How Indian industry can prepare for REACH

3rd India-EU Environment Forum

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cefic

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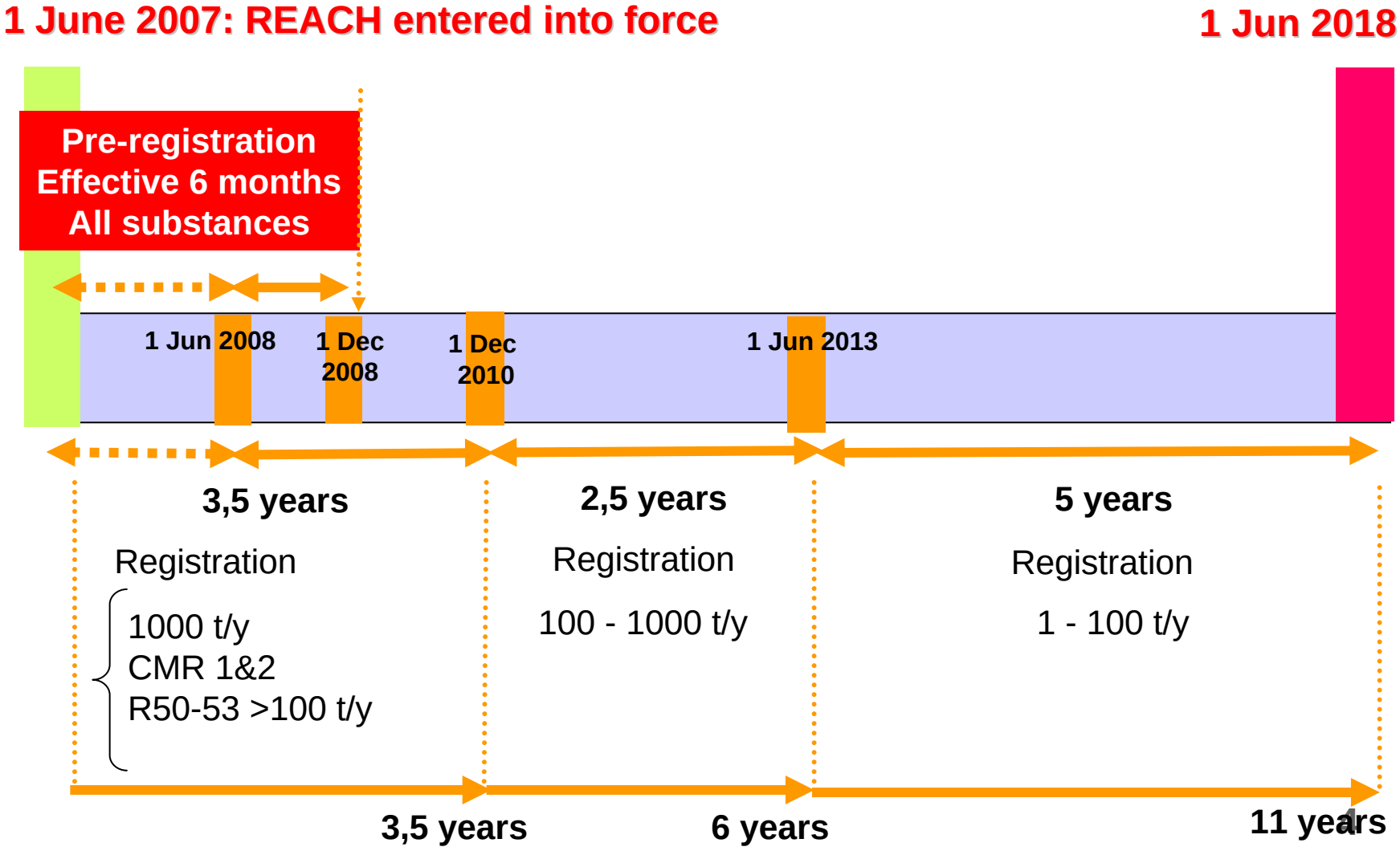
Glossary

CBI	Confidential Business Information
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
C&L	Classification and labelling
Dist	Distributor
DU	Downstream User
ECHA	European Chemicals Agency
EEA	European Economic Area
EU	European Union
Form	Formulator
Imp	Importer
LE	Legal Entity
Man	Manufacturer
M/F	Manufacturer / Formulator
OR	Only Representative
Q+A's	Questions and Answers
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SVHC	Substance of Very High Concern
TPR	Third Party Representative

REACH time-line



How to prepare: short overview (1)

1. Determine your ‘REACH’ role: non-EU Manufacturer, Formulator, Distributor/Downstream User
2. Produce your company inventory of substances, preparations and articles exported into EU
3. Determine composition of preparations and substances in articles intended to be released.
4. In case of polymers, determine the monomers they are made off
5. Determine the volumes of the substances in the different non-EU supply chain.
6. Aggregate the volumes per substance
7. Determine, if applicable, volume transported isolated intermediate
8. Establish the registration deadlines for the substances

Non-EU Manufacturer or Formulator:

1. Define your strategy: ‘REACH’ importer, Only Representative or leave it to downstream non-EU supply chain
2. Inform your present EU importers of your intentions
3. Inform your present non-EU customers of your intentions
4. Prepare for substance data collection

Non-EU article producer:

1. Determine substances intended to be released
2. If not, no registration obligation
3. If yes see Non-EU Manufacturer or Formulator
4. Determine SVHC in articles and prepare for notification ECHA

- Non-EU Downstream User or Trader:

- Can not nominate Only Representative
- Should rely on EU-Importer or establish own EU based importer to do the REACH obligations
- Prepare for substance data collection from non-EU supplier

How to prepare: Two possibilities to register under REACH

In case of Importer:

1. Importer should be EEA based
2. Assure that your importer will (pre)-register
3. Consider CBI and Third Party Representative
4. Prepare for substance information
5. Prepare for CSA/CSR

In case of Only Representative:

1. Establish a competent Legal Entity in EEA
2. Prepare for pre-registration. **Deadline is 1 Dec 2008!**
3. Prepare for OR obligations
4. Prepare substance information and collect use and exposure data from EU supply chain
5. Prepare for working in SIEF and Consortia
6. Prepare for CSA/CSR

REACH roles for non-EU

- Non-EU manufacturer
  - Manufacturers a substance
  - Cannot register under REACH
  - May appoint EU based Only Representative to fulfill the obligations under REACH
- Non-EU formulator
  - Mix substances into preparations, but no chemical reaction
  - Cannot register under REACH
  - May appoint EU based Only representative to fulfill the obligations under REACH
- Non-EU article producer
  - Substances intended to be released should be registered under REACH
  - May appoint EU based Only Representative to fulfill the obligations under REACH

Roles under REACH

- **Non-EU distributor, Trader or Downstream User:**
  - **Does not manufacture, formulate or produces an article**
  - **Cannot nominate Only Representative under REACH**
  - **Should rely on REACH registration by a OR nominated by any of the M/F in his non-EU supply chain or on EU based importer**
  - **May establish EU based importer. REACH obligations can be done.**

Only Representative (OR)

- Non-EU manufacturer cannot register under REACH
- EU based importer can register under REACH
- Non-EU manufacturer should appoint EU based Legal Entity to take care of REACH obligations: **Only Representative**
- Any Non-EU Manufacturer, formulator or article producer may appoint an OR
- OR may represent > 1 non-EU manufacturer, but should do for each a registration
- Distributors can not appoint an OR

Only Representative (OR)

- OR Registration:
  - 14 April DG ENT: multiple registrations and multiple fees
  - 04 June: Change in OR, only administration fee, no new registration (provided contract arrangement)
  - 04 June: Non-EU manufacturer upstream the supply chain may register, however good administration on REACH compliance required

Following slides are from a ECHA presentation given in RIW III, 24 June 2008

Who can appoint/be an OR?

Who can appoint an OR?

- "non-Community" manufacturers (non-EU substance manufacturers, formulators, producers of articles)
- but not distributors (as they are not mentioned)

Who can be an OR?

- legal entity established in the EU which has sufficient background in the practical handling of substances and the information related to them

Obligations of OR's (1)

OR is fully liable for fulfilling importer obligations under REACH

- not only registration but also pre-registration, communication in the supply chain, notification of SVHC, C&L, authorisation and restrictions

OR must keep up-to-date list of EU importers, incl.:

- tonnage covered for each of the importers
- information on the supply of the latest SDS
- ⇨ *this information must be presented to enforcement authorities upon request*

Obligations of OR's (2)

NEW (not yet in guidance):

No distinction between different types of imports

- **i.e. OR of non-EU substance manufacturer may cover imports into the EU even if:**
  - **they are traded in a supply chain outside the EU or**
  - **integrated into a formulation before import**
- **however, there is a need for clear documentation which imports are covered**
- ***documentation must be presented to enforcement authorities upon request***

Obligations of OR's (3)

NEW (not yet in guidance):

Change of OR

- can now be done via an update under the condition that the earlier OR agrees (needs to be documented in update)
- it is recommended to include a clause on the eventuality of a later change into the OR contracts

⇨ *in the absence of an agreement, a new registration dossier must be submitted*

Obligations of OR's (4)

NEW (already implemented in guidance):

Tonnage aggregation

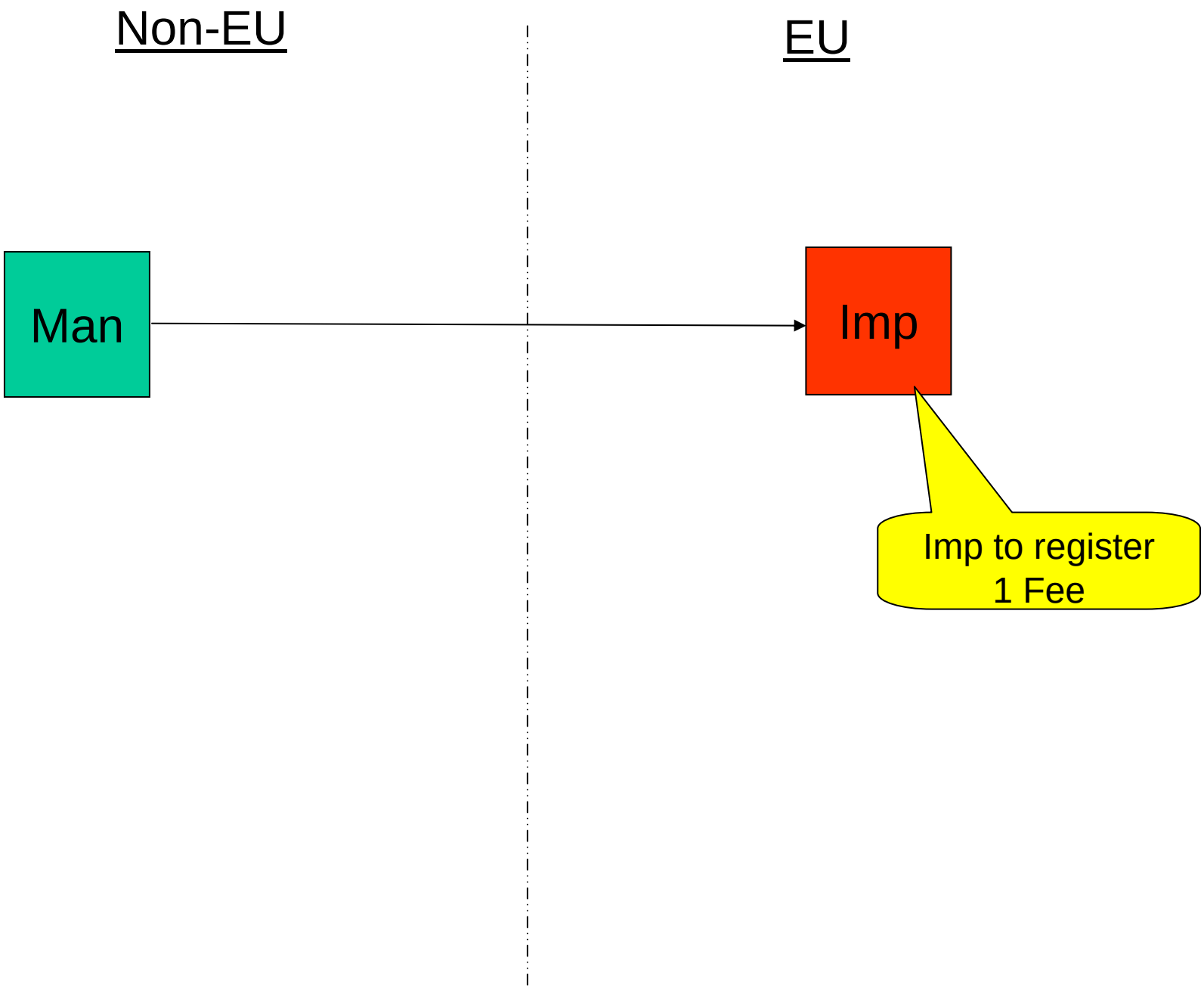
- **An only representative acting on behalf of several "non-Community manufacturers" must submit a separate registration for each of these manufacturers**

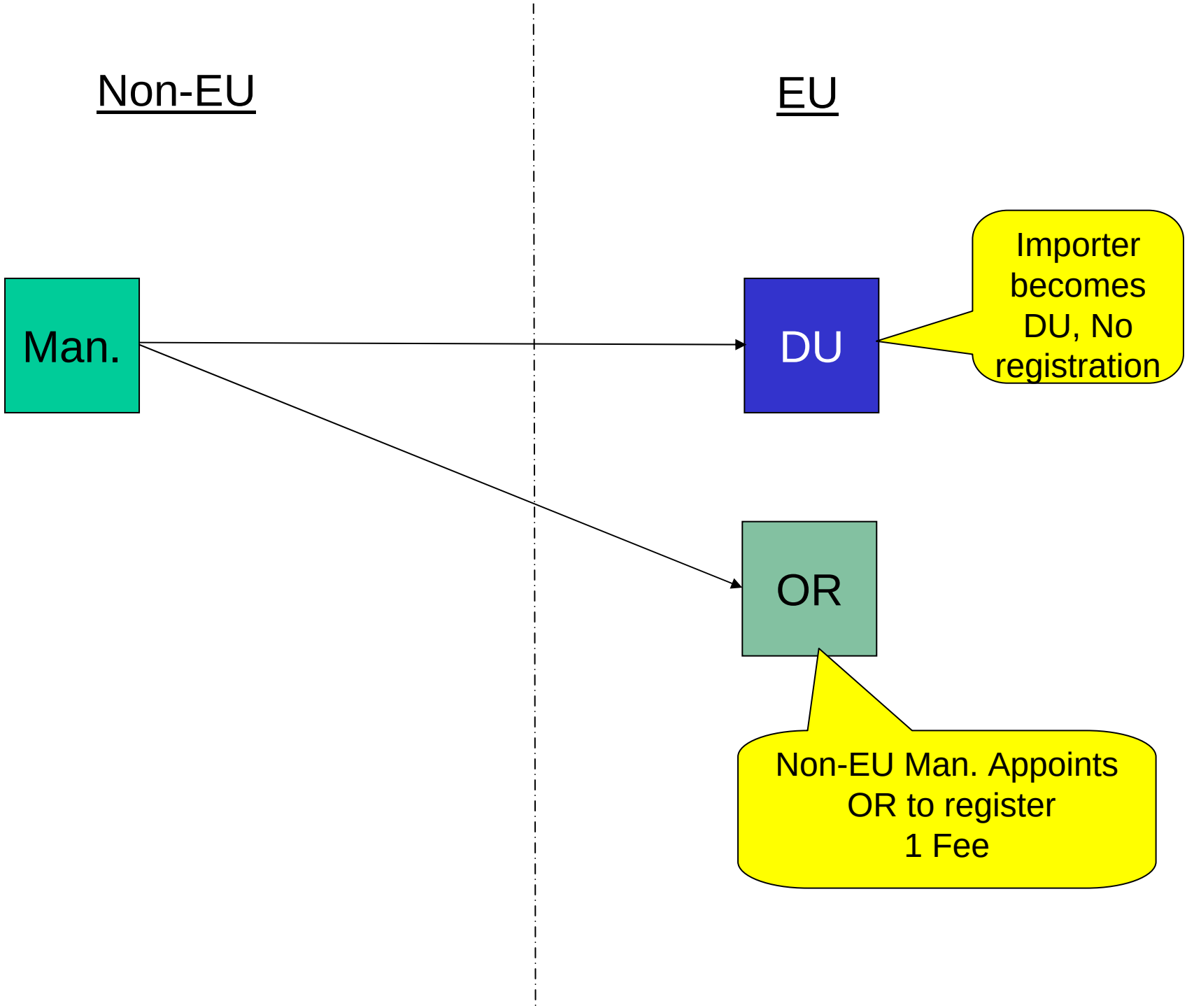
Further open issues

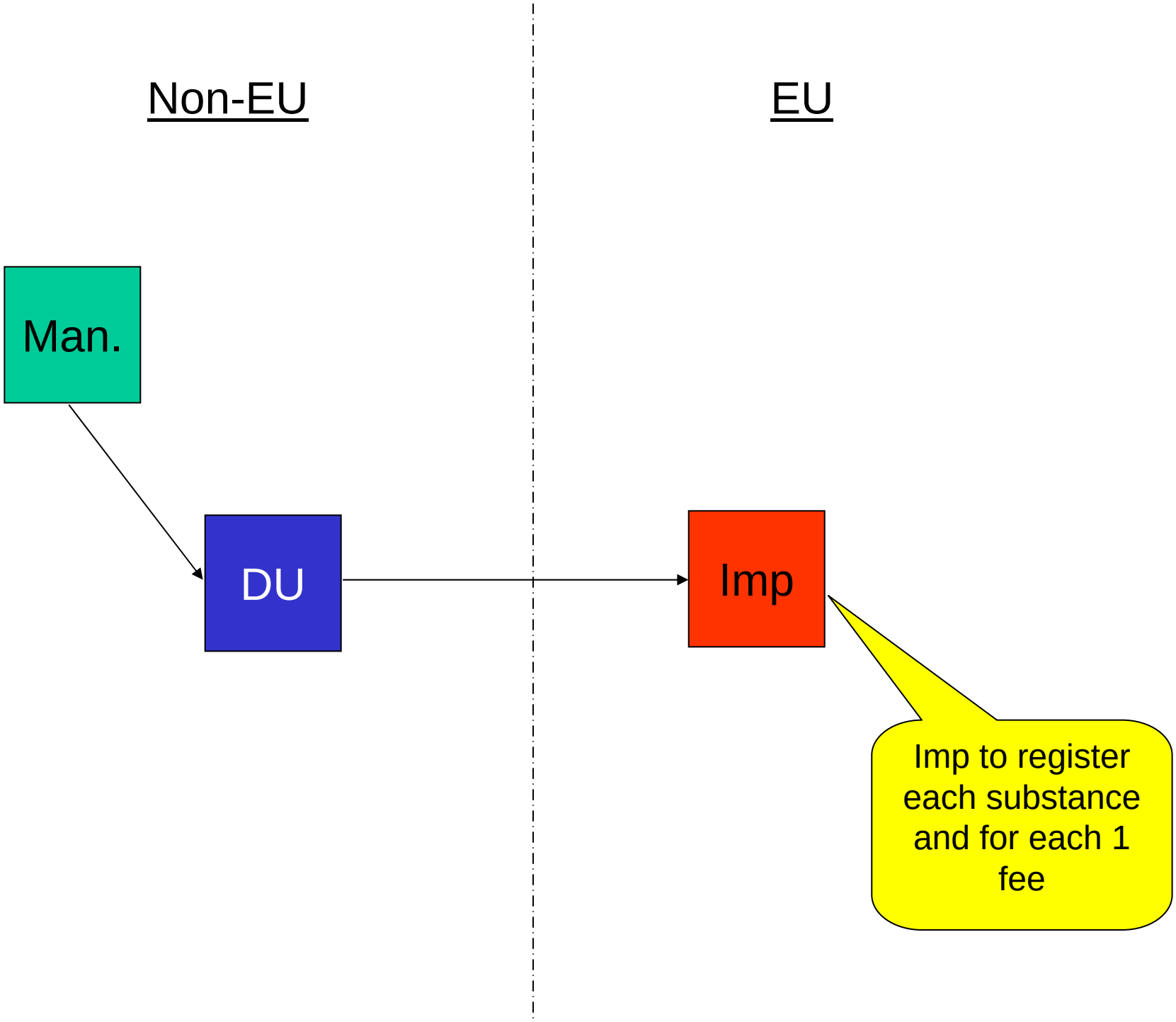
Will be discussed and probably integrated into the next update

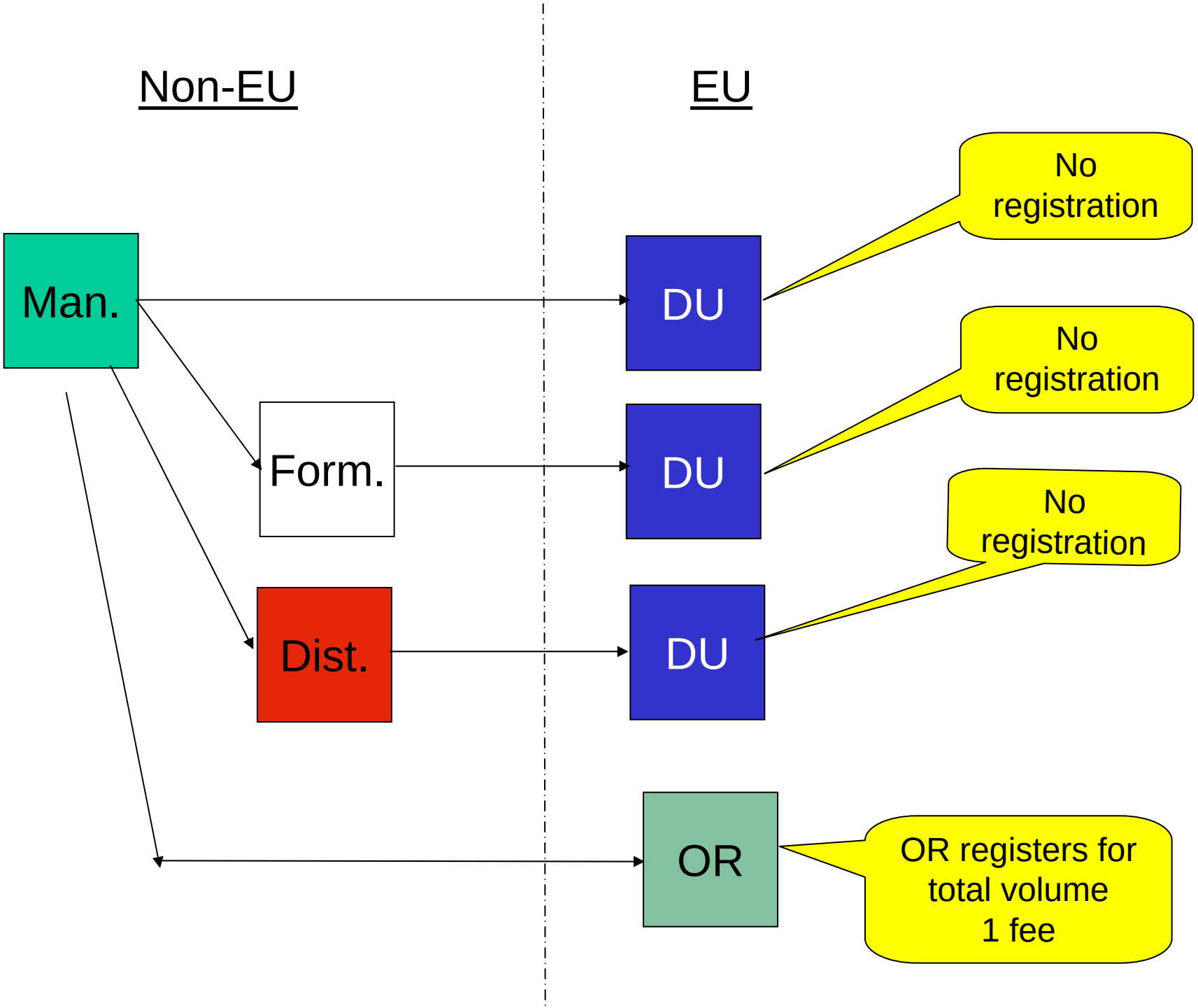
- **Is the whole volume of a substance manufactured by a “non-Community manufacturer” and exported to the EU to be covered by the OR registration?**
- **What are the timelines for OR´s using Article 28(6) (first time manufacture/import)?**
- **Transitional provisions for sole representatives**

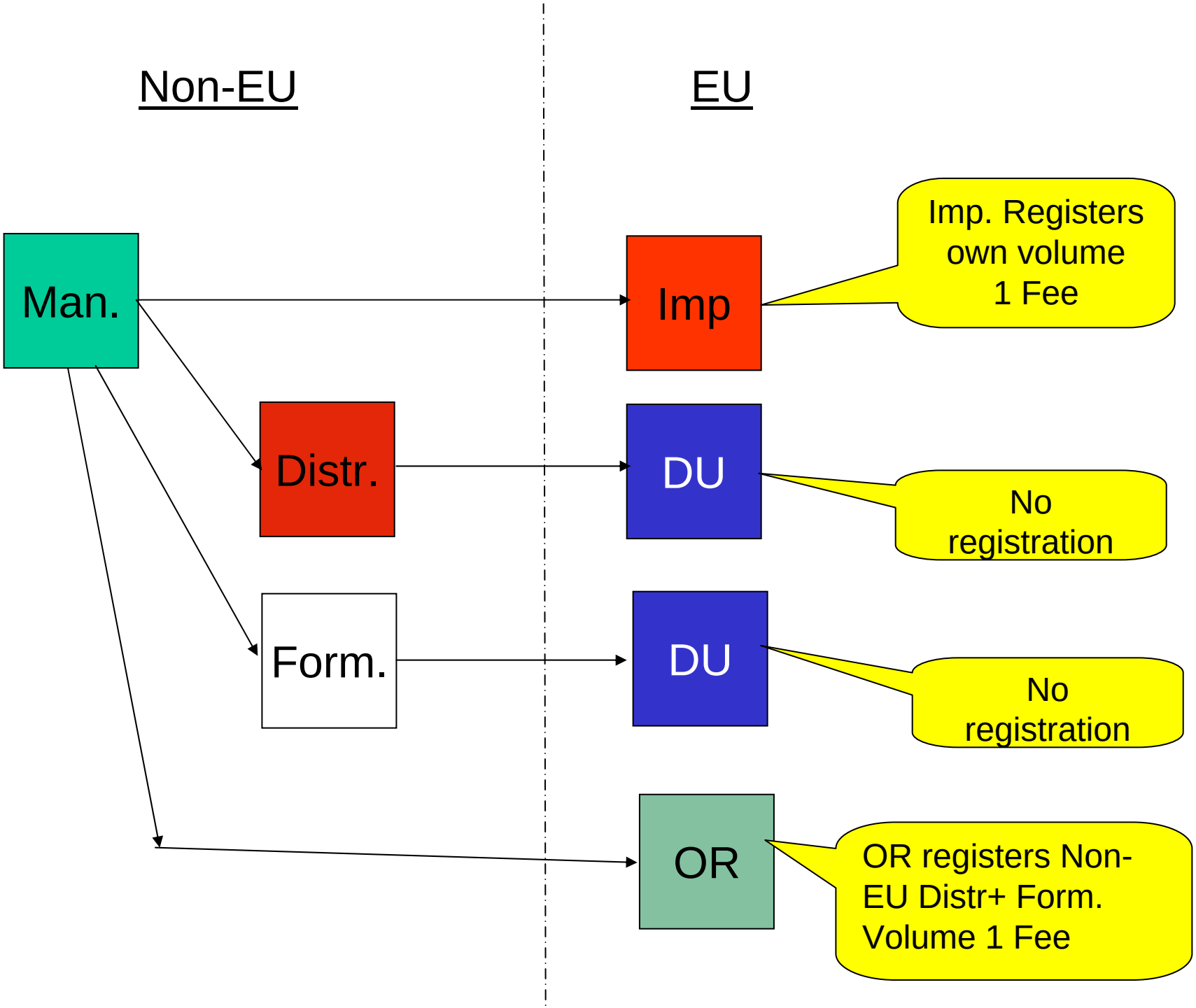
⇨ ***At the last REACH CA meeting, CEFIC also raised the question whether an OR can appoint a third party representatives***

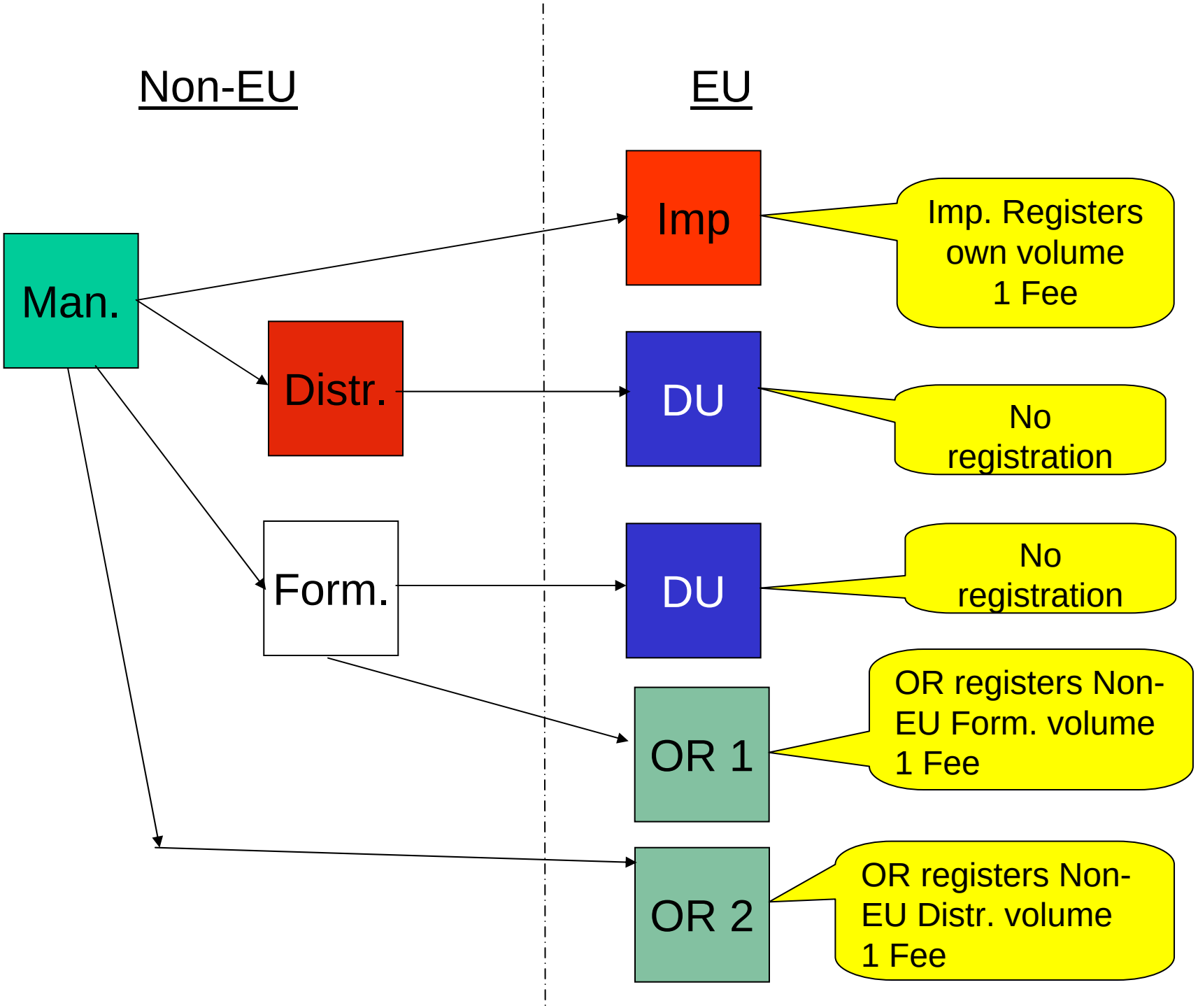

Non-EU
EU
Man
Imp
Imp to register
1 Fee

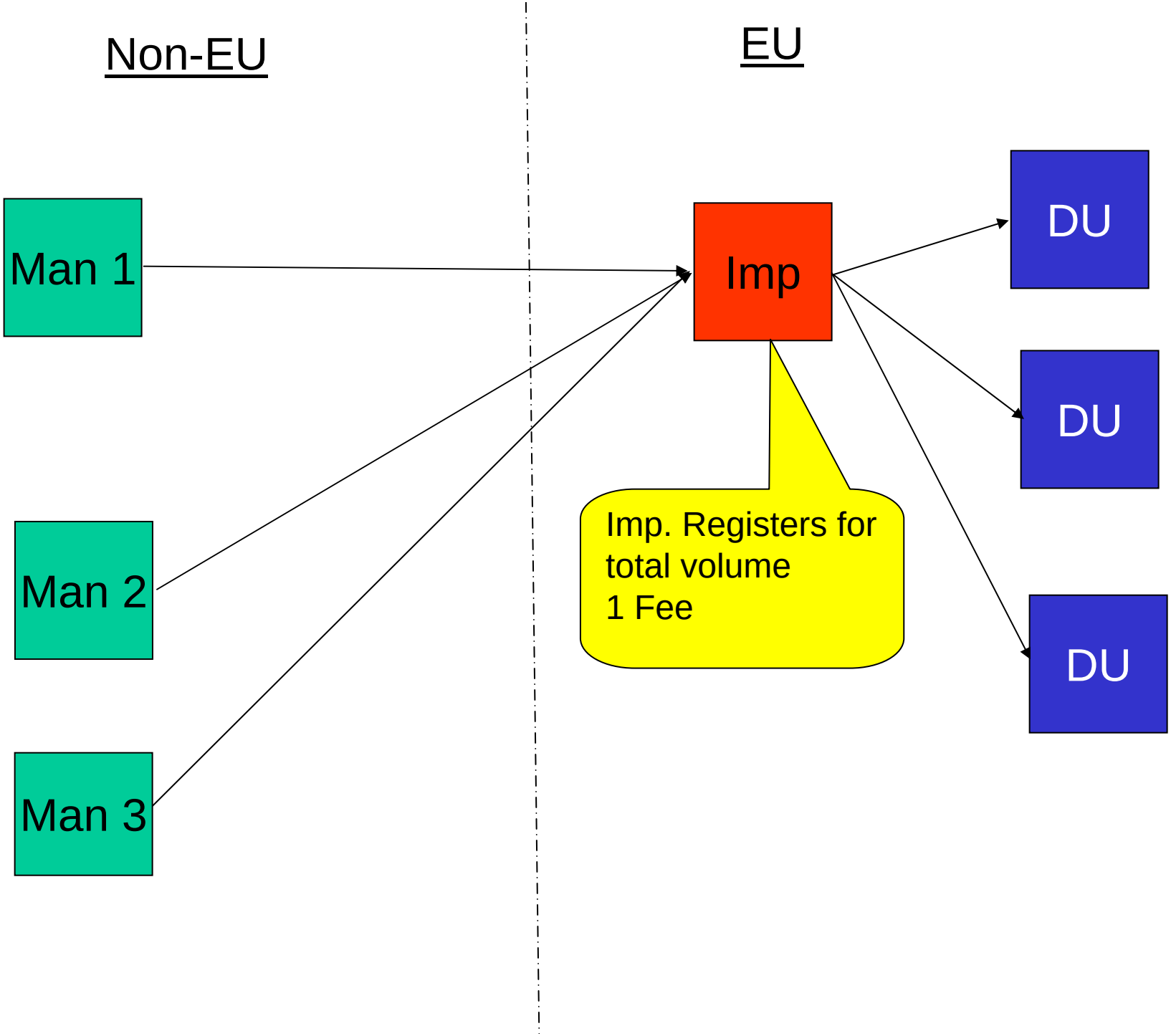

Non-EU
EU
Man.
DU
Importer becomes DU, No registration
OR
Non-EU Man. Appoints OR to register
1 Fee

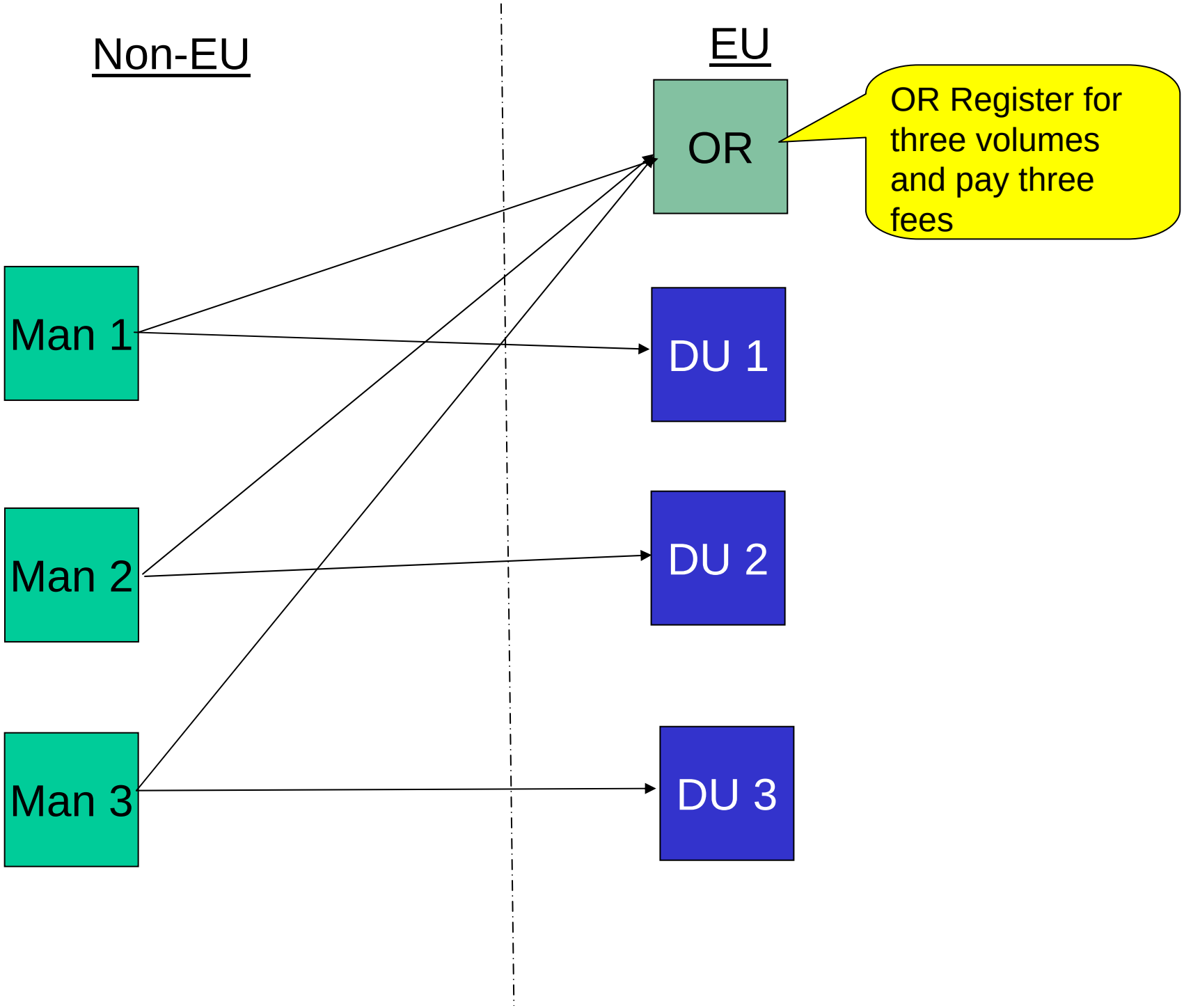

Non-EU
EU
Man.
DU
Imp
Imp to register each substance and for each 1 fee

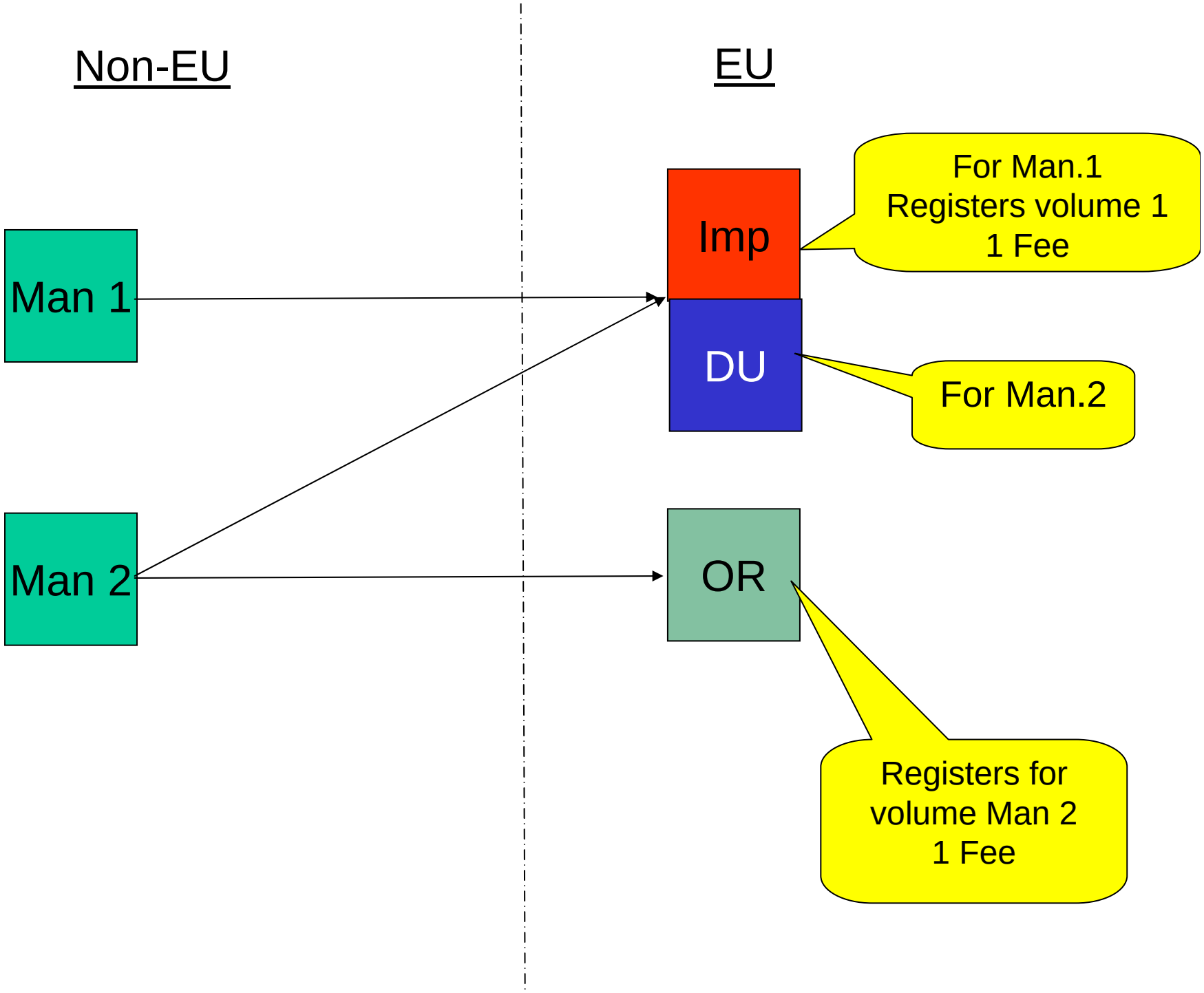

Non-EU
EU
Man.
Form.
Dist.
DU
DU
DU
No registration
No registration
No registration
OR
OR registers for total volume 1 fee


Non-EU
EU
Man.
Distr.
Form.
Imp
DU
DU
OR
Imp. Registers own volume 1 Fee
No registration
No registration
OR registers Non-EU Distr+ Form. Volume 1 Fee

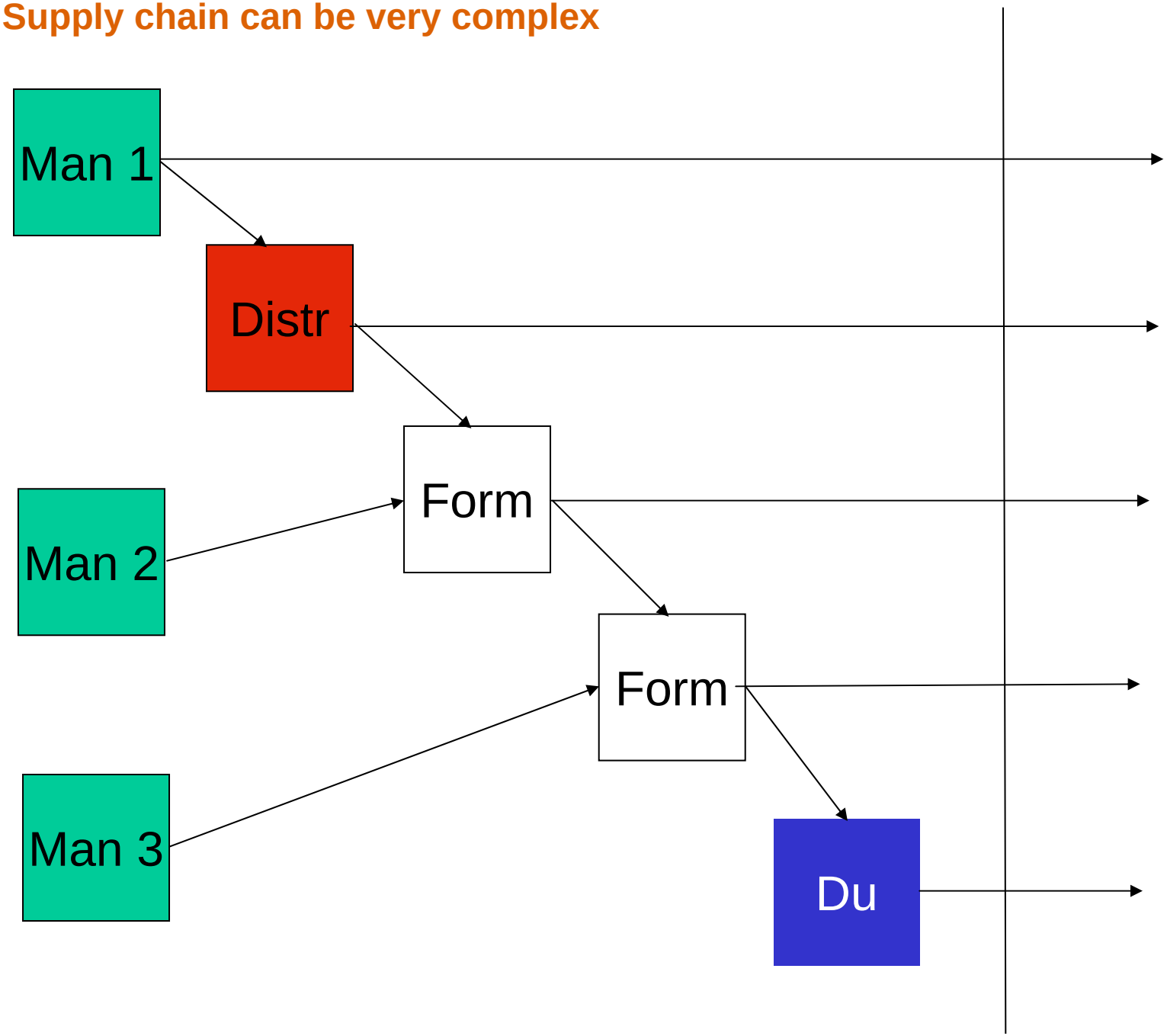

Non-EU
EU
Man.
Distr.
Form.
Imp
DU
DU
OR 1
OR 2
Imp. Registers own volume 1 Fee
No registration
No registration
OR registers Non-EU Form. volume 1 Fee
OR registers Non-EU Distr. volume 1 Fee


Non-EU
EU
Man 1
Man 2
Man 3
Imp
DU
DU
DU
Imp. Registers for
total volume
1 Fee


Non-EU
EU
OR
OR Register for three volumes and pay three fees
Man 1
Man 2
Man 3
DU 1
DU 2
DU 3


Non-EU
EU
Man 1
Man 2
Imp
DU
OR
For Man.1
Registers volume 1
1 Fee
For Man.2
Registers for
volume Man 2
1 Fee

Supply chain can be very complex



Importer – Only Representative

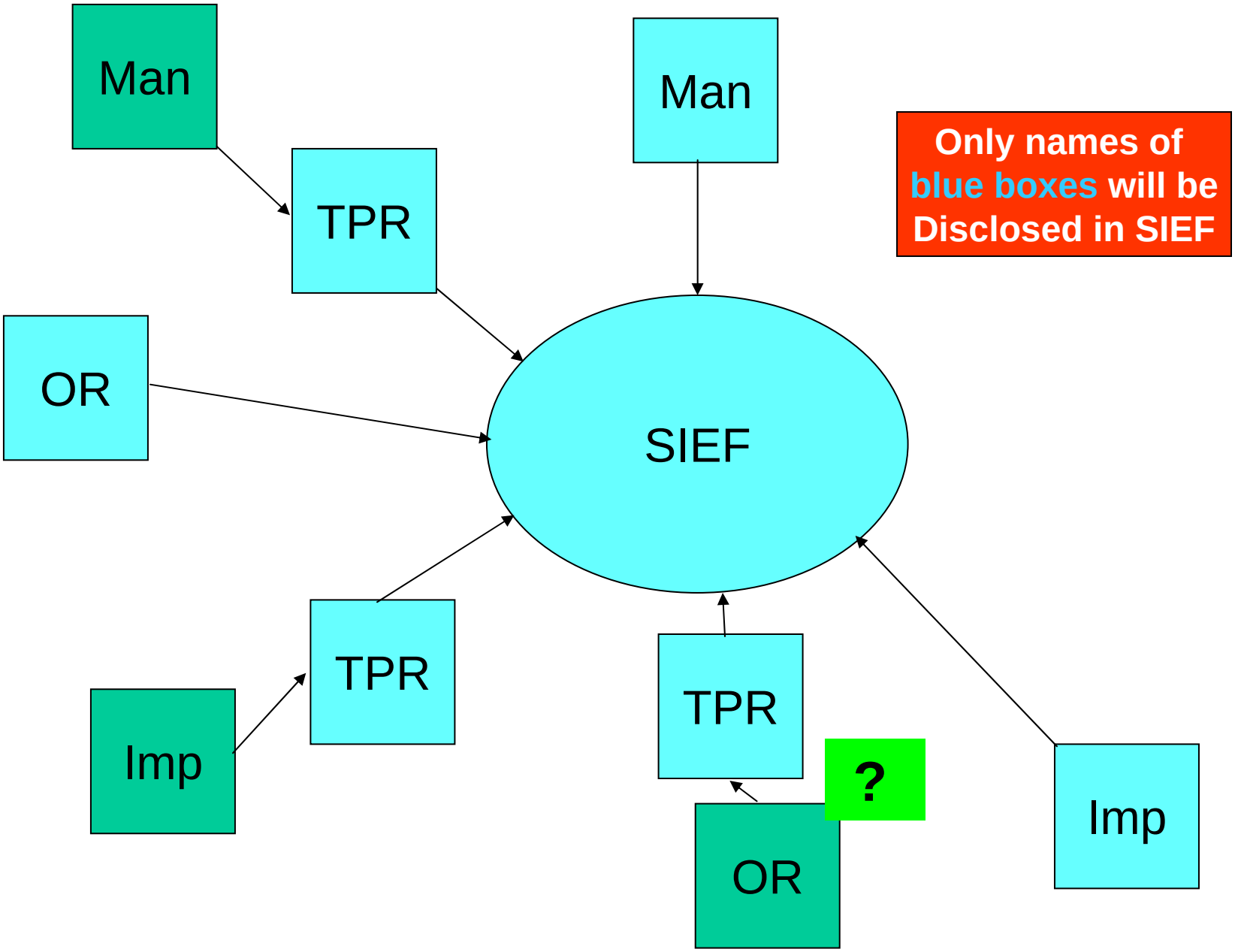
- Importer
  - **Pushes responsibility downstream**
  - **Allows importers to source from different manufacturers**
  - **Importer needs formulation information (CBI)**
- Only Representative
  - **Pushes responsibility upstream**
  - **Allows multiple routes to EU**
  - **Importer becomes DU and cannot buy freely, only from registered sources**
  - **CBI can remain with manufacturer**

Multiple route for non-EU manufacturer

- **How to prove REACH compliance?**
  - DU need to see evidence of registration
  - Registration number will not work, as non hazardous substances have no MSDS obligation
  - Composition of preparation will be CBI
  - Timing of registration different for substances in preparation (2010 – 2013 – 2018)
  - Exempted substances
- **Creation of declaration REACH compliance?**
  - Supplied by upstream supplier
  - Signed by respective OR

Third Party Representative

- **EU Manufacturer or Importer may appoint TPR to represent in SIEF, to prevent disclosure of company name**
- **Not clear yet if OR may appoint TPR**


Man
TPR
Man
Only names of
blue boxes will be
Disclosed in SIEF
OR
SIEF
TPR
TPR
Imp
?
OR
Imp

Reference documents

- **ECHA website for:**
  - **REACH legislation**
  - **Guidance documents**
  - **Navigator**
  - **IUCLID 5**
  - **REACH IT**
  - **Q + A's**

http://echa.europa.eu/home_en.asp

- **Cefic website for:**
  - **Supply chain questionnaires**
  - **Industry guidance documents and tools**
  - **Libraries**

http://www.cefic.org/Templates/shwStory.asp?NID=494&HID=643&PHID=494

Thank you