

**Lubrizol**



# Is REACH Within Reach?

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## Definition of REACH

Regulation (EC) No. 1907/2006 concerning the

- **Registration**
  - **Evaluation**
  - **Authorisation and Restriction of**
  - **Chemicals**
- 
- Published on 18 December 2006
  - Entered into force on 1 June 2007

## Where is REACH Applicable?

**REACH is applicable in all countries within the European Economic Area (EEA).**

- **28 member states of the European Union (EU):** Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden & The United Kingdom.
- **Plus:** Iceland, Lichtenstein & Norway
- **REACH does not apply in Switzerland**
- **REACH will not apply in the United Kingdom from 11 pm 31 December 2020\***

\*Based on the latest information available

## Aim of REACH

- **Protection** of human health and environment
  - By restricting the use of chemical substances (consult Annex XVII: <https://echa.europa.eu/substances-restricted-under-reach>)
  - By forcing businesses to request authorizations for substances of very high concern (SVHC) (consult Annex XIV: <https://echa.europa.eu/authorisation-list>)
- **Promotion** of alternative methods for assessment of hazards of substances
  - Elimination of unnecessary vertebrate testing
  - Encourage innovation
- **Free circulation** of substances on the EEA market

# Scope of REACH

	Registration	Evaluation	Authorisation	Restrictions	Safety Data Sheets
Medical products or Veterinary	Out of scope	Out of scope	Out of scope	<b>In scope</b>	Out of scope
Food and Feedingstuffs	Out of scope	Out of scope	Out of scope	<b>In scope</b>	Out of scope
Medical Devices (articles)	Out of scope	Out of scope	Out of scope	<b>In scope</b>	Out of scope
Cosmetic Products	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>	Out of scope
<b>Lubricants</b>	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>
Chemicals, Cleaning Products	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>	<b>In scope</b>

## Scope of Registration

- **In scope:** chemical substances manufactured by a **legal entity** based in EEA or imported into the EEA by **legal entity** in 1 metric tonne per calendar year or more
- Registration applies when the chemical substance is placed on the market:
  - On their own
  - In mixtures
  - In articles, if they are intended to be released during use

## Scope of Registration (cont.)

- **Registration not required** for chemical substances:
  - That present minimum risk because of their basic properties (e.g. water, nitrogen) listed in **Annex IV** of REACH
  - Occurring in nature (e.g. minerals, ores and ore concentrates that are not chemically modified) where registration is deemed inappropriate or unnecessary. See **Annex V** of REACH
  - Already registered, then exported from and **re-imported** into the EEA, by an actor in the supply chain
  - Already registered and recovered through a waste recovery process



## Scope of Registration (cont.)

- **Total exemption from registration** for:
  - Radioactive substances
  - Substances in temporary storage under customs supervision, provided they are not being transformed or processed in any way
  - Substances used in the interest of defence when (these are) covered by specific national exemptions
  - The transport of hazardous substances on their own or in mixtures
  - Non-isolated intermediates – these are substances that appear between two successive chemical reactions and that are not removed from the system, except for sampling

## Scope of Registration (cont.)

- **Partial exemption from registration** for chemical substances when used in:
  - Medicinal products
  - Food, feedstuffs, food additives and flavours
  - **Product and process orientated research and development (PPORD)** for a period of five years. To benefit from this exemption, a PPORD notification must be submitted to ECHA
- If the chemical substances are used in other products, they require registration

## Scope of Registration (cont.)

- **Out of scope for registration:**

- An active substance in a biocidal product, which is approved under BPR
- Polymers (monomers required registration)
  - Monomers and other substances chemically bound to polymers are subject to registration obligations if both the following conditions are met:
    - **Monomer(s)** or other substance(s) in the form of monomeric units and chemically bound substance(s) represents **2% or more** weight by weight (w/w) of the polymer
    - **The total quantity of monomer(s)** or other substance(s) makes up **1 tonne or more per year**

## Who is Required to Register?

- The **manufacturer** of the chemical substance in the EEA
- The **importer** of the chemical substance into the EEA
- An **Only Representative** based in the EEA acting as registrant on behalf of the manufacturer of the chemical substance not based in the EEA or a formulator using the chemical substance outside EEA

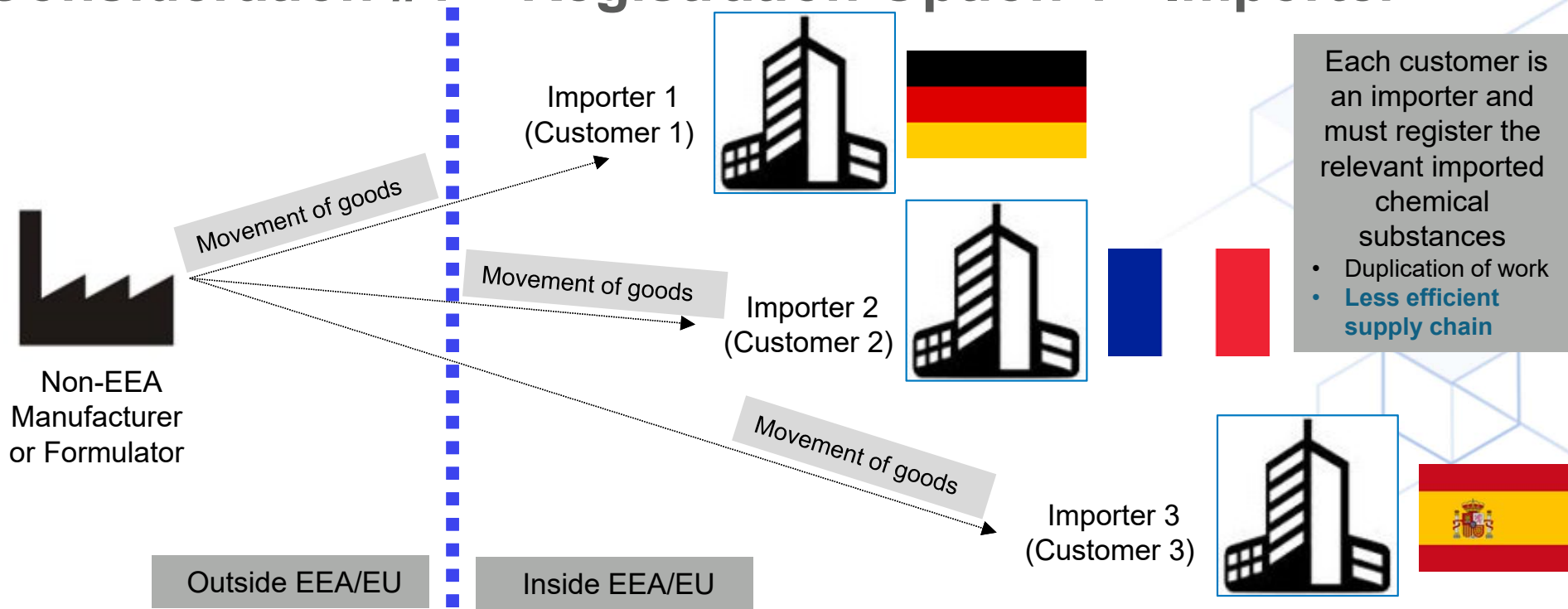
## Who is Not Required to Register?

- Companies established outside the EEA
  - These companies **are not bound** by the obligations of REACH, even if these companies export their products into the customs territory of the European Economic Area.
  - The **responsibility** for fulfilling the requirements of REACH, such as registration **lies with the importers** established in the European Union, or with the **Only Representative** of a non-EU manufacturer established in the European Union.



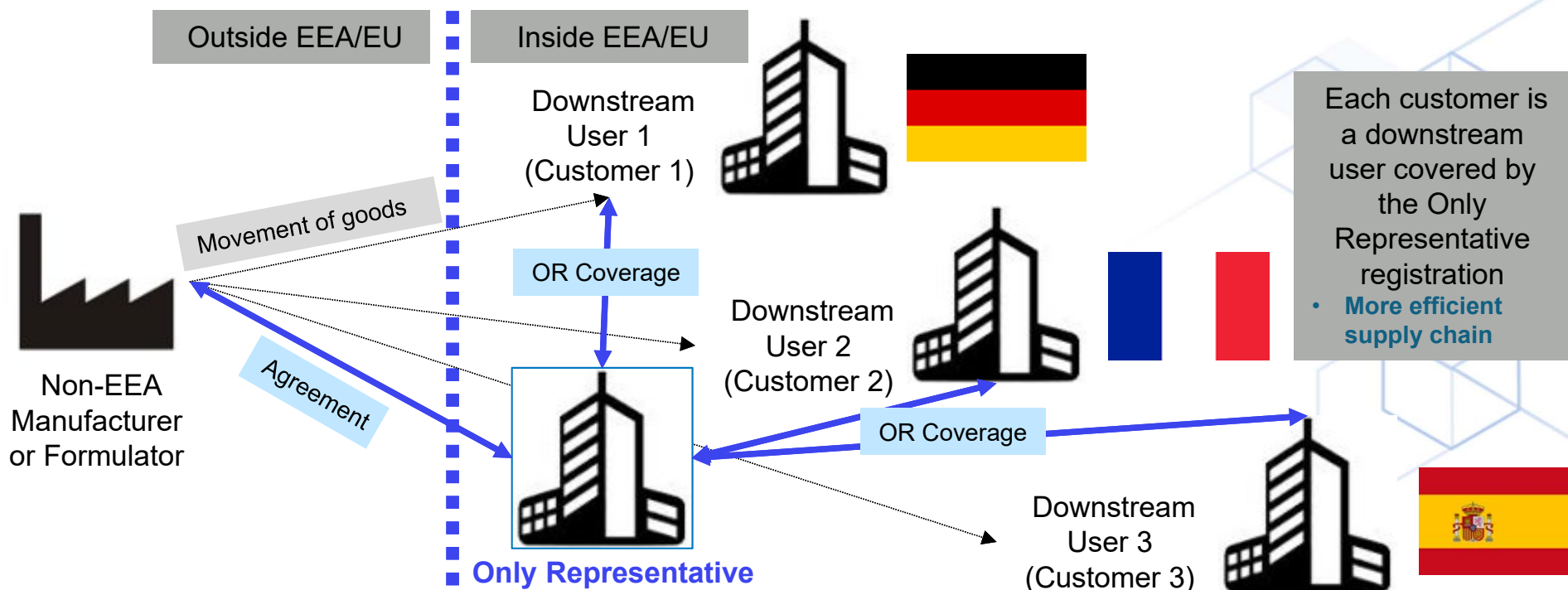
# REACH Considerations When Exporting to the EEA

# Consideration #1 – Registration Option 1 - Importer



**Registrants in a blue square**

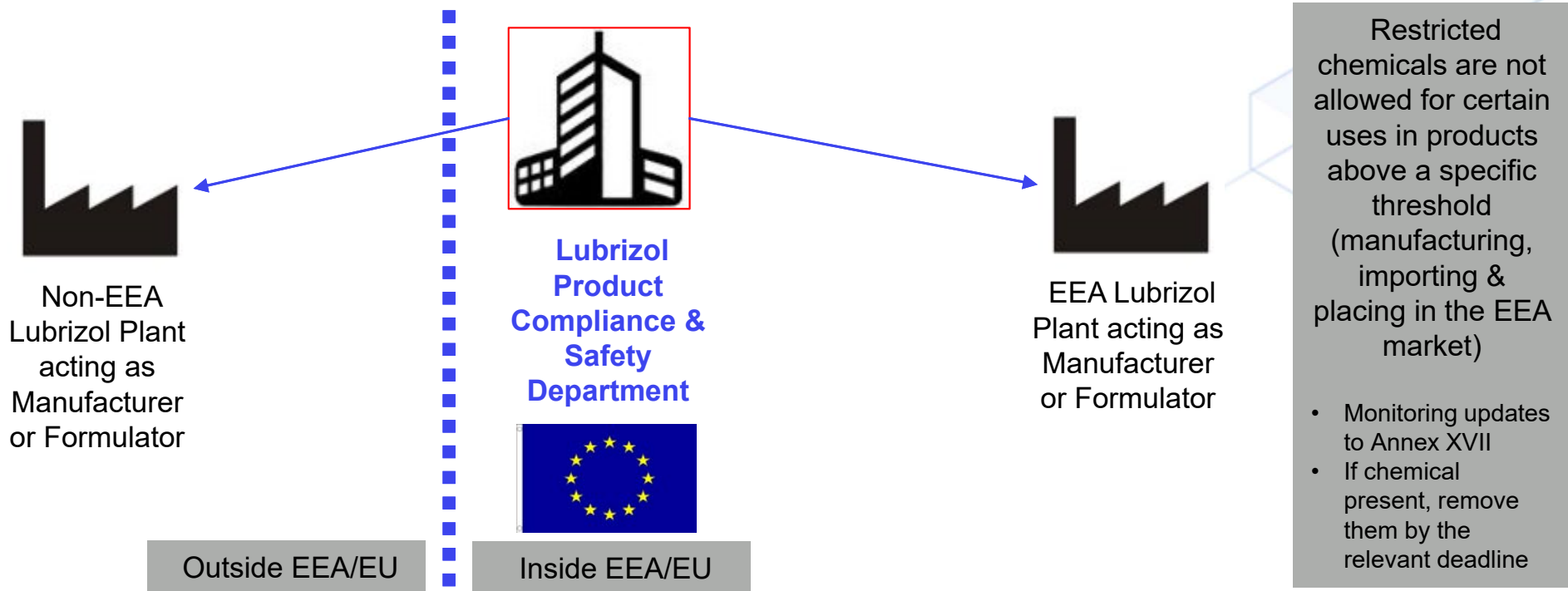
# Consideration #1 – Registration Option 2 – Only Representative



**Registrant in a blue square -  
Lubrizol acts as reliable Only Representative for key chemicals**

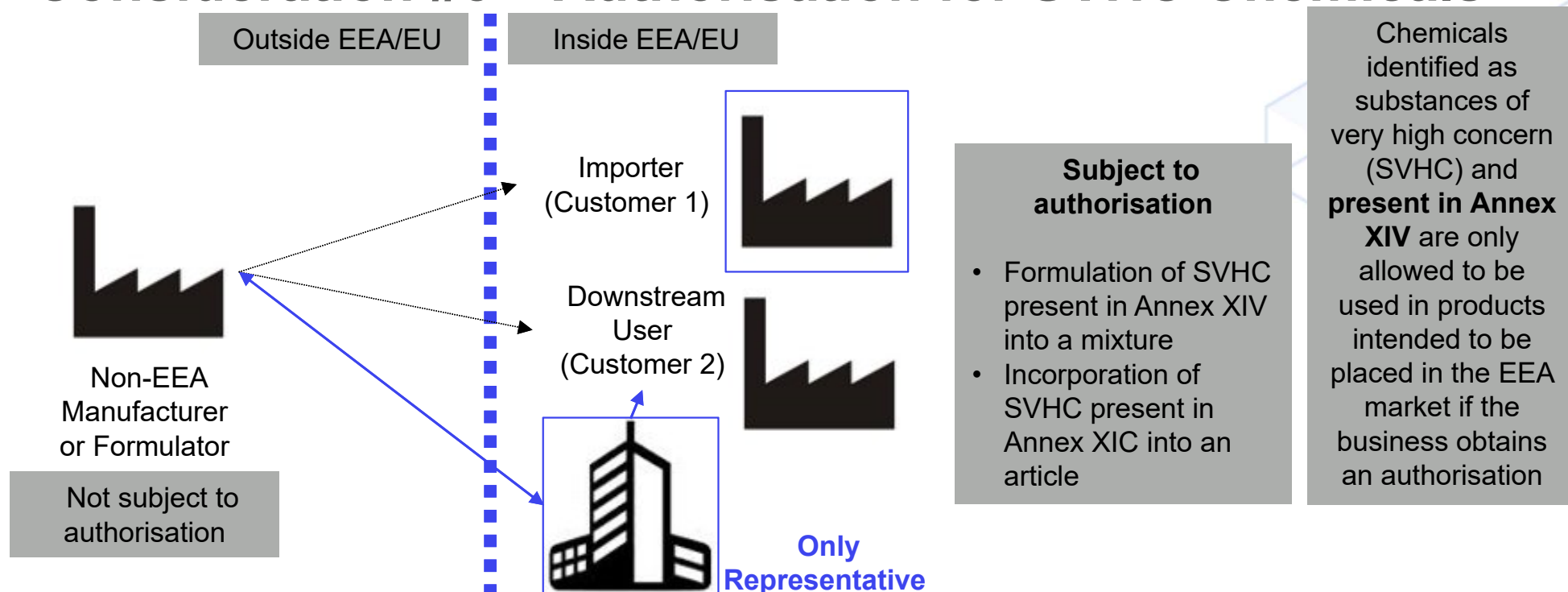


## Consideration #2 – Restriction of Chemicals



**Lubrizol closely monitors proposals for restriction chemicals**

# Consideration #3 – Authorisation for SVHC Chemicals



**Historically, Lubrizol has avoided the use of chemicals that require authorisation**

## Comparison of EU-REACH and K-REACH (ARECS)

	EU-REACH	K-REACH (ARECS)
<b>New Chemicals &lt;1 MT/year</b>	No registration required	<100 Kg notification ≥100 Kg simplified registration
<b>Polymer Registration</b>	Not required* (monomer required)	Required
<b>Non-isolated Intermediate Registration</b>	Not required	Application of confirmation of registration required
<b>Substances Intended to be Released from Articles</b>	Impacted by registration, SVHC, restriction	Impacted by registration May be impacted by authorisation and restriction

\*EU Commission is intended to publish a regulation stating new requirements for the registration of polymers (Expected in 2022/23)

**Be aware of the differences among the different REACH like regulations**

The background is a vibrant blue gradient. It features several overlapping, semi-transparent geometric shapes, including hexagons and diamonds, arranged in a pattern that suggests a molecular or crystalline structure. Thin white lines connect the vertices of these shapes, creating a network of paths. The overall effect is modern and technical.

Any Questions?

**As a blender / exporter, we have put the REACH burden on our EU distributors as the importer of record. We have moderate success in working with our base oil and additive suppliers in providing constituent data, but not all. In some cases, we have vendors stating they do not intend for their products to be exported to the EU. Thoughts or suggestions?**

Let me highlight that only those chemical substances imported by a customer legal entity in one country in 1 MT or more are subject to registration. Multiple customer legal entities importing into the EU quantities less than 1 MT per annum is a compliant activity that does not require registration.

My suggestion is to work with existing suppliers to explain the requirements and just request the relevant information. For example, if you do not know the full chemical composition of a material from your supplier, ask them to disclose only the chemicals that you will export over 1 MT to a EU customer legal entity. Another consideration is to explore the possibility to have EU suppliers or suppliers with presence in multiple countries including in the EU.

### **What do you know about Turkey REACH (KKDIK)?**

- Published in 2017 and repealed the CICR
- Like in REACH, pre-registration, registration, authorization and restriction
- Pre-registration deadline 31/Dec/2020
  - No opportunity for late pre-registrations
  - Compulsory Info: Substance name, CAS No, EC N
  - Voluntary Info: Tonnage, type of substance (mono, multi, UVCB)
- Registration deadline 31/Dec/2023 for the 4 tonnage bands
  - Industry is expected to make use of data generated for EU REACH
  - Dossier must be in Turkish and certain sections must be signed by certified Chemical Assessment Experts
- Only representative appointment letter needs to be written and signed

## **What other countries are putting in registrations?**

This is not an exhaustive list, but here are some examples:

- United Kingdom
- Eurasian Economic Union
  - Russia
  - Belarus
  - Kyrgyzstan
  - Kazakhstan
  - Armenia
- Brazil
- India
- Saudi Arabia
- Thailand
- Vietnam
- Philippines



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