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COMPLIANCE. SUSTAINABILITY.

April 2023
14:40-15:20hrs IST

Chemical Regulatory Updates in Turkey, UK, India & EU

ChemExpo INDIA

Chemical Regulatory Updates in Turkey, UK, India & EU

Presenter

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Chemical Regulatory Updates in EU, UK, Turkey & India

Purpose of the presentation

- The basic knowledge of the Chemical Regulatory Updates in Turkey, UK, India & EU.
  - Turkey REACH: Registration (Co- and Lead), ways to comply and costs
  - UK REACH: Extension of registration deadlines, implications, and benefits of being part of a substance group already now
  - India BIS: Updates on new chemical inclusion in 2023/2024
  - EU REACH: overview of regulatory updates from 2022-23, what is coming next, enforcement etc

You may request copy of this presentation from chemexpo

AGENDA

- REACHLAW IN BRIEF
- CHEMICAL REGULATORY UPDATES
- CONCLUSIONS
- Q&A
- CONTACT

1. REACHLAW IN BRIEF
2. CHEMICAL REGULATORY UPDATES
3. CONCLUSIONS
4. Q&A
5. CONTACT

REACHLAW

COMPLIANCE. SUSTAINABILITY.

OUR FOCUS

Providing Support for REACH and REACH-Like Chemical Regulations Globally

* Upon entry into force
** Through REACHLaw Global Partners

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ABOUT US

Established in Helsinki, Finland 2006

Offices in five (5) countries

Multidisciplinary team - Business, Legal & Technical: *Toxicologists, Eco-toxicologists, Chemists, Socio-econ. analysts and Environmental specialists*

20+ local partners in Europe, Asia, Latin-America & USA Support in 10+ different languages

Major industries served: *Oil, Chemicals, Specialty Chemicals, Metals, Aerospace sector, Pulp & Paper and Other downstream users (DU) industries, etc.*

More info at: www.reachlaw.fi

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SOME STATISTICS

Customers: 900+

Continents: 5

Countries: 60+

Pre-Registrations: 8 000+

Co-Registrations: 1 000+

Lead Registrant cases: 200+

Authorisation Applications: 30+

Classification Notifications: 4 000+

Global Chemical Notifications: 12 000+

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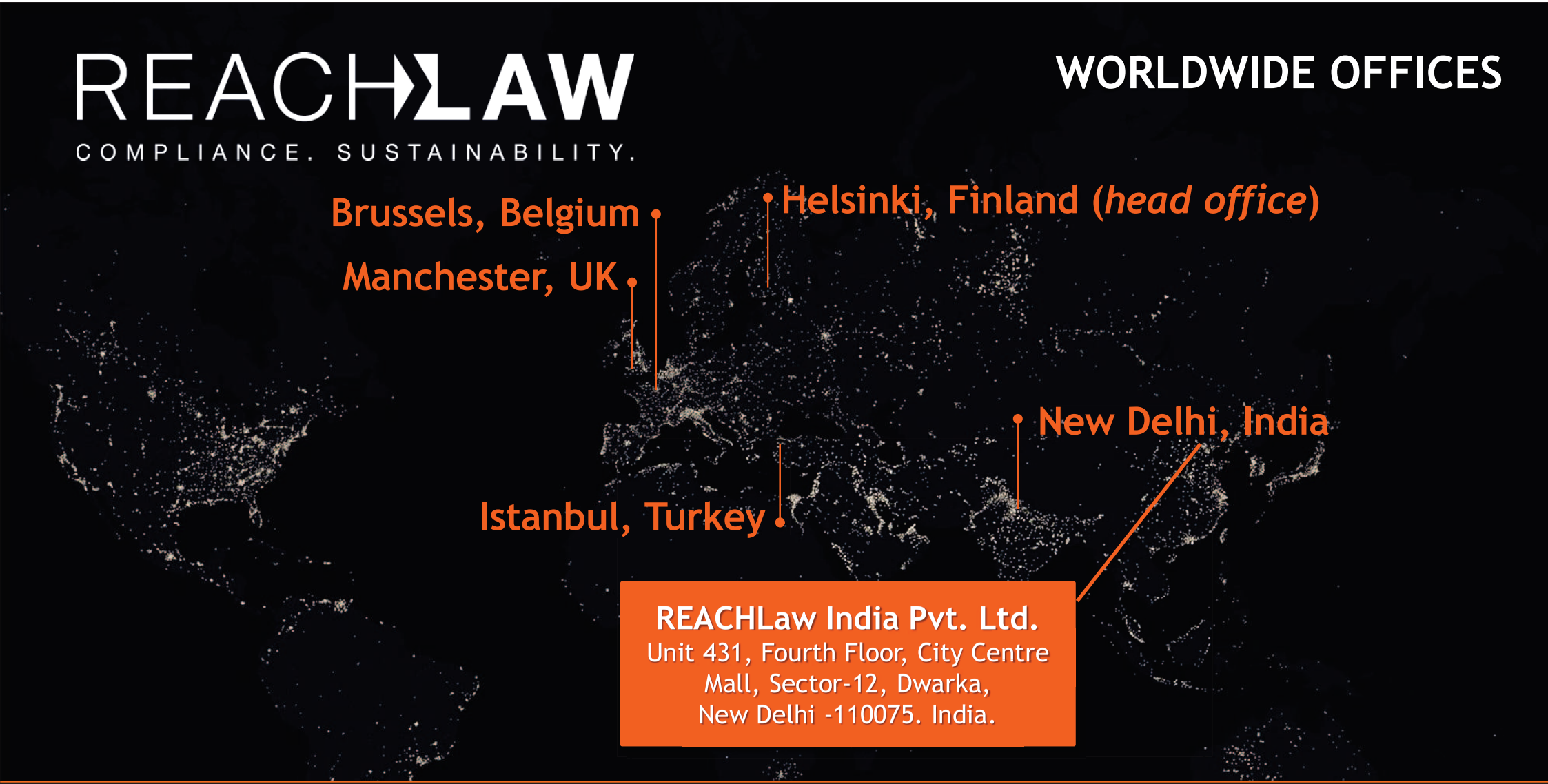
WORLDWIDE OFFICES



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MARKET ACCESS SERVICES FOR CHEMICAL PRODUCTS AND MORE

- Only or Authorized Representation *(EU, UK, Turkey, India*, South Korea**)*
- Pre-Registration/ Notifications / Product Registry Notifications
- Registration (Lead & Co) *(EU, UK, Turkey, India*)*
- Authorisation *(EU, UK, Turkey***)*
- SVHC Advocacy & Consultancy
- Outsourcing of Chemicals Regulatory Compliance Functions
- Classification and Labelling
- SCIP Strategy and Notification Services
- Circular Economy Services
- Legal & Technical Services
- Consulting
- Training *...etc*

Regulations Supported:

- *EU REACH & CLP*
- *UK REACH & CLP*
- *Turkey KKDIK & SEA & GBF*
- *India REACH**
- *Korea REACH*
- *Swiss ChemO*
- *China "REACH" & GHS*

...and more

* *Upon Entry Into Force*
** *Through local partner*
*** *When obligations enter into force*

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Only Representatives in the EU,
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(North America, South America, non-EU/EEA Europe,
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We Specialize in Chemical Regulatory Compliance and Sustainability

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1. REACHLAW IN BRIEF
2. CHEMICAL REGULATORY UPDATES
3. CONCLUSIONS
4. Q&A
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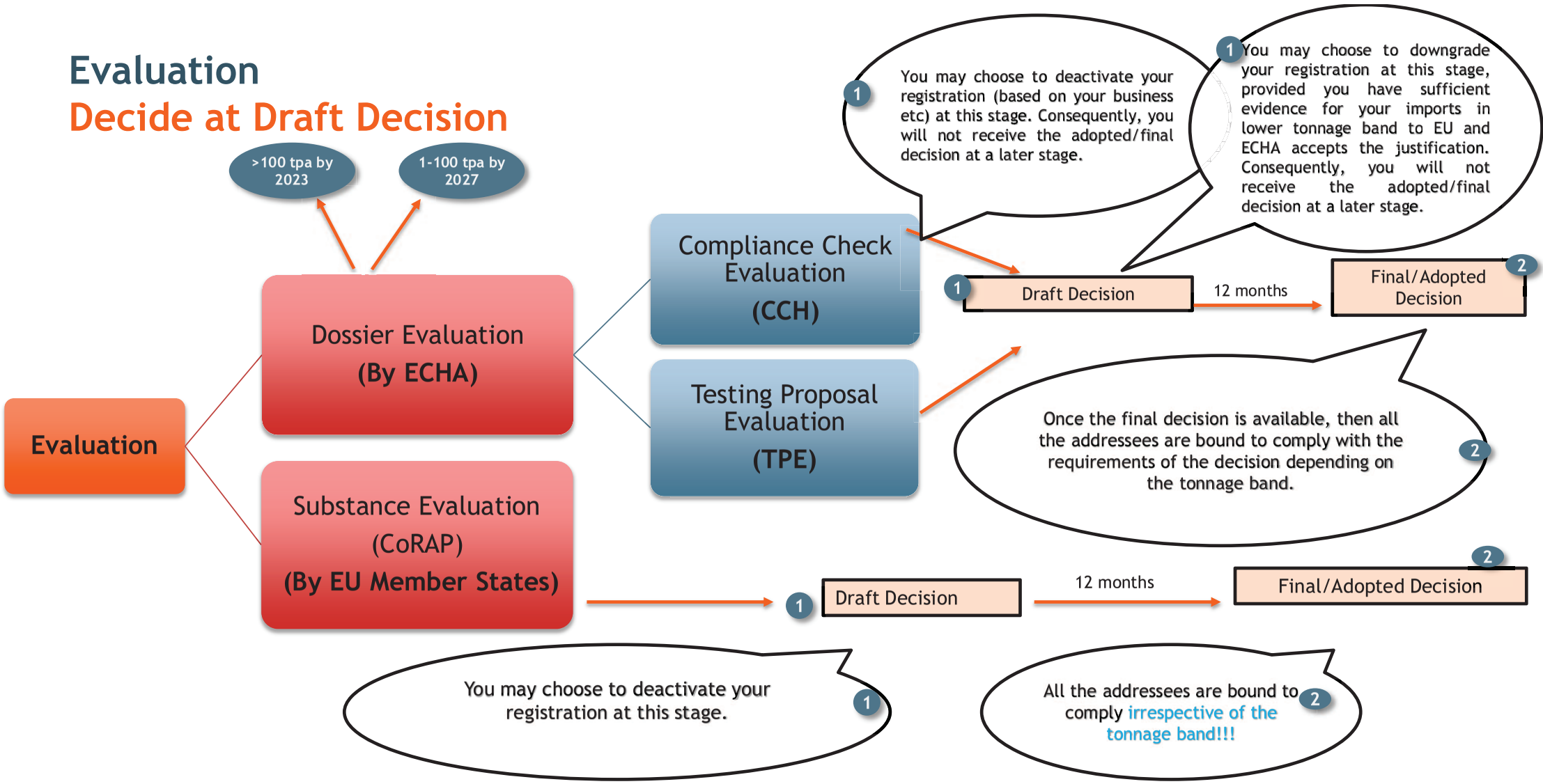
EU REACH

Evaluation
Post Registration additional cost

- The LoA process under EU-REACH is driven by the principle of cost sharing.
- The costs are subject to change due to new study request from ECHA & recalculation.
- The costs can go up or down resulting in Refunds or Top-ups (additional invoice)
- There can be extra costs due to:
  - By ECHA or Member states : Evaluation
    - Substance Evaluation (CoRAP) by EU Member States
    - Compliance Check Evaluation (CCH)
    - Testing Proposal Evaluation (TPE)

    } Dossier Evaluation by ECHA
  - By Lead Registrant (LR) or Consortium or Only Representative : Dossier update
    - Lead dossier update due to evaluation
    - Co-reg dossier update by OR_CSR,USES, Tonnage quantities.

Evaluation
Decide at Draft Decision



Deadlines and changes
Recent updates under REACH

Already in force, Applicable from 14.10.2022

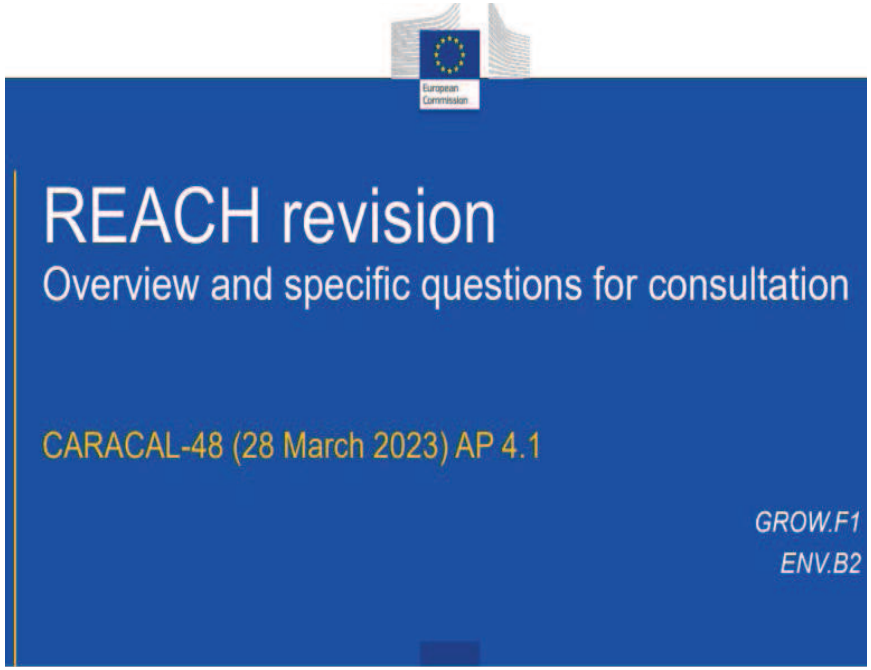
1. Additional test requirements, REACH Annex VI-X are updated Commission Regulation (EU) 2022/477
2. ECHA: Only Representative are obliged to provide details of the non-EU manufacturers they represent.
3. Substance identification information including
   - ✓ Nanoforms
   - ✓ UVCBS
   - ✓ clarified requirements for reporting constituents, impurities, and additives as well as for analytical information.

Already in force

4. Update Member Dossier in 3-6 months Commission Regulation (EU) 2020/1435
5. REACH Annex II SDS regulation Commission Regulation (EU) 2020/878.
   - ✓ Safety data sheets not complying with the Annex to this Regulation may continue to be provided until 31 December 2022.

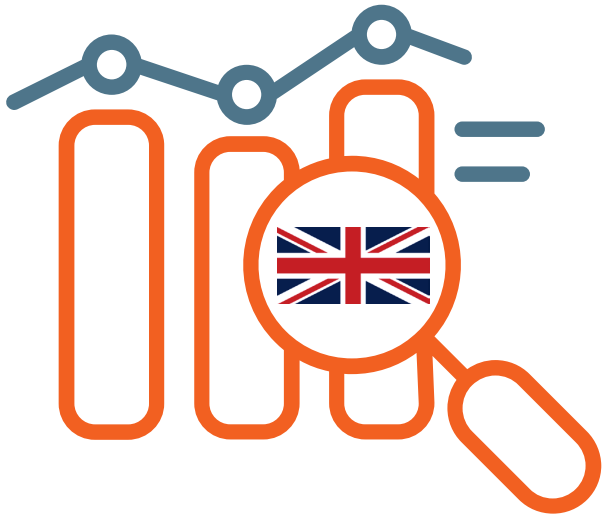
REACH Revision & Enforcement
Few Major highlights

1. Increased information requirements for low tonnages/most harmful substances, Chemical Safety Assessment & Report also for 1-10 tonnes
2. Registration of polymers
   - ✓ Notification of all polymers
   - ✓ Registration of polymers requiring registration (PRR)
3. Revocation of registration & Evaluation
4. Authorisation and restriction reform to streamline these regulatory tools and reduce the burden on companies and authorities
5. Audit Capacity + provisions for MSs' control systems
6. Strengthen automated custom control of registration, safety data sheets
7. Current Enforcement: chemical control at customs for restriction & safety data sheet compliance as per Annex II



UK REACH

UK REACH Overview
Some Statistics



- Number of **DUIN submissions**: ~ 1 000 000
  (no exact figure officially available)
  - Number of **submitting Legal Entities** (*GB importers and Only Representatives*): >5 000
- Substances notified under the **UK REACH Grandfathering process**: 4 042
- Some 22 000 different substances have been either DUIN notified or Grandfathering *(Different EU REACH substances registered: **22 244**)*
- Inquiries submitted: **ca. 5 000** *(Compiled from multiple sources)*
- New Registration of Existing Substances (NRES): **ca. 500**
- Novel substances registered under the **UK REACH**:
  ca. 20 - 50 *(Data from May)*

UK REACH Overview

Comparison EU REACH vs. UK REACH

Task / Scope	EU REACH	UK REACH
Pre-registration	No longer possible	No, **DUIN applicable** for GB based importers of EU REACH registered substances
Inquiry	Yes	Yes
Registration	All chemicals at ≥1 t/a (exemptions apply)	All chemicals at ≥1 t/a (exemptions apply). When to register depends on whether substance was on the UK market in 2019 and/or 2020 and the hazards and t/a of the substance. ***Registration deadlines to be extended by 3 year per deadline***
Grandfathering	No	Yes, but deadline passed (30.4.2021)
Polymers	Exempted, but not monomers. REACH Review may bring a change to this for some polymers	Exempted, but not monomers
Data requirement	More volume, more data	More volume, more data. ***Likely changing for some substances of lesser concern***
Joint Registration	Yes	Yes
Only Representative	Yes	Yes
R&D / PPORD Exemptions	Yes	Yes
Product notification	No	No
Safety Data Sheets	Yes	Yes

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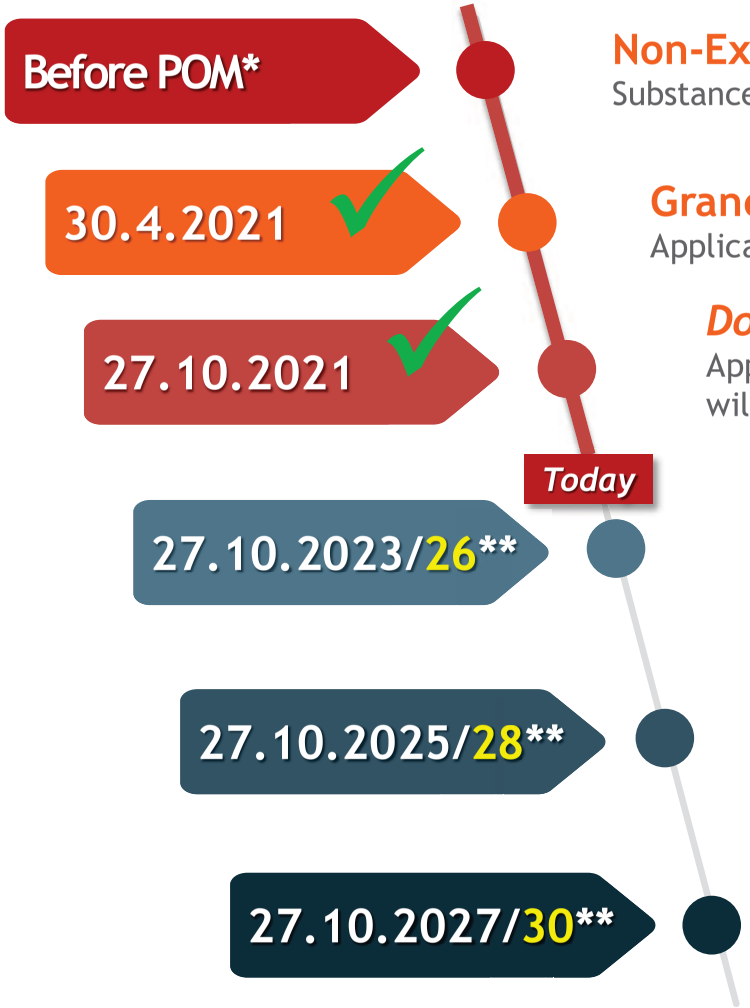
* **POM** = Placing on the Market in GB
** Deadline Extensions pending

Registration, the Basics

Registration and Related Deadlines - Current Legal Text



Non-Existing Supply Substances / NRES Substances

Substances that cannot benefit from Transitional timelines at **≥ 1 t/a**

Grandfathering notification deadline

Applicable only to GB based EU REACH registration holders

Downstream User Import Notification (DUIN) deadline *(Late DUIN possible)*

Applicable to GB importers of substances from the EU/EEA/NI and Only Representatives that will need to UK REACH register substances at 1 t/a or more

Registration deadline 1

≥ 1000 t/a substances
≥ 100 t/a Very toxic to aquatic organisms (acute or chronic)
≥ 1 t/a Carcinogenic, Mutagenic, or toxic for Reproduction (CMR) substances
≥ 1 t/a Candidate list SVHCs as on EU List on 31 December 2020 (transposed to UK)

Registration deadline 2

100 - 1000 t/a substances
≥ 1 t/a Candidate list substances (*unless already covered above*) that are on the UK REACH Candidate List as of the 27th of October 2023

Registration deadline 3

1 - 100 t/a substances

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Registration Deadline Extensions - Who's Affected & What's Next

Background: 3 Options for Extending the Registration Deadlines

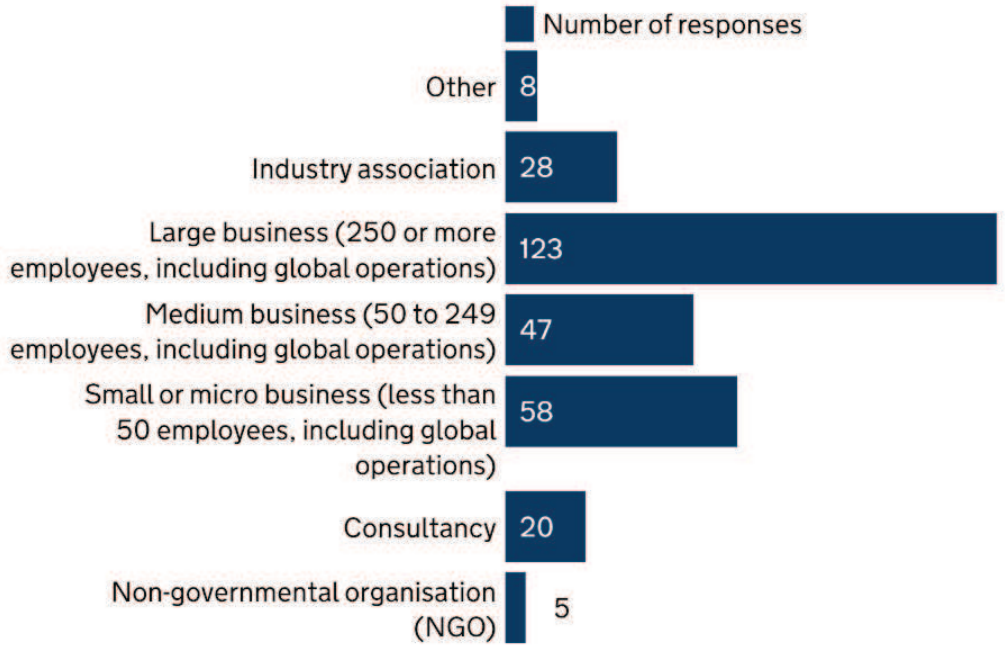
Type of Substances	Transitional Registration Deadlines		
	Option 0 *(Current DL)*	Option 1 *(3:3:3)*	Option 2 *(3:2:1)*
Substances at ≥1000 t/a and CMR substances at ≥1 t/a *and* substances Very toxic to aquatic organisms *(acute or chronic)* at ≥100 t/a *and* Candidate list substances *(as of 31 December 2020)* at ≥1 t/a	27 October 2023	27 October 2026 (= Current DL + 3 years)	27 October 2026 (= Current DL + 3 years)
Substances at 100 - 1000 t/a *and* Candidate list substances as of 27 October 2026 at ≥1 t/a	27 October 2025	27 October 2028 (= Current DL + 3 years)	27 October 2027 (= Current DL + 2 years)
Substances at 1 - 100 t/a	27 October 2027	27 October 2030 (= Current DL + 3 years)	27 October 2028 (= Current DL + 1 years)
	(Do nothing option)	**Selected**	**Preferred by the GOV**

Registration Deadline Extensions - Who's Affected & What's Next

Background: Option 1 (3:3:3) Selected

- A total of **289 responses** to the consultation were received
- **Question 8:** What is your preferred option on extending the registration deadlines?

Respondents by role	Number of responses
Option 1	82%
Option 2	13%
Do nothing	3%
No preferred option	2%



Source: Defra, Consultation outcome - Summary of responses and government response (Updated 29 November 2022)

Registration Deadline Extensions - Who's Affected & What's Next

New Transitional Registration Deadlines

Type of Substances	New Transitional Registration Deadlines*
Substances at ≥1000 t/a and CMR substances at ≥1 t/a *and* substances Very toxic to aquatic organisms *(acute or chronic)* at ≥100 t/a *and* Candidate list substances *(as of 31 December 2020)* at ≥1 t/a	27 October 2026
Substances at 100 - 1000 t/a *and* Candidate list substances as of 27 October 2026 at ≥1 t/a	27 October 2028
Substances at 1 - 100 t/a	27 October 2030

These applies to **Grandfathering**, **DUIN** and **NRES** (*Joining the joint submission part*) only.
New substances must still be be fully registered before placing on the GB market at ≥1 t/a.

*** Pending legislative updates**

Registration Deadline Extensions - Who's Affected & What's Next

What's Next

- Registration Deadline Extensions are **expected to become** law during summer 2023 *(…that's a bit late but better late than never)*
  1. Draft Statutory Instrument before Parliament
  2. Debate and vote in both Houses of Parliament
  3. Signed into law by the Secretary of State
  4. Entry into force: **Before 27 October 2023** *(…hopefully)*

UK Parliament

- **Risks**: Potential for legal challenges resulting in delays…?
- If legislation will not be in place by the first registration deadline (*27 October 2023*), **emergency legislation will be introduced to implement the changes to the registration deadlines** (*Defra*)

You will need to follow the legislative process for introducing the registration deadline changes into law

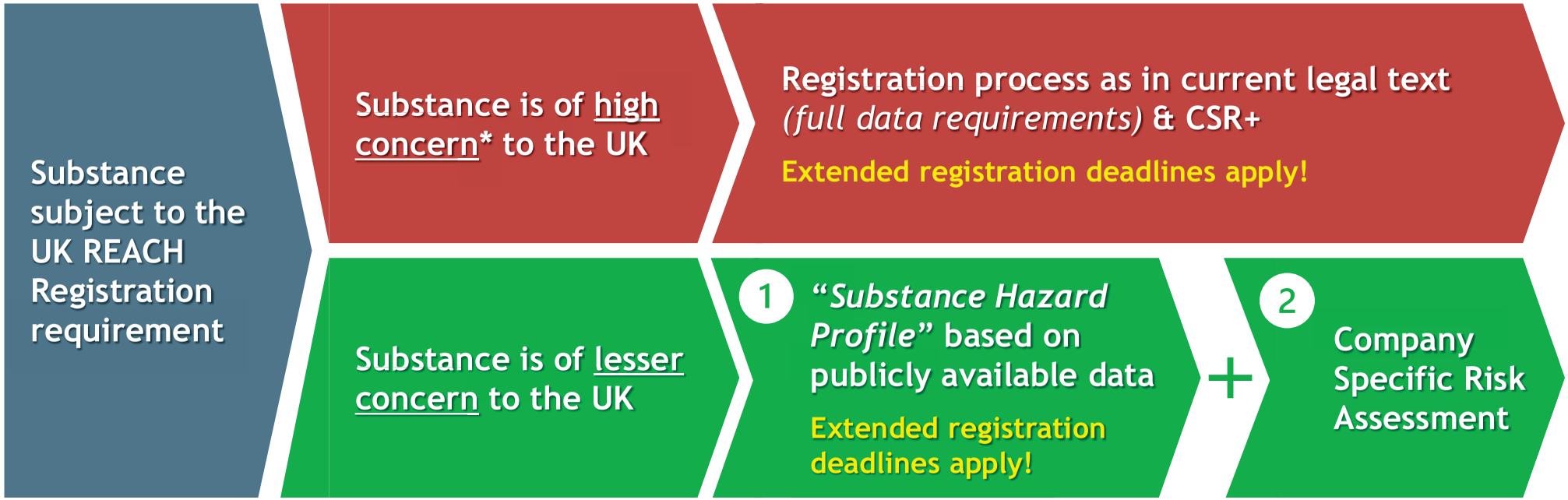
Only rejoice once that happens and happens on time

Warning:

This section is highly speculative so take it with a large pinch of salt…

New Registration Model - What We Know So Far

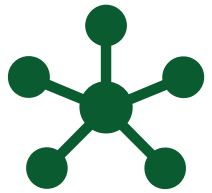
The "Two Tracked" Approach



* Substances of high concern to the UK likely to be *same* as SVHCs

New Registration Model - What We Know So Far

1 "Substance Hazard Profile"



- Companies part of the **same Substance group** (*inquiry needed for access unless substance was Grandfathered*) need to agree on a **"hazard profile"** for the substance.
- The "***Substance Hazard Profile***" ("*SHP*") should **demonstrate that the substance properties have been assessed by the registrants**
- The SHP should be populated with **"publicly available data"** ***(without IPR issues…)*** and **data held within the substance group**
- The SHP will be **compiled in IUCLID** (*UK specific template may become available*)
- SHP work will headed by the "***Lead Registrant***" as elected by companies of the substance group and **is submitted Jointly as part of the Joint Submission**
- The *SHP* is **submitted to the HSE** as a IUCLID dossier via the "***Comply with UK REACH***" IT system
- HSE **Registration fees would apply**

New Registration Model - What We Know So Far

2 Company "Specific Risk Assessment"

- Companies submitting the "***Substance Hazard Profile***" (*any registration*?) would also provide a **registrant / Company "Specific Risk Assessment** *("specific CSR")* focusing on the **GB use and exposure of the substance**.
  - The information should be useful in a GB context and not "*as broad / generic*" as the equivalent EU Chemical Safety Report (*CSR*)
  - May also apply to 1 – 10 t/a substances … ?
- More **registrant specific data** should be included (*compared with EU REACH CSR's*):
  - Data on tonnage per use
  - Number of sites used at (*more details of the supply chain*)
  - Evidence of GB specific data and exposure supporting the risk assessment
  - Disposal, waste and recycling information *…etc.*
- Registrants could submit a **confidential and non-confidential version** of the specific CSR, one that is "*publicly available*" in the supply chain the other not (?)
- Prepared and submitted **individually by each registrant to the HSE** (?) but could be based on common template of the Joint Submission (?)

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Companies would only need to provide full data sets for chemicals "deemed to be of most concern to the UK"

***Defra Recommends* inquiring early**
(according to UK REACH Art.26) ***in order to be able to follow what is going on in the substance groups and participate in the discussion on data sharing and more regardless of the registration model***

Turkey KKDIK

Turkey REACH: Current status

- Competent Authority: Ministry of Environment, Urbanisation and Climate Change (MoEUCC)
- Importers information: add to the registration dossiers
- The Chemical Safety Assessment and Reporting System (KGDRS), which allows the Chemical Safety Report to be prepared through the data entered in the KKS, has been integrated into the KKS and ready to be used.

REPUBLIC OF TURKEY
MINISTRY OF ENVIRONMENT,
URBANIZATION AND CLIMATE CHANGE

Pre-registration of substances
All substances placed on Turkey market ≥ **1 t/a**

Lead/ Co Registration Submissions *(Late pre-registration possible)*
Applicable to all pre-registered substances

Registration deadline
≥ **1000 t/a** substances
100-1000 t/a substances
10-100 t/a substances
1-10 t/a substances

Registration before placing on market
Registrations through inquiry

KKDIK Registration – An Overview

The KKDIK Registration Basics

Registration Threshold = 1 t/a

- All in Turkey **manufactured** or into Turkey **imported substances** as such or as part of mixtures **at 1 t/a or more** must be **KKDIK registered** by 31st of December 2023
  - Registration window for <u>all substances from 1 t/a</u>: 1st of January 2021 → 31st of December 2023
- **Registration tonnage bands:** *(Same as EU REACH)*
  - ≥1 - <10
  - ≥10 - <100
  - ≥100 - <1 000
  - ≥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 <u>whole supply chain</u>!*
- **Submissions** in **Turkish language** using the **KKS System**

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KKDIK Registration – An Overview

Information Requirements

Tonnage band	Annex 7	Annex 8	Annex 9	Annex 10
1-10 t/a	●			
10-100 t/a	●	●		
100-1000 t/a	●	●	●	
≥ 1000	●	●	●	●

Annexes of the KKDIK regulation listing data requirements

+ including a:
Chemical
Safety
Report

When there is an information gap that cannot be filled by any existing data (non-testing method), the Lead Registrant will need to:

- **For data according to Annexes 7 or 8 → Generate new information**
- **For data according to Annexes 9 or 10 → Prepare a testing proposal**
- Annex 11 provides general rules to adapt information requirements

GLP applies in some cases

Not applicable to intermediates under strictly controlled conditions

KKDIK Registration – An Overview
Joint Submission Concept

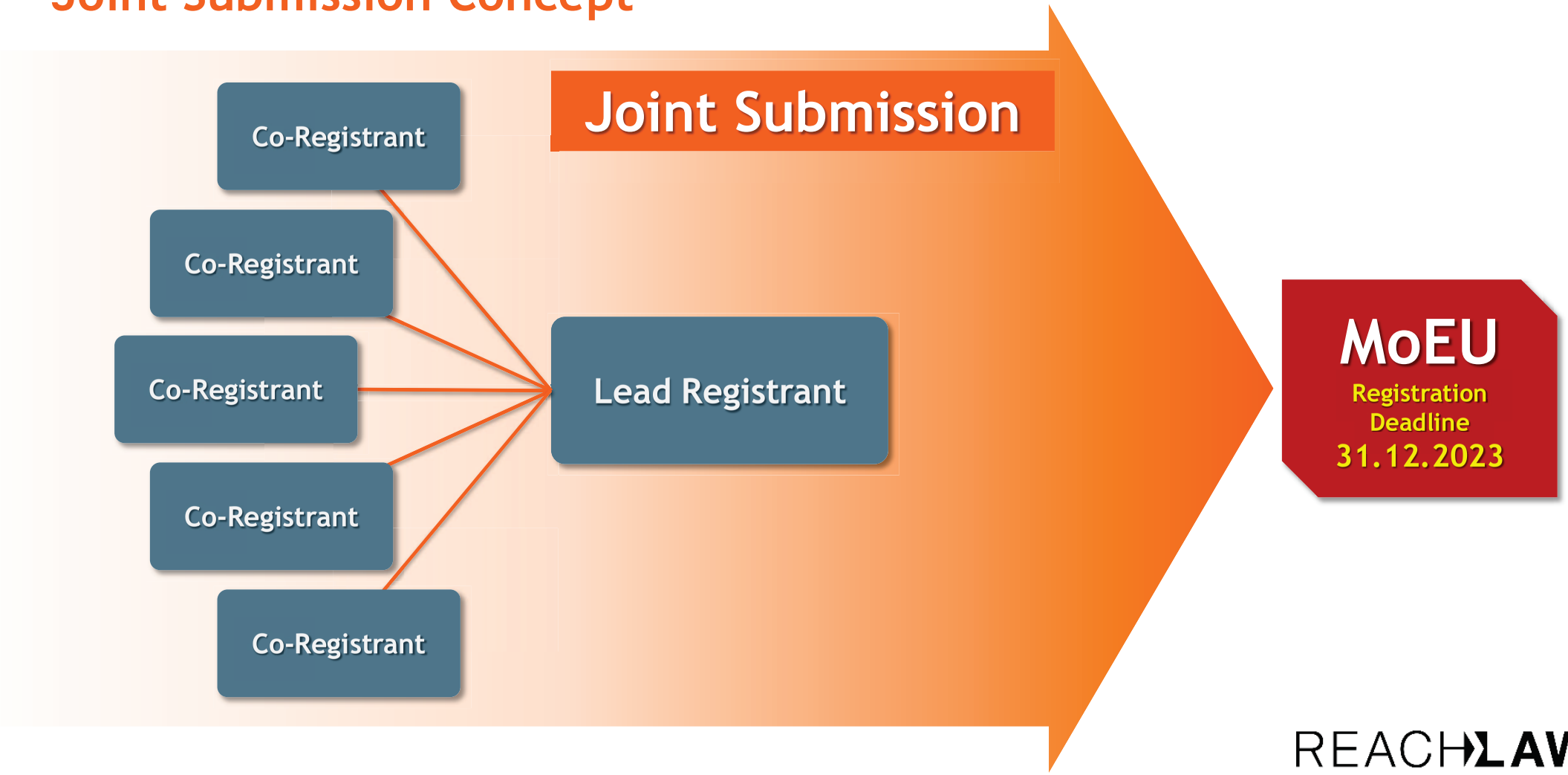
- **When a substance is intended to be KKDIK registered by one or more companies, a Joint Submission of "core registration data" is required**
  - Individual submission seems not to be possible (*will implement OSOR principle as in the EU)*
  - Opt-Out's are possible

These form the ***Substance Information Exchange Forums*** ("SIEF") where **data needs to be shared** in a ***"fair, transparent and non-discriminatory way"*** *(as with EU REACH)* eventually becoming a ***Joint Submission*** upon submission of the registration to the MoEU

- *Defined in KKDIK Articles 12, 23 and 26*

KKDIK Registration – An Overview

Joint Submission Concept



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Joint Submission is Mandatory

Individual submissions will not be possible without special permission

KKDIK Registration – An Overview

MoEUCC KKDIK Registration Fees

- MOEUCC fee (Authority fee) for registration has been increased by the authority on January 17, 2023 :

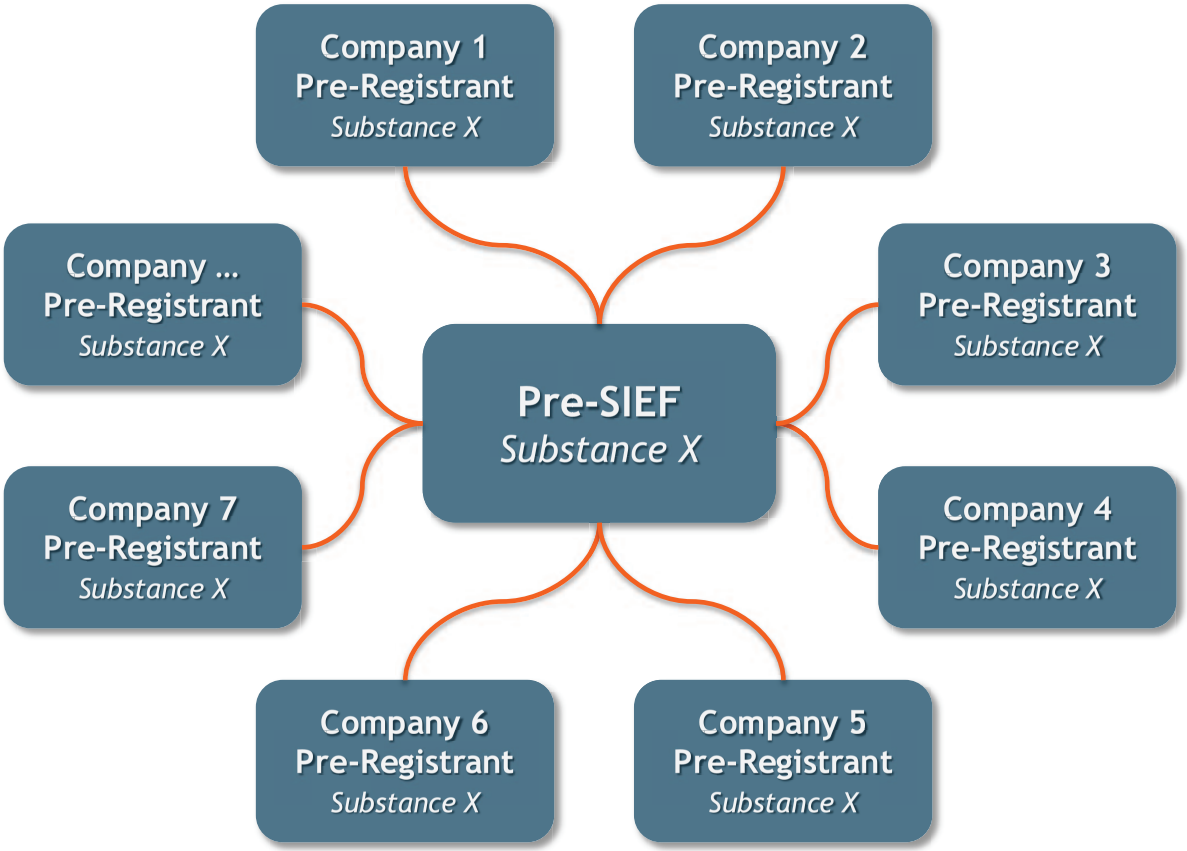
	MoEUCC Fee /substance (Updated)		MoEUCC Fee /substance (old)	
Tonnage band (t/a)	Individual Submission	Joint Submission	Individual Submission	Joint Submission
1-10	2 200 TL (110€)	1 660 TL (83 €)	1200 TL (59 €)	900 TL (46 €)
10-100	5 500 TL (275 €)	3 880 TL (194 €)	3000 TL (147 €)	2100 TL (107 €)
100-1000	15 500 TL (775 €)	11 100 TL (555 €)	8400 TL (412 €)	6000 TL (305 €)
>1000	33 300 TL (1 665 €)	26 600 TL (1 330 €)	18000 TL (882 €)	14400 TL (705 €)

MOEUCC website: https://kimyasallar.csb.gov.tr/taslak-kkdik-ucretleri/333

From PRE-SIEF to Joint Submission

Pre-SIEF *(Substance Information Exchange Forum)*

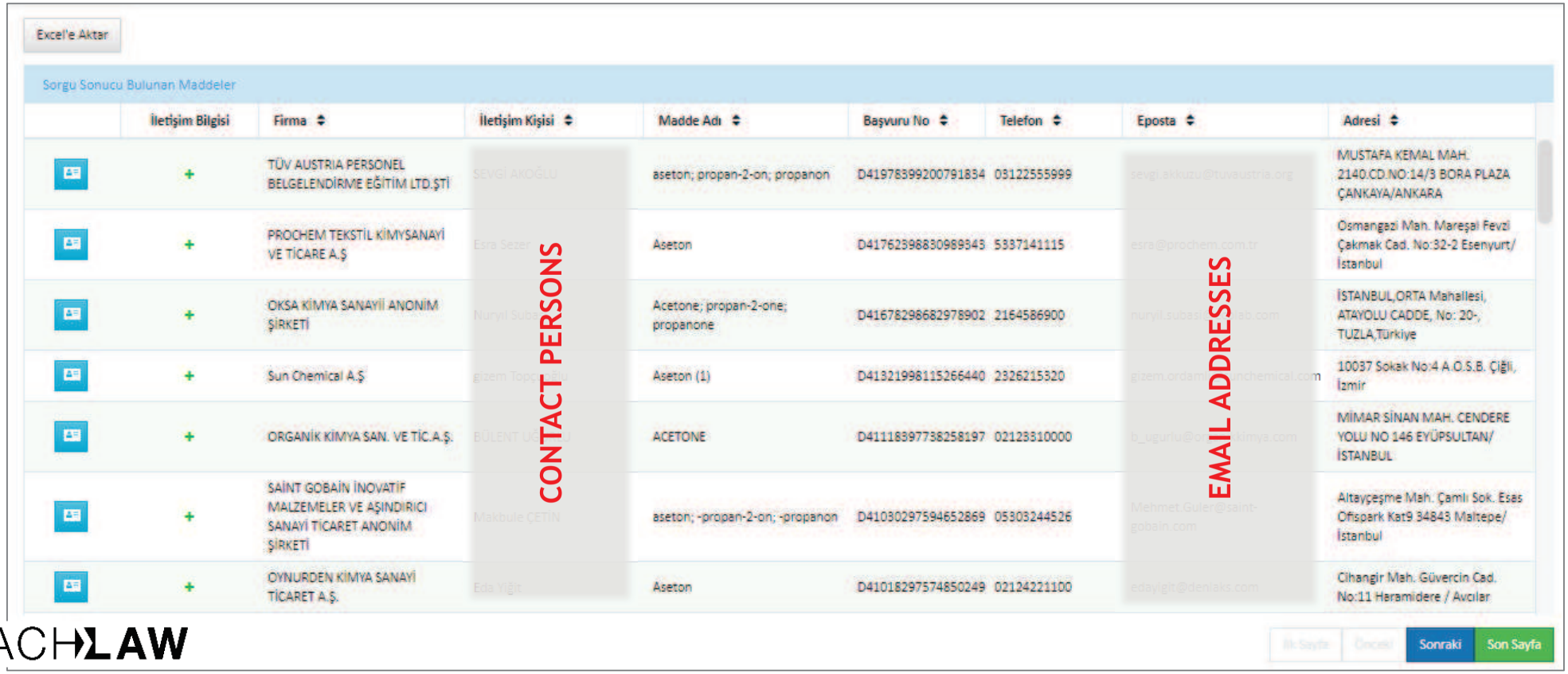
- By KKDIK pre-registering a substance, you have **become a member of the Pre-SIEF for that substance**
- Pre-SIEFs allows for early collaboration in preparing for the **Joint Registration** together with other companies that have **pre-registered the same substance**
- Functionality is provided in the **KKS system**



From PRE-SIEF to Joint Submission

Pre-SIEF in the KKS System → Contact Information

Example view of the "*Acetone*" (*EC#: 200-662-2, CAS#: 67-64-1*) Pre-SIEF in KKS system.
You can see what company has pre-registered this substance and you can also see their full contact details.
Information can be exported to an EXCEL file for easy management.



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From PRE-SIEF to Joint Submission
Lead Registrant Selection / Election (Page 1/2)

- In the Pre-SIEF (*can also be done later in the SIEF*), **you should select a Lead Registrant to take the Joint Registration development work forward**
  - Typically, companies wishing to become the **Lead Registrant, expresses their interest to do so in the Pre-SIEF, usually by email**
- If there are **two (2) or more Lead Registrant candidates, a Lead Registration election needs to be carried out**
  - There is **no formal authority for this → Pre-SIEF members need to self-organise this**
  - Typically the Lead Registrant candidates will ask for support to become the Lead Registrant and give **e.g. 2 weeks time to cast a vote of support** (by email)
    - **If you do not vote, you cannot affect who becomes the lead registrant**
  - The Lead Registrant is **elected by a simple majority vote**

From PRE-SIEF to Joint Submission
Lead Registrant Selection / Election (Page 2/2)

- A "**good**" Lead Registrant is typically a company that is ***data rich*** and/or has the ***highest annual volume*** and/or is the ***EU REACH Lead Registrant*** for the same substance and is a "***serious player***" on the market for the substance.
- **An Only Representative can also become the Lead Registrant**
- Sometimes**, industry associations / EU REACH Consortia / other Consortia** may take the lead in the development of the joint registration and the Lead Registrant selection may be postponed to later

If there is NO Lead Registrant, there is NO Registration

Co-Registration – An Overview

What is a Co-Registrant?

Pre-Submission

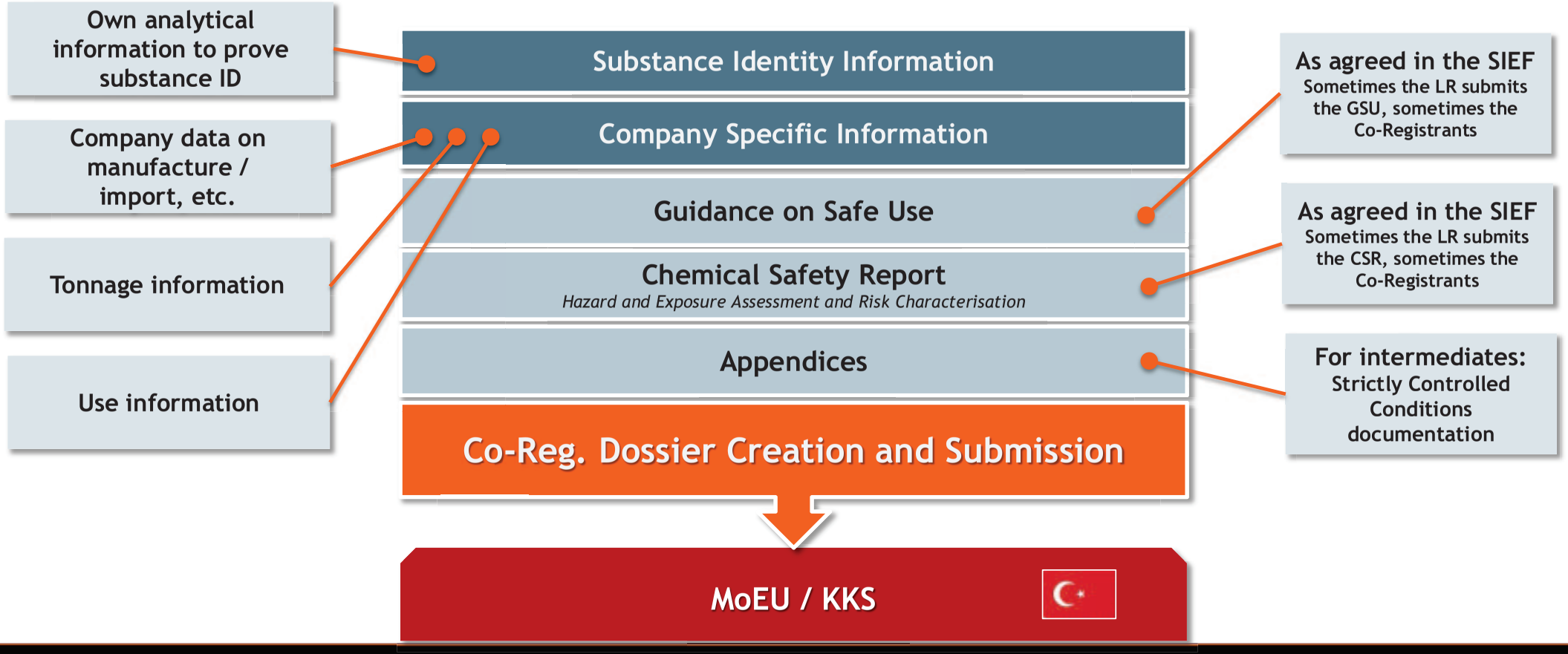
- **The Co-Registrant is responsible for its own registration:**
  1. Cooperate in the (Pre-)SIEF
  2. Agree on substance identity *(verify that the substance truly is the same as your substance)*
  3. Share data (*if available*) – *You may own data for EU REACH purposes?*
  4. Share costs *(e.g. purchase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

Post-Submission

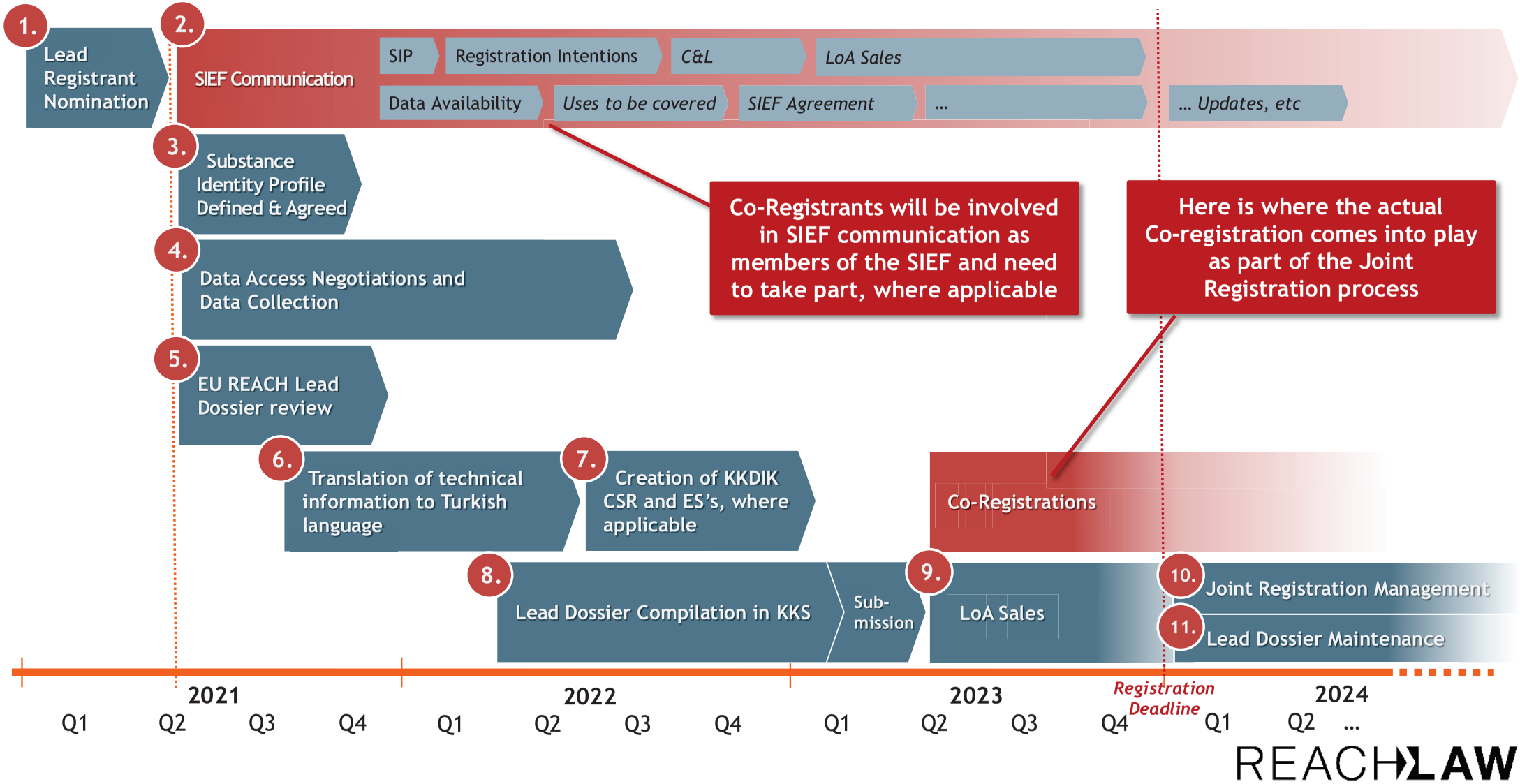
6. Keep the Co-Registration dossier up-to-date
7. Record keeping and communicate with authorities

Co-Registration – An Overview

What does the Co-Registrant Dossier Contain?



Co-Registration - An Overview | KKDIK Lead Registration Process



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Access to the Joint Submission

LoA Process

Closer to the completion of the Joint registration and when all costs are know (*sometimes only after the LR dossier submission*), the Lead Registrant / Consortium will issue a LoA

LoA

Latest 6 months before 31.12.2023 (Registration deadline)

The Co-Registrant should then check the LoA and pay the applicable fee related to its Co-registration:

- Type of registration
- Tonnage band, etc.

Do this as soon as possible when the LoA is available

Lead Registrant will provide access to the Joint Submission

The Co-registrants has to join the Joint Submission in KKS

Do this <u>asap after receipt</u>

Submit your Co-registration as part of the Joint Submission

+

Pay the MoEU registration fee

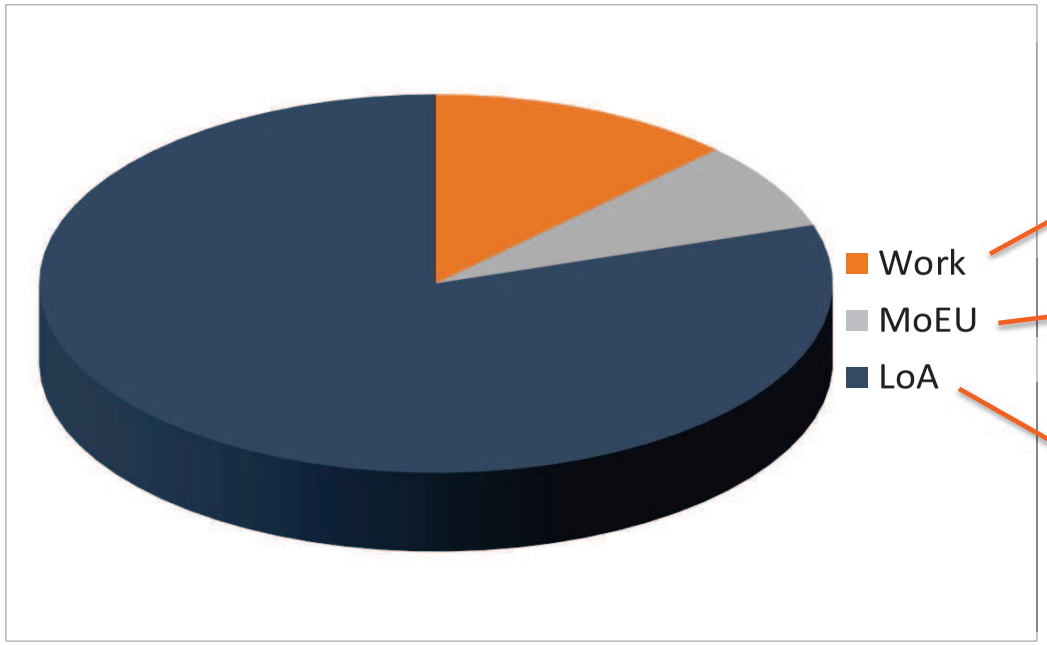
Do this <u>well before</u> the registration deadline 31.12.2023

You only have to pay for data that you actually need for your registration. You do not have to pay for data you already have (own) to fulfil your data requirements for your registration and tonnage band.

"Fair, Transparent and Non-Discriminatory"

Cost of Co-Registration

Rough Estimate of KKDIK Co-Registration Cost Distributions



Work:
Internal resources
Service provider costs

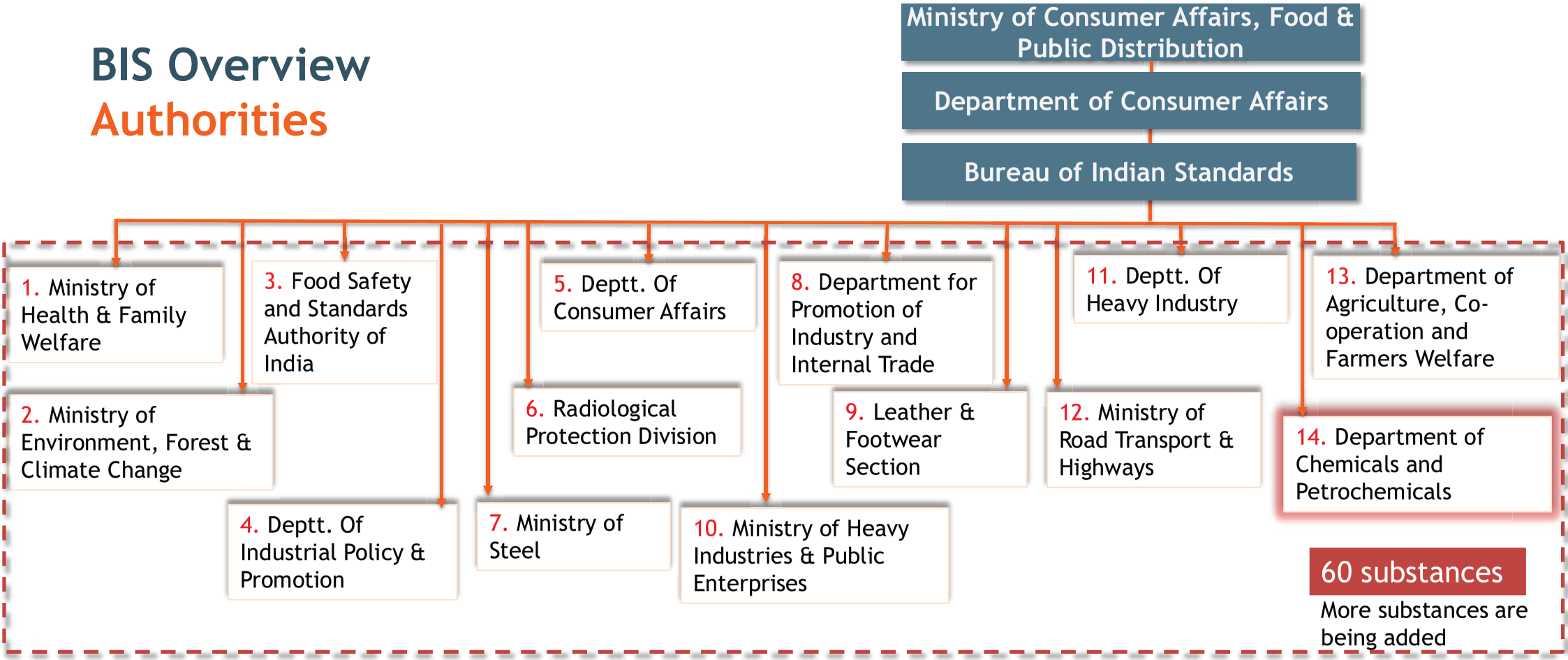
MoEU fixed fees:
Depends on company size and Type of registration (tonnage band, joint submission or individual submission, full or intermediate registration)

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

India BIS

BIS Overview
Authorities



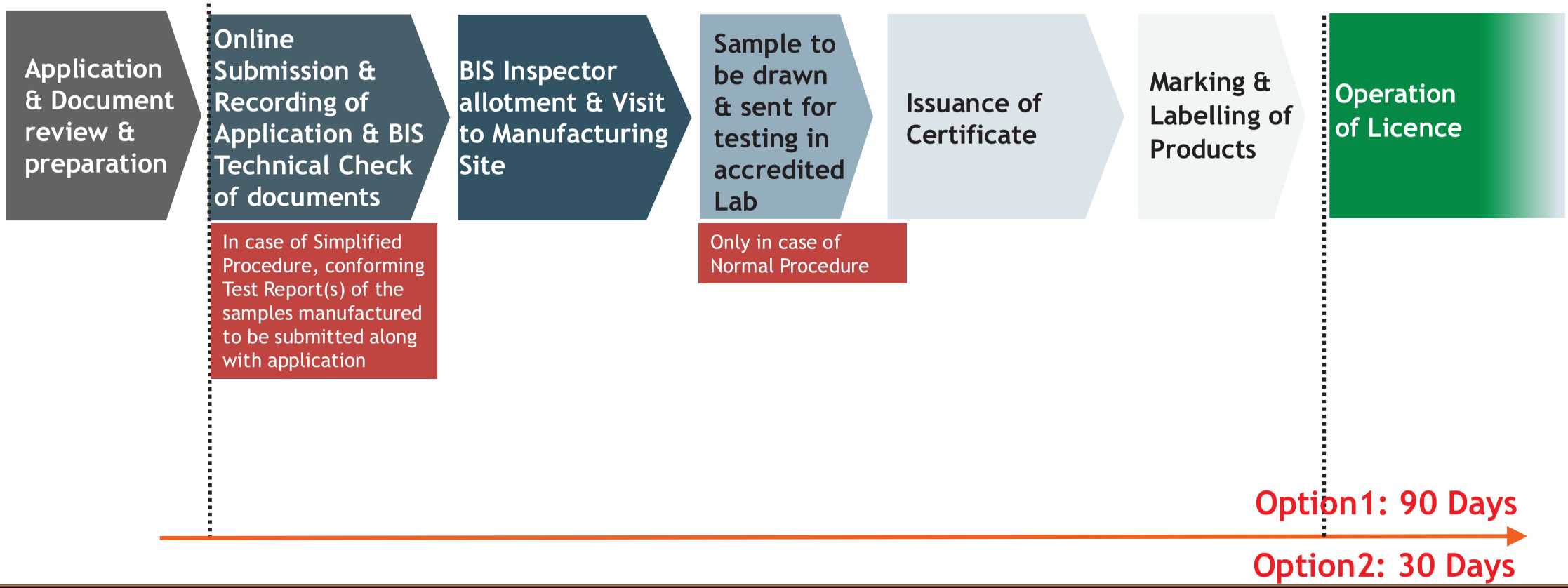
14 regulators (Line ministries) under central govt. are responsible for development of Quality Control Order (QCO) including their amendments/ extensions

Requirements, Process & Timelines

Process & Timelines

Option1: Normal Procedure
Products under Annexure-I(B)

Option2: Simplified Procedure
Products under Annexure-I(C)



Requirements, Process & Timelines

Requirements

Documents Required

9. Proposed Levels of Controls for Inspection and Testing, Form III

Form - III

(Refer clause (c) of sub-paragraph (1) of paragraph 3 of Scheme - I)

PROPOSED LEVELS OF CONTROLS FOR INSPECTION AND TESTING

Name of Applicant/Licensee: M/s

Address of Applicant/Licensee

IS

Product

Scheme of inspection and testing (SIT) No:

(1) Test Details			(2) Levels of Control as per Scheme of inspection and testing specified by the Bureau			(3) Proposed Levels of Control by the manufacturer		
Cl.	Requirement	Test Methods Clause Reference	No. of Sample	Frequency	Remarks	No. of Sample	Frequency	Justification for change, if any

Seal of Firm

Signature
Name
Designation
Date

Form - III

(Refer clause (c) of sub-paragraph (1) of paragraph 3 of Scheme - I)

PROPOSED LEVELS OF CONTROLS FOR INSPECTION AND TESTING

Name of Applicant/Licensee: M/s

Address of Applicant/Licensee

IS

Product

Scheme of inspection and testing (SIT) No:

(1) Test Details			
Cl.	Requirement	Test Methods Clause Reference	

IS : 12540 - 1988

TABLE 1 REQUIREMENTS FOR ACRYLONITRILE

(*Clause* 2.2)

Sl. No.	Characteristic	Requirement	Method of Test (Ref to Clause No. in Appendix A)
(1)	(2)	(3)	(4)
i)	Distillation range at 760 mm Hg:		
	a) Initial boiling point, *Min*	74·5°C	A-2
	b) Dry point, *Max*	79·0°C	
ii)	Assay, percent by mass, *Min*	99·0	A-3
iii)	Water content, percent by mass, *Max*	0·8	A-4
iv)	Specific gravity, at 27°C/27°C	0·800 to 0·802	A-5
v)	Refractive index at 27°C	1·388 2 to 1·389 2	A-6
vi)	Hydrocyanic acid content, percent by mass, *Max*	0·001	A-7
vii)	Soluble iron content, percent by mass, *Max*	0·000 01	A-8

Seal of Firm

Signature
Name
Designation
Date

TEST REPORT

CM/A - or CM/L -
Valid up
to

Product

Sr. No.
Any other information
Date of completion of testing

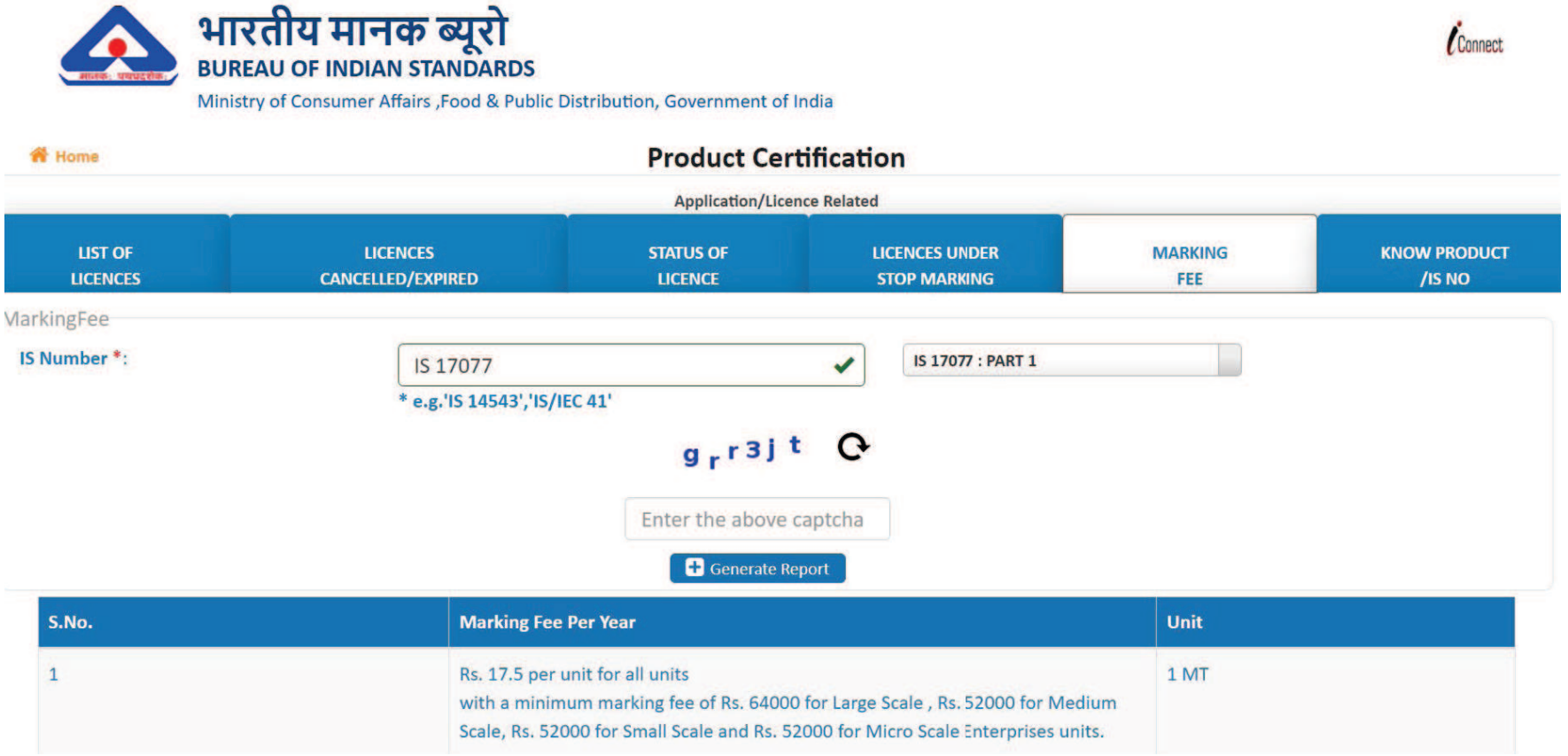
Sr. No.	Test	Clause	IS Reference	Specified Requirement/values	Observed Value (s)	Remarks
1						
2						
3						
4						
5						

REACHLAW

Factory Inspection - Things to be remembered

- ✓ Copy of set of documents submitted to BIS
- ✓ Manufacturing unit in running condition, may be different grade but process and equipment should be same
- ✓ Sizeable Stock of Product (Grade) – 1 or 2 batch/controlled unit should be available
- ✓ Lab personal & signatory on documents or person authorized by him/her should be present at the time of inspection
- ✓ Factory testing and drawl of sample for third party laboratory testing, as applicable
- ✓ Translator, if language is other than English

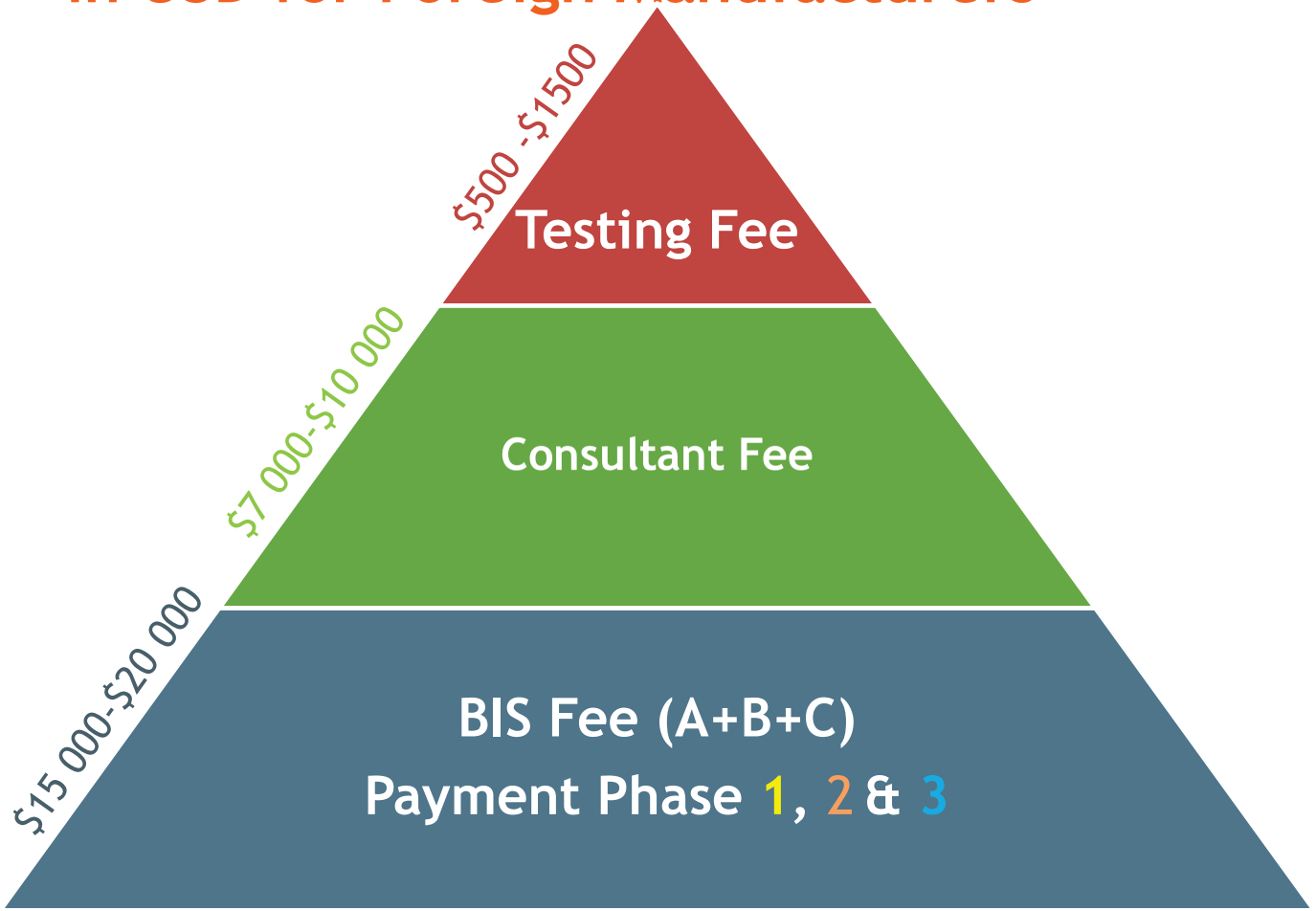
Marking Fee


भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
Ministry of Consumer Affairs ,Food & Public Distribution, Government of India
iConnect
Home
Product Certification
Application/Licence Related
LIST OF LICENCES
LICENCES CANCELLED/EXPIRED
STATUS OF LICENCE
LICENCES UNDER STOP MARKING
MARKING FEE
KNOW PRODUCT /IS NO
MarkingFee
IS Number *:
IS 17077
IS 17077 : PART 1
* e.g.'IS 14543','IS/IEC 41'
g r r 3 j t
Enter the above captcha
Generate Report
S.No.
Marking Fee Per Year
Unit
1
Rs. 17.5 per unit for all units
with a minimum marking fee of Rs. 64000 for Large Scale , Rs. 52000 for Medium Scale, Rs. 52000 for Small Scale and Rs. 52000 for Micro Scale Enterprises units.
1 MT

Role of Authorized Indian Representative (AIR) for Foreign manufacturers

1. Shall be an Indian resident
2. preferably at least graduate by qualification
3. shall declare his consent to be responsible for compliance to the provisions of the BIS Act, Rules, Regulations and Terms & Conditions laid down in BIS Licence, Agreement, Undertaking etc. executed by or on behalf of the foreign manufacturer in connection with grant and operation of the licence.
4. Shall represent one manufacturing firm only
5. In case of foreign manufacturers belonging to one group of companies and importers, one AIR can be nominated.
6. No conflict of interest with respect to their role as AIR with testing of sample(s) in third party laboratories.
7. Submit and make available records without delay upon request to any competent authority
8. Has a written AIR Nomination letter/agreement in place
9. Communicate proactively with BIS Authority, handling queries (if any) with client
10. Monitoring of the legislation and ministry guidance to ensure compliance with BIS License (FMCS)

BIS Licence Cost/Product/Site
in USD for Foreign Manufacturers



A. Variable

- Inspection Fee[2]
- BIS inspector visit charges

B. Fixed

Marking Fee[3] (Applies to Annual Import Quantities)

C. Fixed

- Application Fee[1]
- Processing & Approval Charges
- Annual License Fee
- Renewal Fee/ Late Renewal Fee
- Indemnity bond[3]
- Bank Guarantee ($ 10 000)

Conditions of license

The holder of licence or certificate of conformity shall,

- upon expiry (if not renewed), suspension or cancellation, discontinue its use & withdraw all promotional material;
- return the licence document to the Bureau in the event of licence being surrendered, suspended or cancelled;
- inform the Bureau of any changes in management or address of the firm or conditions which were declared earlier;
- implement changes w.r.t. amendment to Indian Standard or revised Indian Standard, upon issue of amendment or revision within the stipulated time as specified by the Bureau;
- inform the Bureau in writing of discontinuance of operations exceeding three months.

Maintain records as specified by the Bureau from time to time.

The liability of the holder of licence or certificate of conformity, incase complaints about non-conforming system are established, shall be as provided in the Act and rules made thereunder.

The Bureau shall have the right to amend the conformity assessment scheme or any of the conditions by giving 1 month notice

The conformity assessment activities relating to grant and operation of licence or certificate of conformity may be carried out or witnessed by the auditors authorised by the Bureau in this regard during an audit as per the requirements of conformity assessment schemes.

The Bureau may suspend the licence or certificate of conformity based on evidence of nonconformance to the specified requirements or conditions or non-payment of dues.

Any violation of conditions of the licence or certificate of conformity may lead to cancellation of licence or certificate of conformity.

1. REACHLAW IN BRIEF
2. CHEMICAL REGULATORY UPDATES
3. CONCLUSIONS
4. Q&A
5. CONTACT

Conclusions

EU REACH

- Information requirements for registering chemicals under REACH
- OR obligation: to provide details on the non-EU manufacturer they represent in REACH-IT
- Evaluation: Decision after receipt of Draft Decision
- Dossier update
- REACH Revision & Enforcement

UK REACH

- Transitional Registration deadlines are dependent on the substance type and annual tonnages – Currently they are 27.10.2023 / 27.10.2025 / 27.10.2027 but will be somewhat postponed (To be determined by how much)
- The Registration process is also in flux as a new registration approach is under discussion

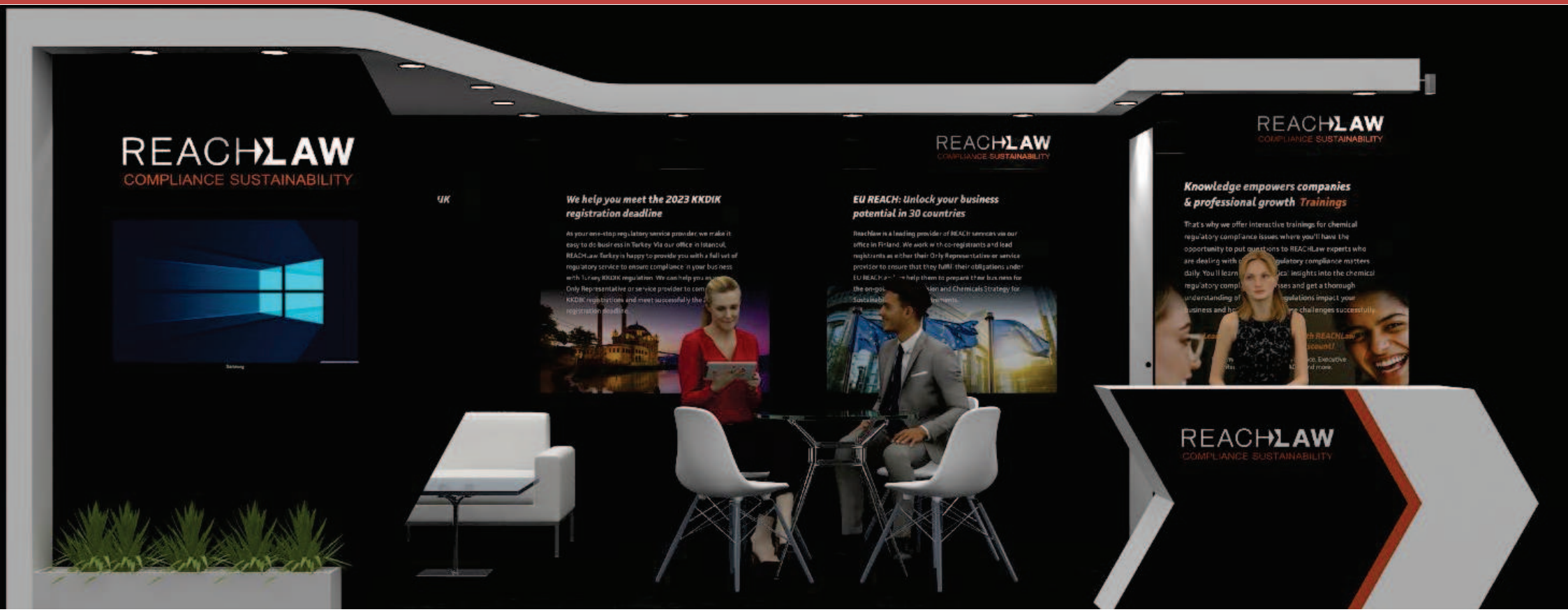
Turkey REACH

- No official extension on registration deadline→ **31.12.2023**
- **Act now→** Register few substances in 2022 to ensure all substances are registered by 2023

India BIS

- Mandatory (QCO) proposed for 76 Chemicals
- 9000 Indian Standards for Chemicals to be developed
- Quality Control Orders for 782 existing Indian Standards for Chemicals to be decided in two phase

SIGN UP NOW!
Chemical Regulatory Training Courses
Visit us at Booth # E47A



1. REACHLAW IN BRIEF
2. CHEMICAL REGULATORY UPDATES
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Questions & Answers

Thank You for Your Attention!

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END OF SLIDES