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REACH FOR PREPARATIONS

Seoul, May 27th 2009

Scope & Definitions

- **Preparation** *means a mixture or solution composed of two or more substances*
- Typical examples: paints, varnishes, inks,...
- Preparations are not the same as multi-constituents substances:
  - Preparation is gained by blending several substances
  - Multi-constituent substance is the result of a chemical reaction only.
- REACH obligations apply individually to each of those substances
- Within the Globally Harmonised System for classification and labelling (GHS), a preparation is named a "mixture".

- Only substances have to be registered, preparations do not

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Preparations: Who has to Register?

- Each individual substance of a preparation needs to be registered
  - by the substance manufacturer or importer of same supply chain
  - or by the preparation manufacturer or importer

  when reaching the threshold of 1 tonne per year, if not exempted.

- An importer of a preparation importing from a non EU company who has appointed an “only representative” is considered as a downstream user.

- A non E.U. *manufacturer* or supplier exporting a substance or preparation has no responsibilities under REACH

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Preparations: What to Register?

All and any substances except:

Substances exempted from REACH	Substances exempted from registration	Substances regarded as registered
Radioactive substances (specific legislation)	Food or feeding stuff (Food Safety Regulation)	Active substance for use in biocide
Substances under customs supervisions	Medicinal products section (EMeA, veterinary,…)	Active substance for use in plant protection products
Substances used in the interest of defence and covered by National exemptions	Annex IV substances (68 substances such as N_2, O_2, H_2,…)	Notified substances (Directive 67/548/EEC) such as ELINCS
Waste	Annex V substances	
Non isolated intermediates	Recycled or recovered substances already registered (fuel, solvent for regeneration, recycling,…)	
Transported substances	Re-imported substances (if registered)	
	Polymer (if monomer registered)	
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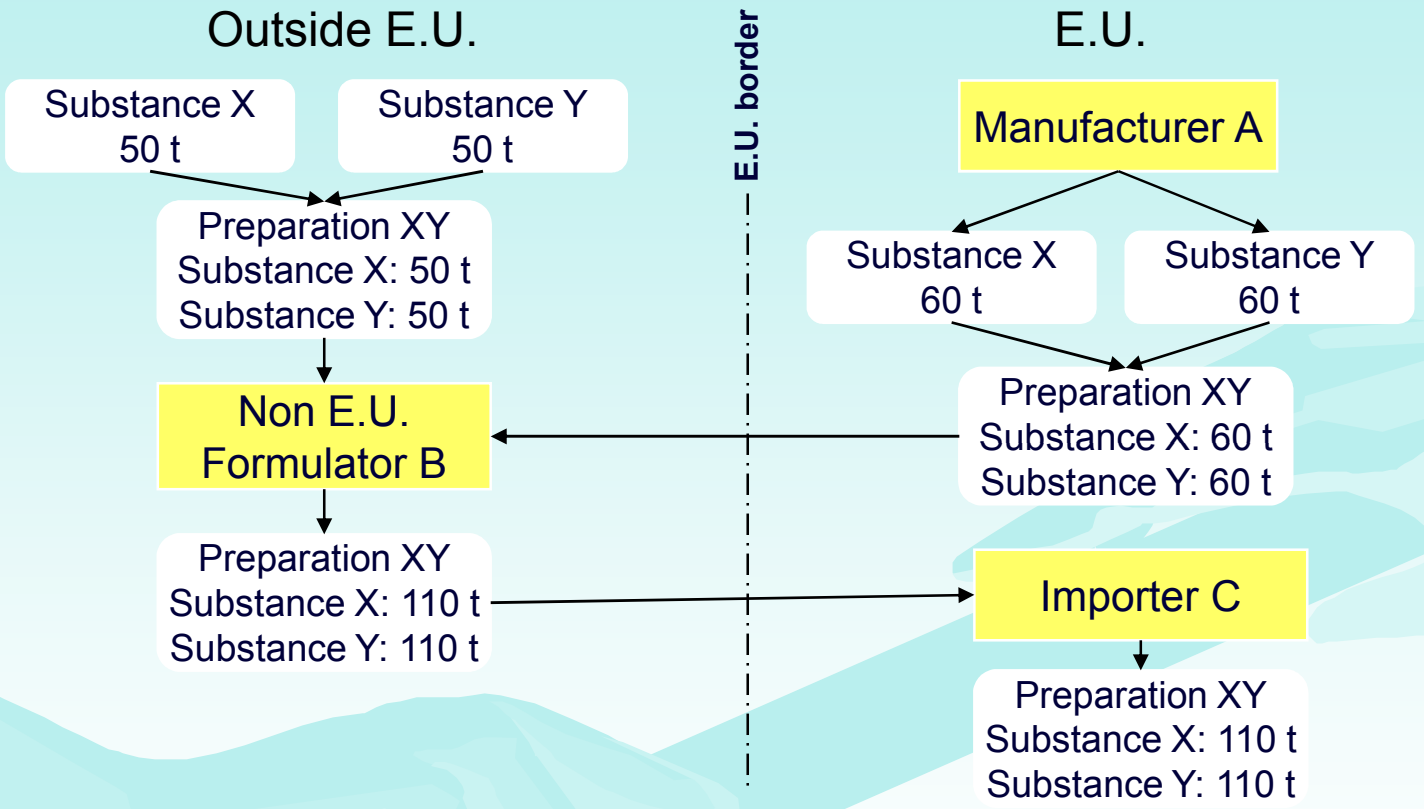
Tonnage Calculation Preparations Example



- **Manufacturer A** registers 60 t of substance X and 60 t of substance Y
- **Non E.U. Formulator B** (through Only Representative) or **Importer C** exporting/importing the preparation XY made of 110 t of substance X and 110 t of substance Y need to register only 50 t of substance X and 50 t of substance Y

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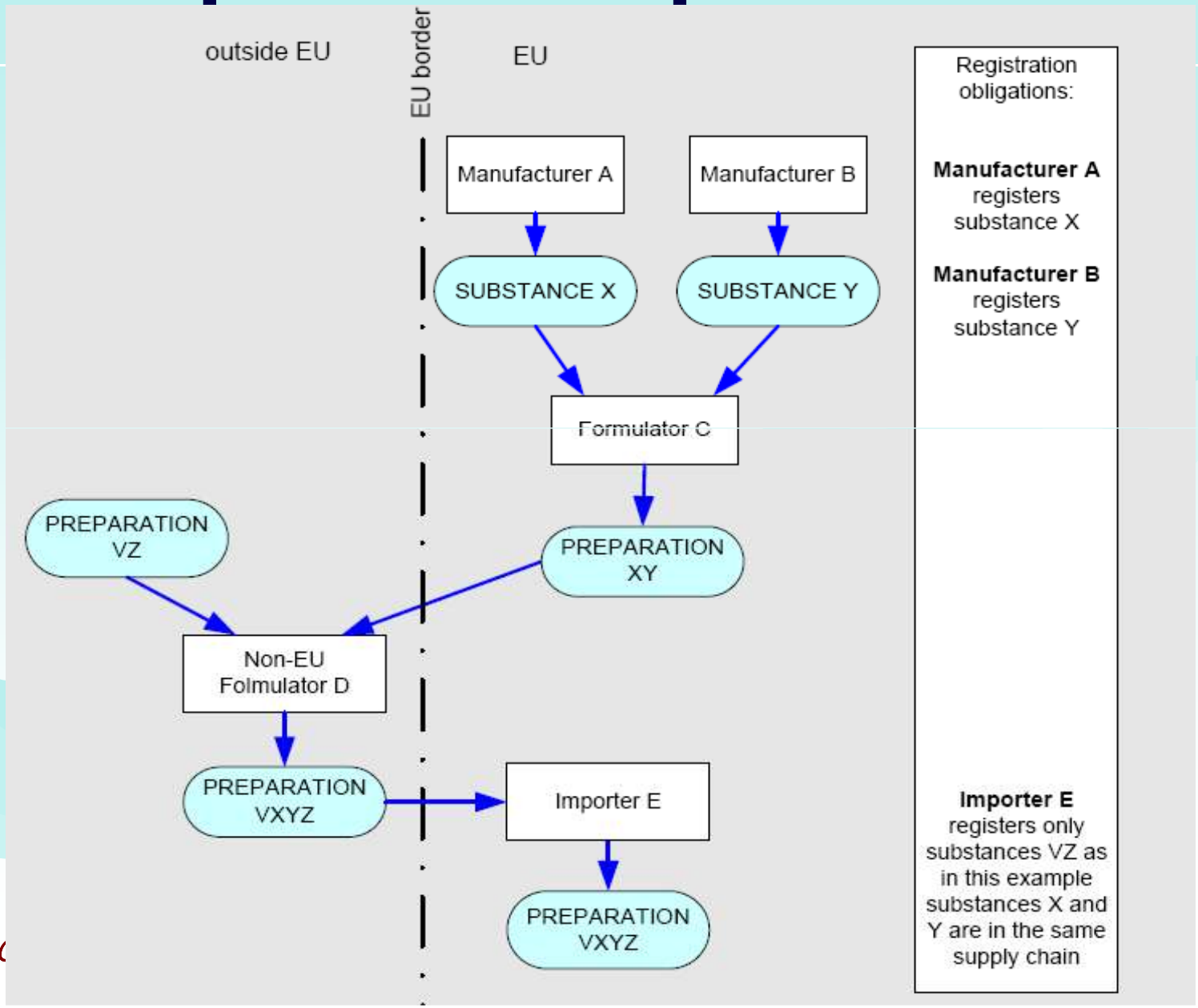
Reimported Preparations



CSR/CSA need for Substances in Preparations

- CSR is needed for substances in preparation when substances tonnage registered is above 10 ton/year

- CSA is not needed for a substance in preparation if its concentration is less than the lowest of any of the following:
  - Applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;
  - Concentration limits given in Annex I to Directive 67/548/EEC;
  - Concentration limits given in Part B of Annex II to Directive 1999/45/EC
  - Concentration limits given in Part B of Annex III to Directive 1999/45/EC;
  - Concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI of this Regulation;
  - 0,1 % (w/w), if the the criteria in Annex XIII (PBT, vPvB) is met.

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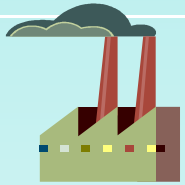
Exposure Scenarios

Substances



Preparations

Articles

All applications to be described and studied in the CSA/CSR and listed in SDS if approved. A lot of complex factors:

- Market kowledge
- Long supply chain
- Confidential applications
- Generic Exposure Scenario
- Complex Exposure Scenario
- Risk Management Measures
- …

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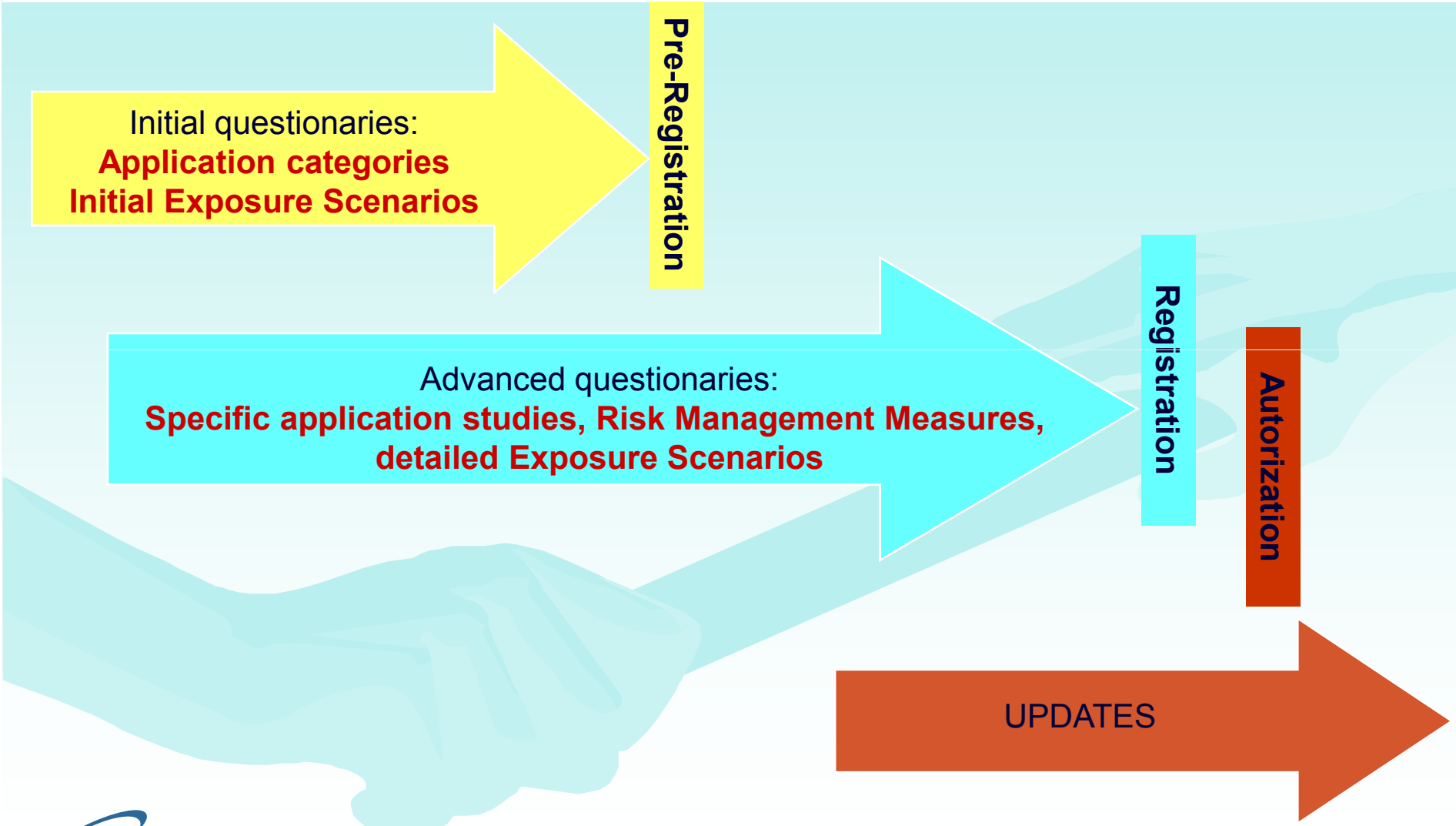
NO DATA NO MARKET!

Data Communication with D.U. Specific Questionaries Needed



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Duty of Communication

- When supplying a substance or a preparation for which a Safety Data Sheet is not required (see section above), the supplier still has to provide some information to all the downstream users and distributors he supplies as of 1st June 2007 (*Article 32*). If the substance is subject to authorisation or subject to restriction he will have to provide the following information to the recipient of his substance:
  - Registration number, if available
  - Authorisation request and details of the granted authorisation or information if authorisation has been denied
  - the details of the restriction
  - Any available and relevant information necessary to enable appropriate risk management.

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Confidential Information

Further information must not be published on the Agency website or disclosed otherwise, with an exception when urgent action is essential to protect human health, safety or the environment:

- *details of the full composition of a preparation;*
- *precise use, function or application of a substance or preparation;*
- *precise tonnage of the substance or preparation manufactured or placed on the market;*
- *links between a manufacturer or importer and his distributors or downstream users.*

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Preparation exempted from Title IV « Information in the Supply Chain"

- Medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 or Directive 2001/82/EC or Directive 2001/83/EC
- Cosmetic products as defined in Directive 76/768/EEC;
- Medical devices so far as Community measures lay down the same level of information provision and protection as Directive 1999/45/EC
- Food or feedingstuffs in accordance with Regulation (EC) No 178/2002 within the scope of Directive 89/107/EEC or Directive 88/388/EEC or Decision 1999/217/EC or Regulation (EC) No 1831/2003 or Directive 82/471/EEC.

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Preparation - Safety Data Sheet need

Supplier of preparation has to provide a SDS if:

- The preparation containing the substance is classified as dangerous under Directive 1999/45/EC,
- Substance is (PBT) or vPvB,
- Substance is in candidate list of SVHC.

Supplier needs to provide a SDS for any preparation which does not meet the criteria for classification as dangerous but contains:

- ≥1% w/w for non-gaseous preparations (or ≥0.2% v/v for a gaseous preparation) of a substance posing human health or environmental hazard, or
- ≥0.1% w/w for non-gaseous preparations of a PBT or vPvB or included in the candidate list of substances subject to authorisation
- Substance for which there are Community workplace limits.

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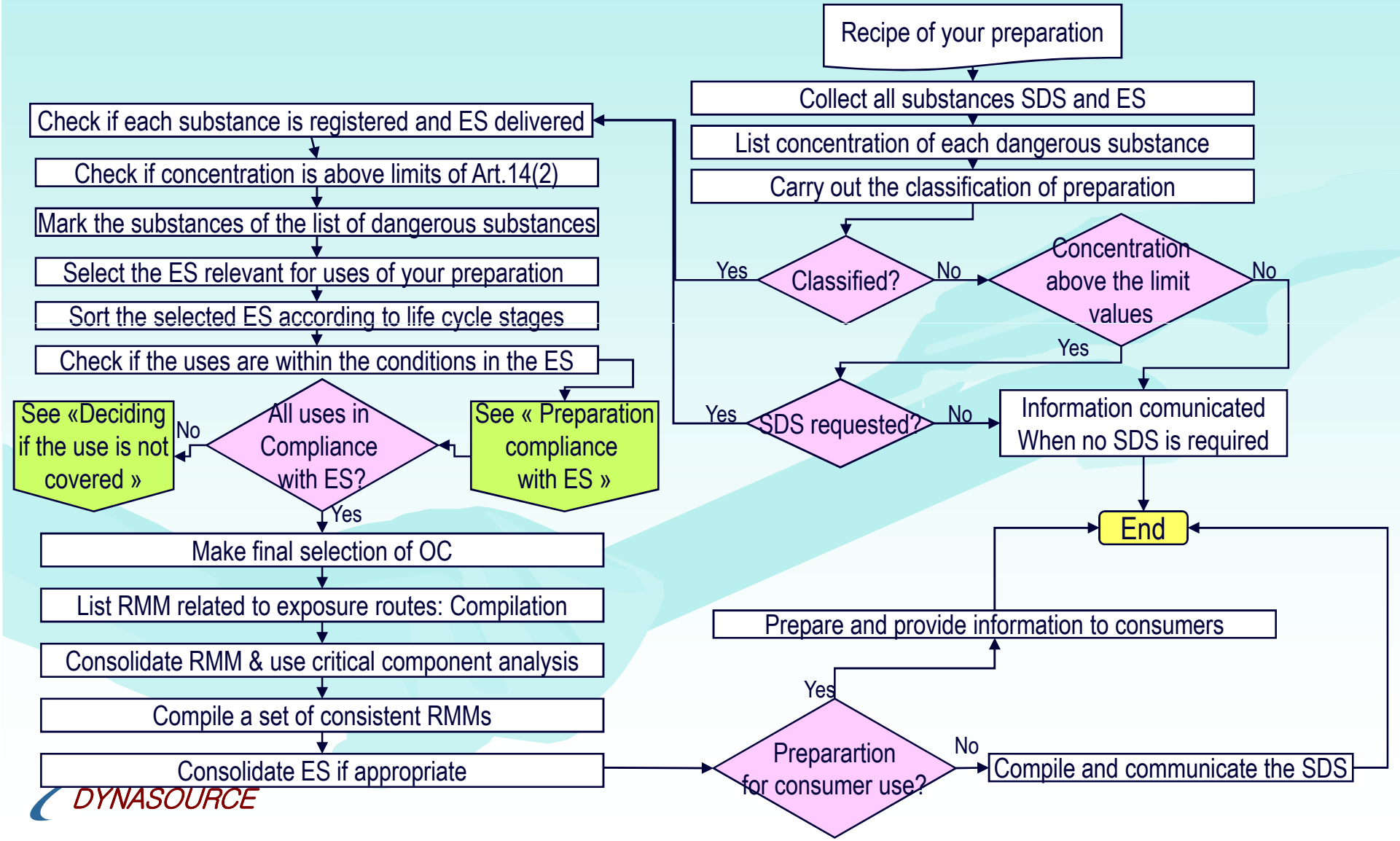
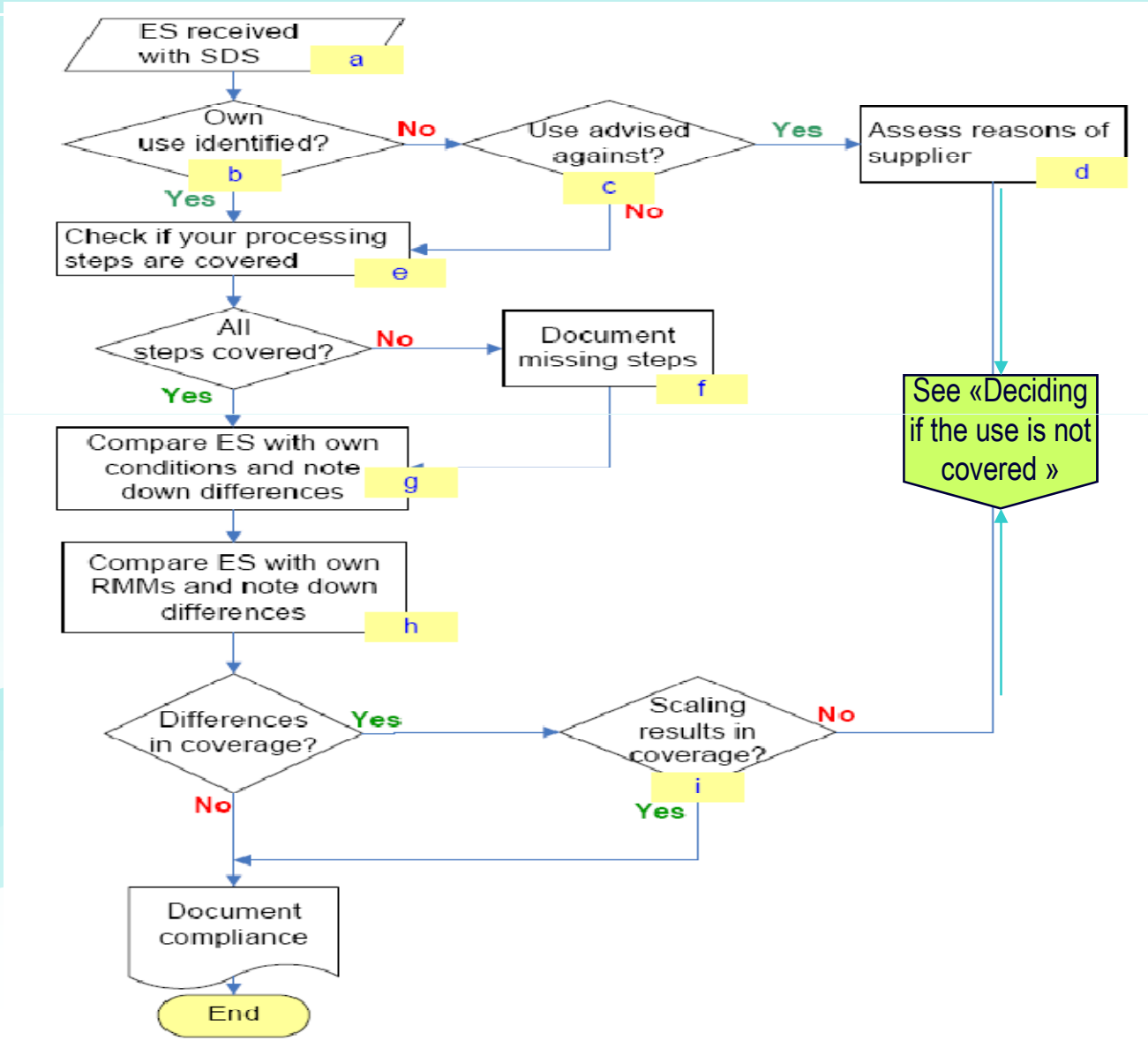
Information on Preparation when Substances Registered by Supplier



Preparation Compliance with ES



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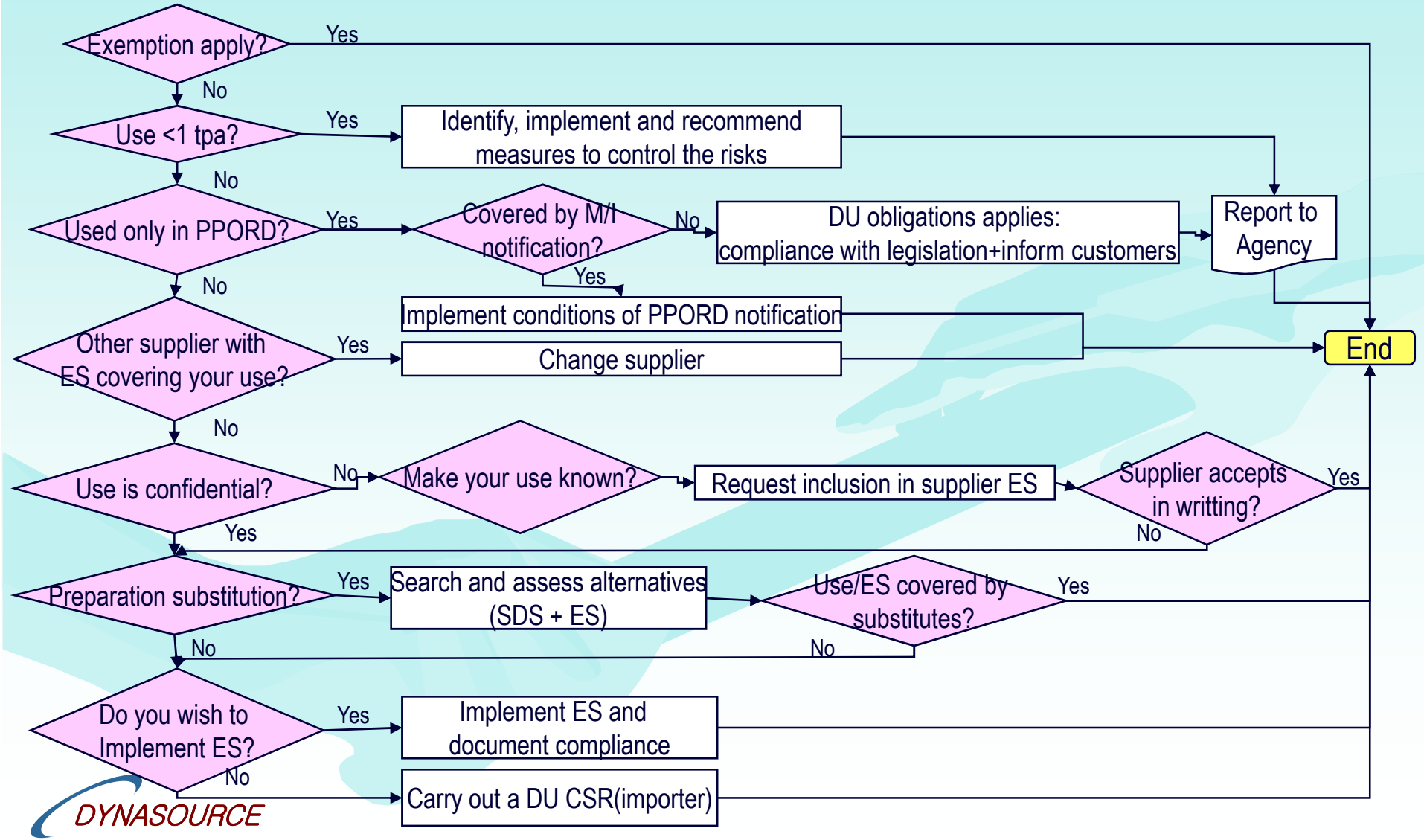
Preparations: What if your Use is not Covered by Supplier Dossier?



Classification and Labelling

- Registrant must notify information related to its classification and labelling for:
  - Substance subject to registration not yet registered on 1st December 2010
  - Substance within the scope of Article 1 of Directive 67/548/EEC classified as dangerous on its own or in a preparation above the concentration limits specified in Directive 1999/45/EC
- Notification has to be done
  - before 1st December 2010 for substances already on the market
  - as soon as the substance is placed on the market after 1st December 2010.

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Preparations - Conclusions

- All substances (>1 ton/year) added intentionally in the preparation need to be (Pre)-registered
- Even if your substance supplier announces it will regsiter it:
  - Pre-register all key substances with supply risk
  - Communicate with your DU on exposure Scenarios and forward them to substance suppliers
  - Establish preparation SDS and communications with DU according to REACH requirements

- REACH will change business habits, imposing more transparency
- Risk of confidential information disclosure makes the choice of the interface even more important

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Your Contacts For Further Information

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