



OR & SDS

Enforcement Workshop with Stakeholders



***Erwin Annys***  
***Director REACH / Chemicals Policy***



# OR and SDS

---

## Legal framework

- **Article 8(1)**: *A natural or legal person established outside the Community [.....] a legal person established in the Community **to fulfill**, as his only representative, the **obligations on importers** under this Title.*
- **Article 8(2)**: *“The representative [....] shall keep available and up-to-date information on quantities imported and customers sold to, as well as **information on the supply of the latest update of the safety data sheet referred to in Article 31**”*

Any manufacturer, importer, downstream user or distributor placing on the market (\*) a substance, on its own or in a preparation, or a preparation (Art. 3(32))

Downstream user or a distributor being supplied with a substance or a preparation (Art. 3(34))



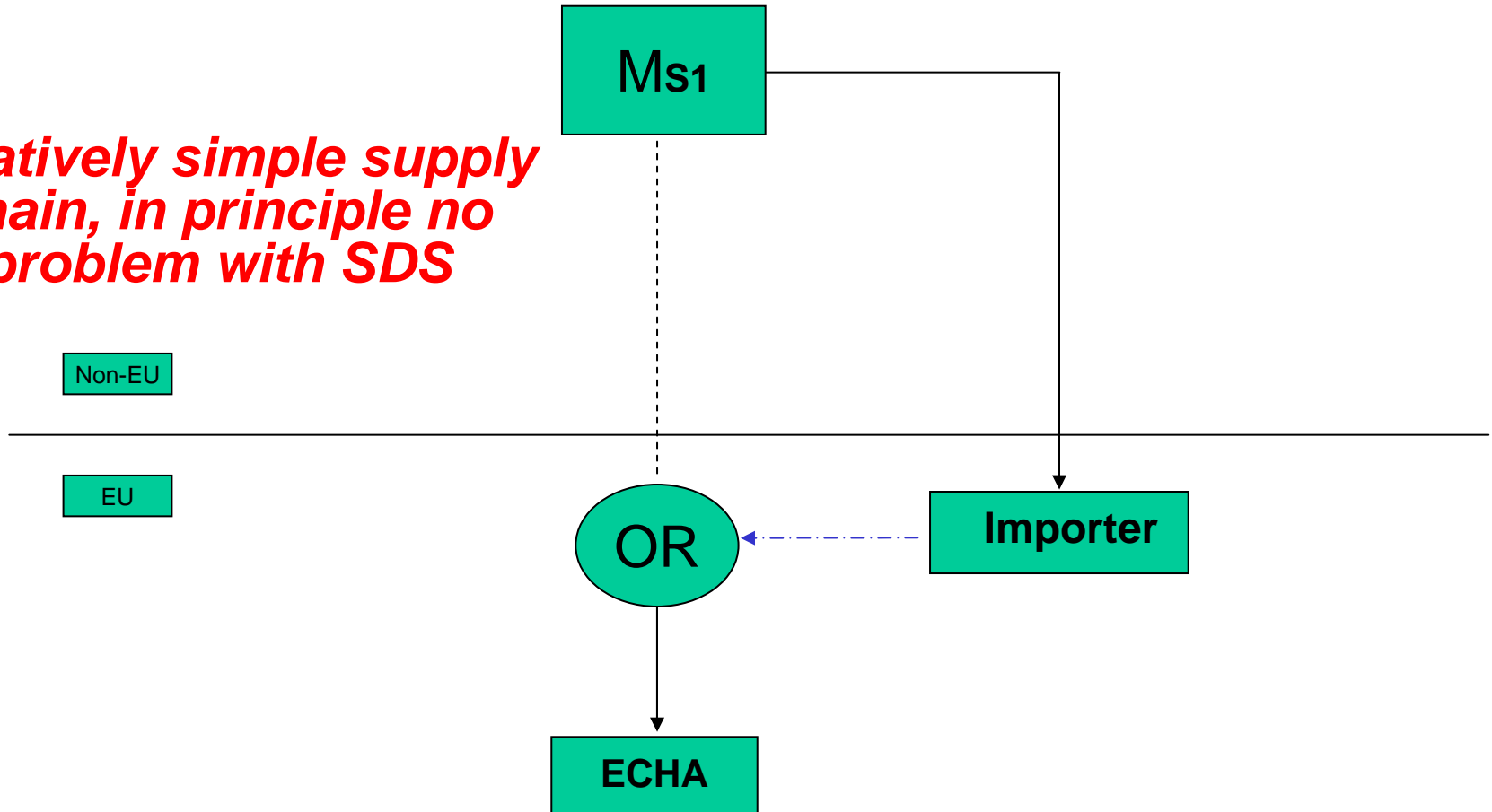
- **Article 31(1)**: *“The **supplier** of a substance or a preparation shall provide the recipient of the substance or preparation with a **safety data sheet compiled in accordance with Annex II**, if it meets the criteria of (a) through (c)”*
- **Article 31(3)**: *“The **supplier** shall provide the recipient at his request with a **safety data sheet compiled in accordance with Annex II**, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC but contains substances from (a) through (c)”*

\*Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;( Art. 3.12))

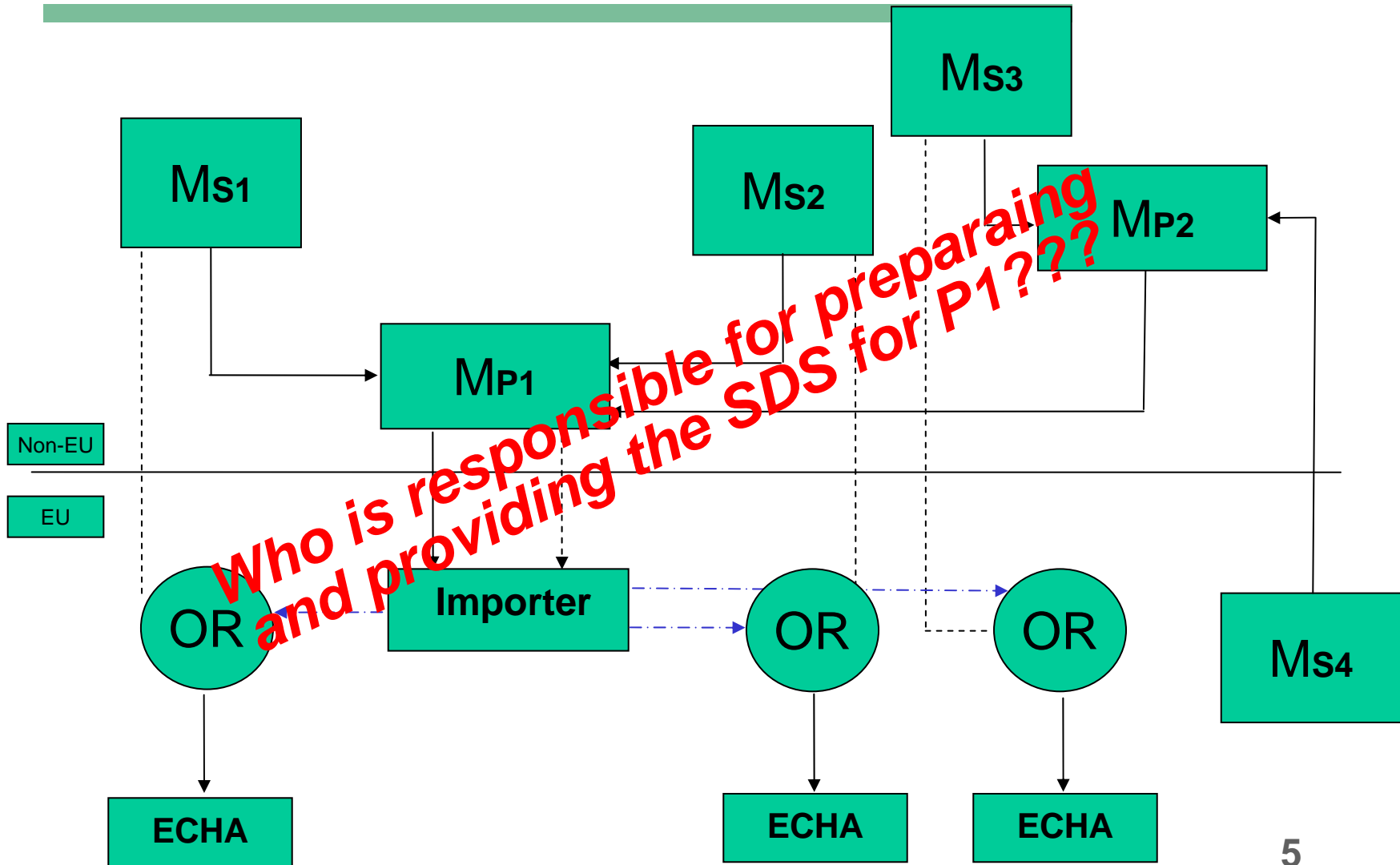
# A direct supply chain of a mono-constituent substance and the non-EU manufacturer has appointed an OR



*Relatively simple supply chain, in principle no problem with SDS*



# An indirect supply chain of a mixture and several OR's



***“The OR shall keep available information on the supply of the latest update of the SDS”***



---

- The **OR** does not have the obligation to provide the SDS, but he **shall keep track of the communication on the supply** of the latest update of the SDS
- **The importer** can be considered as supplier of the substance, which means that he **is responsible for providing an SDS to his recipient.**
- It is up to the non-EU manufacturer to decide by contractual agreement, if he wants to outsource the compilation of the SDS to the OR
- In case of imported mixtures the OR cannot be held responsible for the compilation of the SDS for the mixture<sup>6</sup>



## OR and SDS

---

- **The non-EU formulator of mixtures** containing multiple substances with different ORs **should ensure** (by contractual arrangements) that he **receives the relevant information from the registration dossiers from each OR** for each substance included in his mixture.
  
- The non-EU formulator should:
  - **supply the EU REACH compliant SDS for the mixture** to the EU importer.
  - **provide the OR with the evidence that the SDS for the mixture was sent** to the EU importer