

# REACH Specifics

## Roles & Responsibility

Case studies

A: Clarifications

B: Case studies

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## Manufacture

### Manufacturing without placing on the market

- Manufacture for its own use:
  - **Isolated intermediates** in the case of batch-wise manufacturing with temporary storage between processes
- Manufacture for use by other “manufacturers”
  - **Transported isolated intermediates**

### Requirements

- (Transported) isolated intermediates to be registered with limited set of data



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2

# Import

- **Import means physical introduction into the customs territory of the EEA**
  - Trading within EEA is no importation
  - Basic principle if REACH is a.o. free trading within EU (EEA)
- **Example:**
  - “Import” from Bulgaria to Croatia is not an import as defined under REACH, but “free” trading within the internal market. So, a registered substance by a BU company (M/I/OR) does not require further registration
  - “Import” from Switzerland to Croatia is physical introduction from outside the EU/EEA and requires registration by an I/OR within the EU/EEA.



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3

# Specific situation: re-import

- **Re-import of an exported substance**
  - Manufactured or imported substance, fully registered, exported as such or in a mixture and re-imported as component in another mixture within the same supply chain
  - does not need to be registered, if ....
    - registered before export
    - must be the same substance
    - must proceed from the same supply chain
    - re-importer must have the information from the exported substance
- **Example:**
  - See next slide



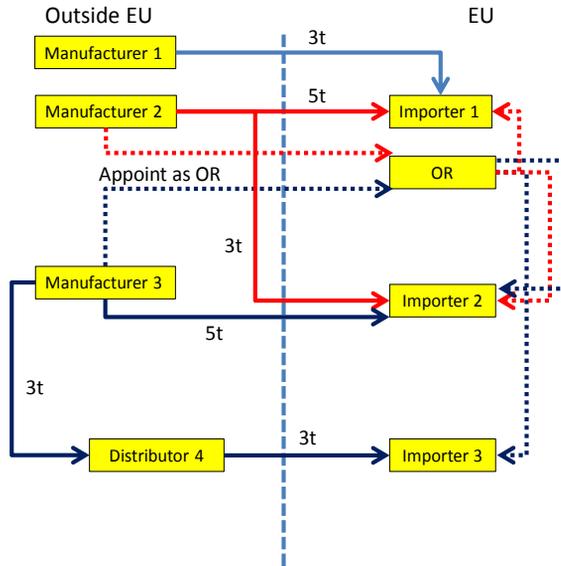
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4

# Explaining roles



**Roles and Registration obligations**

M1, M2, M3 and D4 no REACH obligations

I1 registers 3t

OR for M2 /M3 registers 8t S1 and 8t S2

I2 no registration required = "DU"

I3 no registration required = "DU"

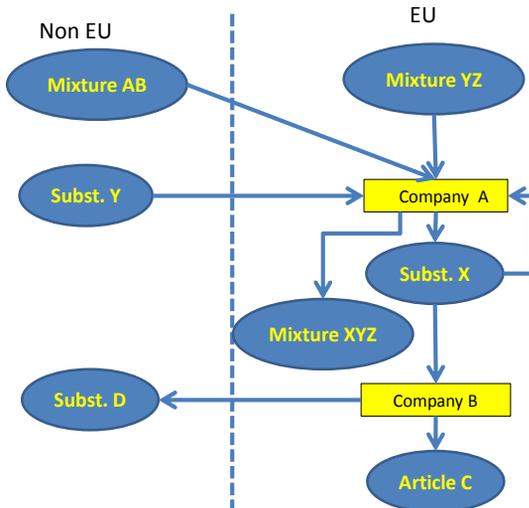


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# Company may have different roles



**Roles**

**Company A:**

- + Manufacturer of X
- + partly isolated intermediate
- + Importer of A, B, and Y
- + DU (user) of mixture YZ
- + DU (formulator) of XYZ

**Company B:**

- + DU of X for further processing
- + Producer of article C
- + Manufacturer of D solely for export

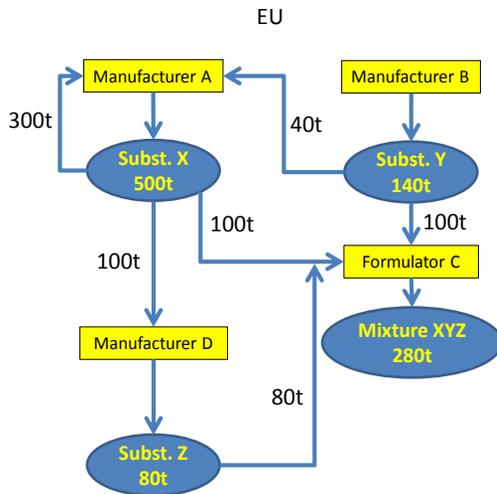


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# Examples of manufacture



**Registration obligations**

**Manufacturer A registers**  
 + 300t X (isolated inter.)  
 + 100t X (transp. Isolot. interm.)  
 + 100t X (full registration)

**Manufacturer B registers**  
 + 40t Y (transp. Isolot. Interm.)  
 + 100t Y (full registration)

**Formulator C no registration requirement**

**Manufacturer D registers**  
 + 80t Z (full registration)

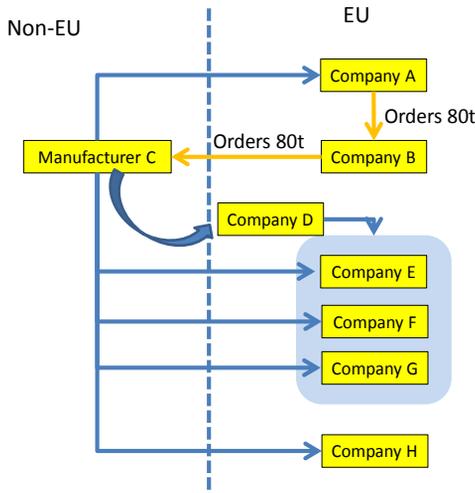


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# Examples of import



**Roles of companies**

**Standard:**  
 Company A is importer (Reg.)  
 Company B is sales agency  
 Company C is non-EU manufacturer

**But, also possible:**  
 Company A is DU  
 Company B is importer (Reg.)

**Example OR:**  
 Company D = OR for E, F, G (Reg.),  
 should be appointed by C  
 Companies E, F, G become DUs  
 according to REACH  
 Company H is importer (Reg.)

**Note: Only non-EU M/F/P-article may appoint an OR**

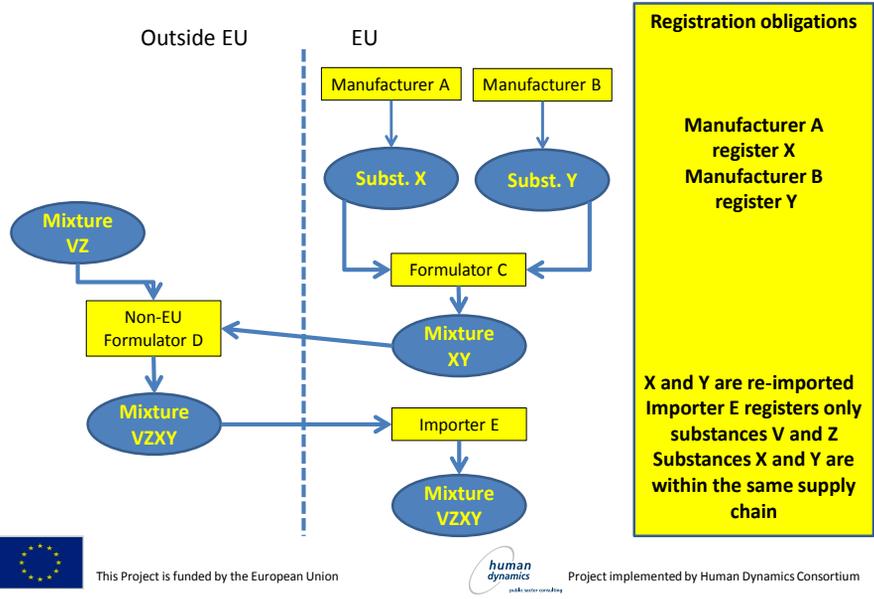


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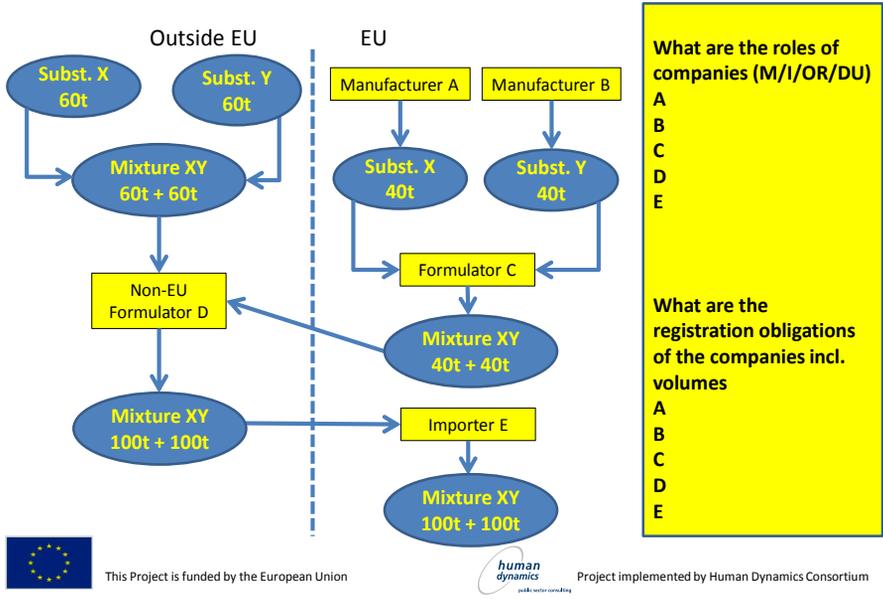


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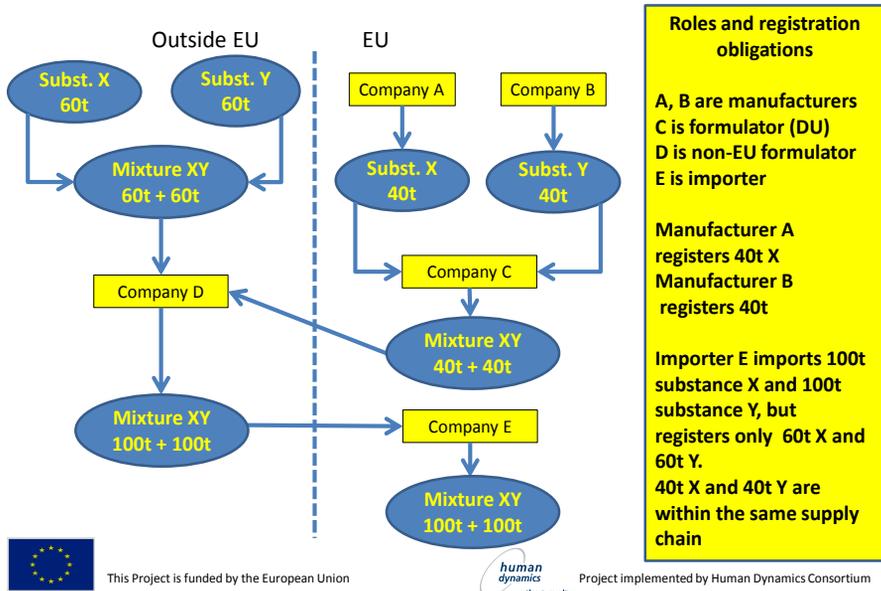
# Example of re-import



# Exercise



## Exercise explained



11

## Producer of an article

### Is a DU with specific additional requirements

- Registration requirement for a component in an article intended to be released during normal or reasonable foreseeable use
- Notification requirement for non-releasing Candidate List substance(s) in an article if ....
  - > 1 tpa per producer/importer of an article
  - Present in article > 0.1% (w/w)
- Information down the supply chain, certainly if article contains candidate list substance(s)

**Note: Most "articles" with intended release during normal use are considered to be containers of substances/mixtures and not articles according to REACH**



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12