



REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals
Regulation (EC) No 1907 / 2006



Table of contents

- General REACH requirements
- Pre-registration
- Registration



REACH in Brief

- REACH is a **regulatory issue**, necessary for the access to the European market. Compliance with REACH must be with a EU legal entity.
- Registration of all **substances** – as such, in preparations or articles – manufactured in or imported into EU ≥ 1 t/a per entity at the European Chemical Agency (**ECHA**).
- **Obligations** for EU-based **manufacturers, downstream users and distributors**, as well as for non-EU based manufacturers, provided they want to have access to the European market.

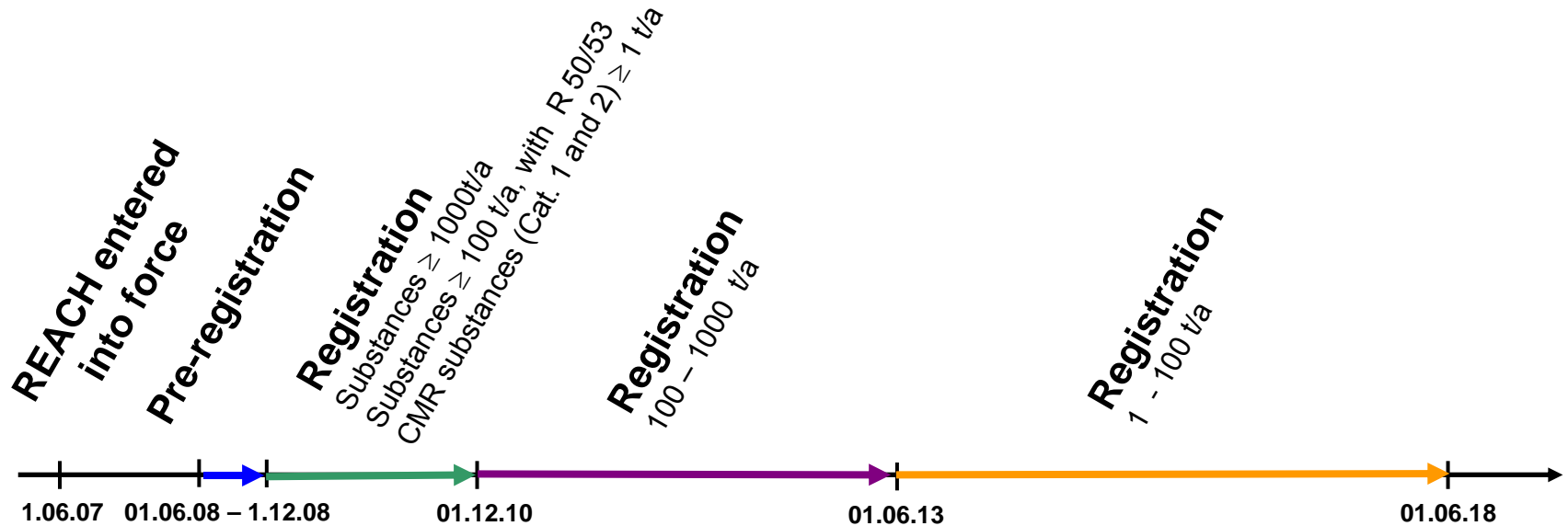


Main steps in REACH

- **Pre-registration**
- **Information** in the supply chain
 - Strategy for REACH
 - Down-up: Description of uses
 - Up-Down: MSDS
- **Registration** of manufactured/EU-imported substances \geq 1 t/a
- **Evaluation**
 - Dossier evaluation by ECHA
 - Substance evaluation by ECHA in cooperation with the Member States
- **Authorisation** of substances of very high concern



REACH Timeline



Only pre-registered substances can benefit from the transitional regime for registration



Pre-registration (1.6. – 1.12.2008)

- **Submission** to ECHA of:
 - Name of the substance (including EINECS and CAS numbers)
 - Company name and contact details (EU legal entity)
 - Tonnage band and envisaged deadline for registration
 - Relevant substances for read-across
- **How** to pre-register
 - On-line (REACH-IT)
 - IUCLID 5 – single or bulk upload
- Pre-registrants of a substance will be linked to the same **SIEF** (Substance Information Exchange Forum)



How to get prepared? (I)

EU-based organisations:

- Inventory REACH relevant substances as soon as possible
 - Name, identification codes, substance type, composition, hazardous profile, REACH roles, identified uses, tonnages, registration deadlines
- Get familiar with IUCLID 5 or REACH-IT interface
- Communication within the supply chain
 - Strategy for REACH



How to get prepared? (II)

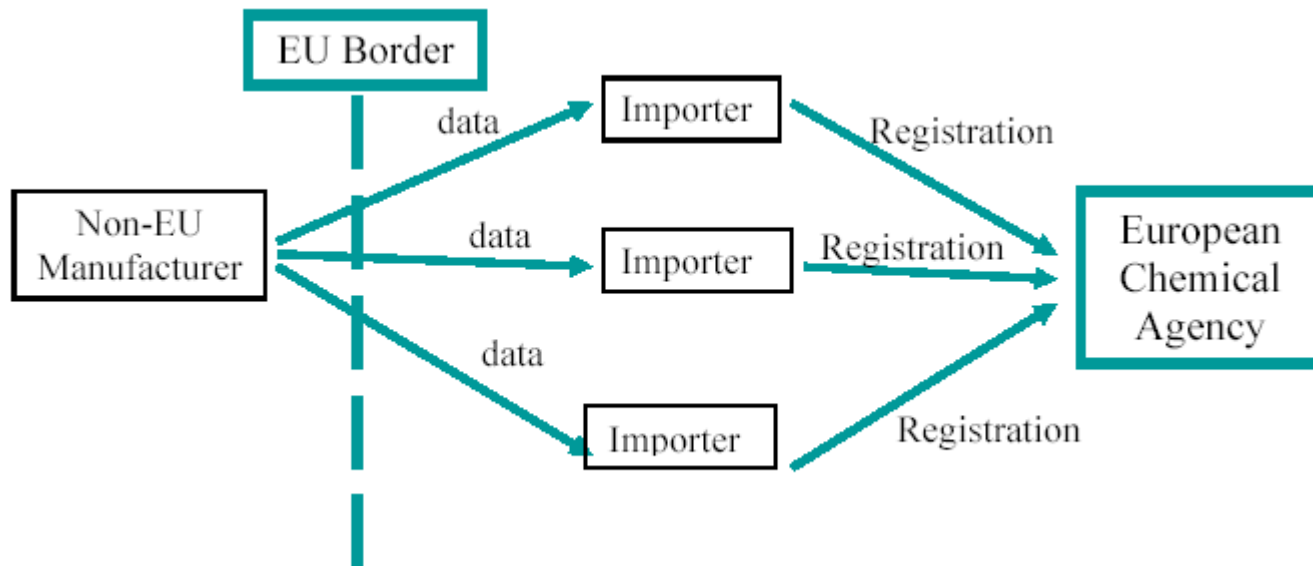
Non EU-based organisations:

- Inventory REACH relevant substances as soon as possible
- Get familiar with IUCLID 5 or REACH-IT interface
- Align your EU strategy (assuming you wish to remain in, or start business in, the EU):
 - Question your EU supply chain on their REACH plans: Who will (pre-)register substances imported from you – customer, trader, subsidiary, agent?
 - Become an European importer or appoint an only representative (OR)?
- Communication within the supply chain



EU Strategy for non EU-based organisations

You cannot pre-register and register, so who will?



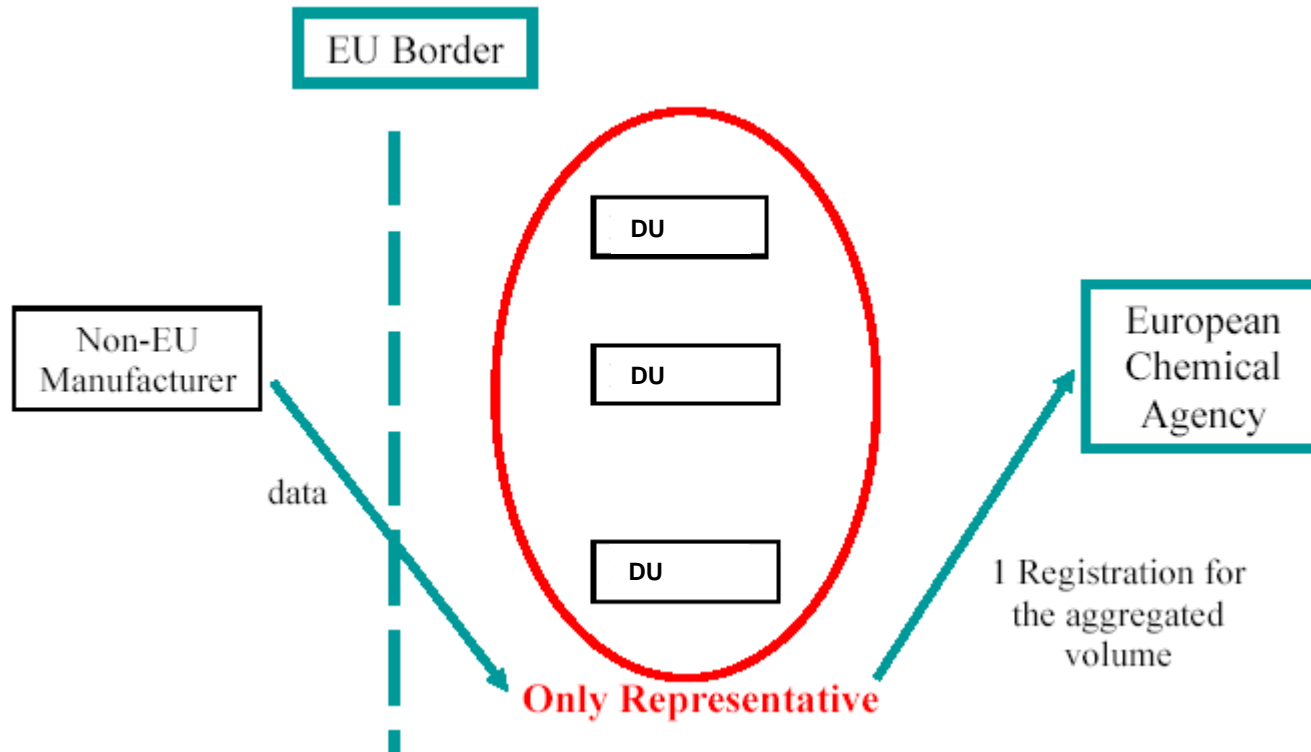
1. **Rely on** your EU customers to comply with REACH

Advantages: Low involvement in the registration process
Possible reduction of data requirements

Disadvantages: Dependency on EU customers
Disclosure of CBI



EU Strategy for non EU-based organisations



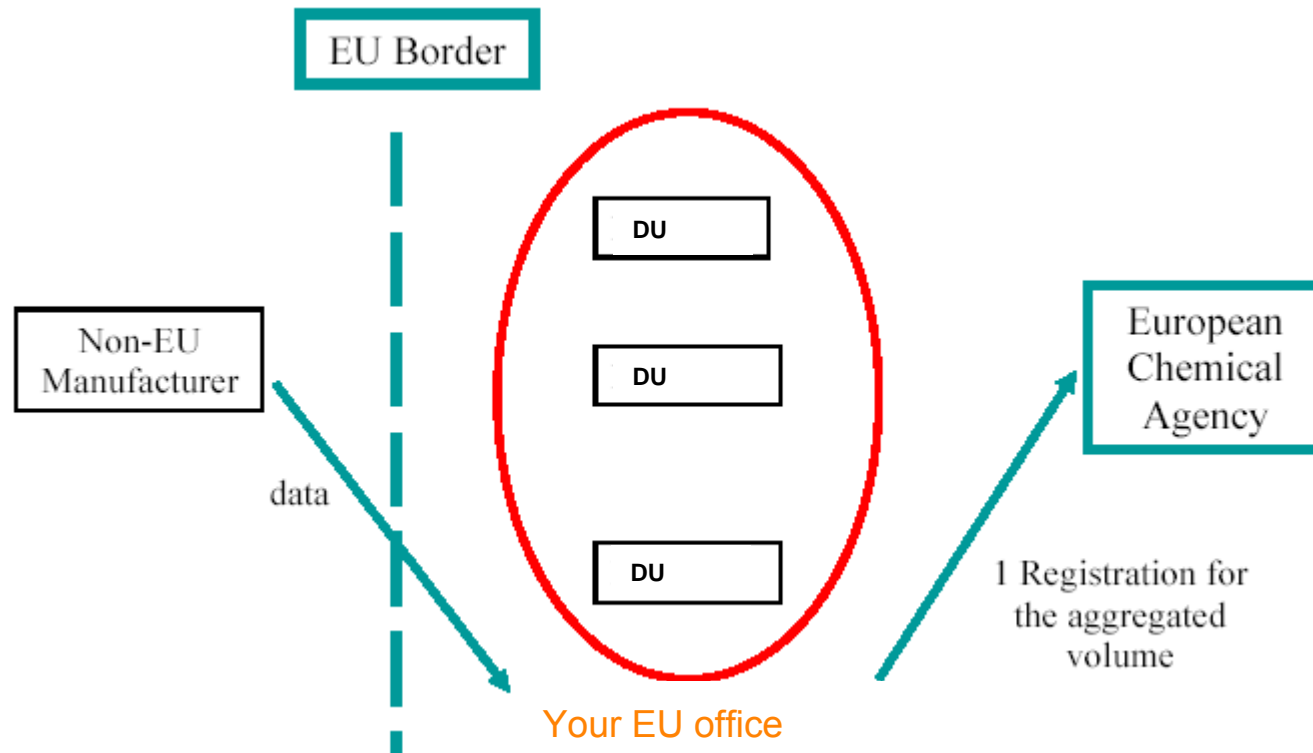
2. Appoint an **Only Representative (OR)**

Advantages: Keep control of your supply chain and CBI
Reduction of bureaucratic hurdle

Disadvantages: Dependency on your OR
Support the registration costs



EU Strategy for non EU-based organisations



3. Own EU subsidiary as your OR

Advantages: Highest control of your supply chain and CBI
Hold the registration

Disadvantages: Full responsibility for compliance
High costs (EU office & registration)



Registration

- Registration will occur in different phases **over time** for pre-registered substances
- Registration of substances ≥ 1000 t/a (deadline 1.12.2010) comprises:
 - Technical Dossier: identity of the manufacturer and substance, classification & labelling, guidance on safe use, study summaries, robust study summaries, proposals for testing
 - Chemical Safety Report: human health, physicochemical, environmental & PBT / vPvB hazard assessments. If required additionally exposure assessment and risk characterisation
- **VC** will coordinate data gathering and evaluation as well as the preparation of a joint submission of data by multiple registrants



Why join the VC?

- Share **expertise** now
- **Agreement** finalised with defined participation rules, voting rights and shared costs
- Support the pre-registration
- **Data** gathering and evaluation for registration
- Preparation of a **registration dossier** for a joint submission by multiple registrants
- **Support** SIEF discussions



Vanadium REACH Association for Research and Development

Vanadium REACH Forschungs- und Entwicklungsverein



Table of contents

- Legal Status
- VC Aims
- Structure
- Voting Rights
- Cost Sharing Model
- Substance List
- Action plan
- Budget
- Participation Rules



Legal Status

Vanadium REACH Association for Research and Development is...

- Legal entity since 7th of March 2008
- Registered office in Treibach, Austria

- Three committed members
- About thirty interested parties



Purpose of the Consortium

The Consortium will...

- Work with **Vanadium substances of interest**
- Assist with REACH obligations in a structured and managed way
- Provide **legal certainty** through the Agreement
- Share resources, expertise and costs in the most effective way
- Offer **clear** cost sharing and voting rights **structure**
- **Budget** and plan for compliance in a transparent and organised fashion
- Co-ordinate the **evaluation** of existing data and the **generation** of new data
- Support **SIEF** discussions



Purpose of the Consortium

The Consortium will not...

- **Pre-register** (only EU-based M, I, OR)
- **Register** (only EU-based M, I, OR)
- Act as an **Only Representative** to non-EU based manufacturers
- Act as the **Lead Registrant** for OSOR



Consortium Structure

- **General Assembly:** all members/Assembly Representatives
- **Steering Committee:** elected members /Assembly Representatives
- **Executive Board:** President, Vice-President, REACH Manager
- **Technical Committee(s):** will be task specific
- **Trustee, Accountants**



Voting Rights (per interested member)

	Group 1	Group 2	Group 3	Group 4
REACH Tonnage band [mt/a]	1 – 9	10 - 99	100 - 999	>1000
Votes / Member	0,5	1	2	4



Cost Sharing Model (per interested member and substance)

Example:

Data cost per substance: € 2.000.000

	Group 1	Group 2	Group 3	Group 4
Tonnage band	1 - 9	10 - 99	100 - 999	>1000
Contribution	€40.000 fixed	25%	50%	100%
Members	1	2	2	2
Fee per Member	€ 40,000	€ 140,000	€ 280,000	€560,000



Substance list

Name	Formula	EINECS	CAS
Vanadium (including ferrovandium and other alloys)	V	231-171-1	7440-62-2
Divandium pentaoxide	V ₂ O ₅	215-239-8	1314-62-1
Divandium trioxide	V ₂ O ₃	215-230-9	1314-34-7
Divandium tetraoxide	V ₂ O ₄	-	12036-73-6
Vanadyl sulfate (Vanadium oxide sulphate)	VO(SO ₄)	248-652-7	27774-13-6
Ammonium trioxovanadate (Ammonium metavanadate)	NH ₄ VO ₃	232-261-3	7803-55-6
Ammonium trivanandium octaoxide (Ammonium polyvanadate)	NH ₄ V ₃ O ₈	235-384-0	12207-63-5
Vanadium trichloride oxide	VOCl ₃	231-780-2	7727-18-6
Vanadium tetrachloride	VCl ₄	231-561-1	7632-51-1
Steel plant slag		273-734-4	69012-34-6

Further relevant Substances?



Action plan

- Pre-registration
- Inventory
 - Status under REACH (M/I/DU, intermediate, etc)
 - Data needs for each status
- Available data (global search and V consortium resources, Vanitec etc)
- Ongoing evaluation (Klimisch) of all data to be used
- Identification of major data gaps for each substance
- Develop most cost effective strategy to fill data gaps (grouping, read across,..)

- Identified uses within the EU and need for exposure scenarios
- Implement agreed data strategy
- Provide data for registration dossiers, on time



Costs 2007

- Generic costs € 135.000
 - Administration
 - Travel
 - Legal support
 - Marketing

 - Development of the Consortium Agreement
 - Website
 - Communication/Information issues



Budget 2008

- Generic costs € 180.000
 - Administration
 - Travel
 - Legal support
 - Marketing
- Data cost estimation € 350.000
 - Inventory
 - Data evaluation
 - Data gap analysis
 - Strategy development



Participation rules

Any new member shall pay:

- Their share of the Costs already incurred
- Deadline for admission exempt from penalty → 01.05.08
- A **compensation** for late admittance shall be equal to **2%** of its contribution **due for each month** from the month of entry into effect of the Association to the month of admittance.



Participation rules

- Signing of the Agreement
available at the website
www.vanadiumconsortium.com
- Submission
Vanadium REACH Association
Auer von Welsbach Strasse 1
9330 Althofen
Austria