



IMnI REACH Workshop

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What REACH requires your company to do

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Focus & structure of presentation

Focus: what you need to do for **pre-registration** and **registration** of Mn-containing substances that you manufacture in, or import into, the EU (or export to the EU)

Structure:

- **Purpose of REACH and of registration**
- REACH time line
- Preliminary phase
- Pre-registration
- SIEF and consortium
- Registration
- Tools available to help you

Purpose of REACH

The purpose of REACH is to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market, while enhancing the competitiveness of, and innovation within, EU industry.

Purpose of registration

- Only **registered substances** will be allowed to circulate on the internal market

NO DATA, NO MARKET

- Registration requires that manufacturers & importers of substances, as such and in mixtures (preparations) and articles, **collate existing data and/or generate new data** on these substances; use these data to **assess the risks** related to the use of the substances and **develop and recommend appropriate risk management measures**
- To ensure that they actually meet these obligations, registration requires manufacturers & importers to **submit a dossier** containing this information to the Agency

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REACH timeline

- REACH entered into force on **1 June 2007**

- Pre-registration: between 1 & 1.5 years after entry into force (eif) **i.e. between 1 June 2008 and 30 November 2008**

- Registration no later than 3.5 years after eif **i.e. by 1 December 2010** for
 - Substances \geq 1000 tonnes per annum (tpa)
 - Substances \geq 1 tpa that are CMR Category 1 & 2
 - Substances \geq 100 tpa that are R50/53

- Registration no later than 6 years after eif **i.e. by 1 June 2013** for
 - Substances \geq 100 tpa

- Registration no later than 11 years after eif **i.e. by 1 June 2018** for
 - Substances \geq 1 tpa

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Preliminary phase – what you need to do

- **Develop a company strategy to**
 - **ensure that all the right people understand REACH sufficiently**
 - **audit your company product portfolio to identify the impact of REACH on your company**
 - **develop an action plan with timing (related to tonnages for your substances)**
 - **start preparing the necessary supply chain communications (up and down)**
 - **consider the pros and cons of joining the Mn REACH Consortium**

Preliminary phase – what you need to do

➤ product portfolio

- identify all Mn-containing substances, mixtures/preparations (includes alloys) and articles that you manufacture in, or import into, the EU
- confirm the phase-in (“existing substance”) status of your substances and their tonnage bands
- identify the required substance-specific information (e.g. name/identity, formula, purity, impurities, uses....)
- **determine the tonnage-related data requirements, and possible exemptions and waivers, applicable to each substance**
- determine what relevant information and data you may already have available (e.g. (eco)toxicity studies, classification and labeling, Safety Data Sheets, exposure information....)
- **conduct literature searches to determine data gaps that need to be filled with newly generated data**

Structure of presentation

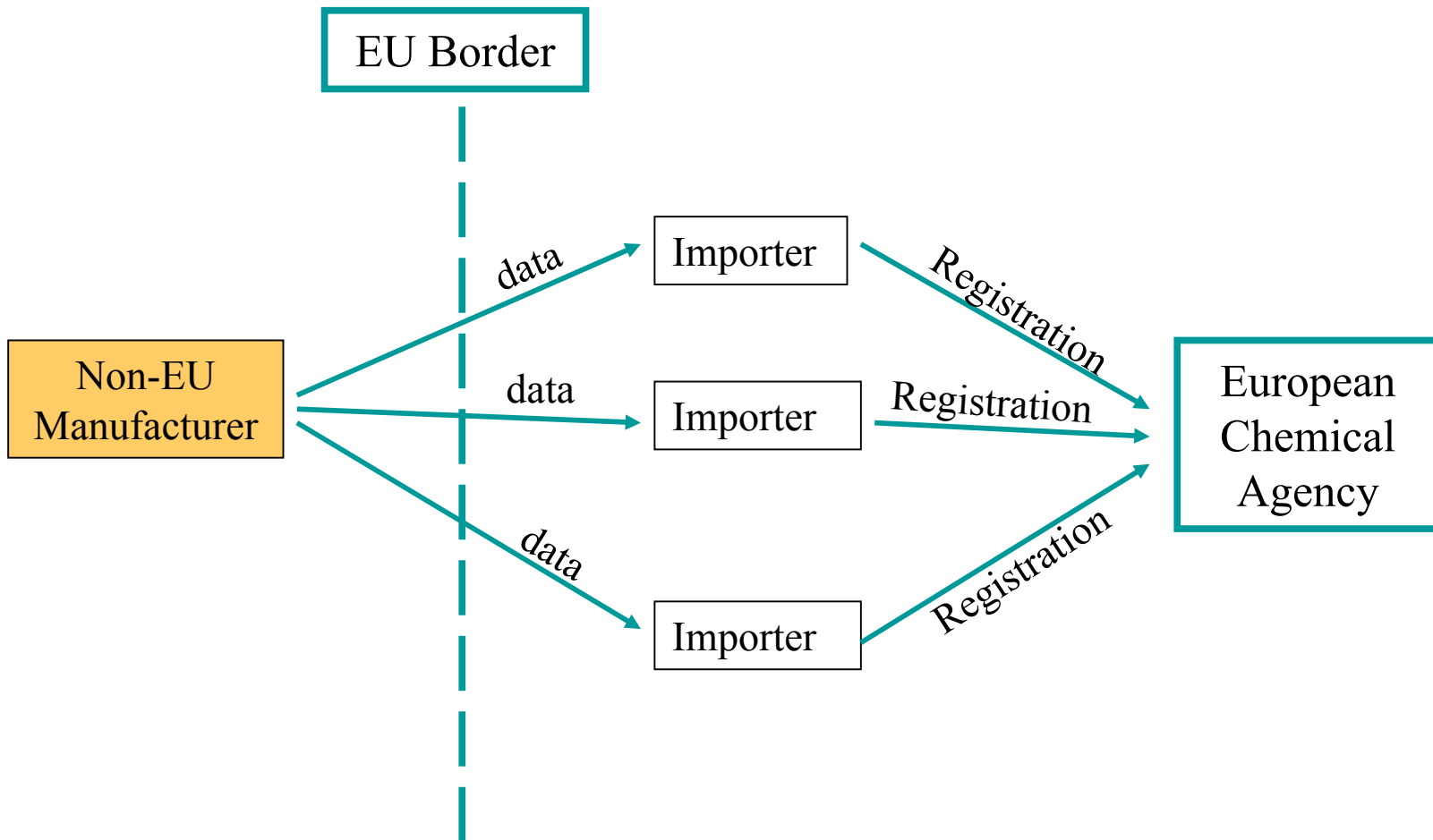
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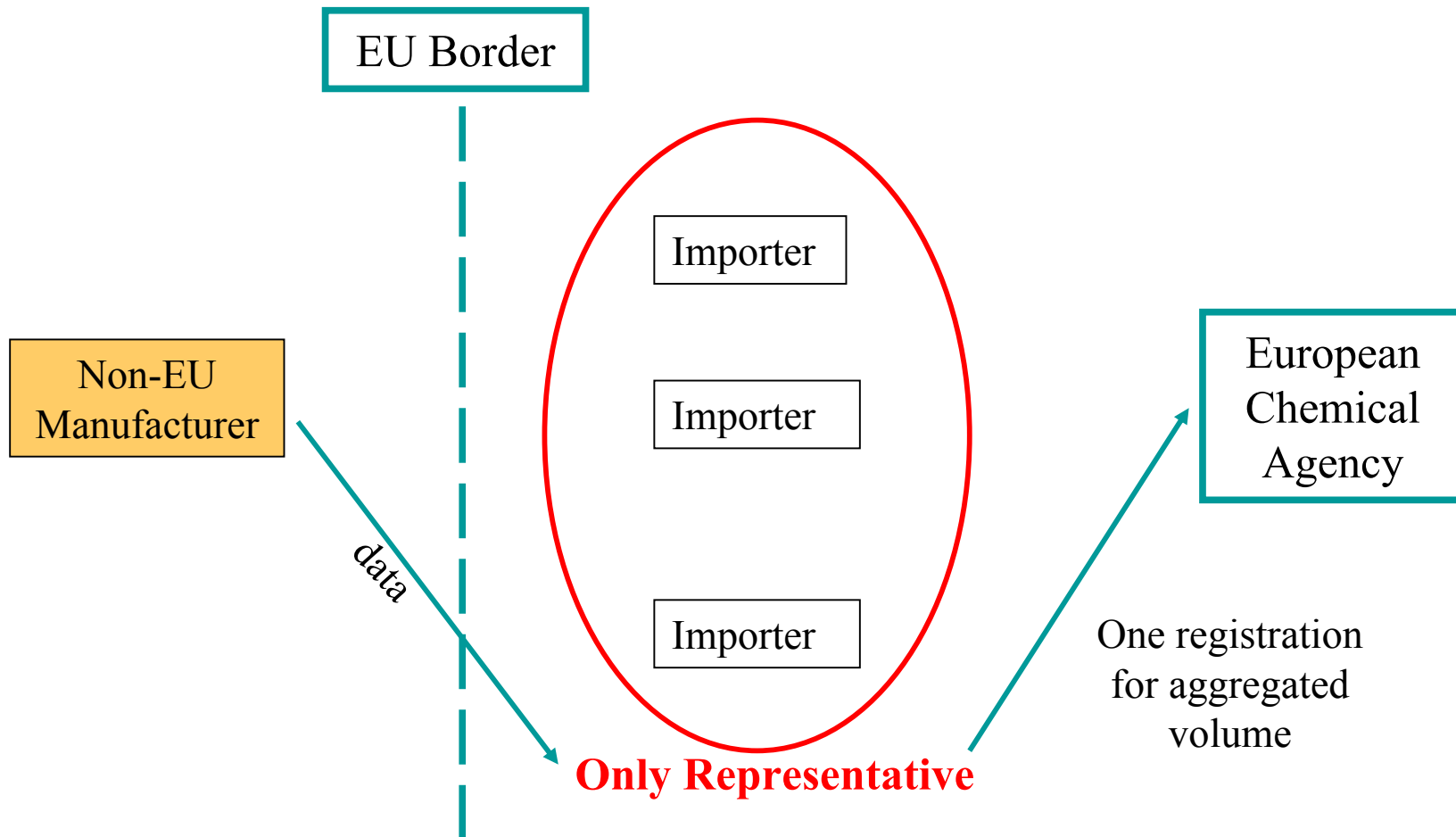
Pre-registration – what you need to do

- Very important step as only pre-registered substances **benefit from the phase-in provisions** (i.e. they can continue to be made/imported/used until their registration deadline is reached)
- Data to be submitted:
 - substance name etc, details of potential registrant, tonnage band and deadline for registration
 - **name(s) of substance(s) relevant for application of (Q)SARs and grouping/read-across approaches, if applicable**
- Non-EU manufacturers may appoint an “Only Representative” who must have a “sufficient background in the practical handling of substances”

Without Only Representative



With Only Representative



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SIEF & Consortium

- **Obligation** for Substance Information Exchange Fora (SIEF) laid down in REACH
 - SIEF members are subject to defined regulatory requirements

- **Consortium formation** is voluntary and results from law of contract
 - Relationships between members of such a consortium are subject to contractual freedom

SIEF – obligation to belong; data sharing

- All those who pre-register a particular substance will be put together in a **single SIEF** – a “virtual” room for all potential registrants of the **same substance**
- There is no exemption from this obligation
- REACH requires SIEF members to collaborate on:
 - sharing existing vertebrate animal studies (cost sharing principles to be agreed or equal shares will be imposed)
 - agreeing on further such studies
 - agreeing on classification and labeling
- SIEF members are free to collaborate on further aspects of the registration (e.g. sharing of other existing data)

SIEF – obligation to submit joint registration

- SIEF members must normally submit jointly the core data on the substance (classification, results of studies, etc.) via a “Lead Registrant”
- It is possible to opt out from joint registration if one or more of 3 conditions are met
 - disproportionate cost of submitting jointly
 - joint submission puts confidential data at risk
 - disagreement on the selection of data to be submitted jointly
- **However**
 - separate submission does not affect the obligation to share vertebrate animal studies
 - separate submission may give priority to the file in the Evaluation work plan of the Agency and can thus bring unwelcome attention to a substance for which there is some level of controversy

SIEF v consortium

- SIEF members must meet the above regulatory obligations

- However, REACH provides
 - no indication as to how SIEF participants shall meet their obligations to share vertebrate animal data
 - only default obligations in the absence of agreement on sharing vertebrate animal data

- SIEF participants are free to define the conditions of data sharing

- Different possible methods
 - bilateral relations between the SIEF members
 - one consortium for all the relevant SIEF members
 - several consortia
 - **one consortium for several related substances** (REACH encourages grouping, read-across)

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Registration: who does what?

- One member of the SIEF (Lead Registrant) submits on behalf of the others
 - core data (phys-chem, envtl fate, ecotoxicity, toxicity)
 - classification and labeling
 - proposals for additional testing

- Can also (but need not) submit jointly
 - Chemical Safety Report
 - guidance on safe use

- Each manufacturer or importer must also register company-specific information before the deadline corresponding to its tonnage band

Registration: further specification

- **Registration requires submission to the Agency of**
 - **a technical dossier**
 - **a Chemical Safety Report (for substances ≥ 10 tpa) – which includes documentation of the Chemical Safety Assessment**

Registration: further specification

➤ **Technical dossier (REACH Art. 10; Annex I)**

- **identity of manufacturer(s) or importer(s)**
- **substance identity**
- **information on manufacture and use(s) of the substance**
- **classification & labeling**
- **guidance on safe use**
- **summary of all tests and studies submitted**
- **indication of any peer-review of the data**
- **statement if information generated by testing in vertebrates**
- **proposal for any supplementary testing**
- **request for information not to be made publicly available, if needed**

Registration: further specification

- **Chemical Safety Assessment, CSA (REACH Art. 14; Annex I)**
 - based on information included in the Technical Dossier
 - for substances ≥ 10 tpa, a CSA shall be conducted either on each registered substance on its own or in a preparation or in an article or on a group of substances; it includes
 - physicochemical hazard assessment
 - human health hazard assessment
 - environmental hazard assessment
 - PBT and vPvB assessment
 - if as a result of carrying out the above steps, the registrant concludes that the substance meets the criteria for classification, also
 - exposure assessment and exposure estimation
 - risk characterisation

Registration: further specification

- **Chemical Safety Report, CSR (REACH Art. 14; Annex I)**

- **For substances ≥ 10 tpa, a CSR shall be completed; it is a risk assessment and risk management summary that must include in addition to the components listed above**
 - a summary of risk management measures (RMM)
 - declarations that RMM are both implemented and communicated
 - Safety Data Sheet (including **Exposure Scenarios**)

Registration: exposure assessment

- For substances classified as “dangerous”, exposure of humans and/or the environment will need to be assessed

- Humans:
 - workers (inhalation, dermal, oral)
 - consumers
 - “indirect”
 - total

- Environment
 - local and regional
 - water (freshwater, marine)
 - soil
 - sediment
 - air

Registration: exposure scenario

- Means the set of conditions, including **operational conditions and risk management measures**, that describe how the substance is manufactured or used **during its life-cycle** and how the manufacturer or importer controls, or recommends **downstream users** to control, exposures of humans and the environment
- These exposure scenarios may cover one specific process or use or several processes or uses, as appropriate

Registration: exposure scenario

- Exposure scenarios are the core of the process to carry out a chemical safety assessment
- **The chemical safety assessment process may be iterative**
- The first assessment will be based on the required minimum and all available hazard information and on the exposure estimation related to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario)
- If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control. The refinement of hazard assessment may require generation of additional hazard information.

Registration: exposure scenario

- The final exposure scenario has to be presented under the relevant heading of the chemical safety report, and included in an Annex to the Safety Data Sheet, using an appropriate short title giving a brief general description of the use
- Exposure scenarios shall cover any manufacture in the Community and all **identified uses**

Registration: data needs

$$\text{Hazard} \times \text{Exposure} = \text{Risk}$$

- Data needs
 - **hazard** (effects: toxicity & ecotoxicity)
 - **exposure** (human and environment)

- **Risk assessment**: is exposure lower than the lowest effect level?
 - human: DNEL > exposure
 - environment: PEC < PNEC

DNEL = Derived No Effect Level

PNEC = Predicted No Effect Concentration

PEC = Predicted Environmental Concentration

Registration: data needs

Requirements for provision/generation of information on substances should be tiered according to the volumes of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substances

Registration: data needs

Tonnage band	≥1-10	≥10-100	≥100-1000	≥1000
Data: REACH Annex	VII	VII & VIII	VII, VIII & IX	VII, VIII, IX & X
Physico-chemical	✓	-	✓	-
Toxicological	✓ ¹	✓ ¹	✓ ²	✓ ²
Ecotoxicological	✓	✓ ¹	✓ ²	✓ ²
Time after entry into force (1 June 2007)	11y	11y	6y	3.5y

¹ Includes a requirement for some data that, if not already available, or subject to waiving, must be obtained via testing in vertebrate animals

² At the level of Annexes IX and X, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of these Annexes (REACH Article 12)

Registration data needs: what does this mean for Mn?

- You will not need to do all tests on all substances
- For most commodity metals and their main compounds there will be published reports on some aspects of both hazard & exposure assessment; some of the available toxicity data may be from studies in humans
- Producer/user companies may have data in-house
- These data need to be collated, assessed regarding their quality and relevance and data gaps identified for further studies ---- but
- Not necessarily per substance but per “Mn-substances group” (REACH - **and the Mn Consortium multi-substance approach** - encourages grouping and a read-across/category approach, which industry needs to use carefully and with scientific/technical justification)

Registration data needs: what does this mean for Mn?

- In addition, column 2 of the tables in Annexes VII to X lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way
- And Annex XI sets out general rules for adaptation of the standard testing regime set out in Annexes VII to X (includes data already available, grouping of substances/read-across etc., and also “weight of evidence”; data from QSAR, “suitable” *in vitro* methods; omission of testing based on exposure scenarios)
- In all cases of deviation from the standard regime, adequate justification and documentation must be provided
- Basic rule: **intelligent testing**

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Registration: tools available to help

➤ A daunting task.....but help is available

- REACH text, including recitals and Annexes
- REACH implementation projects (RIPs) that will form the Technical Guidance Document for implementation of REACH
- MERAG and HERAG (Metals Environmental/Health Risk Assessment Guidance)
- Guidance on assessment of substances in alloys and other “special preparations”
- European Chemicals Bureau and European Chemicals Agency (ECHA) REACH web sites (include all RIP texts, flow diagrams, useful links, FAQ...)
- Help-desks (Member States, industry associations, ECHA)
- Experts, consultants etc
- **AND.....**



Registration: tools available to help

- The Mn REACH Consortium
- Master Services Agreement with SafePharm Laboratories

THANK YOU