Strategies for REACH Compliance

Chicago

23 March 2012

Table of contents

Who is EcoMundo?

Speakers

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EcoMundo history

Projets
EDIT
ECODIS

2001

EcoMundo is launched in 2007

2007

Regulatory expertise

Toxicology & ecotoxicology

Software development

European specialist of REACH

2012

STAFF
37 persons of which **9 PhD** for Research & Development

SALES
75 % realized outside of France

Our solutions

MANUFACTURERS & IMPORTERS

DOWNSTREAM USERS

EcoMundo solutions

EXPERT SERVICES

- REACH registration
- Authorisation dossier
- SIEF/Consortium mgt
- Technical expertise
  - LCA innovation
  - Nanomaterials

SOFTWARE

- Substances/regulations
- SVHC management
- CLP compliance
- SDS management
- LCA management

Our international network

SOCMA – Society of Chemical Manufacturers & Affiliates (USA)

CRIQ – Quebec Industrial Research Center (Canada)

MMTA – Minor Metal Trade Association (UK)

AXELERA – Chemistry & environment (France)

Our customers: small & large

Large international groups

L'ORÉAL®

SANOFI

Schneider Electric

Chemtura

Small & Medium Enterprises

Aurubis

Fosbel CERAMIC TECHNOLOGIES

PETZL®

NEXO

Family companies

GS® GLASS SERVICE

GLUETEC

STEEL INVEST KOŠICE - SLOVAKIA

REACH affects U.S. companies

U.S. loss of foreign markets

U.S. Genetically Modified (GM) corn exported to Europe

U.S. exports to EU
$100 million per year (early 90s)

1992 = Introduction of GM corn

U.S. exports to EU
$8 million per year (mid 90s)

1998 = EU bans GM corn

U.S. beef, with a low level of testing, exported to Europe and Japan

U.S. total exports
$3 billion per year (2000 to 2003)

2003 = mad cow disease in the U.S

2004 = level of testing advised by Japan & Europe rejected by U.S.

U.S. exports = **$550 million** (2004)

Don't miss REACH and the European Market !

Some key figures

USA

Production
17% of the world's chemicals (2010)

Sales
€395 billion (2010)

Market
309 million people (2010)

Regulations
TSCA
OHSA

EUROPE

Production
21% of the world's chemicals (2010)

Sales
€454 billion (2010)

Market
Currently 27 + 3 countries
570 million people (2011)

Regulation
REACH

U.S. exports of Chemicals to Europe = $14 billion/year

Cost of REACH compliance $14 million/year

Before REACH: the chaos !

BEFORE

More than 40 interlocking regulations

Classification & Labelling

Dir. 67/548

Dir. 99/45

NOW

REACH regulation

CLP regulation (based on the GHS)

Consequences of REACH for U.S.

1. New safety information available on the net
2. New restrictions on chemicals
3. A driver for exports of safer chemicals to Europe
4. Reform of US chemicals policy

3 reasons to be « REACH COMPLIANT »

1

Market opportunity

FEWER export competitors thanks to REACH

2

Strengthen your customers portfolio

Generate customer LOYALTY in Europe

3

Be competitive for other markets than Europe

REACH seen as the highest standard

PREPARE FOR REACH NOW

REACH is going GLOBAL

The context of REACH extends to international level

U.S.A. — Safe Chemicals Act in place in 2013?

CHINA — A regulation is already in place

TURKEY — Regulation in place since 2011

→ **IMPOSSIBLE TO ESCAPE FROM REACH**

What does REACH stand for?

Registration — Who manufactures /imports? **Impacts?**

Evaluation — **Verification** of dossiers by ECHA

Authorisation — Use of SVHC with **special permission** only

and **Restriction** of **Ch**emicals — Complete **ban** of certain substances or use cases

Main obligation of REACH

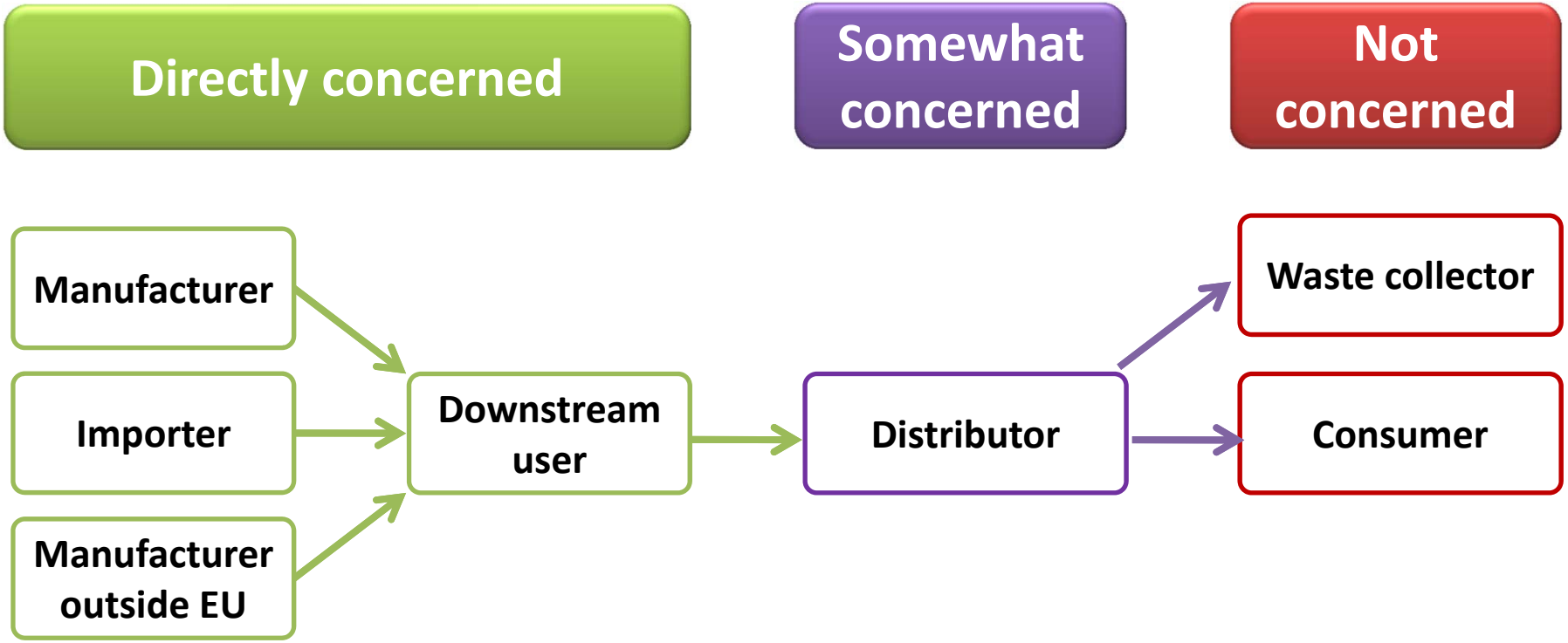
OBLIGATION

REACH requires that all chemical substances **manufactured in the EU or imported to the EU** at quantities of at least **one metric tonne per year** be registered.

NO DATA = NO MARKET

Actors concerned by REACH

The all supply chain is impacted



REACH: the basics

The 3 key principles of REACH

1

“No data, No market”

No business without registration of key data

1 bis

“No Use Cases, No market”

2

The burden of proof is reversed

Chemicals are considered suspect until industry proves they are innocent

3

Traceability & communication within the supply chain

Exchange of data becomes key between companies

The European Union

27 countries since 2007

Candidates:

- Croatia
- Turkey
- Macedonia
- Island
- Montenegro
- Serbia

Key products under REACH

Substance

Chemical element and its compounds

Examples: acid, pigment, pure metals, etc.

Mixture

Solution composed of 2 or more substances

Examples: paint, cream, etc.

Article

Object with a specific shape, surface or design

Examples: phone, metallic tube, etc.

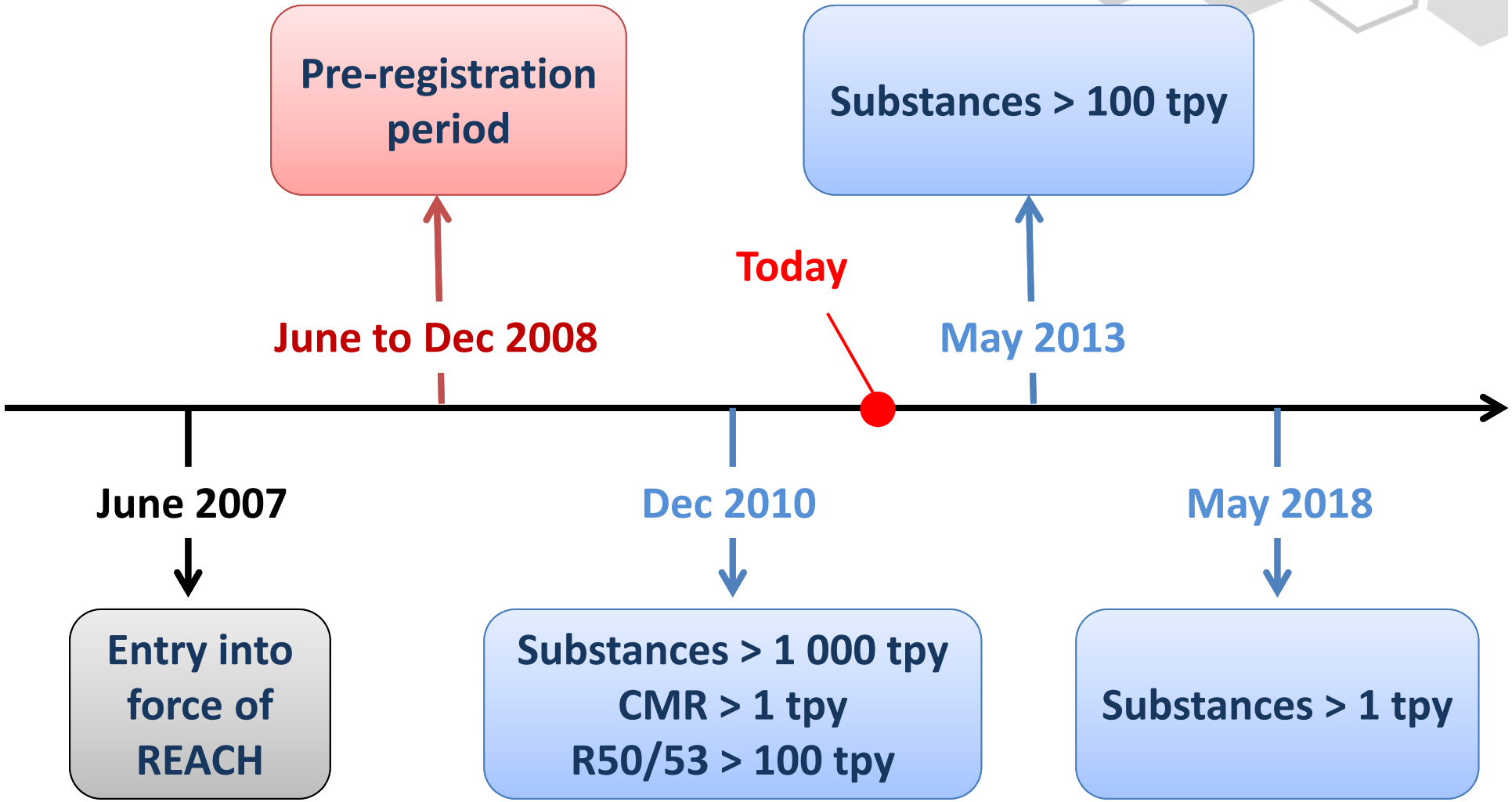
Key dates for the registration

Based on the **annual tonnage** manufactured/imported, and the **risks associated** to the substance:

2010	**> 1 000 tonnes**	CMR, R50/53*
2013	**100 to 1 000 tonnes**	
2018	**1 tonne and more**	

** CMR > 1 tonne per year and R50/53 > 100 tonnes per year*

REACH registration timeline

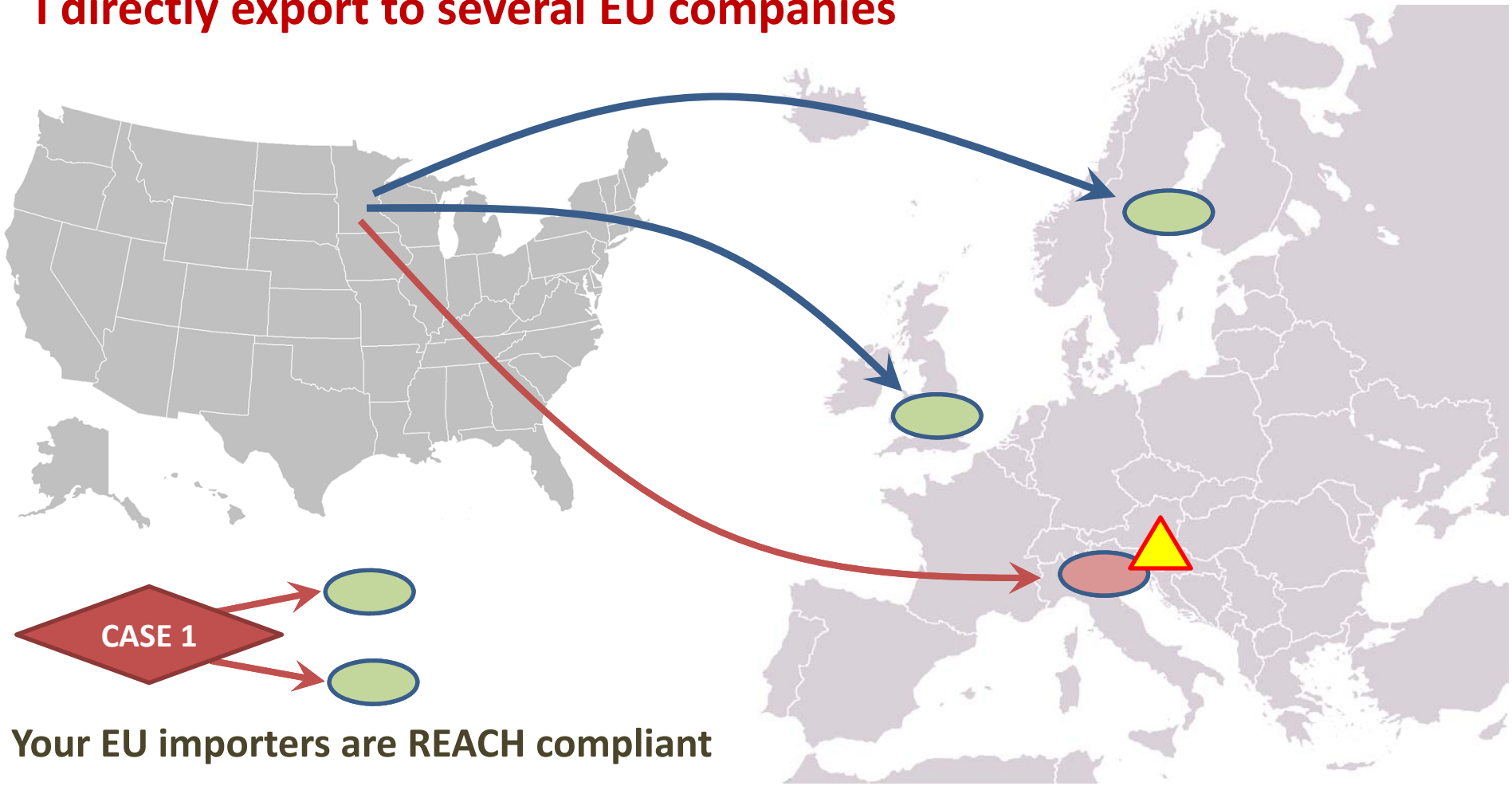


What is your situation > CASE 1

USA

EUROPE

I directly export to several EU companies



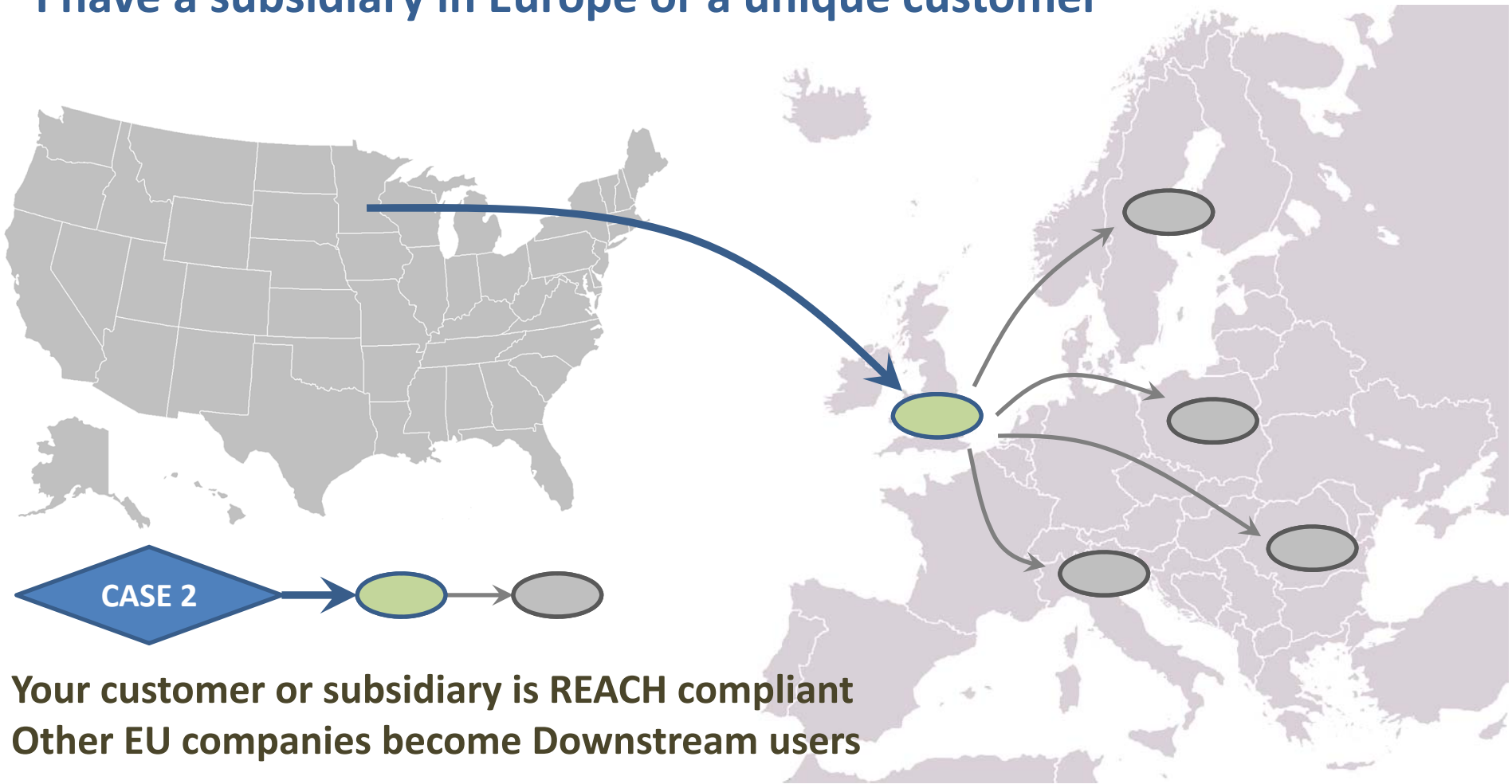
Your EU importers are REACH compliant

What is your situation > CASE 2

USA

EUROPE

I have a subsidiary in Europe or a unique customer



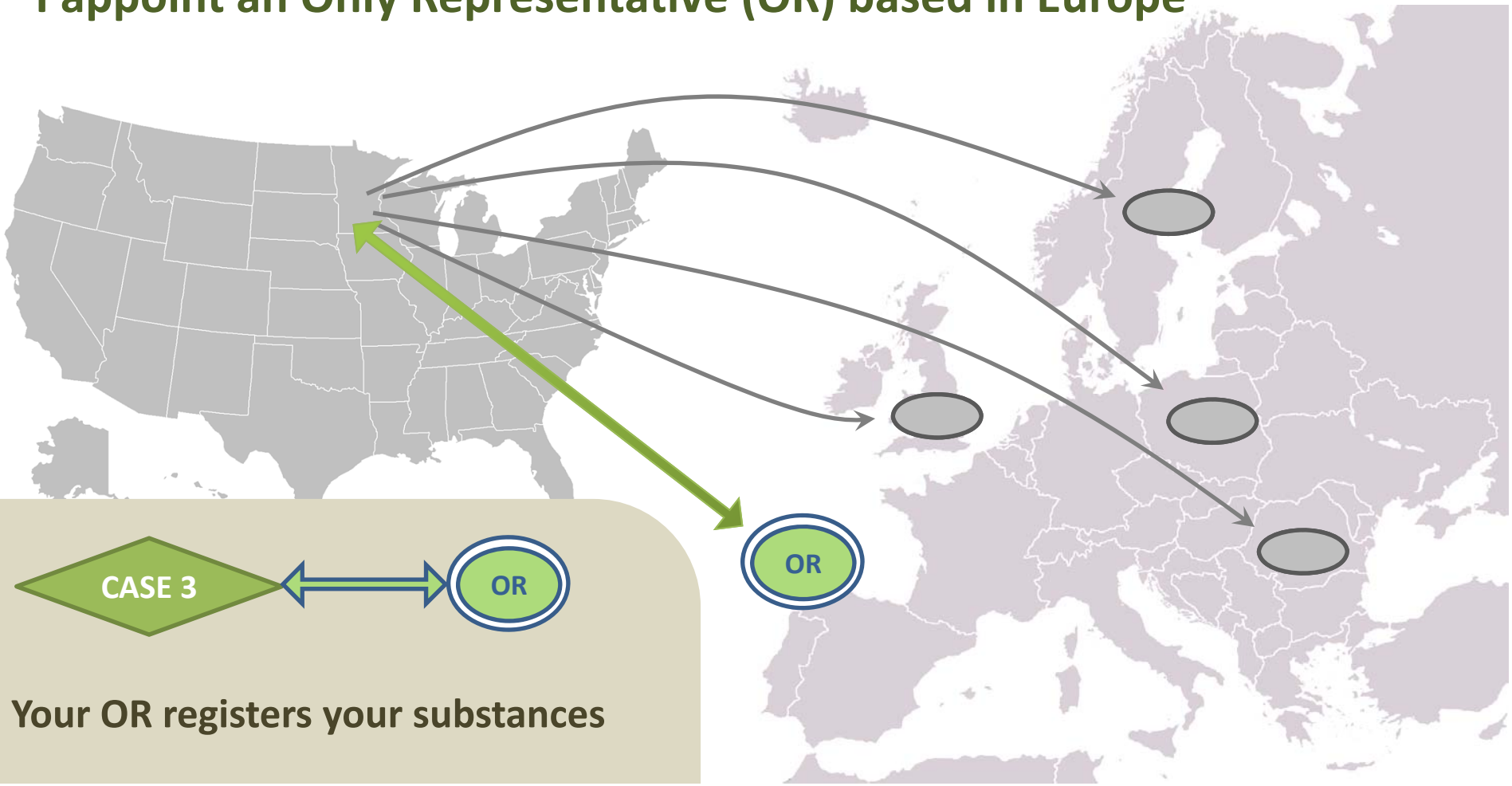
Your customer or subsidiary is REACH compliant
Other EU companies become Downstream users

What is your situation > CASE 3

USA

EUROPE

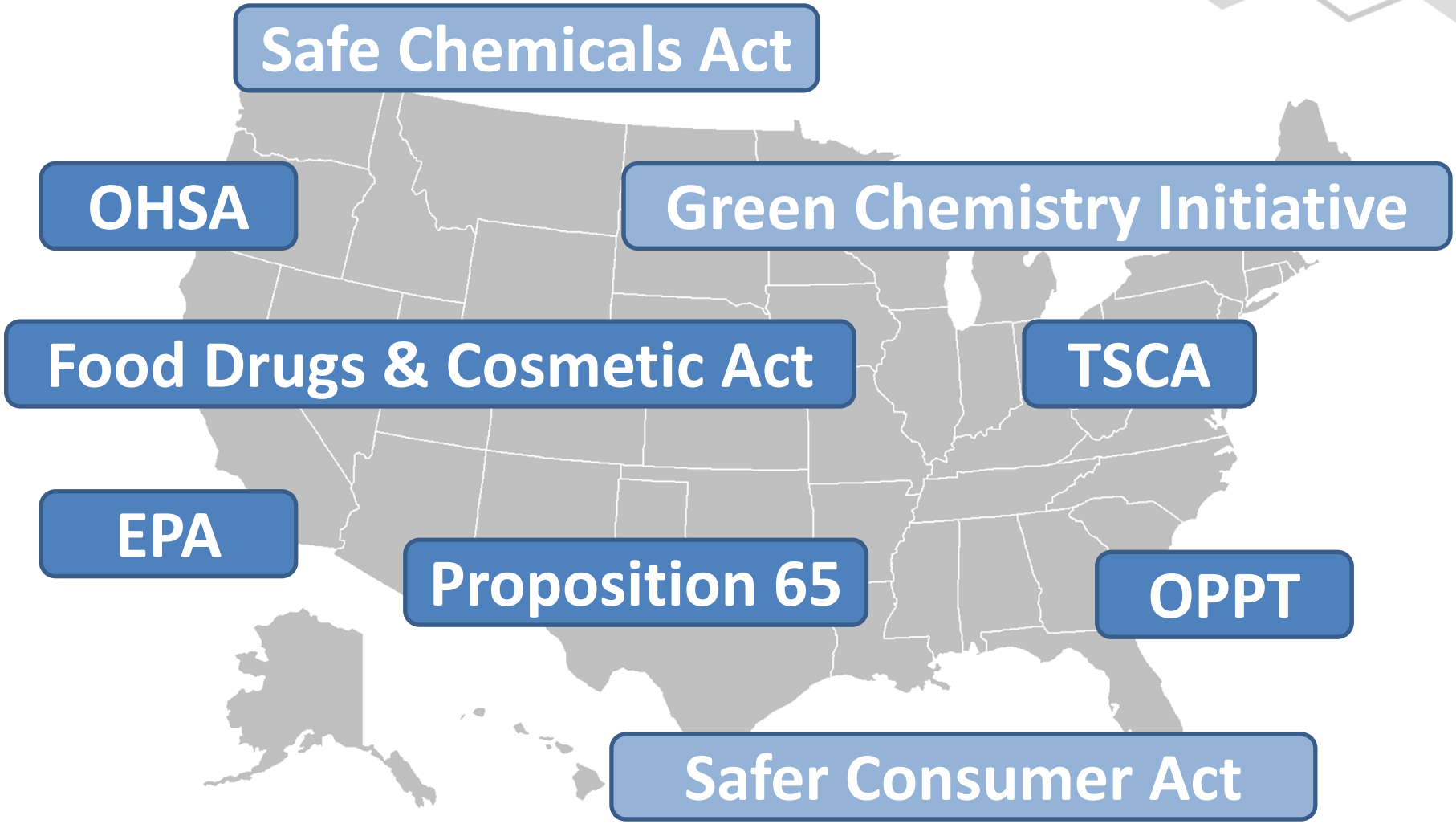
I appoint an Only Representative (OR) based in Europe



CASE 3 ⟷ OR

Your OR registers your substances

U.S. regulatory landscape



COMPLIANCE ACTION PLAN
The 6 facets of REACH

The 6 facets of REACH

1. **Substances/materials** & regulations
2. **Registration** of your substances
3. **GHS / CLP** compliance
4. Workers' **safety**
5. Management of **Safety Data Sheets** (SDS)
6. **SVHC** traceability & authorisation

Substances/materials & Regulations

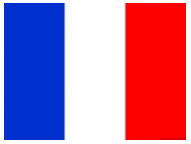
1.

1.1 Inventory of your export portfolio

Know **substances, mixtures & articles** you export




Know the **countries** where you export



Define **international regulations** you need to comply with

REACH **CEPA** **OSHA**

GHS/CLP **TSCA**

MAT FACTORY

Functionalities

- Search substances, materials & regulations worldwide
- Customize the database
- Receive alerts

Benefits

- Database with more than **100,000 substances**
- Any **international regulations** can be added
- **Real-time** update of regulations

Registration of your substances

2.

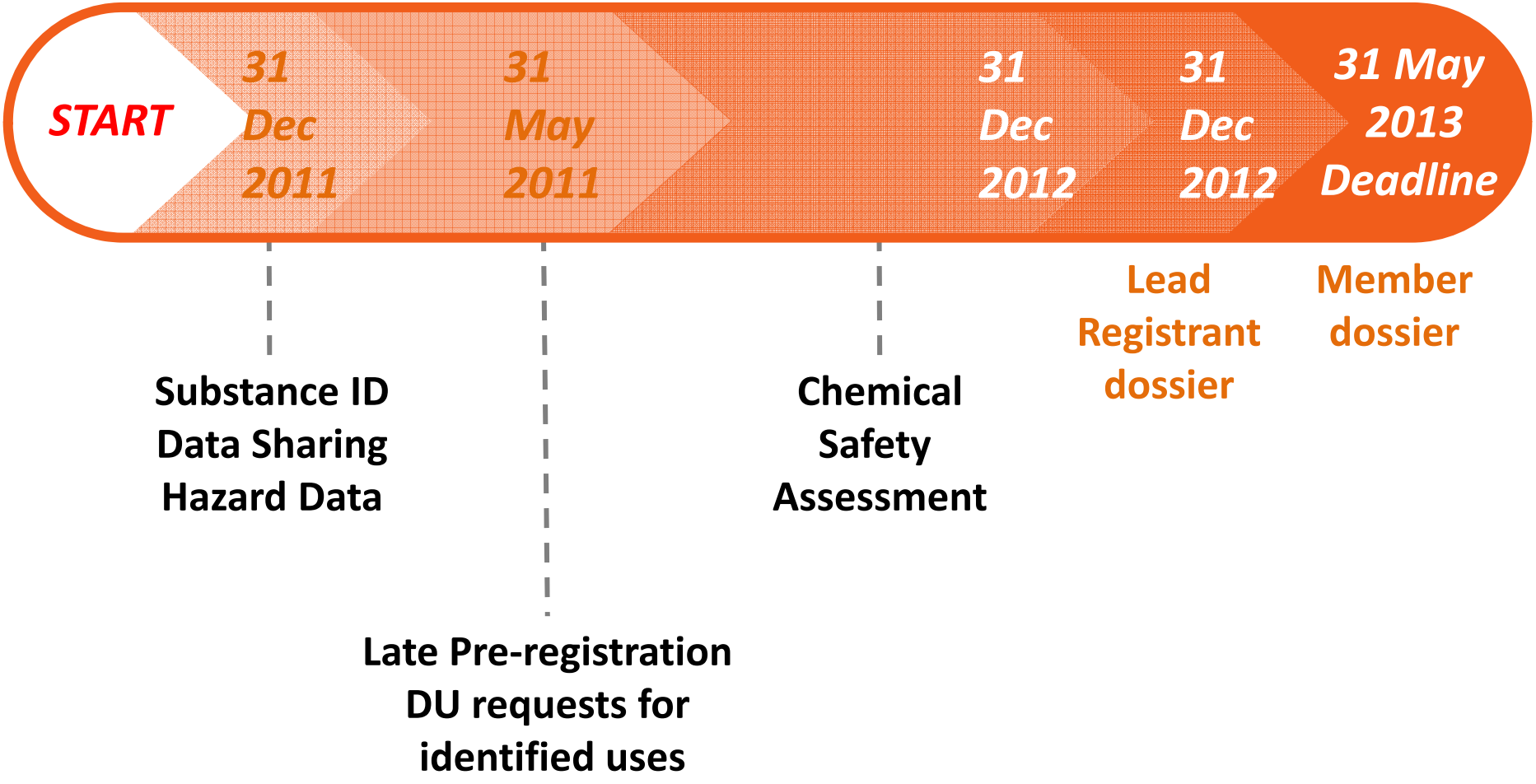
2.1 Chemical products exempted from REACH

- Radioactive substances
- Substances that are only transiting through Europe (re-exported)
- Non isolated intermediates
- Transported mixtures considered as very hazardous
- Waste
- Defense substances

2.2 REACH registration: the next deadline

Anticipate > the 2013 registration deadline !

2.3 Timeline for action for 2013 registration



2.4 Appoint an Only Representative (OR)

Do you have a subsidiary in Europe?

YES

Your European subsidiary can do the registration for you

NO

You need to appoint an Only Representative (OR) based in Europe

2.5 Pre-registration and registration

Pre-registration

- Ended in December 2008
- Benefit from the 3 deadlines: 2010, 2013 and 2018

Late pre-registration

Submit a pre-registration to ECHA to benefit from the 2013 and 2018 deadlines:

« within 6 months of first manufacturing, importing or using the substance in quantities of 1 tonne or more per year

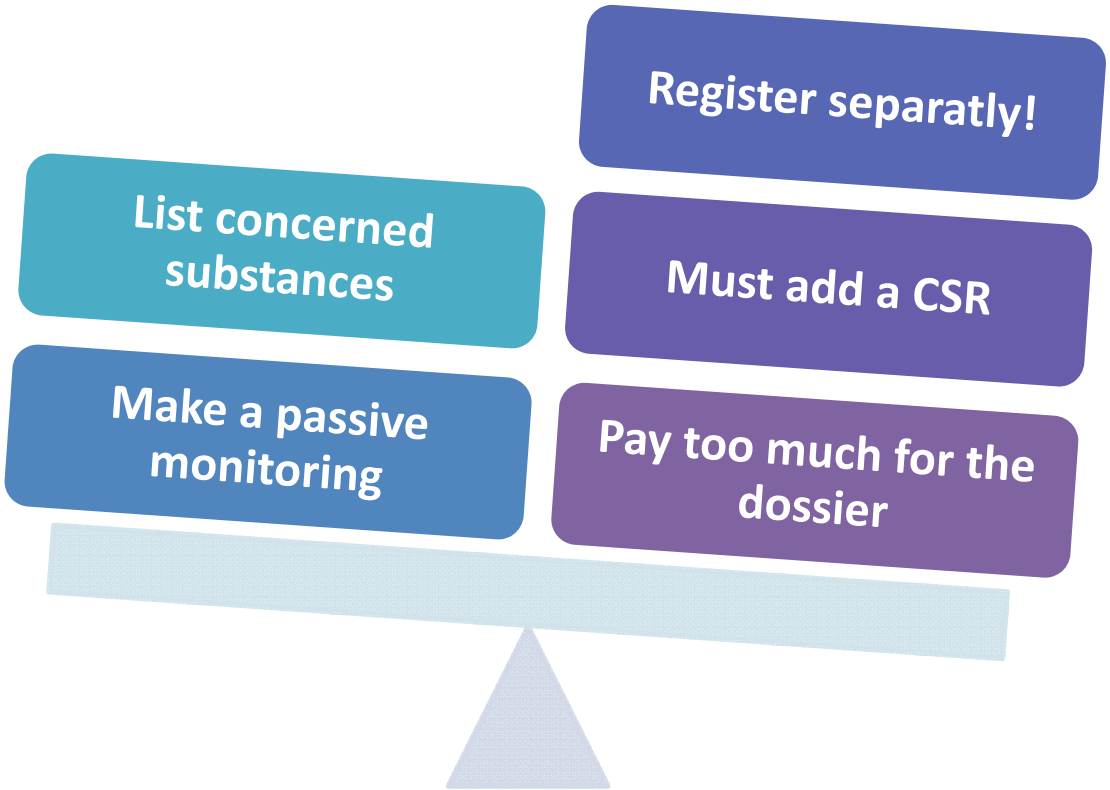
and

no later than 12 months before the relevant deadline »

2.6 Your interest is to anticipate

Necessary actions

Risks not to anticipate



GHS / CLP compliance

3.

3.1 The GHS defines the CLP regulation

World

Global **H**armonized **S**ystem (GHS)

Europe
Since Jan 2009

CLP
Classification, Labelling & Packaging

+ others

3.2 CLP transitional obligations

Classification + Labelling + Packaging

December 1st, 2010

Notification

- **January 3rd, 2011**
- **1 month delay**

Classification + Labelling + Packaging

June 1st, 2015

Substances put on the market before 2010 (et before 2015 for mixtures) benefit from a 2-year period for compliance.

3.3 New CLP pictograms

3.4 Benefits of CLP compliance

1. ANTICIPATE

REACH the most demanding standard in the world

2. HARMONIZE

One unique packaging to be used in glovally

3. MAKE IT EASY

Smoother passage through customs

4.

Workers’ safety

4.1 You are also concerned

1 You are responsible for communicating reliable and updated **SAFETY INFORMATION TO YOUR CUSTOMERS**

Exposure Scenarios (ESs) is a principle which becomes widespread **ANTICIPATE !** **2**

4.2 The Use Descriptor System

For downstream users it is essential to receive from M/I standardized **short titles of exposure scenarios**

Five separate descriptor-lists

- The sector of use category (SU)
- The chemical product category (PC)
- The process category (PROC)
- The environmental release category (ERC)
- The article category (AC)

4.3 Safety Data Sheets, SDS and extended SDS

The new eSDS format includes CLP and Exposure Scenario

1 Exposure Scenario (1)
Title of exposure scenario
2.1 Contributing scenario (1) controlling environmental exposure for ...
2.2 Contributing scenario (2) controlling worker exposure for ...
2.3 Contributing scenario (3) controlling worker exposure for ...
2.n Contributing scenario (n) controlling worker exposure for ...
3. Exposure estimation and reference to its source
Information for contributing scenario (1) Information on contributing scenario (2) Information on contributing scenario (3) Information on contributing scenario (n)
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

4.4 eSDS of your mixture or article

1. Receive **components' eSDS**

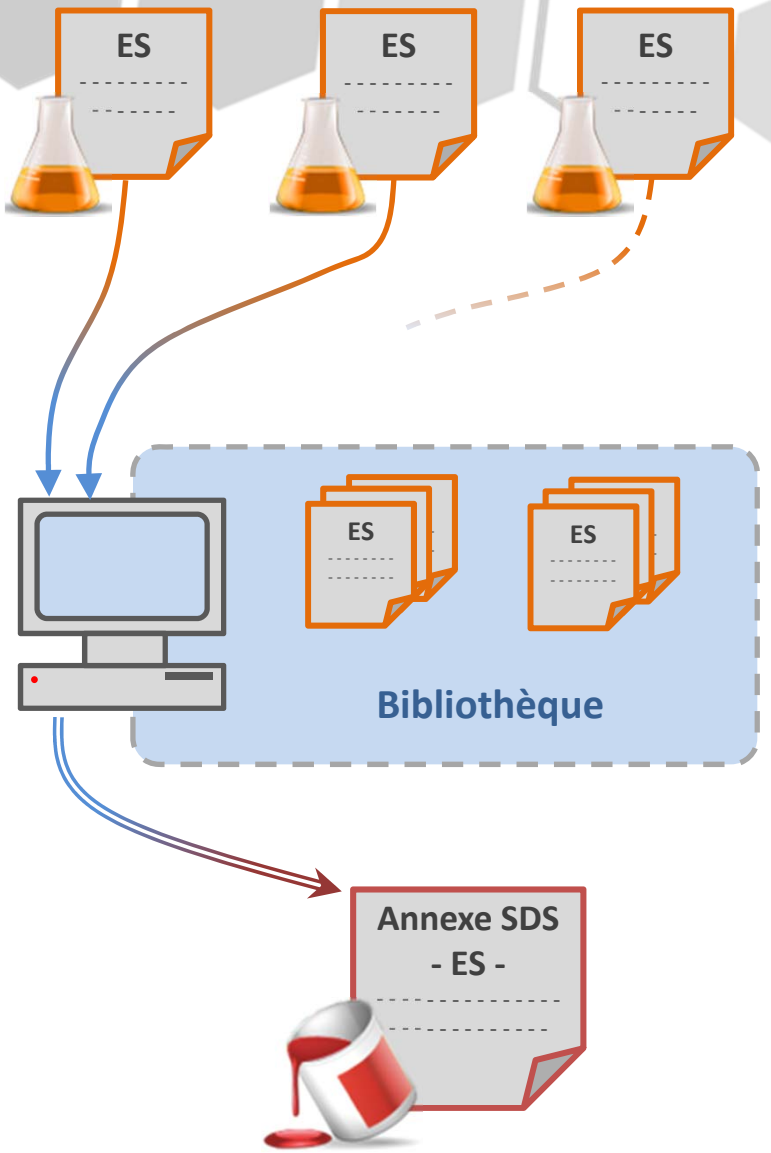
Or use Registration Dossier (**CSR**)

2. Select **components** that should be taken into account

3. Cross with **known uses**

4. Select Operating conditions (**OCs**) and Risk Management Measures (**RMMs**)

5. Spread eSDS of your mixture or article



5.

Management of Safety Data Sheets (SDS)

5.1 What is a Safety Data Sheet?

REACH dossier | **Exposure scenario** | **CLP classification**

Contains information on the hazard of dangerous SUBSTANCES & MIXTURES

Drafted in the LANGUAGE of the EUROPEAN COUNTRY it is intended for

Must be UPDATED each time NEW INFORMATION regarding hazards become available

5.2 As a supplier, you need to provide a SDS

If:

- A **substance classified** as hazardous according to CLP
- A **mixture classified** as dangerous according to the Dangerous Preparations Directive (until 1 June 2015) and according to CLP (from 1 June 2015)
- A substance that is **PBT or vPvB**, as defined in REACH (Annex XIII)
- A substance that is included in the **candidate list** of substances of very high concern

5.3 Update and re-issue of the safety data sheet

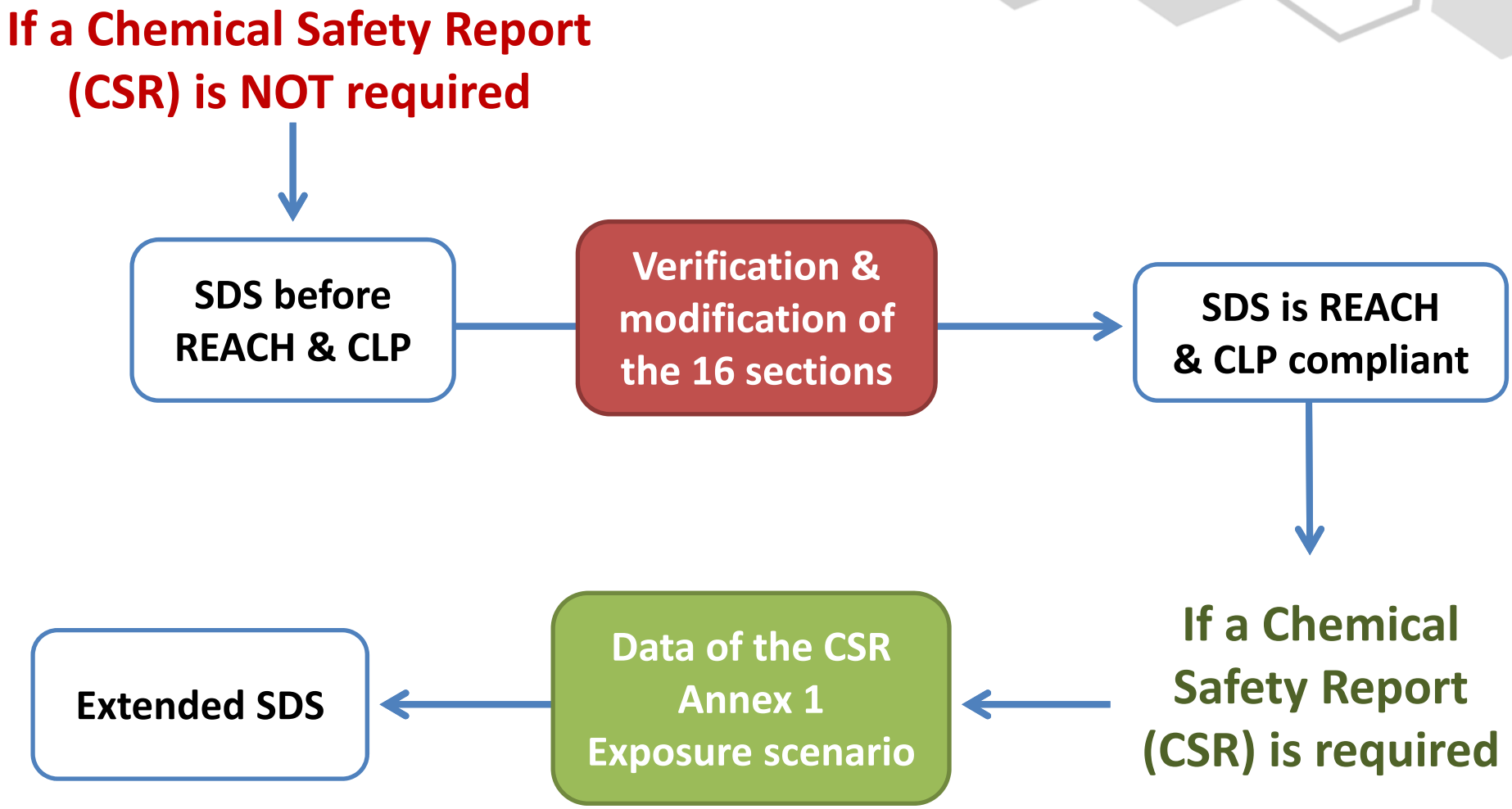
- as soon as **new information** that may affect the risk management measures becomes available
- once an **Authorisation** under REACH has been granted or refused
- once a **Restriction** under REACH has been imposed

5.4 The 16 compulsory section of a SDS

1. Identification of the substance/mixture and the company/undertaking	9. Physical and chemical properties
2. Hazards identification (assessment)	10. Stability and reactivity
3. Composition/information on ingredients	11. Toxicological information
4. First aid measures	12. Ecological information
5. Fire fighting measures	13. Disposal considerations
6. Accidental release measures	14. Transport information
7. Handling and storage	15. Regulatory information
8 Exposure controls / personal protection	16. Other information

5.5 SDS & eSDS: how to manage?

5.6 SDS & eSDS: how to manage?



SVHC traceability & management

6.

6.1 What is a SVHC substance?

Substances of Very High Concern are:

- Carcinogenic, Mutagenic or toxic to Reproduction (**CMR**)
- and/or Persistent, Bioaccumulative and Toxic (**PBT**)
- and/or very Persistent and very Bioaccumulative (**vPvB**),
- and/or identified as of an **equivalent level of concern** as those above, e.g. endocrine disrupters

Substances to be properly CONTROLLED and progressively REPLACED by suitable alternative substances or technologies

6.2 Candidate and Authorisation lists

Registry of Intention RoI

Candidate List
(today : 73 SVHC)

Annex XIV / Authorisation list
(today : 14 SVHC)

Authorisation request necessary to use or keep using those substances

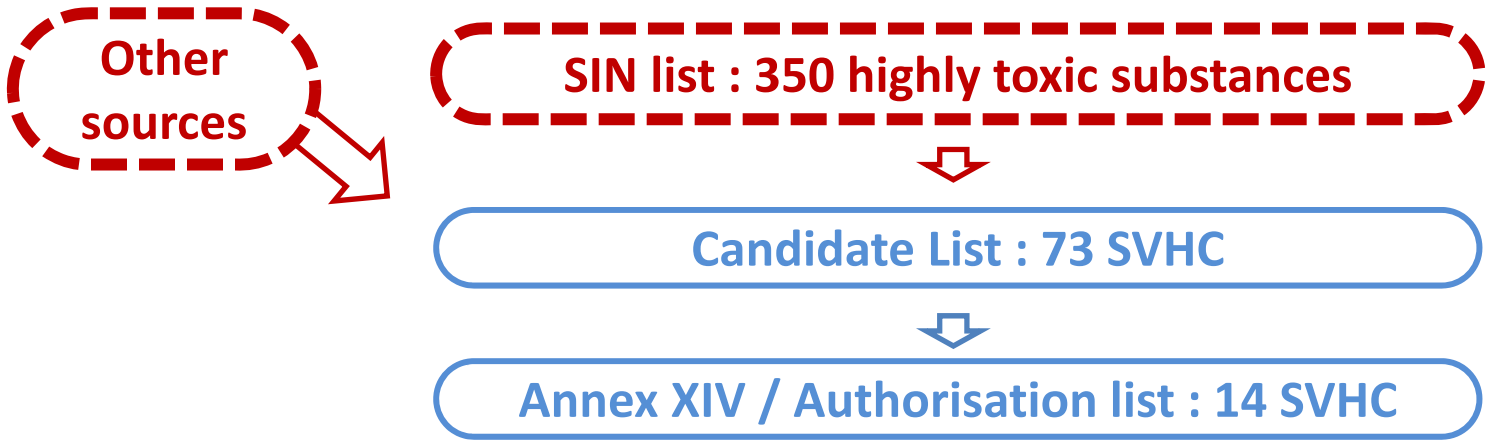
Lists are updated several times a year e.g. 3rd (Dec. 2011) recommendation for inclusion in annex XIV = 13 SVHC
> verify regularly in order to anticipate

6.3 Anticipate SVHC substances with the SIN list

SIN list (Substitute It Now) – from NGOs and industry

List of substances that are likely to make it onto the SVHC list.

The SIN list came about because companies wanted to know if the chosen replacements would turn up banned in the future.



6.4 SVHC obligations for downstream users

Assess your obligation to notify your SVHC to ECHA as from June 1, 2011

You must inform ECHA on the presence of SVHC in your articles if:

- A SVHC is present in your articles in a concentration > 0.1% (w/w), **AND**
- The substance is present in those articles in quantities totaling over 1 ton per producer or importer per year, **AND**
- The substance has not been registered under REACH for that use.

Inform your clients when SVHC are present

If your articles contain SVHC above 0.1% (w/w):

- The supplier must inform spontaneously its clients and provide sufficient information to allow safe use of the article.
- On request by consumers, you must inform them for free of the presence of SVHC within 45 days.

6.5 SVHC forecasts:

Today:

- 73 SVHC in the candidate list
- ECHA lunched a public consultation for 13 SVHC for inclusion in Annex XIV

In 2012: Probably 136 new SVHC

In 2018: Probably 300 new SVHC

6.6 8 new SVHC in annex XIV:

(Regulation EU/125/2012)

- DIBP (diisobutyl phthalate)
- Diarsenic trioxide
- Diarsenic pentaoxide
- Lead chromate
- Lead sulfochromate yellow
- Lead chromate molybdate sulphate red
- TCEP(Tri (2-chlorethyl) phosphate
- 2,4-DNT (2,4-Dinitrotoluene)

6.7 Autorisation decision

shall specify:

- ✓ the person(s) to whom the Authorisation is granted
- ✓ the identity of the substance(s)
- ✓ the use(s) for which it is granted
- ✓ any conditions under which it is granted
- ✓ a time-limited review period (case-by-case approach)
- ✓ any monitoring arrangement

6.8 US companies and Authorization

- **A US-importer can continue placing an Annex XIV substance on the market for a use for which his immediate downstream user has been granted an Authorization.**

- **A US-Importer can apply for an Authorization through a duly mandated Only Representative (OR)**

(Manual and IUCLID 5 last version will be published & released during summer 2012)

6.9 Obligation of notification to ECHA

If:

One SVHC > 0.1% (w/w)

AND

Substance has not been registred in REACH for this use

AND

Substance in articles
> 1 tonne / year / manufacturer or importer

6.10 Obligation to inform

1.

Collect information from suppliers

2.

Calculate % (w/w) of each SVHC

3.

Communicate to clients use conditions

4.

Communicate to consumers on request within 45 days

6.11 Your actions for full compliance

- Set up a **SVHC traceability policy** for your products.
- Spontaneously **inform your clients** when SVHC are present above 0.1% (w/w).
- **Anticipate** Authorization or/and Restriction status of SVHC substances.
- Improve the **communication with your suppliers**.

6.12 Autorization: a COMPLEX procedure

Applicant can be:

- A manufacturer, an importer, or a downstream user,
- Or any combination.

Submission can be for:

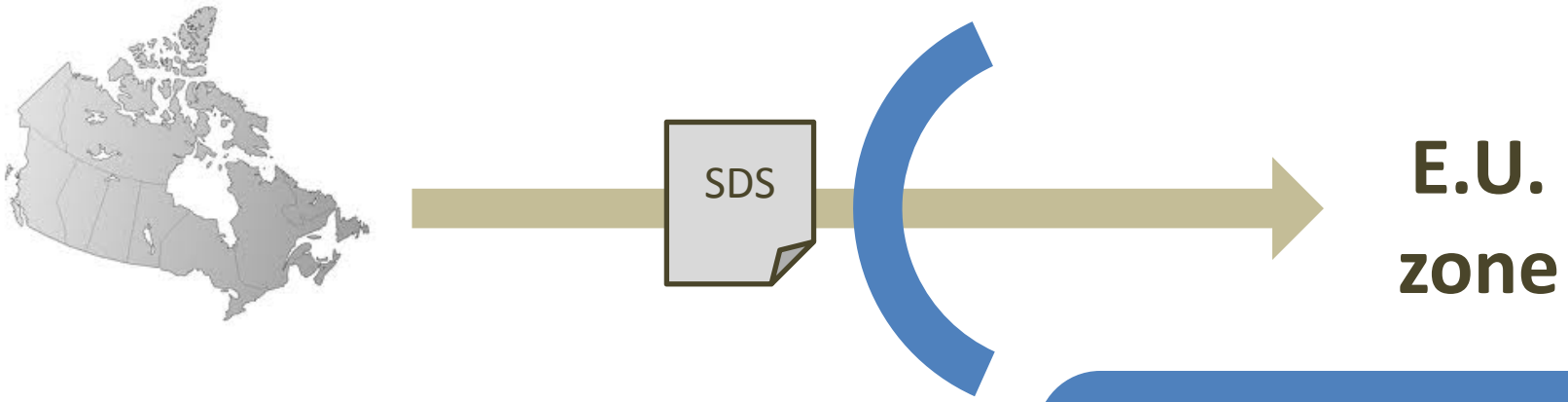
- One or several uses
- One substance or one group of substances

Elaboration of the dossier requests:

- Bringing together different facets of the company
- Deciding of a strategy in the way of using the data (including confidential aspects)

Practical questions

REACH and EU' customs



SDS is the principal control tool

The enforcement is of the responsibility of the member-states and differs among them

Penalties:

fine, seizure, ban on manufacturing or on export.

Customs sanctions

Example of France:

- A national text (Circulaire, DGDDI, 30 March 2010) allows customs to **control frequently**
- Controls are concentrated on **products coming from outside the EU zone**.
- More than **3500 controls in 2009**; among them, 2000 on the **SDS**
- **Many services are involved:** National Labs, Occupational inspectors, business Competition agency...
- Fine can be up to **€ 75 000**

Costs / REACH conformity

Registration cost

Low scenario
30% cases

ECHA expenses	1 200 €
Access to the studies	< 2 000 €
Elaboration of the dossier	2 000 €
Total	**< 5 000 €**

Middle scénario
60% cases
in 2013

ECHA expenses	2 000 €
Access to the studies	5 - 20 000 €
Elaboration of the dossier	3 000 €
Total	**10 000 – 25 000 €**

High scénario
10% cases

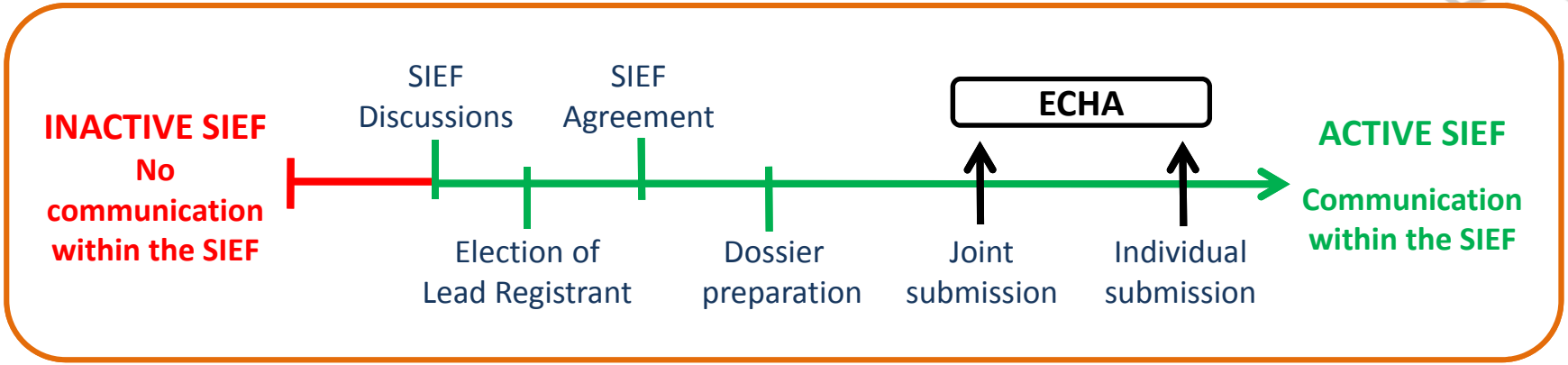
ECHA expenses	25 000 €
Access to the studies	50 000 – 200 000 €
Elaboration of the dossier	25 000 €
Total	**100 000 - 250 000 €**

Costs / REACH conformity

SDS	Regulatory fees	0 €
	Time for updating	**2 - 8 hours / SDS**
SVHC	Regulatory fees	0 €
	Time for updating	**4 hours / supplier**
CLP Notification	Regulatory fees	0 €
	Time for updating	**1 hour / substance**

You should not neglect the costs bound to the implementation of a system of follow-up and traceability.

What is the functioning of a SIEF?



- **Process:**
- **Exchange of data with other SIEF members**
- **Sameness**
- **Share of the costs**

> very complex to handle communication + sharing of data + costs

Difference between a SIEF/consortium

SIEF

Substance Information Exchange Forum

One SIEF = One susbtance

A SIEF includes all the companies that preregistered the same substance.

Purpose of the SIEF

- Exchange toxicological & ecotoxicological data
- Name a Lead Registrant
- Share the cost of testing
- Agree on the hazard classification

Mandatory participation

CONSORTIUM

Le consortium is not ruled by REACH

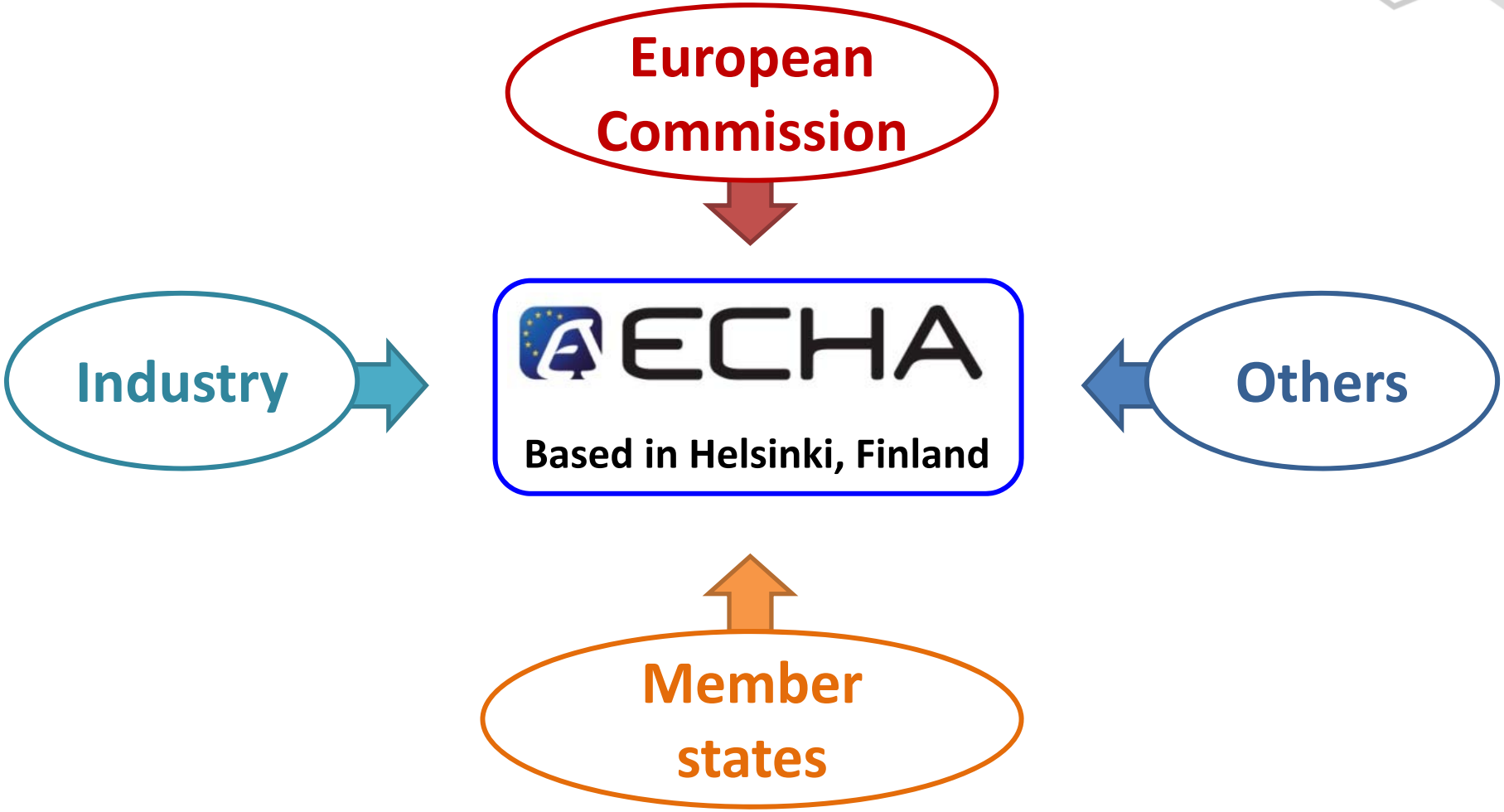
Purpose of the consortium

- Define a legal context
- Cover a family of substances
- Encourage read-across

Voluntary participation

2010 – → **2018**

Who rules REACH in Europe?



REACH Registration dossier

Technical dossier

Compulsory if produced / imported subst. > 1 t/y

Contents the argued intrinsic properties:

- physico-chemistry,
- toxicology,
- ecotoxicology.

\+

Chemical Safety Report

Compulsory if produced / imported subst. > 10 t/y

Contents

- Hazards' evaluation,
- Exposures evaluation (if dangerous),
- Risk characterization (if dangerous).

FDS is the communication tool for chemical risk management

A REACH regulation soon in the US?

- Since 1976, the Toxic Substances Control Act (TSCA) interpretation and enforcement have been fleeting >> According to US-EPA, the only sensible way to improve it is to create a registration, evaluation, and authorization process.

- The California Green Chemistry initiative has REACH-like requirements.

- State by state, regional laws are trying to regulate chemicals in products but the result makes often managing compliance a challenge… Whereas manufacturers and chemical companies want one simple set of rules to adhere to.

Key actions & solutions

3 situations: your key actions

YOU EXPORT SUBSTANCES

Appoint an OR → Plan your Registrations → Contact SIEFs → REGISTRATION

YOU EXPORT DANGEROUS SUBTANCES

Calculate classification → Verify uses → Update SDS → COMMUNICATE

YOU EXPORT ARTICLES

Assess material → Ask information to suppliers → Compare to SVHC list → COMMUNICATE

REACH conformity in 10 actions

1. **"Who am I " (according to REACH):**
    a. A substances exporter
    b. A mixtures exporter
    c. An articles exporters

2. **My compliance: what is at stake?**
    a. It’s a customer communication stake.
    b. It would affect me on my market.
    c. It’s critical for my business.

REACH conformity in 10 actions

Substance or mixture importer:

3. Calculate your tonnages
4. Check Registration deadlines
5. Calculate costs
6. Take your decision about Registration
7. As you cannot register chemicals by yourself, choose: Only Representative or a Branche in EU or an Importer based in EU

REACH conformity in 10 actions

Article importer:

3. No substance import?
4. Sorting of the portfolio
5. Evaluation of the system of collection
6. Decision to take action
7. Realization of a pilot?

REACH conformity in 10 actions

8. How to perpetuate my REACH actions?

9. Internal and external ressources?

10... Come to greet the speakers ☺

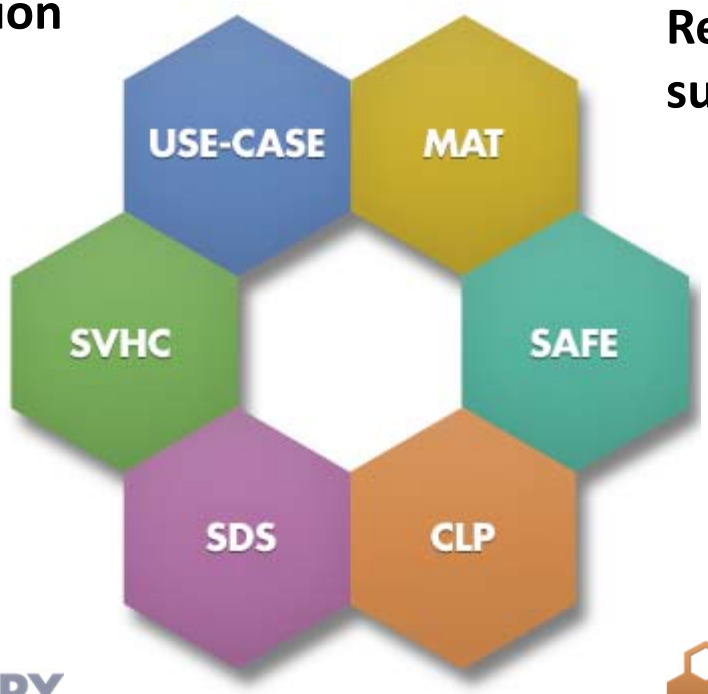
REACH Factory six web tools

USE-CASE FACTORY

Use Cases Collection

MAT FACTORY

Regulated use of substances



SVHC FACTORY

SVHC traceability & management

SAFE FACTORY

Workers' safety

SDS FACTORY

Safety Data Sheets management

CLP FACTORY

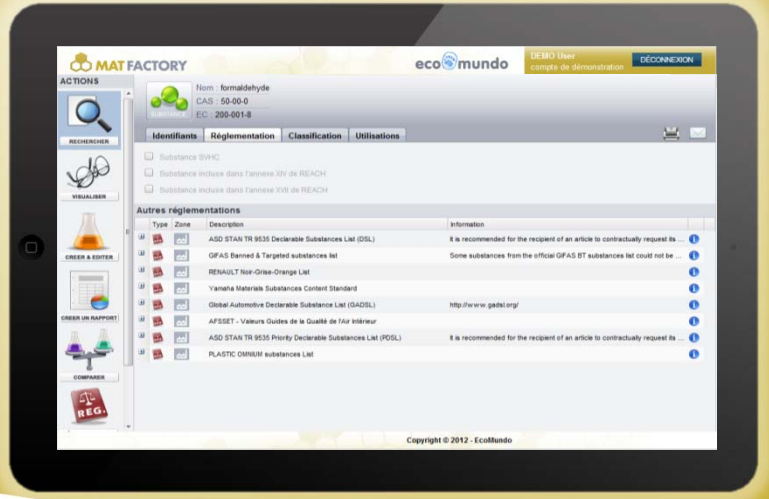
CLP (GHS) compliance

MAT FACTORY

Regulated use of susbtances

Functionalities

- Look into all **substances and materials** use cases depending on regulations, countries and industries
- Customize the database with **your own mixtures**
- Manage your own substances database and **create your alerts**
- **Compare properties** of various mixtures
- Develop your **substitution strategy**



KEY BENEFITS

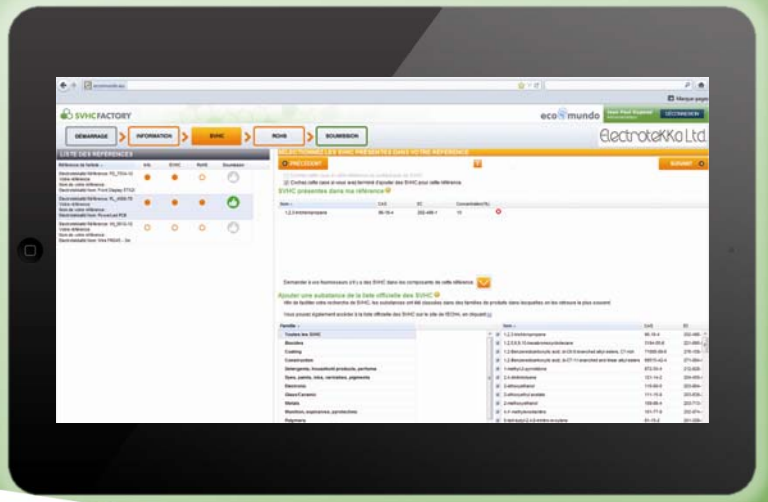
- **A database of more than 100,000 substances & materials**
- **Numerous international regulations already registered**
- **Real-time update of regulations and lists of substances**

SVHC FACTORY

SVHC traceability

Functionalities

- Access the **updated list of SVHC** substances published by ECHA
- Collect information **from all your suppliers** regarding the presence of SVHC in their articles
- Add **your own lists of substances** (blacklist, RoHS, ASD, etc.)



KEY BENEFITS

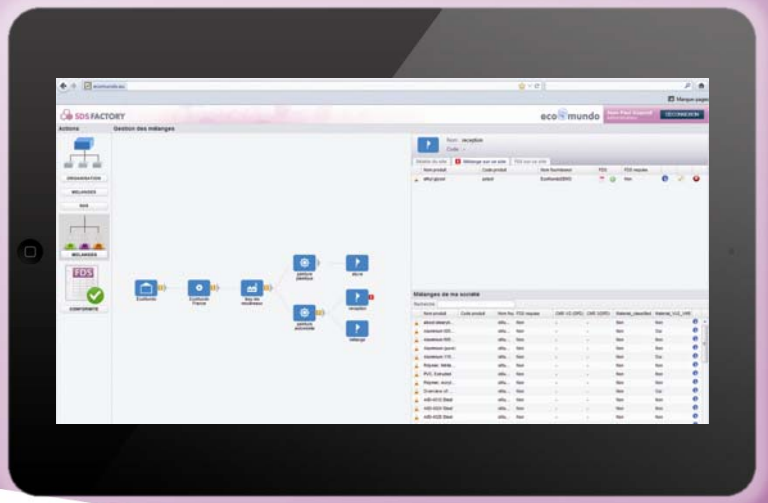
- **Real-time update of very hazardous substances**
- **Sharing of information with unlimited number of suppliers**
- **Summary document to be exported**

SDS FACTORY

Safety Data Sheets

Functionalities

- Create **your company's organisation chart**, from legal entities to individual positions
- **Store all your SDS** within one web database
- Link **SDS to mixtures** that are present on site
- Receive **automated alerts** on missing SDS
- Allow each employee to consult his SDS
- Contact **all your suppliers** and collect SDS



KEY BENEFITS

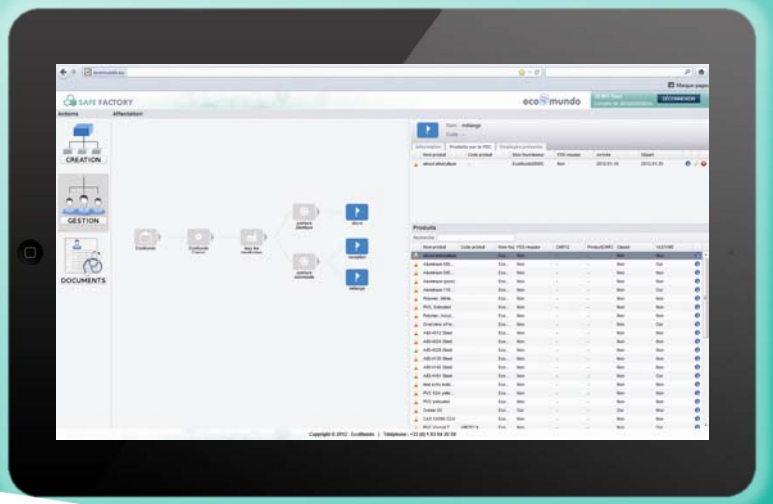
- **Control the compliance of your SDS in all your entities**
- **Save time on the management of SDS thanks to alerts**
- **Easy and quick access to data**

SAFE FACTORY

Workers' safety

Functionalities

- Create the **company's organisation chart**, from legal entities to individual positions
- Manage and track all **workers' exposure** with a unique tool
- Develop **individual exposure data sheets** with standard calculation methods
- Create **position data sheets** for the whole company



KEY BENEFITS

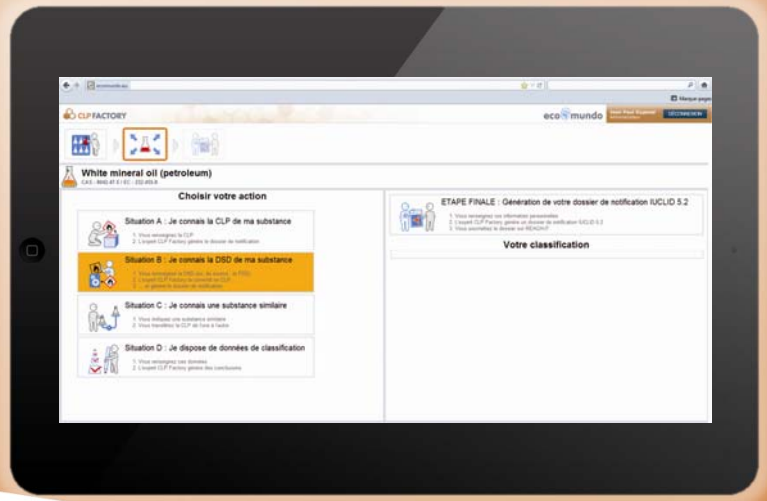
- **Adapted to all companies, from SMEs to larger international groups**
- **Overview of the group's various legal entities**
- **Import and export data easily**

CLP FACTORY

CLP (GHS) compliance

Functionalities

- Convert your substances **from DSD to CLP** classification
- Define **CLP classification** of your substances from existing data
- Generate **IUCLID notification dossier**
- **Create your own mixtures** and get the corresponding CLP classification



KEY BENEFITS

- **Rigorous conversion between old and new classification**
- **Quick creation of your labels**

USE-CASE FACTORY

Use Cases collection

Functionalities

- **Register your use cases** according to use descriptors
- Communicate your use cases **to your suppliers**
- Generate **automated requests** for your customers
- Collect your **customers' use cases**

KEY BENEFITS

- **Quick and easy communication between customers and suppliers**
- **Compliance check of use cases' description format**