Stepan

REACHLAW
COMPLIANCE. SUSTAINED.

15.11.2017 | Webinar

Understanding REACH 2018

Webinar by REACHLaw and Stepan

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Webinar: Understanding REACH 2018

Agenda

1. REACHLaw in Brief
2. REACH (EU) Overview
3. The REACH 2018 deadline and impact on non-EU customers
4. REACH after 2018
5. Stepan's REACH Readiness
6. Q&A
7. Contact

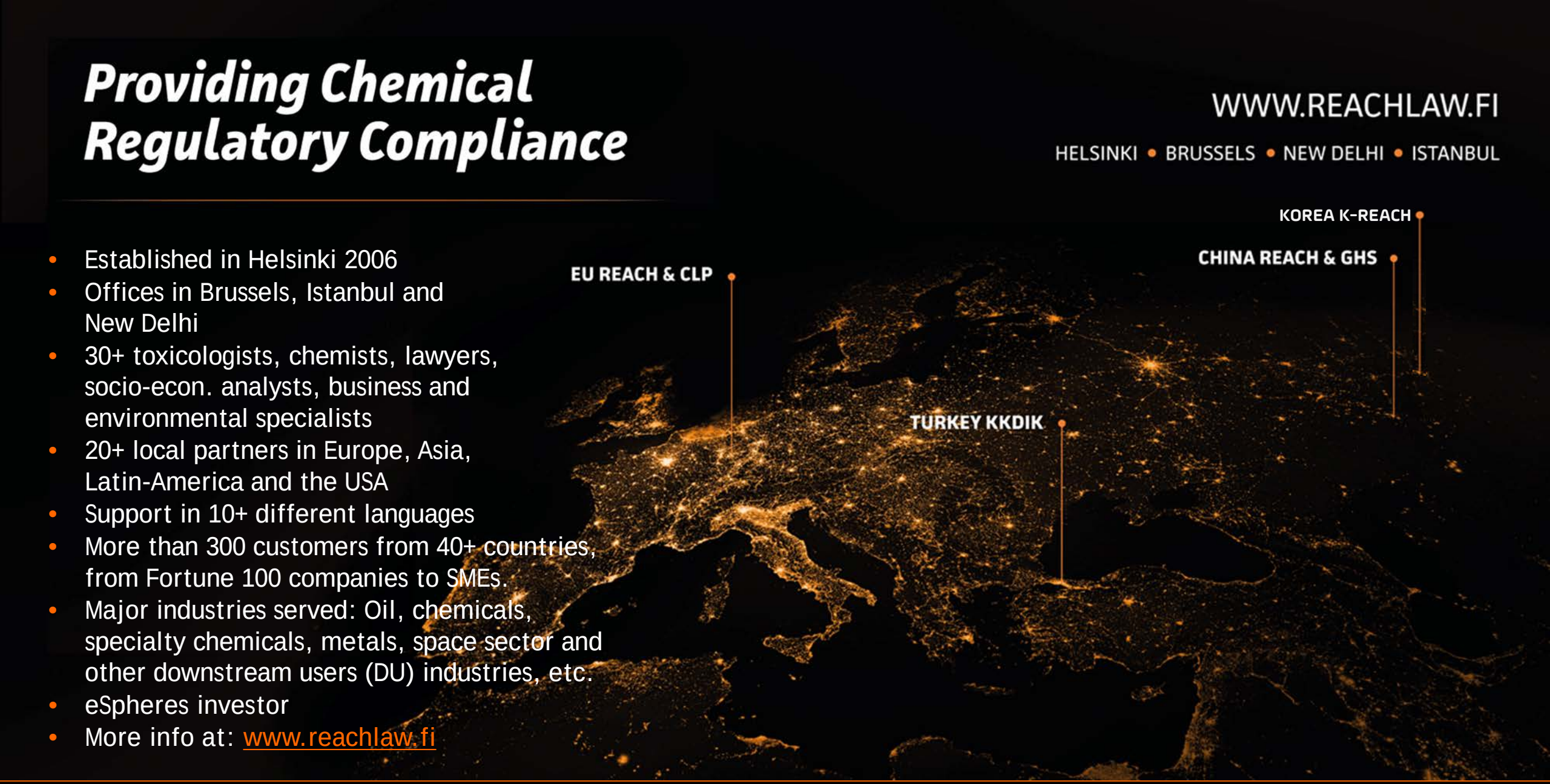
1. REACHLAW IN BRIEF
2. REACH (EU) OVERVIEW
3. THE REACH 2018 DEADLINE AND IMPACT ON NON-EU CUSTOMERS
4. REACH AFTER 2018
5. STEPAN'S REACH READINESS
6. Q&A
7. CONTACT

Providing Chemical Regulatory Compliance

WWW.REACHLAW.FI

HELSINKI • BRUSSELS • NEW DELHI • ISTANBUL

- Established in Helsinki 2006
- Offices in Brussels, Istanbul and New Delhi
- 30+ toxicologists, chemists, lawyers, socio-econ. analysts, business and environmental specialists
- 20+ local partners in Europe, Asia, Latin-America and the USA
- Support in 10+ different languages
- More than 300 customers from 40+ countries, from Fortune 100 companies to SMEs.
- Major industries served: Oil, chemicals, specialty chemicals, metals, space sector and other downstream users (DU) industries, etc.
- eSpheres investor
- More info at: www.reachlaw.fi



REACHLaw Market Access Services

For Chemical Products

- ONLY REPRESENTATION
- REACH CO- / LEAD REGISTRATION
- REACH AUTHORISATION
- SVHC ADVOCACY
- CLP & GHS SERVICES
- GLOBAL CHEMICAL REGULATIONS *(KKDIK, KOREA REACH ...)*
- LEGAL & TECHNICAL SERVICES
- CONSULTING
- TRAINING ***...and more***

REACHLaw Market Access Services

Some “REACH like” Chemical Regulations around the World

- EU REACH & CLP
- Turkey KKDIK & SEA & GBF
- South-Korea ”K-REACH”
- China “REACH” & GHS
- Swiss ChemO
- Taiwan Existing Substance Inventory Available
- USA TSCA and Safe Chemicals Act
- Malaysia Voluntary Registration of Hazardous Substances
- Japan Chemical Substances Control Law
- Russia “REACH”
- Thailand National Inventory
- *... and more is coming*

Chemical Regulations is our Core business, it doesn’t have to be yours

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REACH Overview
The Regulation

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

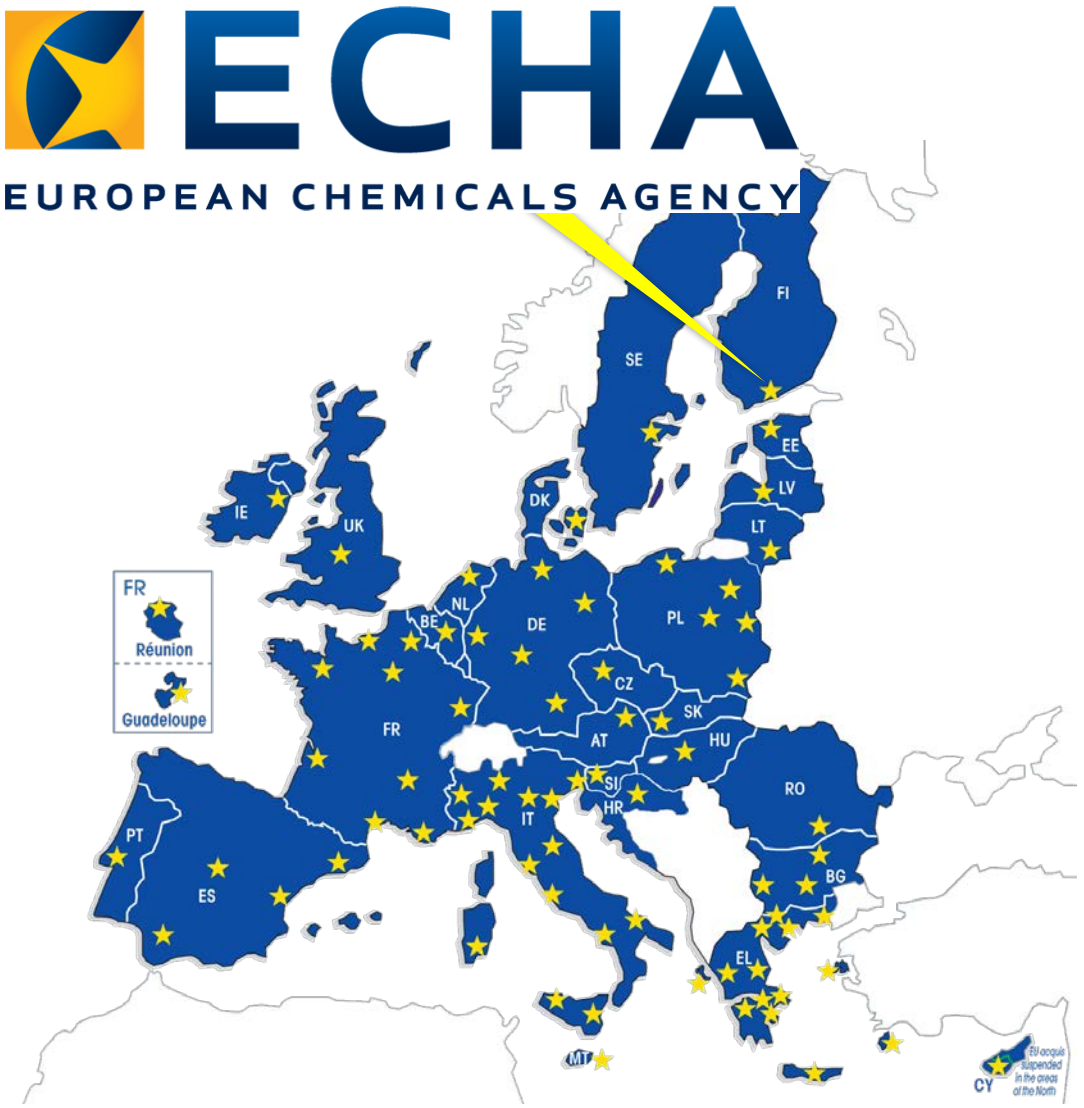
In force since **1.6.2007**

REACH is intended to protect the Human Health and the Environment from risks related to chemicals and their use

REACH Overview

Where Does REACH Apply?

- **Applies directly in all 28** (*…-1 to be*) **EU Member States** + Norway, Iceland and Liechtenstein, but <u>not in</u> Switzerland
  - The UK will exit REACH as of the 29th of March 2019 (“BREXIT”)
- **Managed by the European Chemical Agency (*ECHA*)**
- **Enforced by national authorities (*MSCA*)**



REACH is one of the most complex pieces of legislation in EU history

+1 000 pages legal text
+20 000 pages guidance documents (and the number is growing)

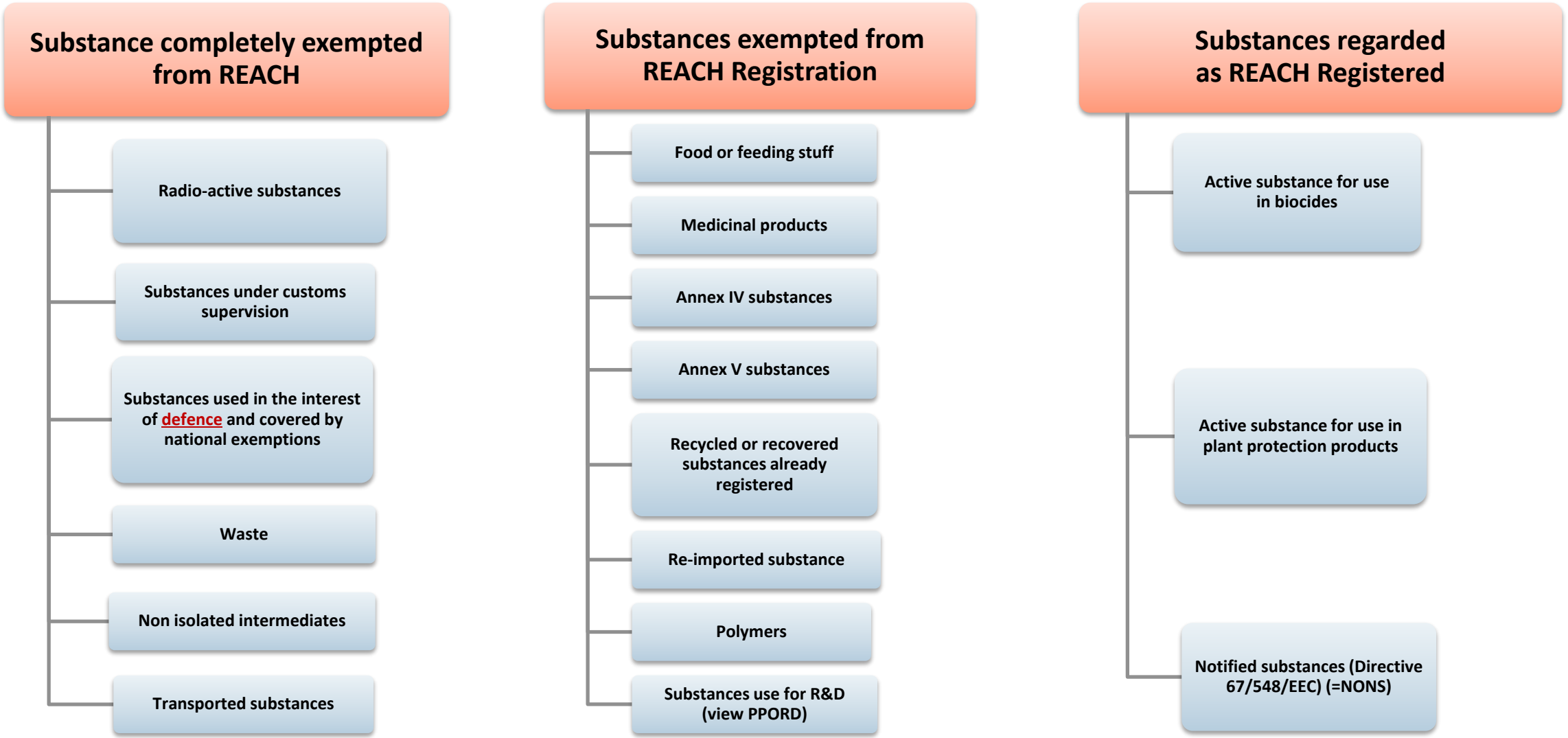
REACH Overview
What does REACH Govern?

	"What"	*"Who"*
Within scope	• **Substances**, on their own or in **mixtures** • **Articles** containing Substances of Very High Concern (SVHC) or substances intended to be released	• **Manufacturers** (M), **Importers** (I) and **Downstream Users** (DU) of substances on their own or in mixtures • **Producers**, **importers** and **suppliers** of articles
Out of scope	• **Exempted substances** (e.g. waste, transport of dangerous goods, radioactive substance) • **Specific exemptions** (e.g. no registration, if below 1 t/a)	• **Non-EU/EEA companies** (e.g. North American companies may appoint only representative)

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

REACH Overview

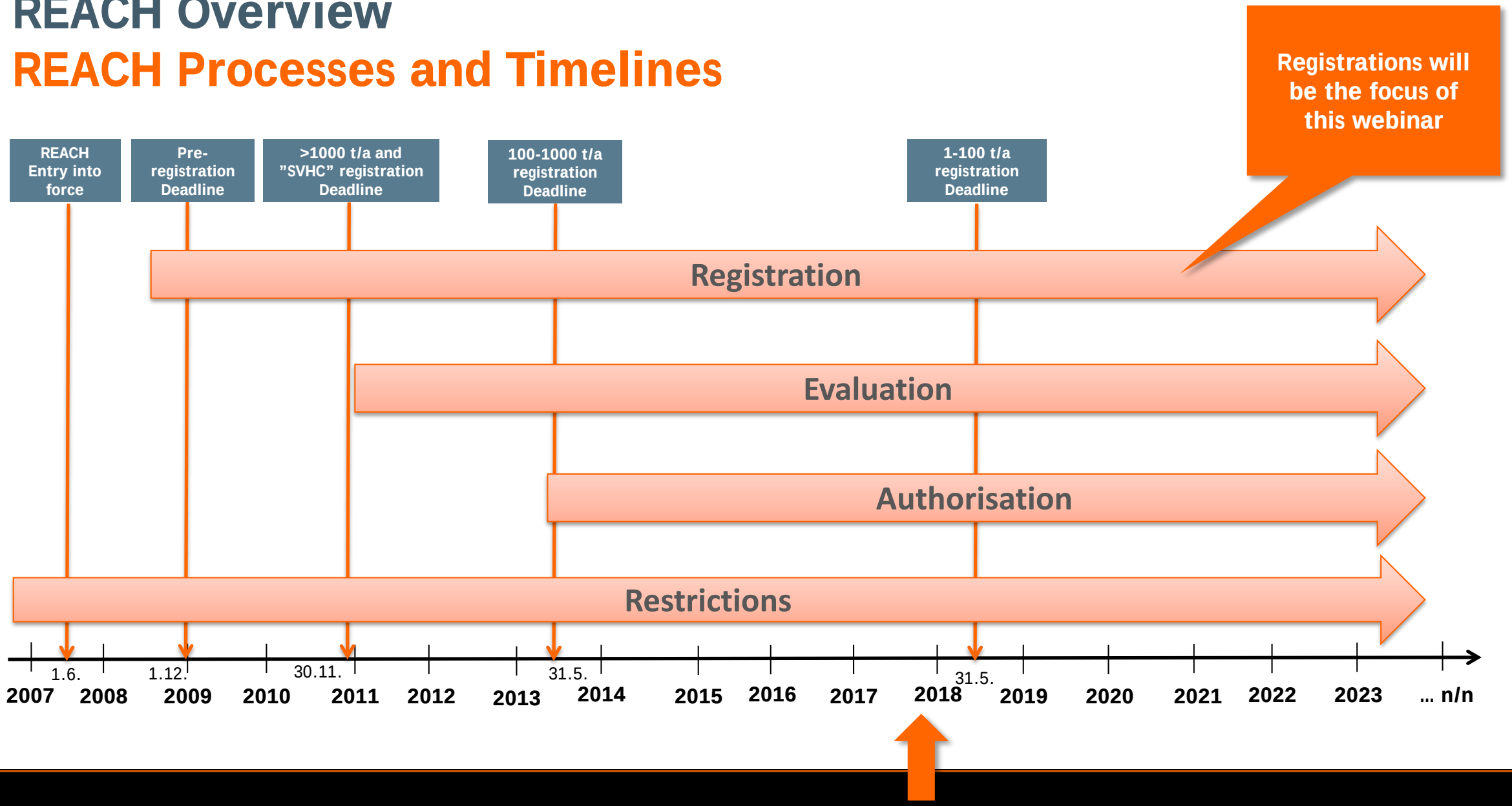
Scope of REACH: Substances Exempted One Way or Another



Good summary of exemptions: https://echa.europa.eu/support/getting-started/am-i-exempt

REACH Overview

REACH Processes and Timelines



REACH Overview

Focus: REACH Registrations

- Companies **manufacturing** in or **importing into the EU/EEA** substances over **1 tonne annually**, are required to **REACH Register the substance** (*unless specifically exempted*)

ECHA
EUROPEAN CHEMICALS AGENCY

- The purpose of the registration is to collect information about the intrinsic properties of the substance to the *European CHemicals Agency's* (ECHA)
  - Information available on the ECHA dissemination portal at: https://echa.europa.eu/information-on-chemicals

REACH Overview

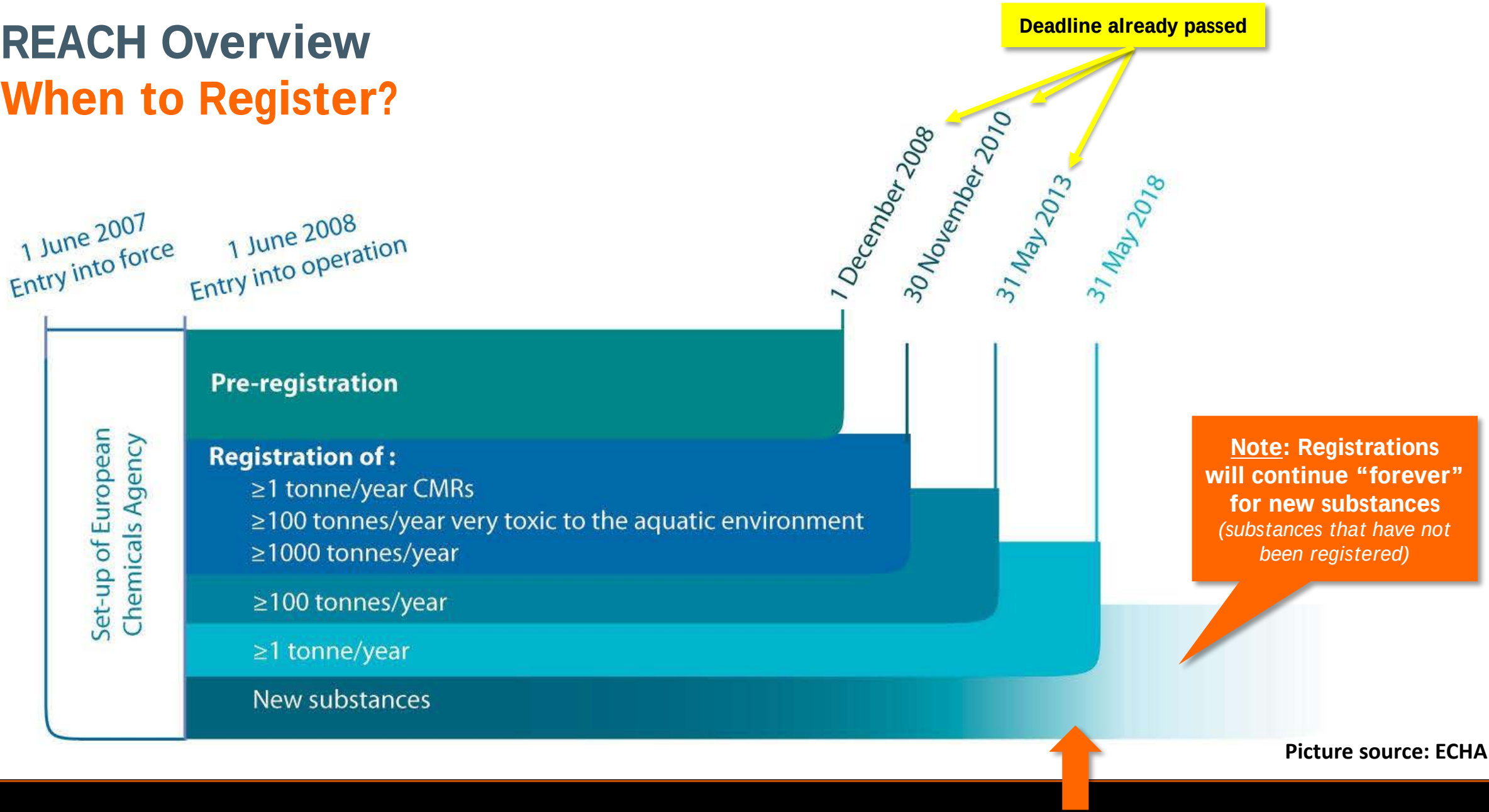
"No Data, No Market"

- Without a proper registration, a substance **cannot be manufactured within** *or* **imported into the EU/EEA**, nor placed on the market within the EU/EEA.
- Registrations are **legal entity (*Company*) specific**
- As of **1.6.2018 all substances** on the EU/EEA market at 1 t/a and above **must be REACH Registered** *(unless specifically exempted)*
  - *More on this later in this presentation*

The threshold for substances requiring a REACH Registration when manufactured in or imported into the EU/EEA is:

1 tonne / year *(= t/a)*

REACH Overview
When to Register?



Picture source: ECHA

REACH Overview
How to Register?

- When a substance is intended to be **manufactured / EU/EEA-imported** by one or more companies (*usually the case*), a **joint submission** of core registration data is **required** for companies registering the **same substance.**
  - **Cooperation is required by law**

- The ***Joint Registration dossier (=Lead Registrant dossier)*** for the Joint Submission is prepared by the

  (1) **"Lead Registrant"**

  acting in agreement with the other

  (2) **"Co-registrants"**

High data requirements!

Lower data requirements!

REACH Overview

How Can Non-EU/EEA Companies REACH Register?

- EU/EEA regulations only have jurisdiction on legal entities (companies) in the EU/EEA → **Non-EU/EEA companies do not have any legal obligations under REACH**
  - Therefore Non-EU/EEA Companies can ask their EU/EEA customer **importing** the substance(s) to the EU/EEA to REACH Register

…however, there is a more efficient way for non-EU/EEA companies

- Under **REACH Article 8**, non-EU/EEA companies that **manufacture** a substance, **formulates a mixture** have the right to **appoint an *Only Representative* (OR)** to take care of the REACH obligations of importers (= *REACH Registrations*)
- This will relieve the **EU/EEA importers within the same supply chain from their registration obligations**, as they will be regarded as **downstream users**.

This is what makes appointing Only Representatives to take care of REACH obligations so efficient!

REACH Overview

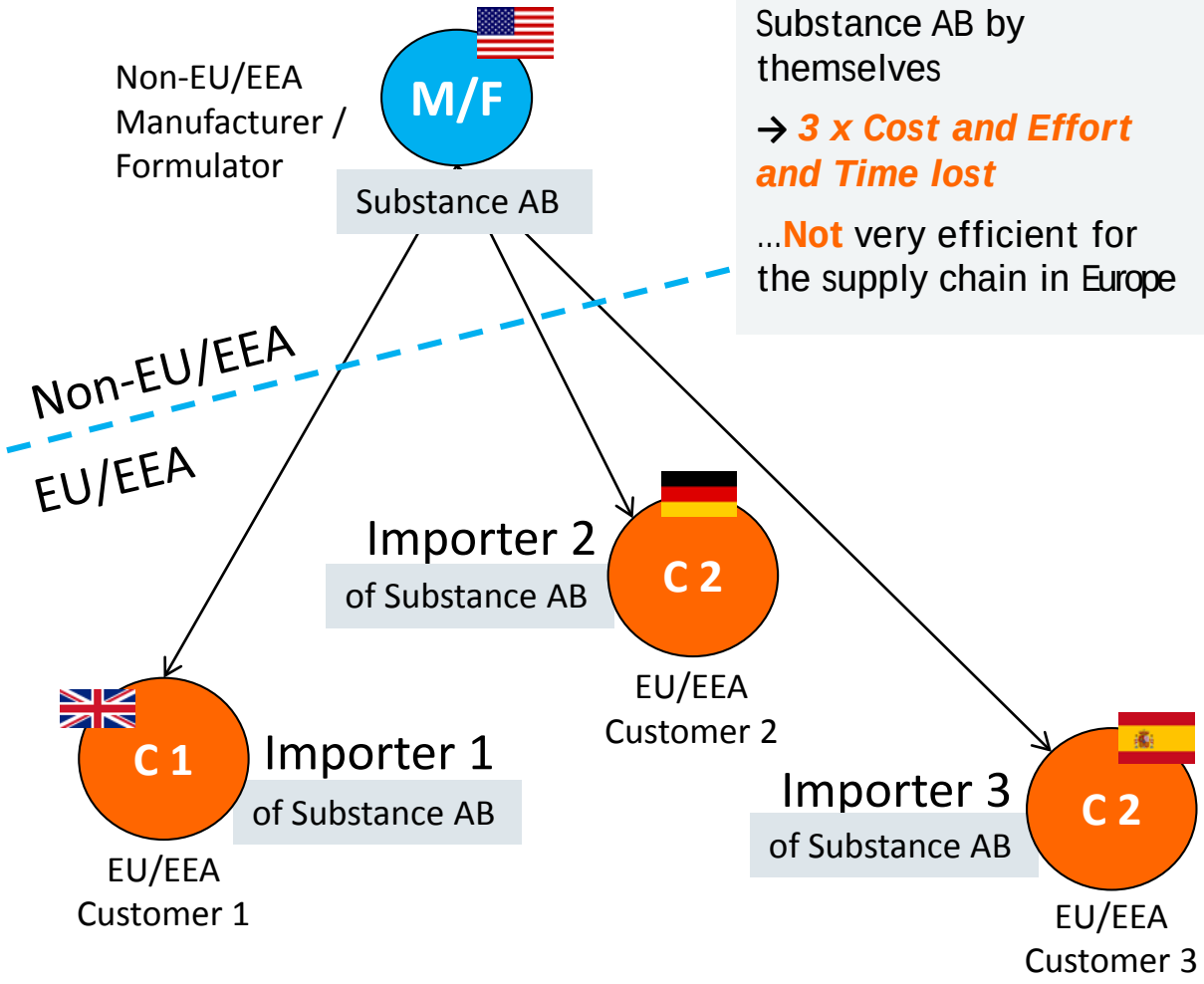
Examples of Importer vs. Only Representative Configuration

Case of Import by Customers

Each importer will have to REACH register (*comply with REACH and CLP*) the Substance AB by themselves

→ ***3 x Cost and Effort and Time lost***

…**Not** very efficient for the supply chain in Europe

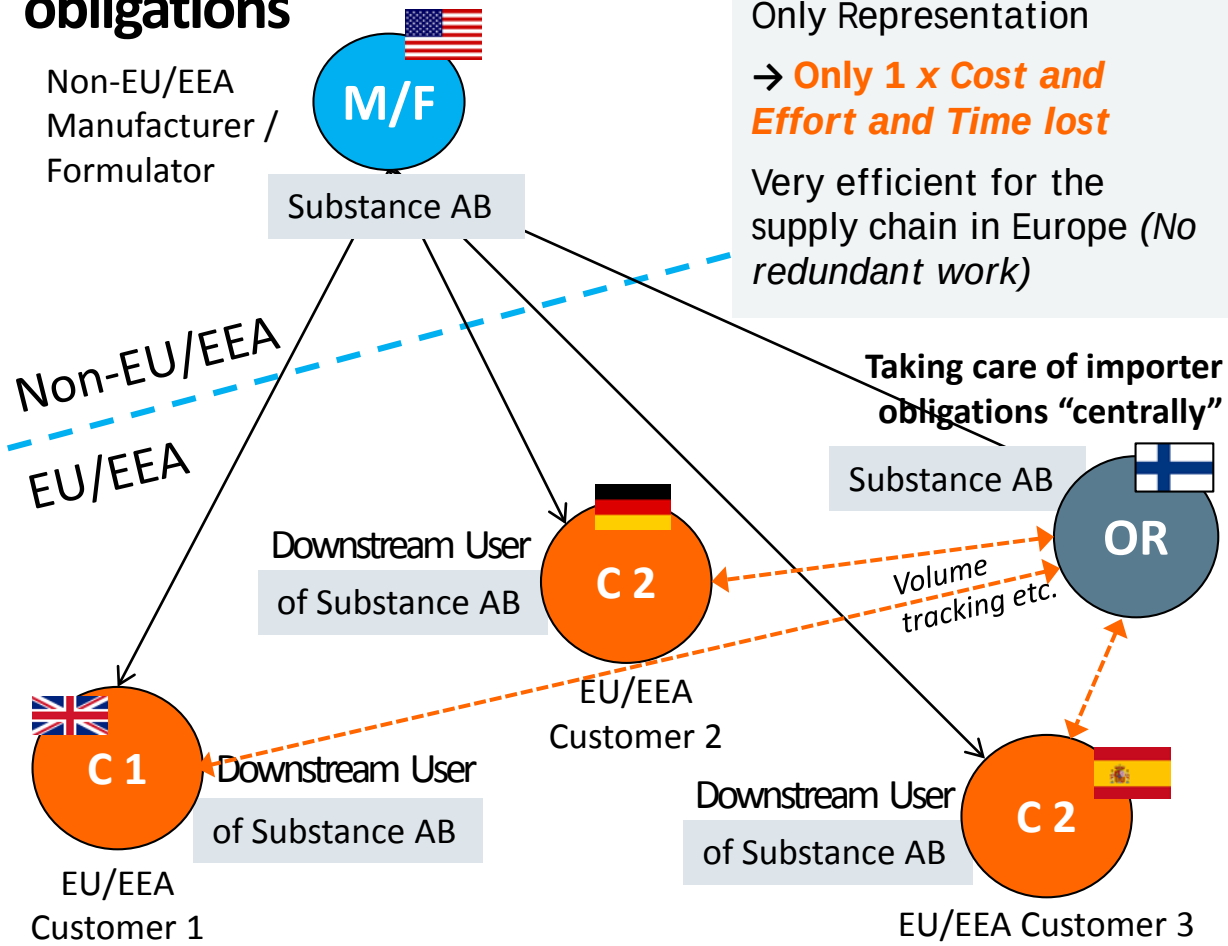


Case of Only Representative taking care of import obligations

EU/EEA importers are regarded as **"downstream users"** of the OR for the tonnage covered by the Only Representation

→ ***Only 1 x Cost and Effort and Time lost***

Very efficient for the supply chain in Europe *(No redundant work)*



Non-EU/EEA chemical traders cannot appoint an Only Representative as they typically are not manufacturing substances or formulating mixtures

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May 31st 2018 will be the last REACH Registration deadline for smaller volume 1 - 100 t/a (non SVHC*) substances

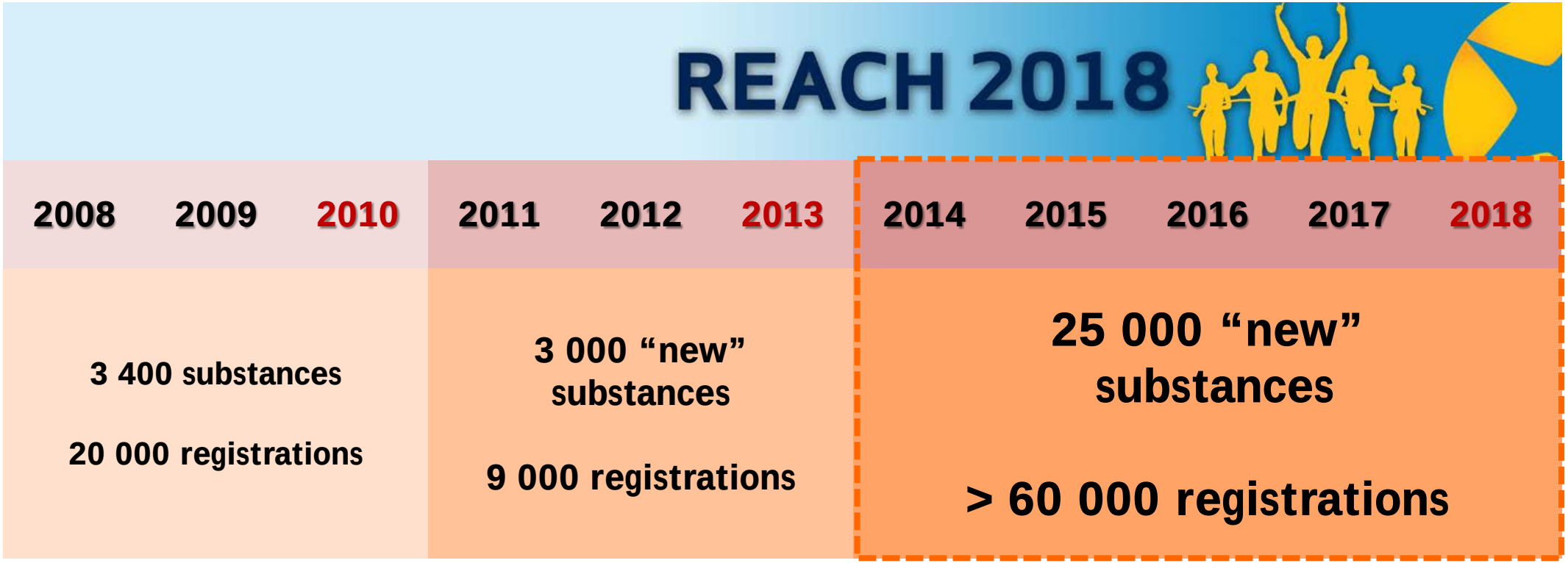
** Substances of Very High Concern at 1 t/a or more had their REACH Registration deadline at 30th of November 2010*

Therefore, as of June 2018, all substances on the EU/EEA market at ≥ 1 t/a must be REACH Registered *

** Unless specifically exempted from REACH Registration*

The REACH 2018 Deadline and Impact on Non-EU Customers

What will the Deadline Look Like?



- As of 20th of September 2017 *(newest available data at the time of preparing this presentation):*
  - Registrations: **52 963** *(this incl. smaller volumes of already registered substances)*
  - Unique substances: **11 570**

The REACH 2018 Deadline and Impact on Non-EU Customers

2018 Deadline, Current status *(October 27th, 2017, newest available data...)*

- **Currently of the 2018 substances:**
  - **5 596** out of ca. *25 000* unique substances have been registered
  - These are covered by **12 131** registrations (*out of ca. 60 000*)
- **Out of these *12 131* registrations*:**
  - **9 085** Registered as full registration (→ 75 %)
  - **3 093** Registered as intermediates (→ 25 %)
  - **85 %** Registered by Large company (→ 10 328)
  - **15 %** Registered by SME (→ 1 803)
  - **28 %** Covered by an Only Representative (→ 3 352)
  - **43 %** Covered by EU/EEA importer (→ 5 183)
  - **24 %** Covered by EU/EEA manufacturer (→ 2 930)
- **On average, there are 4 members in the SIEF**
  (*1 LR + 3 Co-registrants*)

Where are all the rest of the SME's?

* Any combination of one up to three different types can be covered. This is why the numbers do not add up to the total number of registrations.

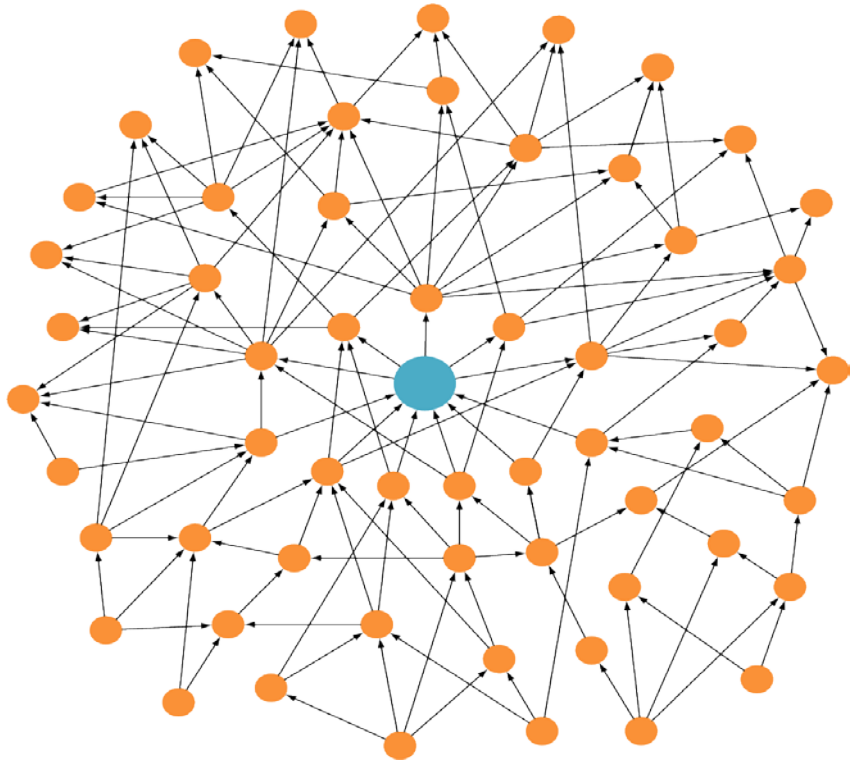
We have only 7 months to go and we still have ca. 19 500 unique substances to register, covered by ca. 48 000 dossiers still to be submitted based on ECHAs statistics…

…that's only ca. 20% done of the estimated number of Registrations

The REACH 2018 Deadline and Impact on Non-EU Customers

Supply Chain Implications *(Related to Registrations)*

- It is expected that substances will **fall of the market** by the 2018 registration deadline due to the following reasons:
  - **Lack of knowhow**
  - **Not enough Resources**
  - **No solid business case** → *No point in registering a substance if revenues are not supporting the costs*
  - **Carelessness**
  - **…**
- This is especially true for **low volume, small market share chemicals** (*typically specialty chemicals*)



The REACH 2018 Deadline and Impact on Non-EU Customers

Supply Chain Implications *(Related to Registrations)*

- **Currently, many companies who would be the lead registrants for 2018 substances are still waiting for a commitment from their customers to sponsor part of the registration costs**
  - This is not the same as cost sharing in the SIEF
- **Many Downstream Users (*customers*) are :**
  - Looking for alternatives to 2018 substances → Avoiding commitment as they can use e.g. already registered (*cheaper*) substances.
  - Calculating their own business case → Is commitment justified from a business perspective.
- **Some such Downstream Users / Customers do not seem to understand that in most cases** *(especially true for 10-100 t/a substances)*, **it's already too late to start with REACH 2018 Lead Registrations mostly due to testing capacity limitations**
  - No capacity and / or tests take too long to have enough time to prepared the dossier by March 2018 …

The REACH 2018 Deadline and Impact on Non-EU Customers

Impact on Non-EU/EEA Customers (Page 1/2)

1. If you **use chemicals** *(substances as such or as part of mixtures)* whose **supply chain originates / crosses the EU/EEA**, you need to **make sure your suppliers are complying with REACH**
   - E.g. ensuring registration for the 2018 deadline (*where applicable*)
   - You need to **ask your suppliers** → If they cannot answer, then **they are not in control** and you should assess the risks and **preferably find another supplier**
2. If you are **supplying chemicals to the EU/EEA**, and you haven't yet REACH Registered, make sure the lead Registrant for the 2018 deadline substance **truly is progressing with their lead registration work** and that they will successfully submit the lead dossier **at the latest during March 2018.**
   - You will need time to prepare your Co-Registration dossier (and by the LoA) and pass ECHA's checks
   - If no progress yet → You most likely need to **take over the Lead Registration process**

The REACH 2018 Deadline and Impact on Non-EU Customers

Impact on Non-EU/EEA Customers (Page 2/2)

3. If you are **the Lead Registrant for 2018 substance(s)** (*your Only Representative / your EU/EEA subsidiary*) and you are still contemplating Lead Registering the substance(s) and you haven't commissioned the testing (*tox-/ecotox studies*), you are **most likely too late in the game** to successfully lead register the substance by May 31st 2018.
   - This is especially true for (*data poor*) 10 – 100 t/a substances
   - **Nevertheless, better to start late than never…!**

Understand that you may not be immune to the affects of REACH (2018) although you are not supplying chemicals to the EU/EEA or directly procuring these from EU/EEA suppliers

No-one knows what will happen after REACH 2018 in the Supply Chain.

Only time will tell…

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The "R" for Registration is only the first letter in "REACH"

Registration has been seen by many companies as the end, but it is really the beginning.

REACH is a journey,
not a destination!

REACH After 2018

Other Processes to Worry About *(in brief only)*

REACH Registration is the Start

Applies to all substances manufactured or imported to EU/EEA ≥ 1t/y (unless exemptions apply)

DE

- **DOSSIER EVALUATION**
  Checks generic compliance and completeness on **standard information requirements**

SE

- **SUBSTANCE EVALUATION**
  Checks content quality, potential issues … on **non-standard information requirements**

Evaluation processes for dossier compliance and additional substance assessments are conducted by ECHA and Member States

AUT

- **AUTHORISATION**
  System of **authorised use** of Substances of Very High Concern (SVHCs) unless tech & economic feasible substitutes are available

Authorisation for SVHCs is running: 100+ Applications for Authorisation, 43 substances on Annex XIV, 174 substances on the candidate list, implementation of the EC SVHC Roadmap to 2020 is progressed

RES

- **RESTRICTION**
  Restrict **certain uses, articles**, … based on proven EU wide risk and proportionate cost benefit in controlling the risk

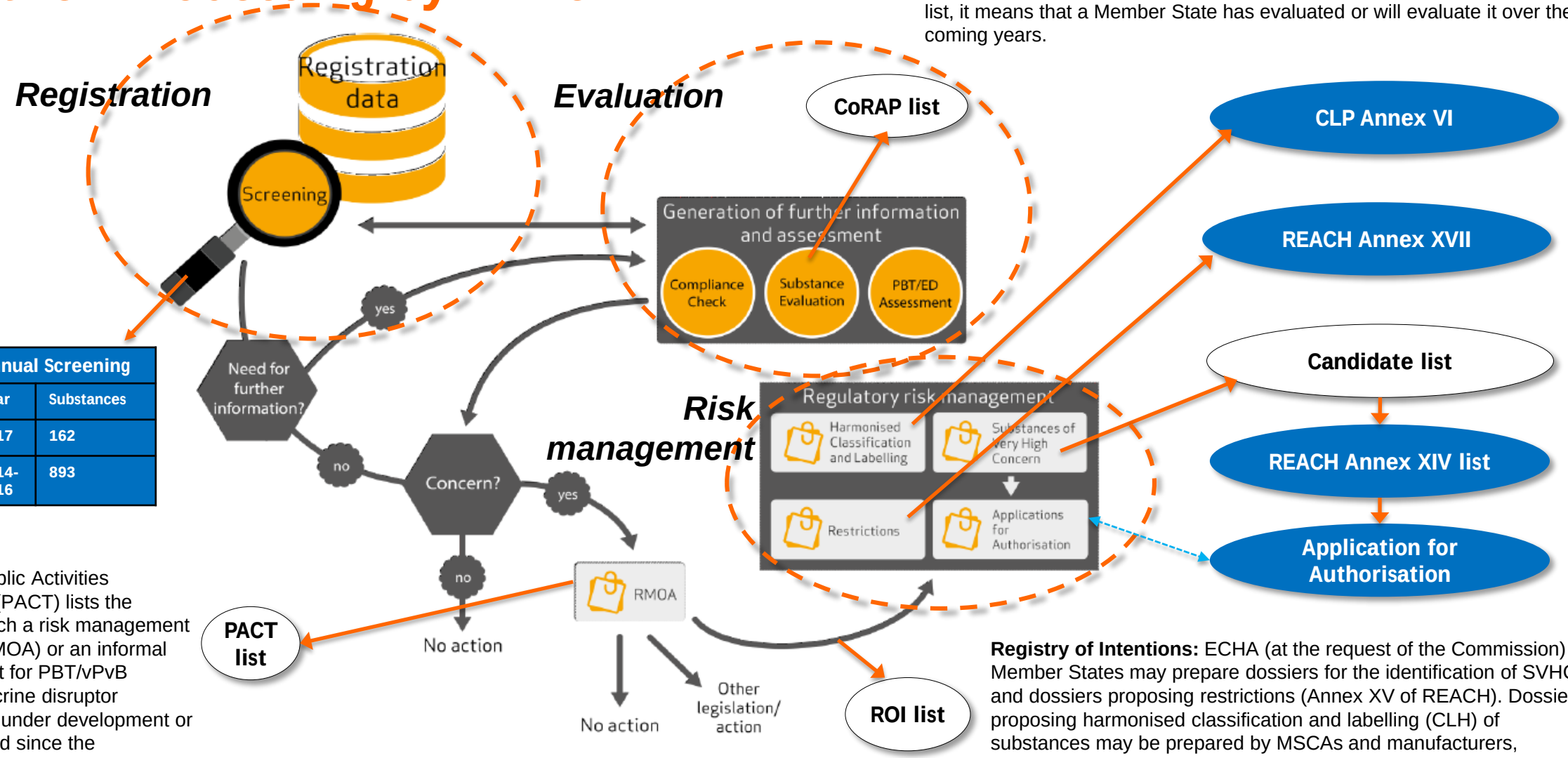
Chemical uses presenting an unacceptable risk are restricted (Annex XVII)

REACH After 2018

SVHC's are Being Identified for Further Processing by REACH

Will not be covered in detail here

CoRAP list: If a substance is on the Community rolling action plan (CoRAP) list, it means that a Member State has evaluated or will evaluate it over the coming years.



Annual Screening	
Year	Substances
2017	162
2014-2016	893

PACT list: The Public Activities Coordination Tool (PACT) lists the substances for which a risk management option analysis (RMOA) or an informal hazard assessment for PBT/vPvB properties or endocrine disruptor properties is either under development or has been completed since the implementation of the SVHC Roadmap.

Source: ECHA

Registry of Intentions: ECHA (at the request of the Commission) or Member States may prepare dossiers for the identification of SVHCs and dossiers proposing restrictions (Annex XV of REACH). Dossiers proposing harmonised classification and labelling (CLH) of substances may be prepared by MSCAs and manufacturers, importers or downstream users.

REACH After 2018
Continuous Update Requirement

- REACH places a mandatory requirement on registrants to update their dossiers "***without undue delay***" whenever new information comes to light. **However, it is based on voluntary action.**
  - However, currently **more than 70% of all submitted dossiers** have been untouched since they were first submitted
  - The vast **majority of updates are currently triggered by ECHA's own regulatory activities**, not by the registrants themselves (pro-actively)
- ECHA is **not happy with the situation** and will be **introducing additional regulatory measures to force registrants to update their REACH Registrations** and keep these registrations up-to-date:
  - One proposed way is to require registrations to be **updated at fixed regular intervals. e.g. every three years** *(as recommended by an expert group to ECHA)*

The recommendations to make dossier updates mandatory at least every 3 years has been sent to the European Commission for their consideration under the REACH Review expected to be finalised by the end of this year.

ECHAs focus will be on high quality data in dossiers and it is the responsibility of the industry to keep this information up-to-date and at a high level of quality

REACH After 2018
BREXIT

- The UK is **Leaving the EU by 2019**:
  - Art 50 Letter sent by the UK Prime Minister May on 29th March 2017
- Negotiations are aiming for orderly withdrawal but both parties also preparing for possible failure (*No Deal Scenario*)
- Two approaches to EXIT the EU:
  1. **The so-called "Hard BREXIT" approach → Chosen by the UK**
     - Leaving the Single Market and the Customs Union without a **comprehensive "deal" being achieved** between the EU and the UK before EXIT.
  2. **"Frictionless" "Soft BREXIT" approach → Highly unlikely as time is running out**
     - All (trade) deals reached before exit
- There will be a **"loss of EU rights" (including REACH rights)** for UK companies upon exit as the EU rights that cannot be converted into UK national law

REACH After 2018

REACH Registration Roles - % of EU/EEA: (ECHA – January 2017)

Country	M	I	M/I	OR
Germany	26%	27%	38%	**16%**
United Kingdom	**6%**	**13%**	**7%**	**23%**
France	11%	8%	9%	**6%**
Netherlands	4%	13%	7%	**12%**
Italy	11%	8%	8%	**1%**

M = manufacturer
I = importer
M/I = manufacturer and importer
OR = only representative of non-EU manufacturer

The UK has a substantial number of Only Representatives…

REACH After 2018
After BREXIT

- **Under current system REACH registrations, authorisations and notifications are not valid after Brexit in the UK**
  - Companies outside the EU/EEA reliant on **UK REACH importers also need to look at alternative arrangements to access the EU**
  - Companies outside the EU/EEA reliant on **UK Only Representatives also need to look at alternative arrangements to access the EU**
- **After EXIT, there will be no REACH in the UK and UK companies will be treated as any non-EU/EEA company**
  - E.g. they can appoint and OR *or* have their EU/EEA importers take care of REACH compliances
- **For non-EU/EEA manufacturers (*and formulators*)**
  - UK based Only Representatives **cannot continue after BREXIT → Change Only Representative**

Under the current system REACH registrations, authorisations and notifications are not valid after BREXIT in the UK

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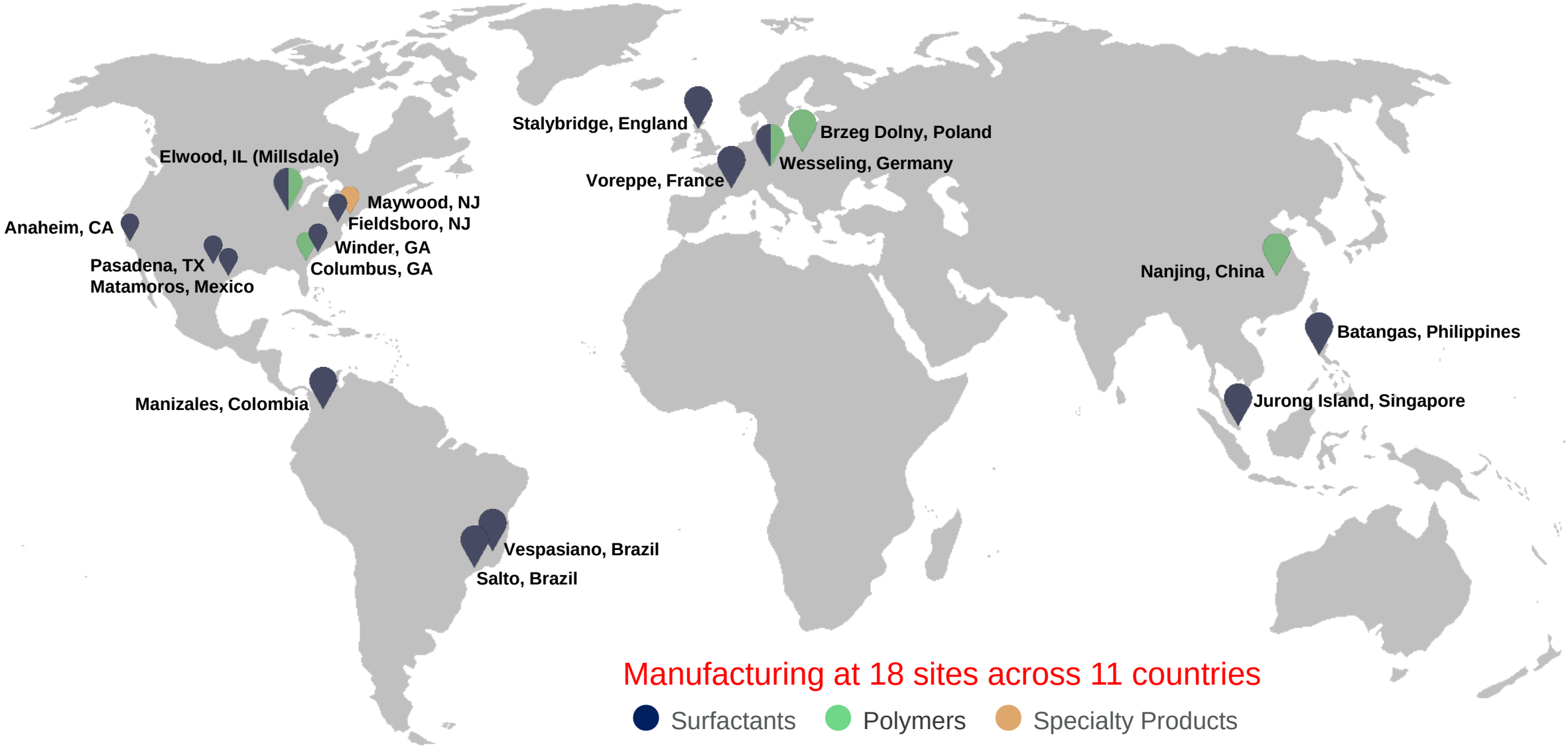
Global Manufacturing



Manufacturing at 18 sites across 11 countries

Surfactants Polymers Specialty Products

Coordinated for REACH

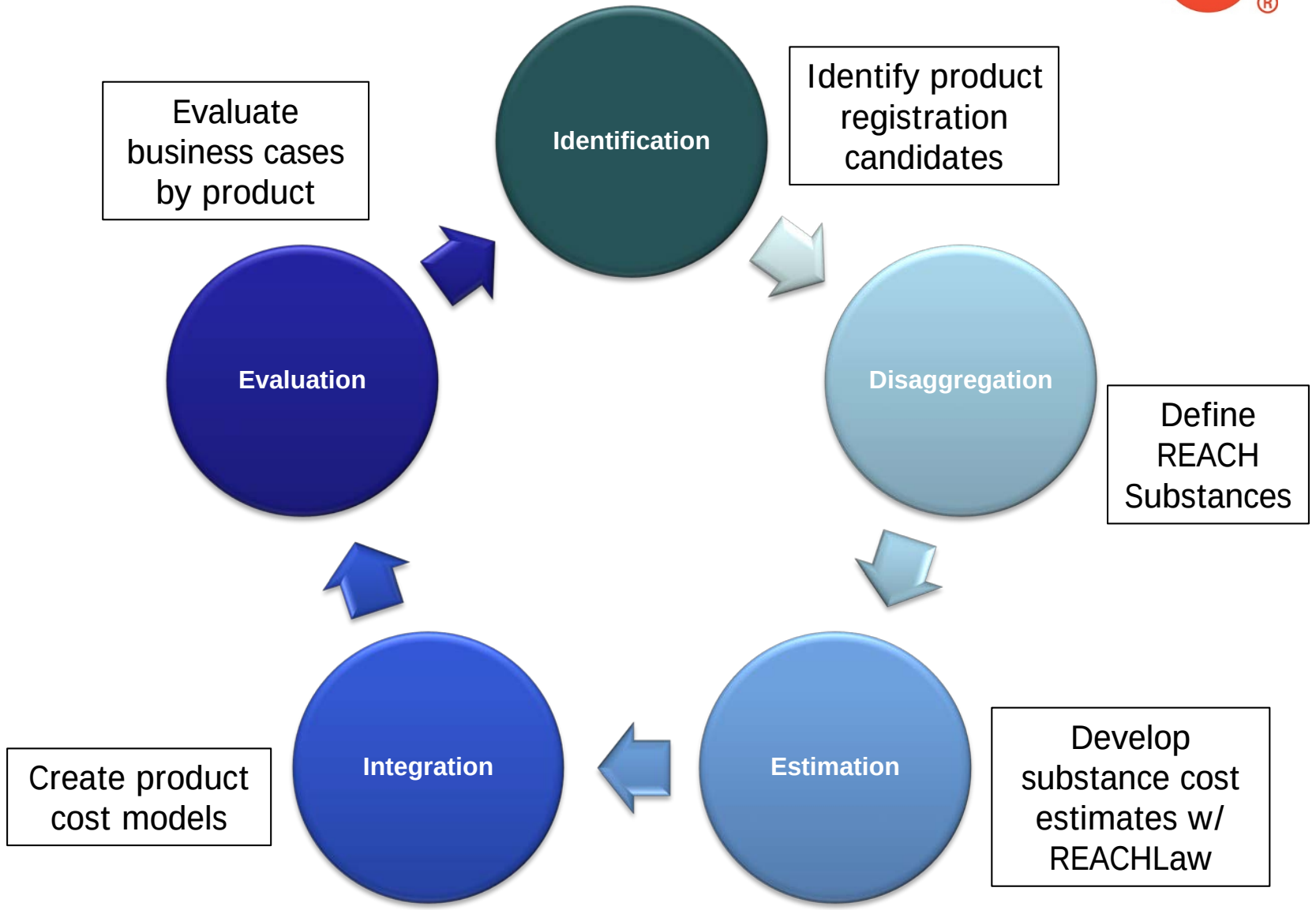
- REACH compliant manufacturing in **UK, France, Germany**, and **Poland** – products can be formulated and re-imported to the EU

- Integrated registration strategies across global manufacturing sites to ensure critical coverage

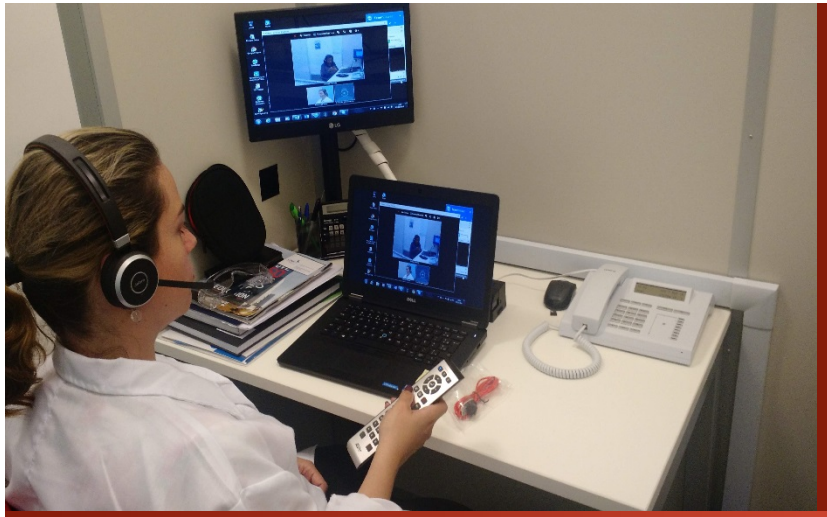
- Harmonized partnerships with customers to meet future demand

Optimized Coverage Process

- Stepan is partnered with REACHLaw to coordinate Phase 3 registrations as Only Representative
- Substances are evaluated on a case-by-case basis by manufacturing site, customer and volume
- REACH OR coverage is strategically provided in support of business growth



Supporting Our Customers



Dedicated technical service teams

virtual lab and web-conferencing ● formulation recommendations
sample fulfillment ● product selection and certification assistance
instructor-led and e-learning training ● audit questionnaire completion

Dedicated customer service department

commercial order placement ● customer order and delivery standards
shipment updates and notifications ● product delivery troubleshooting
pricing, product availability and lead time information

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Contact for REACH / Global Chemicals Regulatory Support

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Questions & Answers

Questions & Answers
Pre-Submitted Questions (Page 1/3)

Question 1: What does Re-import mean and how does REACH apply?

Answer 1: Substances which have been REACH registered, exported out of the EU/EEA and then re-imported **are exempted from "re-registration"** as long as the following conditions are fulfilled:

1. The substance **must have been registered before it was exported** from the EU/EEA.
2. The substance already registered and exported **must be the same**, as the substance being re-imported.
   - If the exported substance itself was modified outside the EU/EEA and then re-imported, the substance has to be registered.
3. The substance **must be from the same supply chain** in which the substance was registered (*a.k.a. be physically the same as was registered by Company X*)
4. The re-importer must have been **provided with REACH information** (safety data sheet, safe use information etc.) on the exported substance

Questions & Answers
Pre-Submitted Questions (Page 2/3)

Question 2: Is it enough that the Company (Group) registers a substance?

Answer 2: REACH requirements are **legal entity specific** meaning that each Company Group Legal Entity (*typically in different EU/EEA countries*) **have to comply with REACH individually**.

This means that **each legal entity** established within the EU/EEA e.g. importing a substance **must REACH register substances individually** (if a registration is required for the substance)

Legal Entity = *Natural or legal person established within the Community*

Questions & Answers
Pre-Submitted Questions (Page 3/3)

Question 3: What happens if you do not register by 31st of May 2018?

Answer 3: You cannot place a substance (≥ 1 t/a) on the EU/EEA market as **all substances** (non-exempt) **will have to be REACH registered starting 1st of June 2018**.

However, **you can always register any substance at any time after 31st of May 2018**.

To REACH (Co-/Lead) register, you will first have to send an **inquiry to the ECHA** with information about your substance identity so that ECHA can put you in contact with the proper Lead Registrant (*if available*). **Only after ECHA has accepted the inquiry, can the REACH registration be submitted**.

Adding the inquiry step to the registration process entails (depending on the substance type) a **1 – 3 month delay in the registration process** which needs to be take into account when determining e.g. the business case for the substance.

Questions & Answers

1. REACHLAW IN BRIEF
2. REACH (EU) OVERVIEW
3. THE REACH 2018 DEADLINE AND IMPACT ON NON-EU CUSTOMERS
4. REACH AFTER 2018
5. STEPAN'S REACH READINESS
6. Q&A
7. CONTACT

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