-Submission

6. Keep the Joint Registration up-to-date → ***Continuous requirement!!!***
7. Record keeping and communicate with authorities

How to Register by the Deadline
What is a Co-Registrant?

Pre-Submission

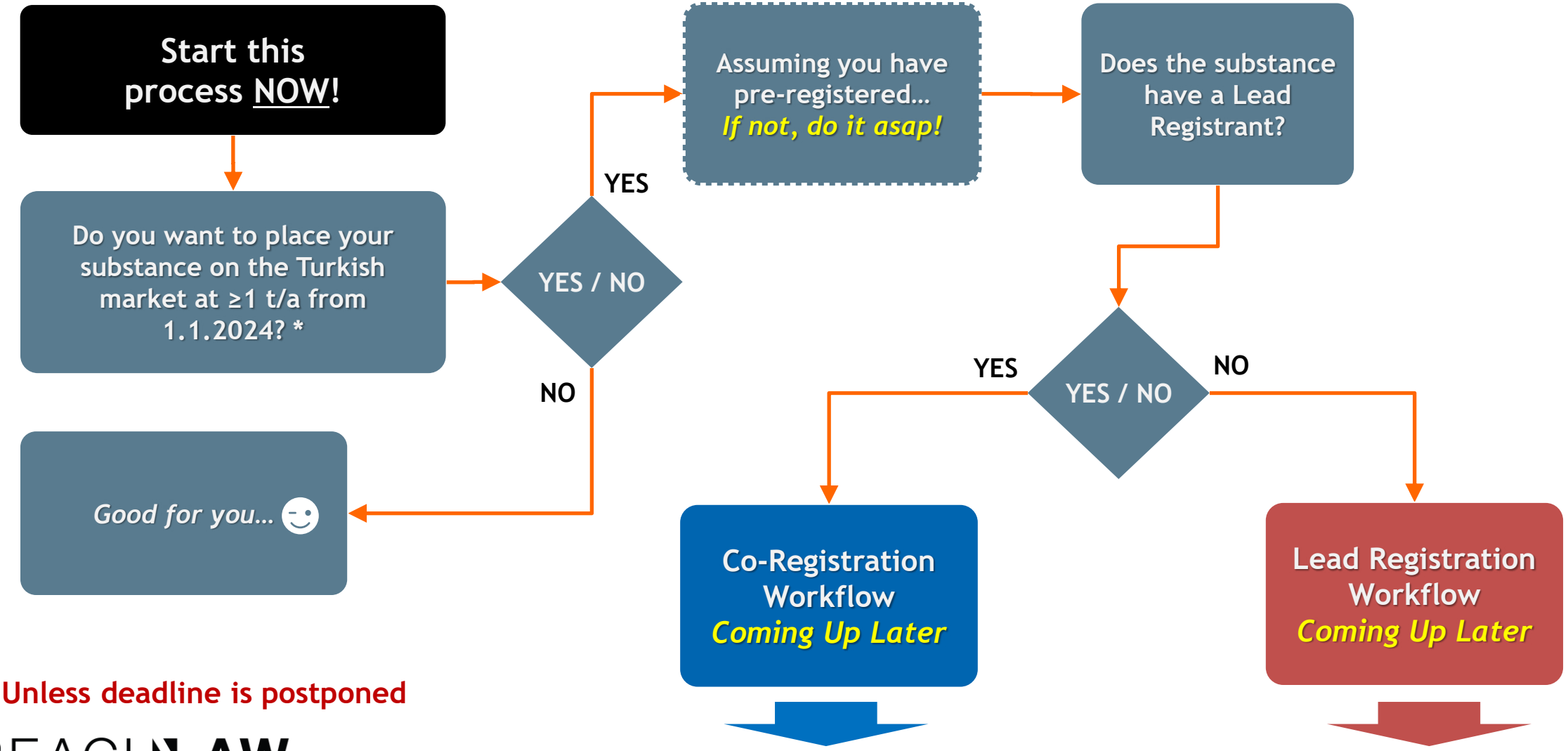
- **The Co-Registrant is responsible for its own registration:**
  1. Cooperate in the (Pre-)SIEF
  2. Agree on substance identity *(verify that the substance truly is the same as your substance)*
  3. Share data (*if available*) – *You may own data for EU REACH purposes?*
  4. Share costs *(e.g., purchase a "Letter of Access")*
  5. Compile and submit the Co-Registration **as part of the Joint Submission** and submit the dossier to the MoEUCC using KKS **before the registration deadline, currently 31.12.2023.**

Post-Submission

6. Keep the Co-Registration dossier up-to-date
7. Record keeping and communicate with authorities

How to Register by the Deadline

KKDIK Registration Workflow



* Unless deadline is postponed

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Lead Registration Workflow Summary

OPTIONAL: Send an email to all (Pre-)SIEF members for a final push to get someone else to become the Lead Registrant

Assuming no-one wants to become the Lead

Nominate yourself as the Lead Registrant!
Give 2 weeks for SIEF feedback

Reasons for becoming a KKDIK Lead Registrant:

1. You are the EU REACH Lead Registrant placing the same substance on the Turkish market
2. You are an EU REACH Registrant, a member of EU REACH consortia for the Substance with access to the data
3. You are a Turkish or non-Turkish manufacturer/formulator or Importer of a strategically important Substance
4. You want to obtain a potentially more significant market share in Turkey for the substance
5. You want to control the joint registration effort on your terms as much as possible.
6. You do not have to work alone on the Lead dossier. Experts are available to support you

Turkey KKDIK Lead Registration work is not that a big of a deal!!!

Prepare the Lead Dossier + Related activities
Data access negotiations / Data sharing, SIEF communication, Cost Sharing, Agreements, Itemisation, Translation, Compilation, KDU certification, etc.

Submit the Lead Registration early enough to allow Co-registrants to join the Joint Submission and submit their dossiers well before the registration deadline

Pay the MoEUCC fee and follow the progress

Sell LoAs and admit members to Joint Submission

DONE!

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How to Register by the Deadline

What Does the Lead Dossier Contain?

Own analytical information to prove substance ID

Company data on manufacture / import / sites / Importers for OR's (*optional*), etc.

Annual tonnage information (t/a)

Use information

Dossier Sections 1 & 3

Substance identify information

Company specific information

Classification & labelling information

Guidance on Safe Use

Chemical Safety Report
Hazard and Exposure Assessment and Risk Characterisation

Robust study summaries and intrinsic substance properties information

Further testing proposal(s)

Appendices (e.g. SCC)

Lead Dossier creation and submission

MoEUCC / KKS

Dossier Sections
2, 4, 5, 6, 7 & 11

Physico-chemical data

Toxicological data

Eco-toxicological data

Read Across data

Exposure data

QSAR …

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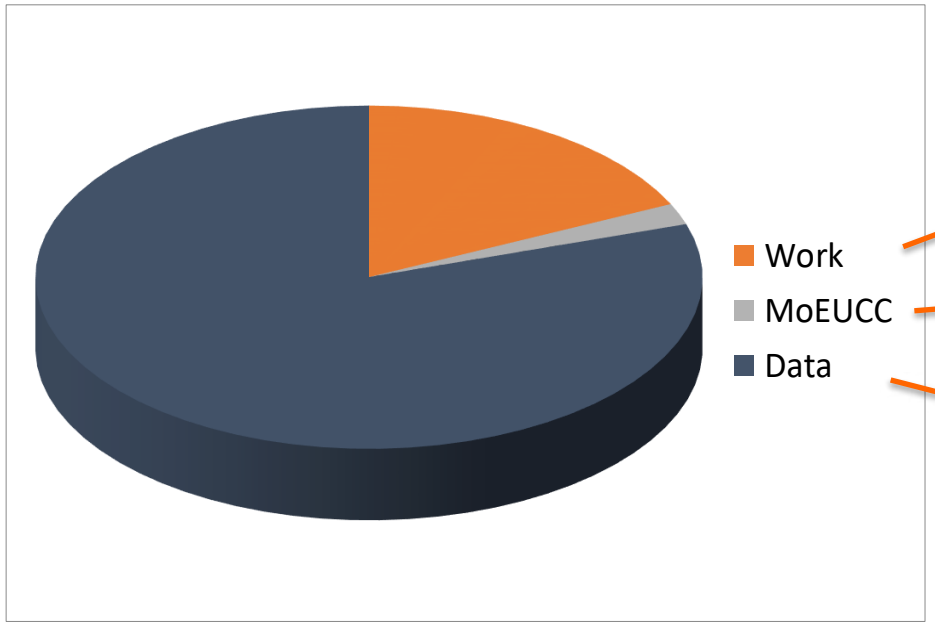
How to Register by the Deadline

Rough Estimate of Lead Registration Cost Distributions



Work:

Internal resources
Service provider costs

MoEUCC fixed fees:

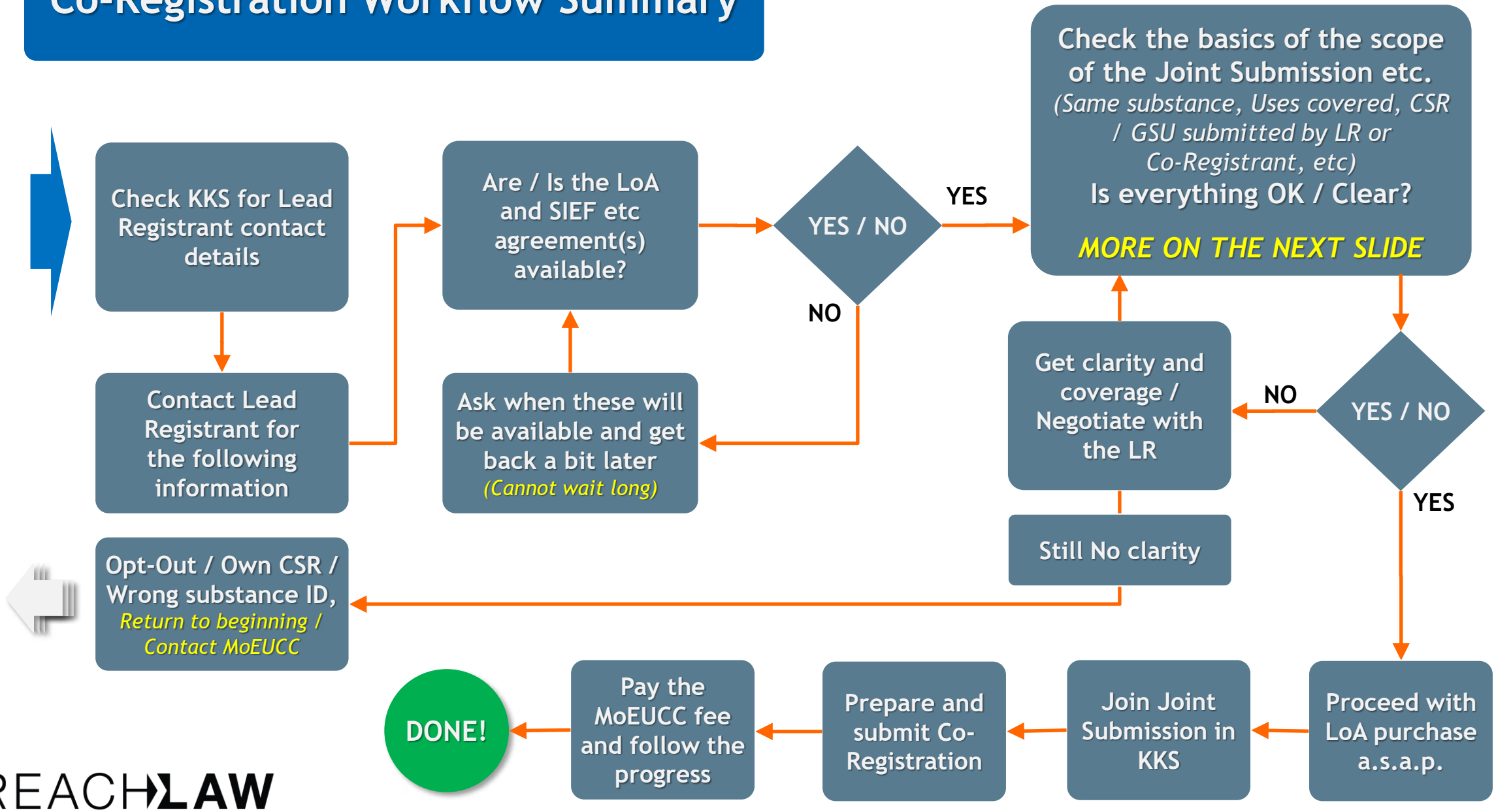
Depends on company size and Type of registration (tonnage band, joint submission or individual submission, full or intermediate registration)

DATA

End-point data
Other data (CSR, …)

These costs will generally be shared between all registrants of the same substance in proportion to the tonnage band registered and type of registration

Co-Registration Workflow Summary



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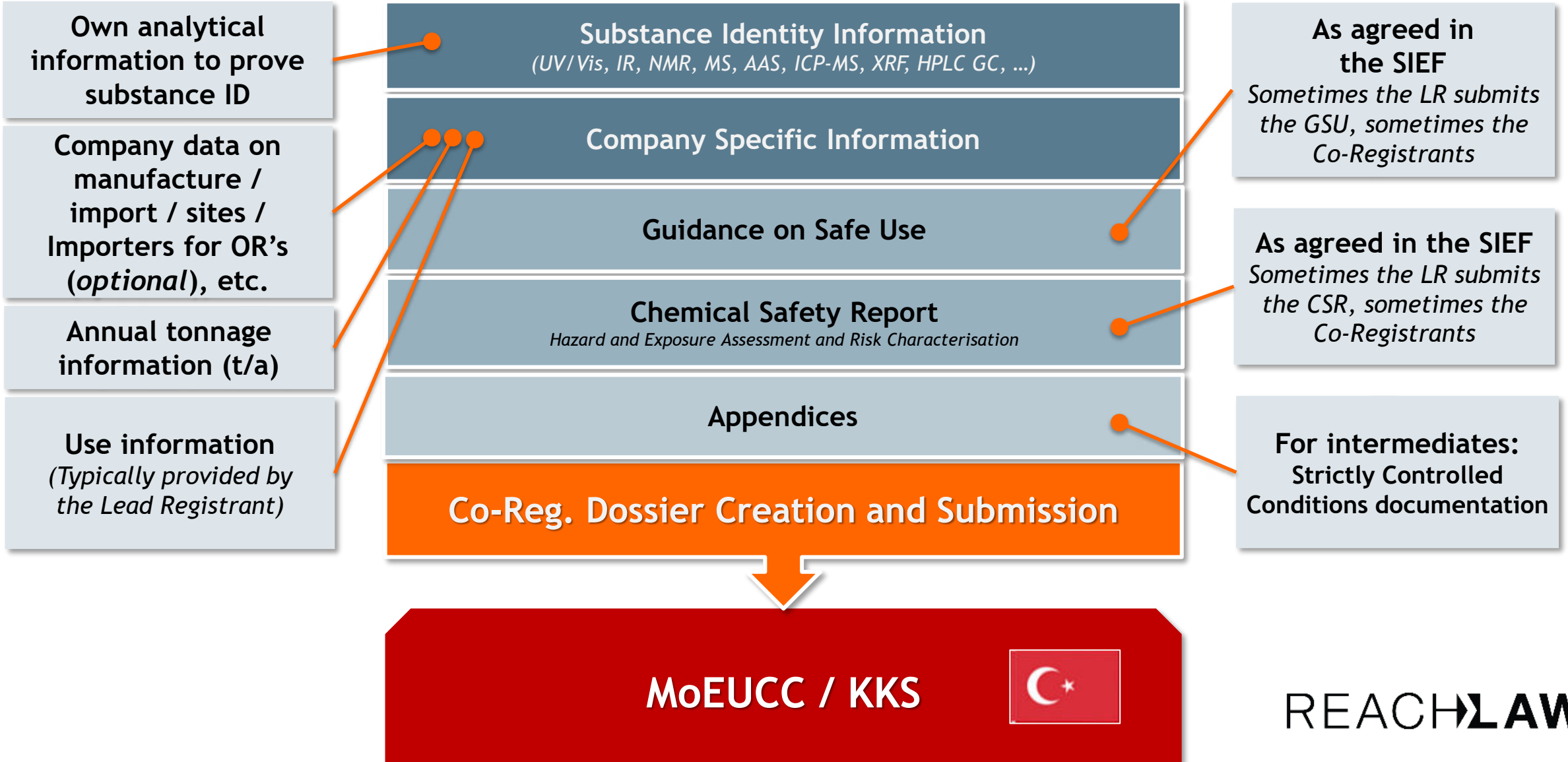
How to Register by the Deadline

What does the Co-Registrant Dossier Contain?



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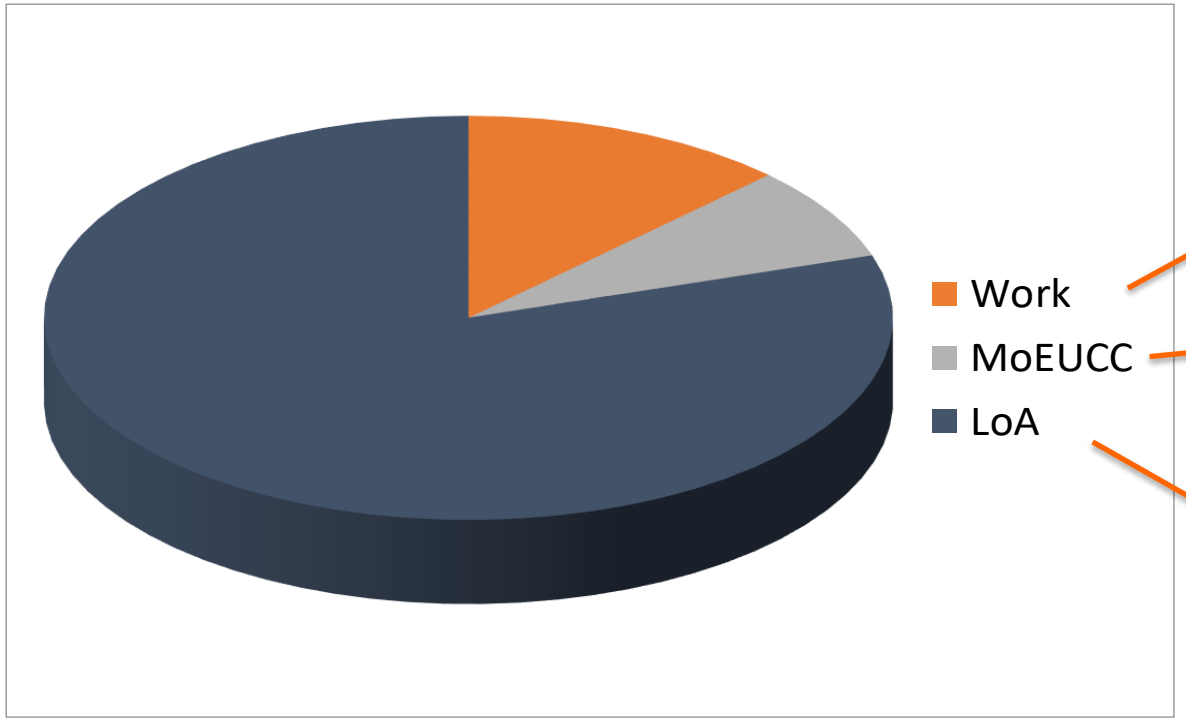
How to Register by the Deadline

Rough Estimate of KKDIK Co-Registration Cost Distributions



Work:
Internal resources
Service provider costs

MoEUCC fixed fees:
Depends on company size and Type of registration (tonnage band, joint submission or individual submission, full or intermediate registration)

Letter of Access fee:
Data costs and Lead Registration work costs

It is expected that the LoA will be the most expensive component of the KKDIK Co-Registration

As there's no more time to waste,
YOU should become the KKDIK Lead Registrant if you want to continue placing the substance on the Turkish market at ≥ 1 t/a after the registration deadline

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KKDIK Registration Action Plan

KKDIK Lead Registration Actions *(through your OR > Not covered in detail)*

1. Have the ***necessary resources and funds ready ahead of the registration effort*** *(ask for budget estimates from your OR)*
2. Someone **must always** become the KKDIK Lead Registrant → **Don't shy away from becoming the Lead Registrant**. *You do not have to be the owner of the data → Data is available from EU REACH and up for negotiation*
3. Preparing the KKDIK Lead Registration dossier and managing the Joint Registration effort ***is not that big of a deal.***
   - But you *may* need **support from someone who knows what they are doing** and, ideally, has done it before
   - If your OR does not have the necessary skill set, **change OR**.
4. Prepare the Lead Dossier according to the ***prevailing requirements and share costs and data fairly, transparently and non-discriminatorily*** → *Issue LoA in good time!!!*
5. Submit the Lead Registration dossier to the MoEUCC through KKS **in good time before the registration deadline and *follow the submission progress*** and ***pay the MoEUCC fees*** to get your **registration number**!
6. Manage the Joint Submission work diligently → *Document everything!*
7. **You are done!** Keep the Lead Registration ***dossier up-to-date*** and ***continue managing the Joint Submission and access to it diligently***.

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KKDIK Registration Action Plan

KKDIK Co-Registration Actions *(through your Only Representative)*

1. Have the ***necessary resources and funds ready ahead of the registration effort*** *(ask for budget estimates from your OR)*
2. Contact the Lead Registrant for ***Letter of Access (LoA) information*** (*cost, scope, timeline*), and if not yet available, ask when it will be
   - Purchase the LoA **as soon as it becomes available**
3. Collect the necessary information for the Co-Registration, such as ***Analytical information*** (*for proving substance ID*), ***information on identified uses***, ***estimated annual tonnages,*** etc.
4. ***Start compiling the KKDIK Co-Registration dossier*** in the KKS IT system in preparation for the submission
5. When the LoA is available and purchased, ***Lead Registrant grants access to the Joint Submission*** and then you should ***submit the KKDIK Co-Registration a.s.a.p.*** *(well before 31.12.2023 DL)*
6. ***Follow the submission progress*** and ***pay the MoEUCC fees*** to get your **registration number**!
7. **You are done!** Keep the Co-Registration ***dossier up-to-date***.

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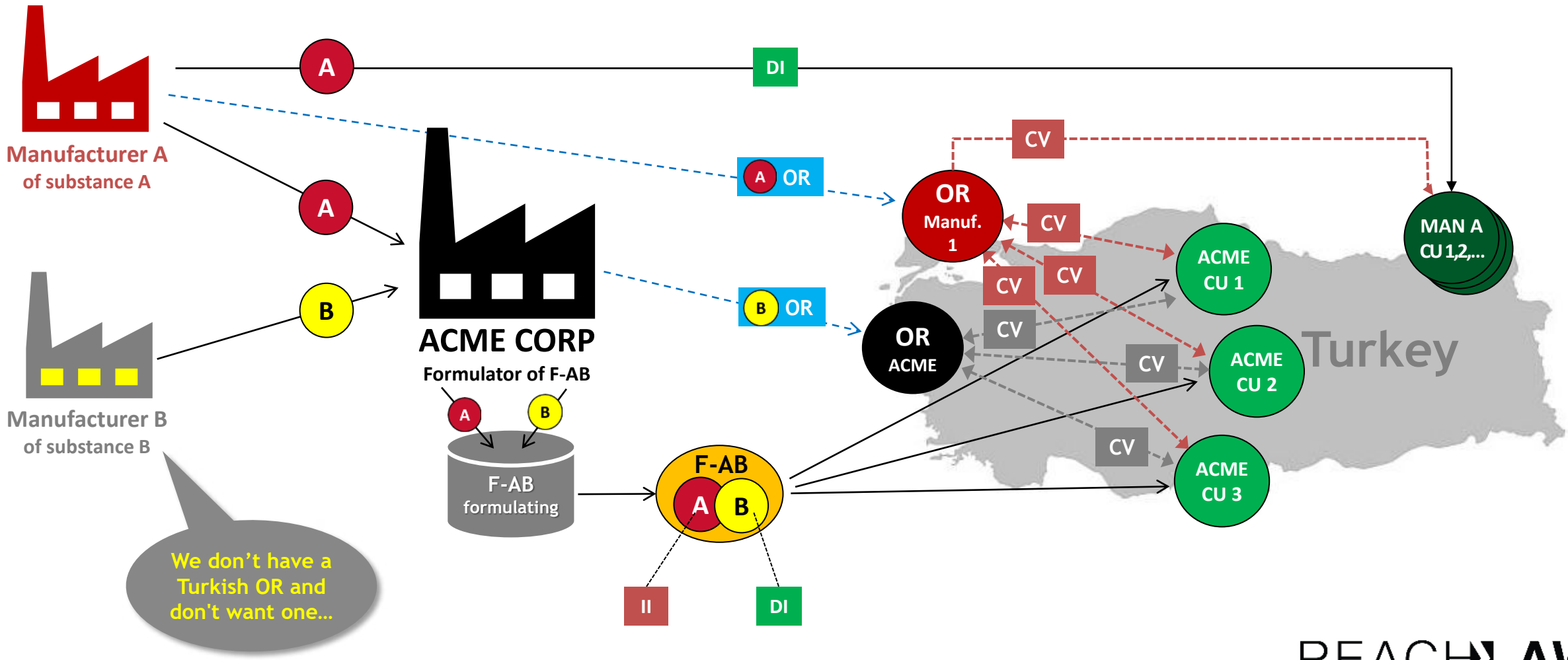
Case Example 1 | Non-Turkish Formulator Seeking Supply Chain Coverage

Example of a non-Turkish Formulator (“***ACME Corp***”) seeking OR coverage for substances “**A**” and “**B**” (≥ 1 t/a) included in the formulation “***F-AB***” but only getting coverage for **Substance** “**A**” by **Manufacturer A’s** OR in Turkey.

II = Indirect Import
DI = Direct Import
CV CV = OR Coverage

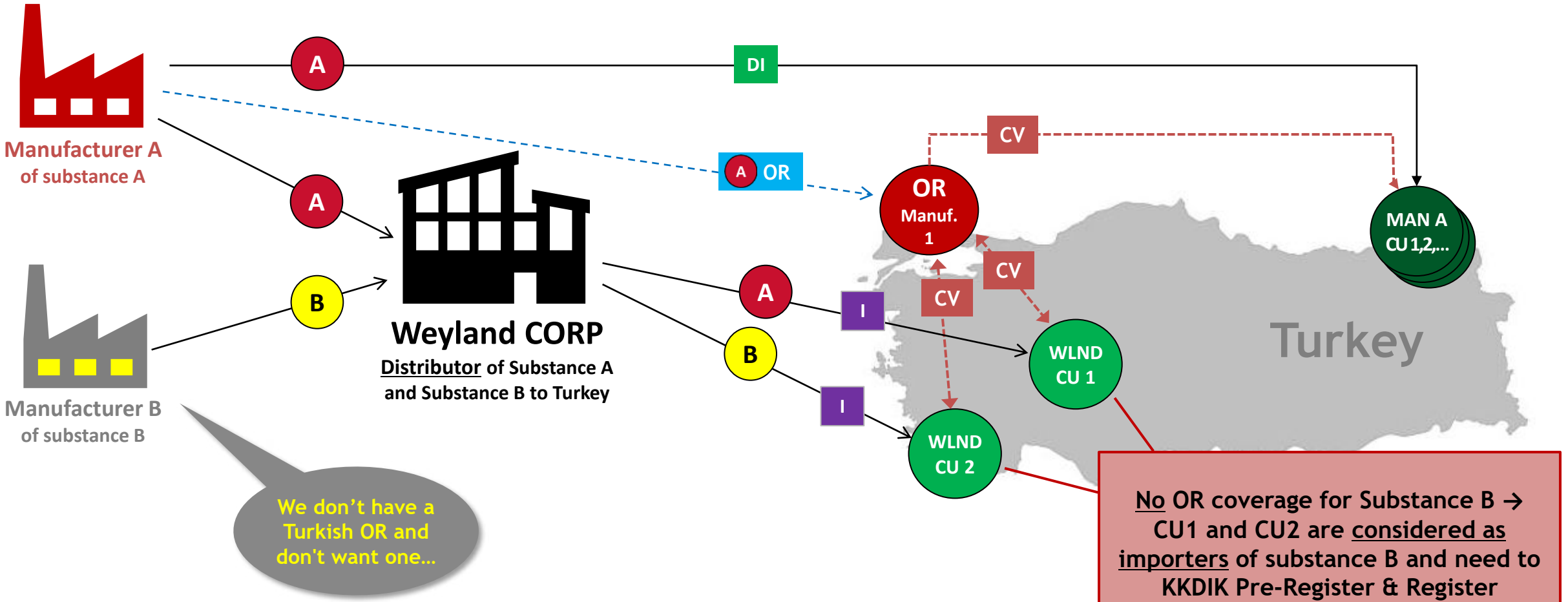


REACHLAW

Case Example 2 | Non-Turkish Distributor Seeking Supply Chain Coverage

Example of a non-Turkish Distributor ("***Wayland Corp***") seeking OR coverage for substances "**A**" and "**B**" that they are supplying to Turkey. Wayland Corp is not formulating (or manipulating) the substances, only exporting the substances to Turkey

I = Import
DI = Direct Import
CV = OR Coverage



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1. TURKEY KKDIK IN BRIEF
2. KKDIK REGISTRATIONS
3. HOW TO REGISTER BY THE DEADLINE
4. KKDIK REGISTRATION ACTION PLAN
5. SOME CASE EXAMPLES
6. CONCLUSIONS
7. QUICK Q&A

Turkey KKDIK Registration Strategy
Conclusions

- The **KKDIK Registration phase is in full swing for** all substances from 1 t/a and will end with the **Registration deadline, currently** 31.12.2023 → MoEUCC fees will apply.
- If you have not already done so, **start your KKDIK registration work now, don't wait!**
- **If there is a Lead Registrant, you will become a Co-Registrant and you should** contact the Lead Registrant for LoA access / timeline a.s.a.p. (*through your OR*)
- **If there is no Lead Registrant yet, YOU must take** extraordinary steps to find one ***or*** become the Lead Registrant yourself (*through your OR*)
- Becoming a KKDIK Lead Registrant **is not that big of a deal,** and **there are experts available to assist in the process**

No Lead Registrant = No Joint Submission = No Registration = No Market for the substance in Turkey from 1.1.2024!

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Quick Q&A

Thank you for your attention!

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