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First steps to REACH compliance

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Contents

- Introduction
- REACH steps
 - Pre-registration
 - Substance Identification
 - Pre-SIEF
 - SIEF/Consortium
- Only Representative
- How to prepare
- Conclusions



REACH

Registration, Evaluation and Authorisation of Chemicals

The purpose of this **Regulation** 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 competitiveness and innovation (article 1)

REACH Substances

- Non-phase-in (New Substances)
 - Transition period until June 2008
- Phase-in (Existing Substances)
 - Registration deadlines depending on tonnage

**Dossier requirements are similar
for both phase-in and
non-phase-in substances**

REACH Implementation Timeline

1 June 2007:

I – Scope, definitions

IV – Information in supply chain

IX – Fees and Charges

X – European Chemicals Agency

XIII – Competent Authorities

XIV – Enforcement

XV – Transitional arrangements

1 June 2008:

II – Registration

III – Sharing of Data

V – Obligations of Downstream Users

VI – Evaluation

VII – Authorisation

XI – Classification and Labelling Inv.

XII – Information

1 June 2009: VIII - Restrictions

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REACH Steps

- Pre-registration
- SIEF (Consortium)
- Joint submission of non-confidential data
- Classification & Labelling
- Registration dossiers (phase in deadlines)
- CSR/Exposure Scenarios
- Authorization

Pre-registration dossier

- the name of the substance
- name and address and the name of the contact person
- the envisaged deadline for the registration and the tonnage band
- Information on possible structural analogues
- Optional: click box willingness SIEF facilitator



Pre-registration: How to submit?

Substance by substance:

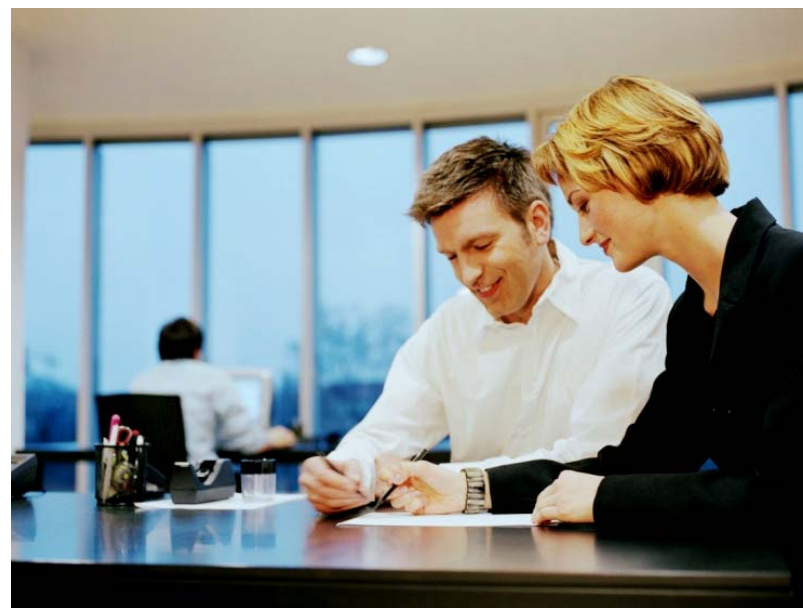
On-line (manual) input of data via a web-based interface

List/batch of substances (only possible when EINECS listed):

- (1) Excel or Access file → XML (compliant with a standard format which will be published in next time)
- (2) IUCLID5 add-on is planned which will enable extraction of pre-registration data in XML format

Substance identity

- Pre-registration does not include information on the composition of the substance
- Potential Registrants who pre-registered their substance under the same identity code need to establish **whether their substances are the same**

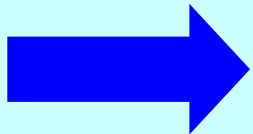


SIEF Formation

- Pre-SIEF agreement on substance identity
- Agency will publish list of pre-registered substances by **1 Jan 2009**:
- Data holder may apply to become SIEF member (shall share data, but must not request data)
- DU who does not find his substance on the published list?

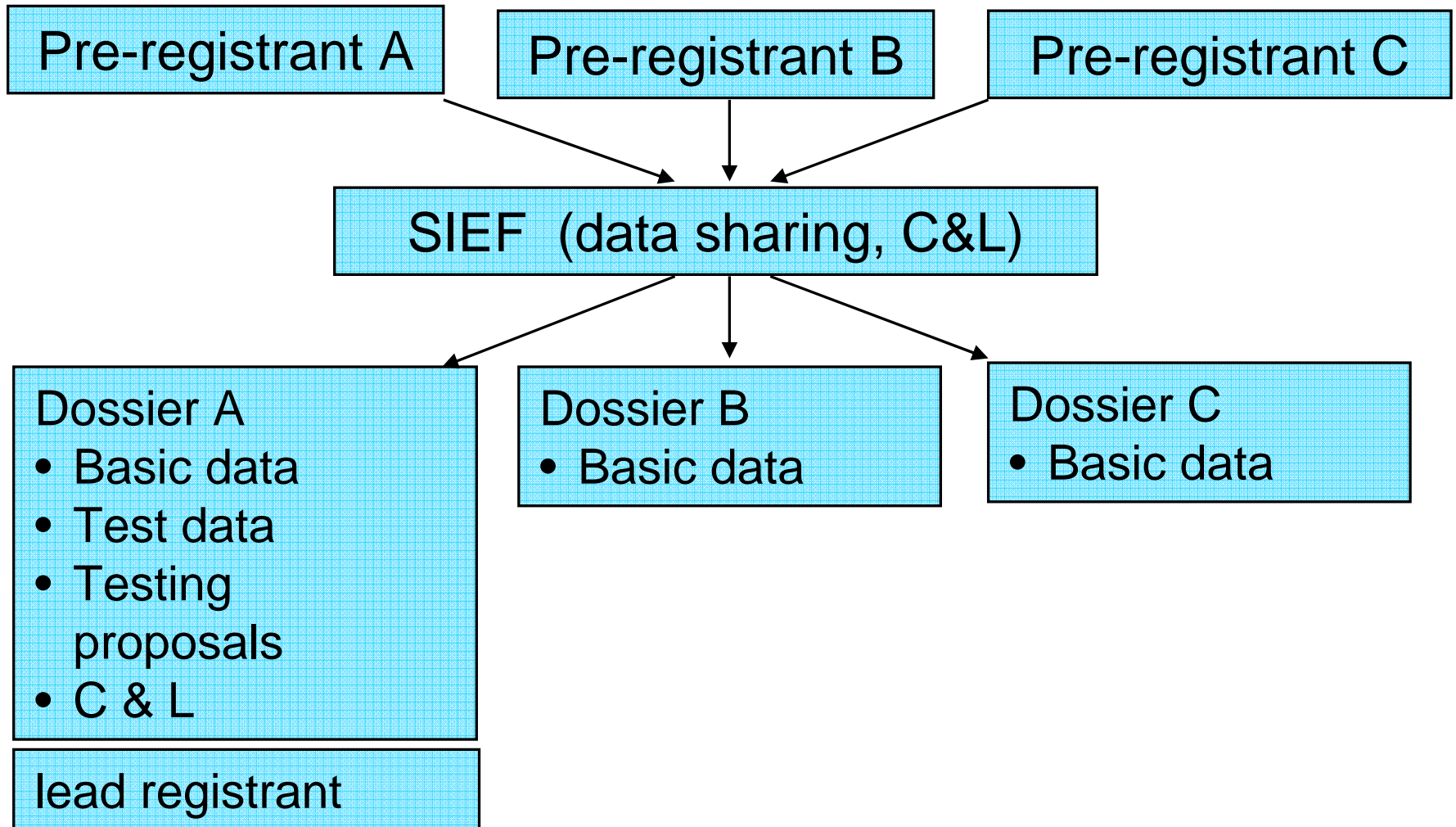
SIEF tasks

- Exchange of information in order to prevent unnecessary (vertebrate) testing
- Mandatory sharing of animal data
- Agreement on classification & labelling



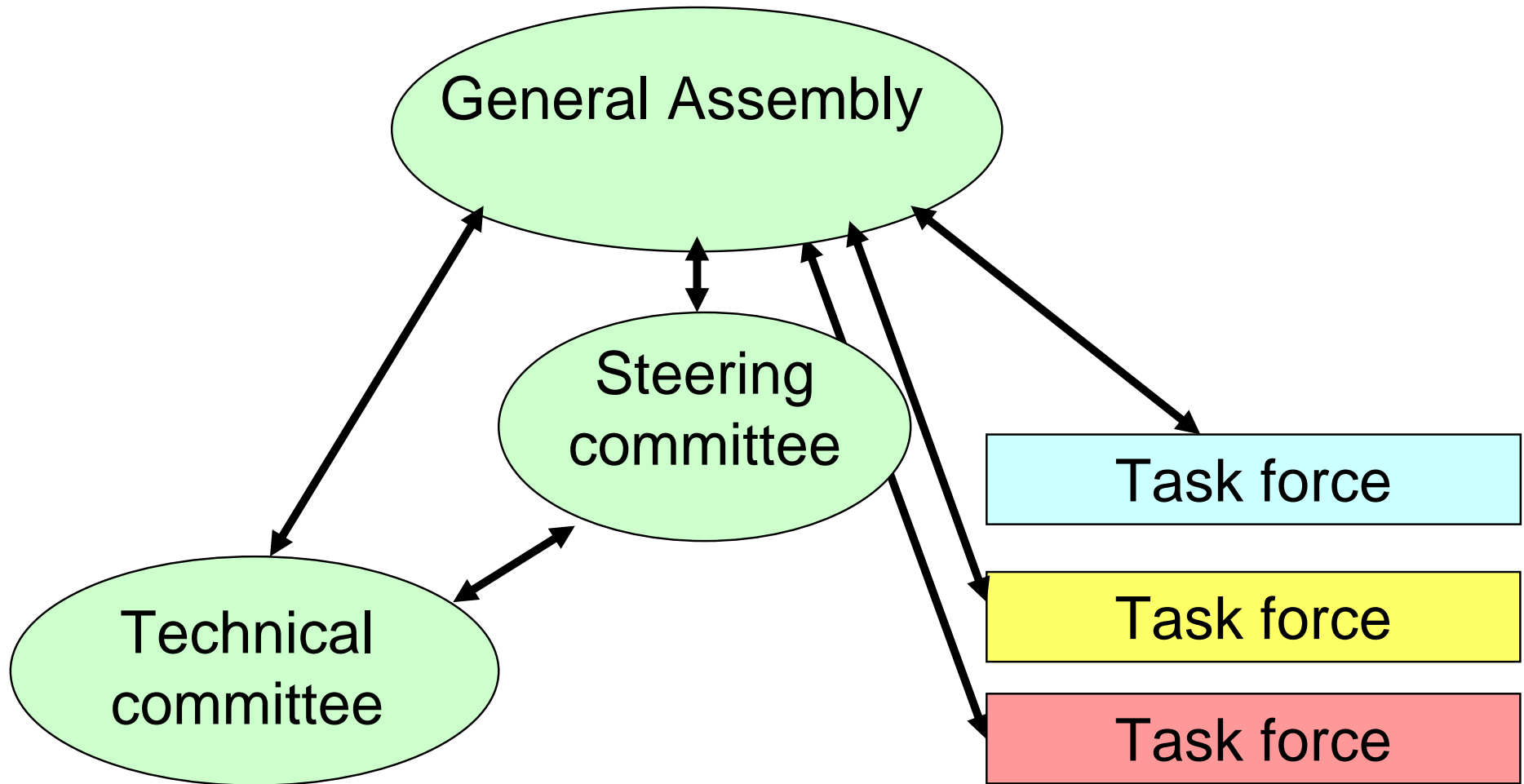
A SIEF is not a consortium

Joint submission of data



Slide H. Grosenick

Consortium



Consortium refers to an organized and formal type of co-operation between parties (signed agreement, working structure, operating rules)

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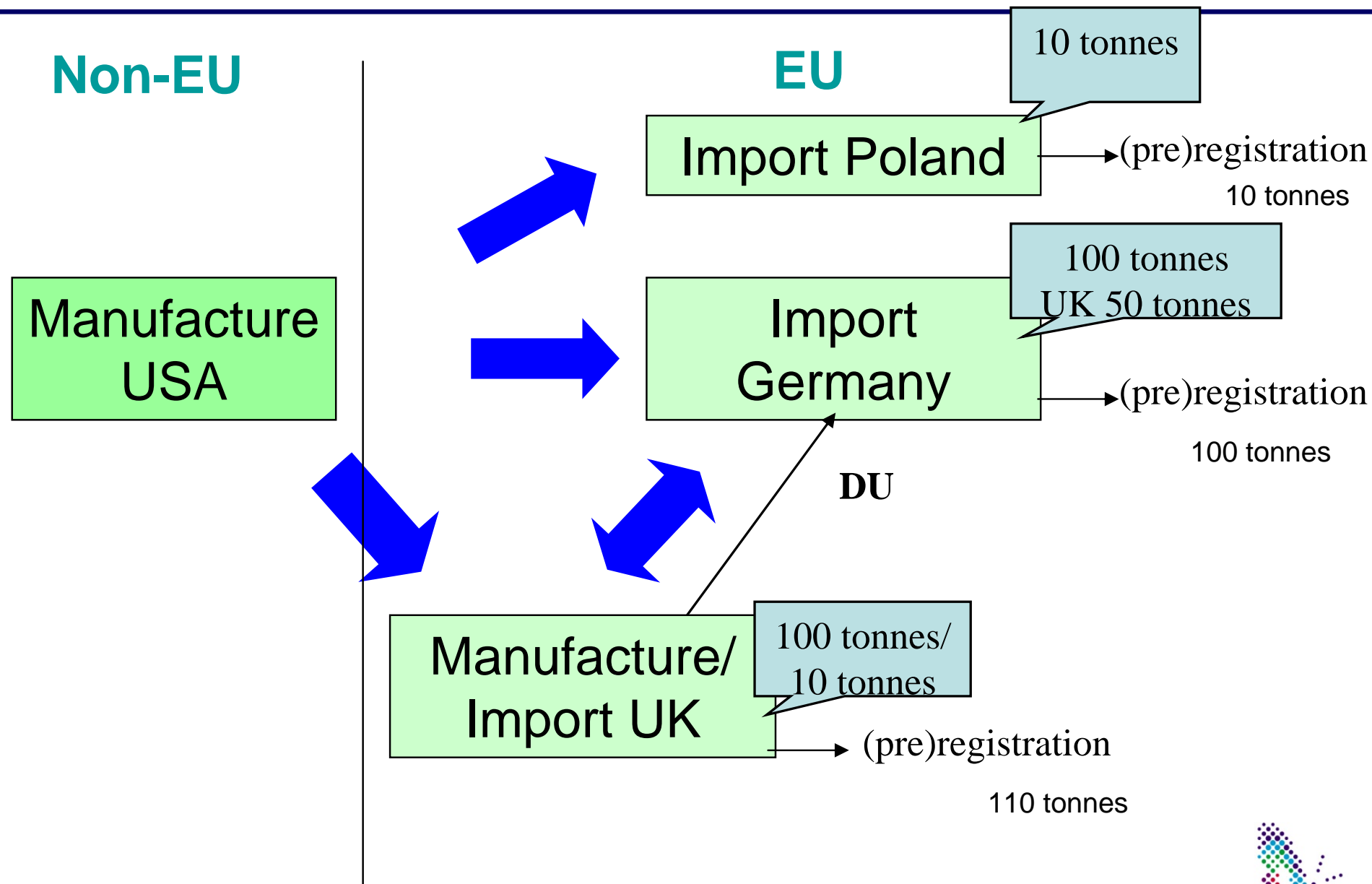
Non-EU manufacturers

- **Does REACH reach you?**
 - Are my products subject to REACH? No
 - What are my obligations? No
- **Does REACH affect you?**
 - Do I need to pre-register? No
 - Do I need to prepare a partial/full registration? No
 - Do I need to prepare a chemical safety report? No
- **Does REACH influence your business?**
 - Will I still be able to market my products in Europe? No Yes
- **Who will be affected?**
 - EU chemical manufacturers Yes
 - Importers of substances, preparations and articles Yes
 - Downstream Users Yes

Legal context

- Import: means the physical introduction into the customs territory of the Community
- Importer: means any natural or legal person established within the Community who is responsible for import.
- Supplier of a substance or a preparation: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;
- Distributor: means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties (a distributor is not a downstream user).

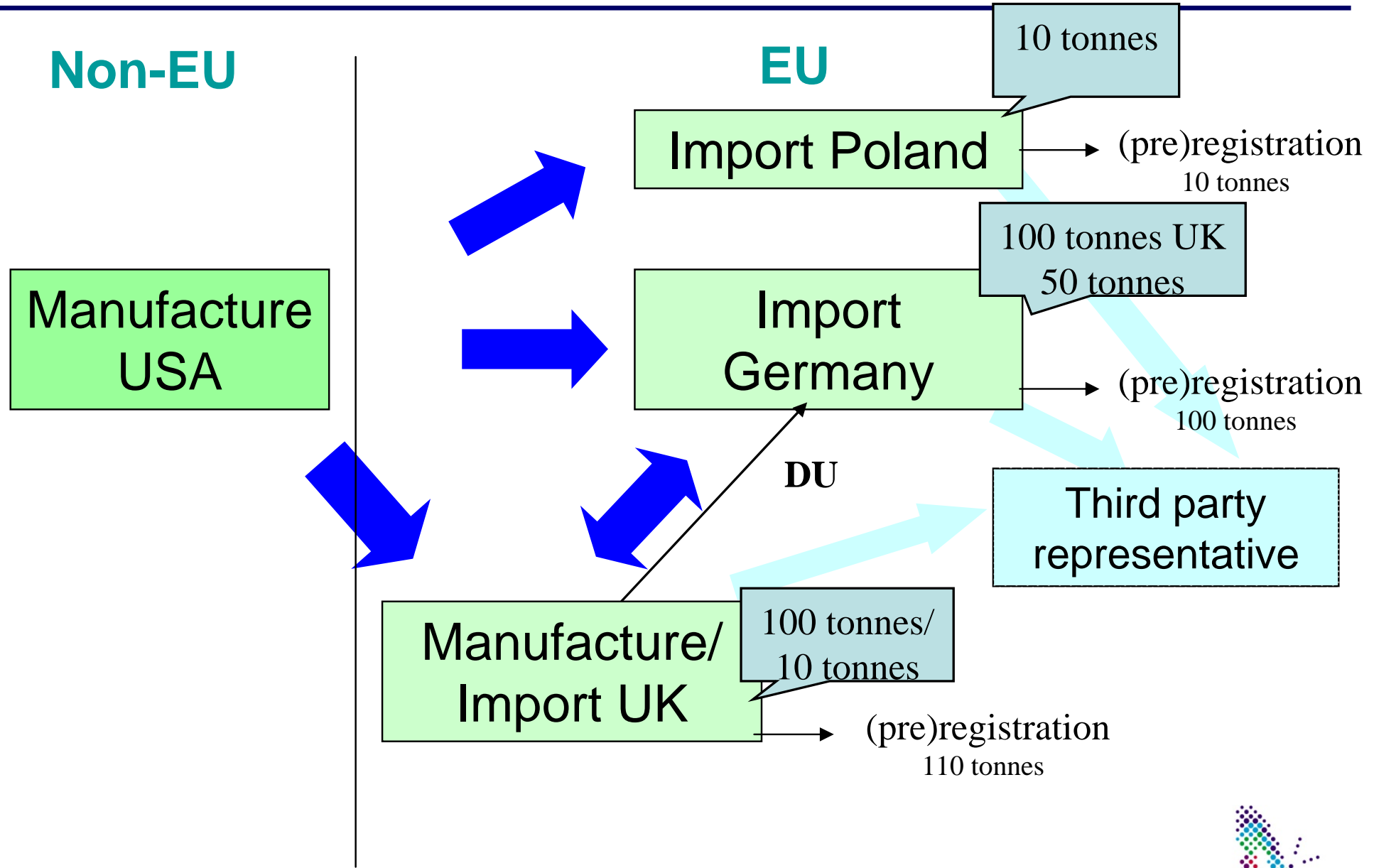
Import of substances (standard)



Strategy

- Responsibility with importers
 - Importers will decide on data-sharing/cost sharing
 - Lower fees/testing costs
 - Limited knowledge
- Large number of registrations (dilution)
- Registrations not related to US producer
 - Importer might have different suppliers
 - Dependence on clients
- US producer not in driver's seat

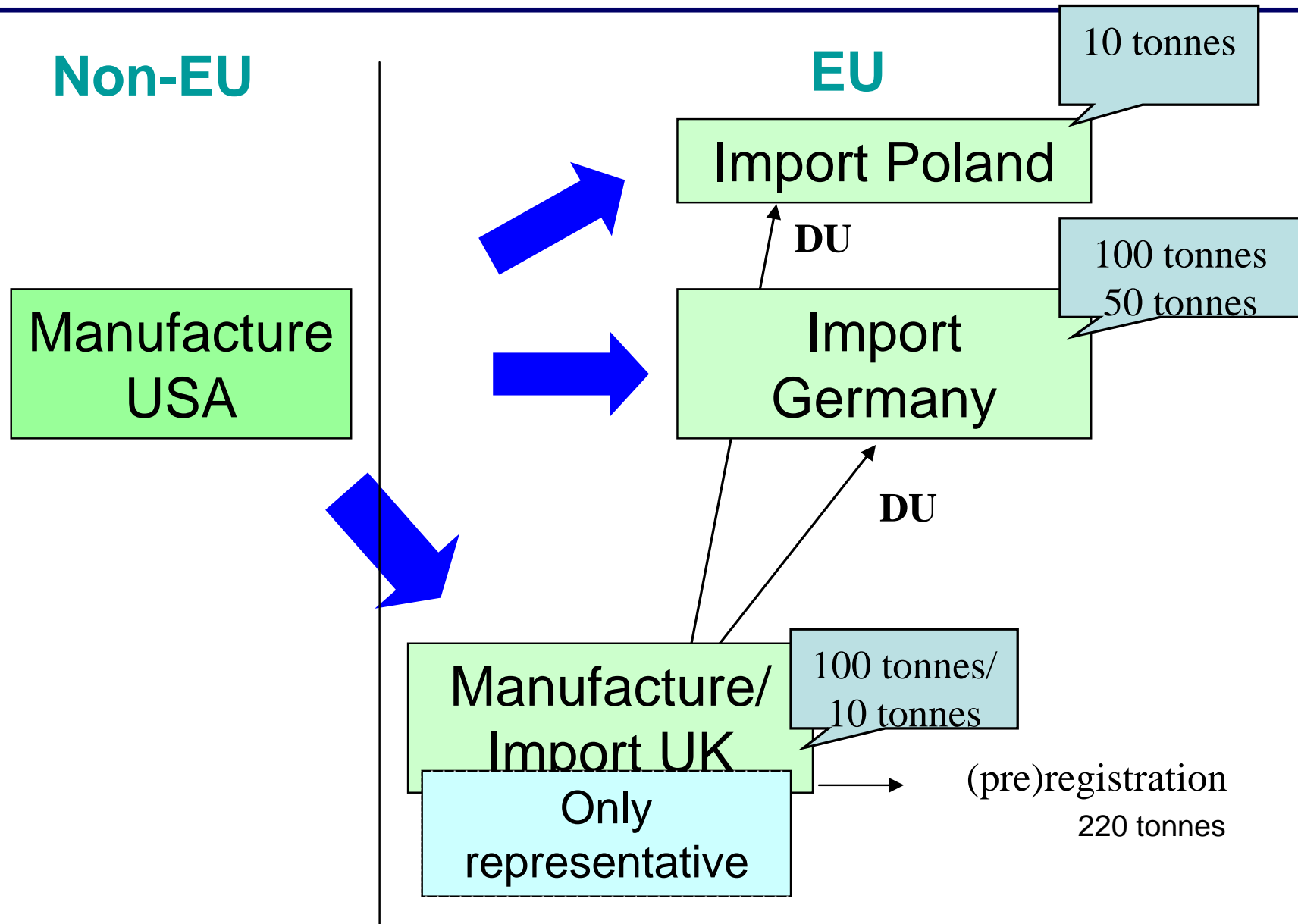
Third party



Third party representative (article 4)

Any manufacturer, importer, or where relevant downstream user, may, **whilst retaining full responsibility** for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

Only Representative (company legal entity)



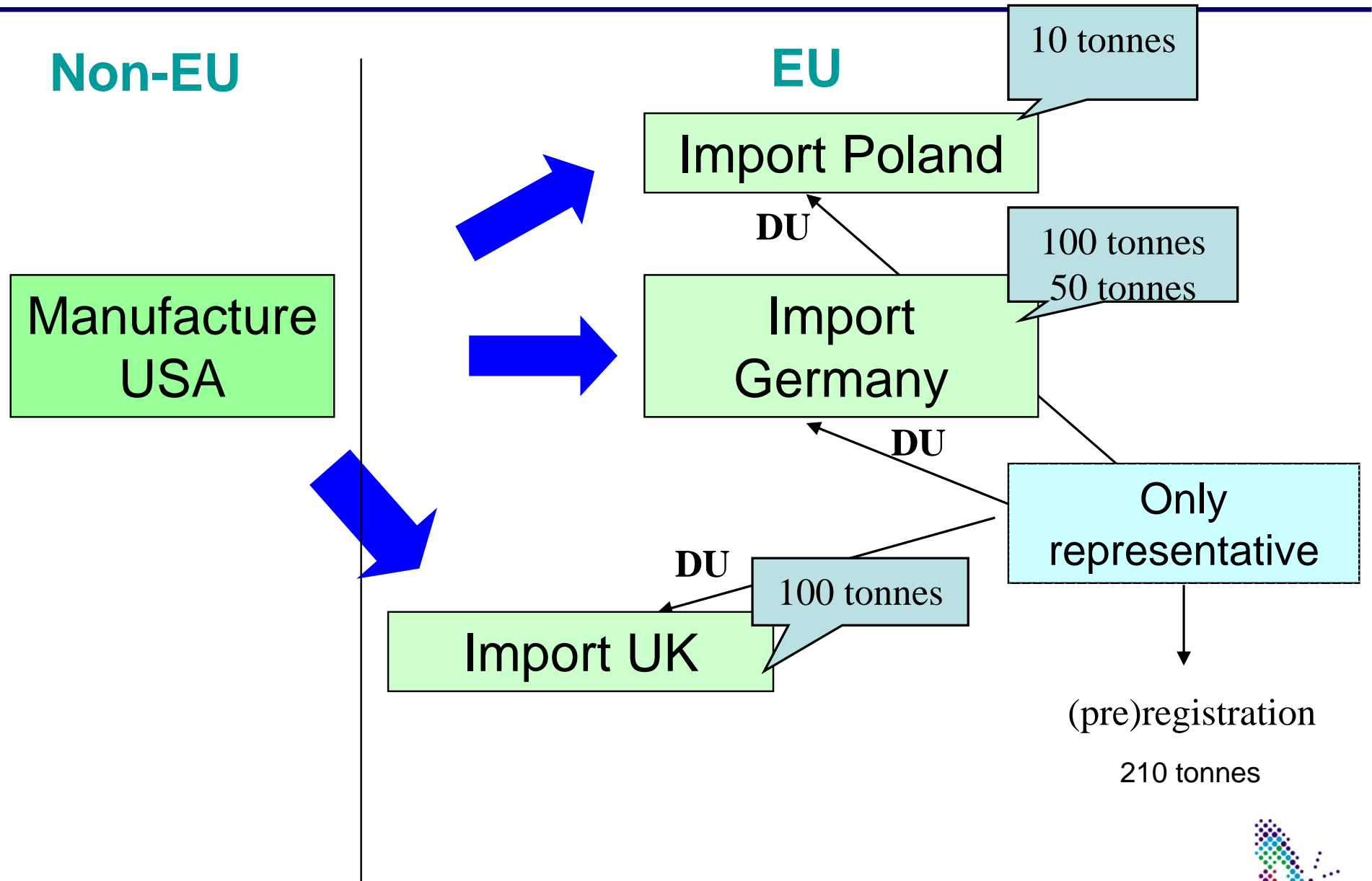
Only Representative (article 8)

- Importers from outside the EU may appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers under this Title (8(1)).
- A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers under this Title (8(1)).

Strategy

- EU affiliate responsible
 - Knowledge on substances/preparations
 - Involvement in data- and cost sharing
 - Administrative responsibilities
- Visibility in SIEF
 - Identity known to competitors
- One registration
 - high fee/ testing costs
 - Independent from importers
- US producer is fully in the driver's seat.

Only Representative (separate legal entity)



Strategy

- Responsibility with Consultant
 - Consultant assists decisions on data-sharing/cost sharing
 - Limited knowledge on substances
 - Extensive knowledge legislation and technical issues
 - Invisibility in SIEF
 - Administrative burden
- One registration
 - High fee/ testing costs
 - Independent from importers
- US producer is fully in the drivers seat.

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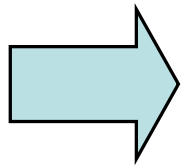
How to Prepare

- Assessment of port-folio
- Within Company Implementation
- Preparation for pre-registration
- REACH Master plan



Port-folio assessment

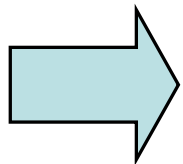
- Identify products
- Inventory substances
- Annual volumes exported to EU (per importer)
- Check exemptions
- Check SVHC
- (Company roles)



Obligations?

Within Company Implementation

- In-house awareness and communication
- Time-plan (what, when, whom)
- Resources estimate
 - Direct costs
 - Indirect costs
- Business opportunities
- Confidentiality issues
- General information on use



Development of strategy

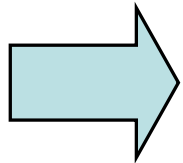
REACH team

- EHS
- Purchasing
- Sales
- Legal
- R&D
- Production
- IT
- Etc



Prepare for Pre-Registration

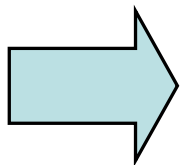
- Identification of legal entity in EU (Only representative)
- Third party representative
- Substance identification
- Investigations of possible analogues
- Identification of company owned and public available data
– data gap analysis
- Review of classification and labelling



Pre-registration and SIEF

REACH Master Plan

- Formation of consortia
- Lead registrant
- Joint submission of non-confidential data
- Registration dossiers (phase in deadlines)
- CSR/Exposure Scenarios (Annex XI)
- Authorisation
 - an analysis of possible alternatives
 - a substitution plan including a timetable for proposed actions by the applicant
 - (a socio-economic analysis)



REACH Compliance

REACH Responsibilities

REACH manager should be an expert in:

- toxicology
- ecotoxicology
- hazard and risk assessment
- classification and labelling
- legal issues
- regulatory issues
- business strategy
- R & D
- production
- sales
- etc.



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Conclusions

- REACH is in force
- REACH will affect you and your business
- Substance inventory and identification
- You will have to cooperate with competitors
- REACH is team work
- Undoubtedly some substances will disappear from the marketplace
- Be prepared and become REACH compliant



Questions?

Thank you for your attention



For more information:

For information on REACH contact:

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