

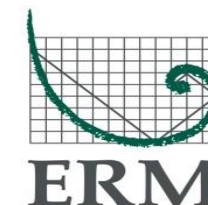


Customs and Chemical Regulation

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Welcome !



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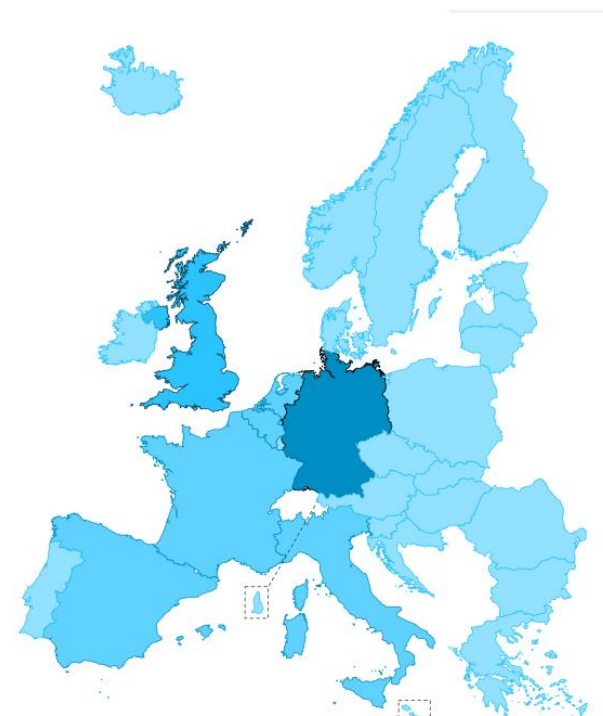
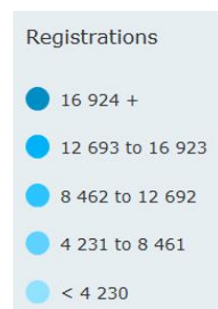
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10 years: REACH has only started....

- Registrations: 82.874
- Substances: 20.612
- Companies: 13.045
- **The journey**
 - Evaluation, new substances, classification, exposure, SDS, authorisations
 - Supply Chain Compliance
 - Enforcement



REACH & CUSTOMS

Enforcement

- Regulations can only be effective with a credible enforcement
- Enforcement only through Member States competent authorities
- Willingness to enforce and resources at national level are different
- Enforcement = revenue for the EU28 – 1
 - Penalties are „*effective, proportionate and dissuasive*“
- Enforcement means **true** improvement of human health, the environment, health of the community as a whole and of the EU budget

Enforcement – the role of customs authorities (1)

- 28 customs authorities
 - Different legal cultures, different prerogatives
 - Talk to each other through committees; in Brussels, chaired by the European Commission
- Primary objective:
 - Collecting the right amount of duty
 - Security and safety of goods entering the EU
- Ancillary objective: making sure that imported goods comply with applicable rules (there are over 70 different regulatory schemes), and do not infringe IP rights
- Limited expertise of customs – shared responsibility with competent agencies

Enforcement – the role of customs authorities (2)

- European Customs Inventory of Chemical Substances ([ECICS](#)):
 - Identifies all chemicals substances, with a reference to their CUS, CAS RN numbers, etc.
 - Based on the classification, the operator knows what regulatory requirements apply
 - Same for customs
- Declarant is responsible for the customs code given in the declaration
- Random checks: risk analysis under a common risk management framework. Relevant risks include threats to human, animal or plant health, the environment and consumers
- Customs will only be aware that there is a breach if they inspect the goods. Most goods are not inspected.
- Allows for non compliant behaviours to develop. Until enough is enough ... → enforcement patterns change

Imports

- Import differently defined under REACH and the Union Custom Code
 - **REACH**: Introduction into the customs territory of the Community
 - 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 (Article 3 (12)).**
 - **Union Customs Code**: Custom status change of non-Union goods into Union goods: goods brought into the customs territory of the Union from countries or territories outside that territory and are *released for free circulation*; duties become payable

Substances under customs supervision

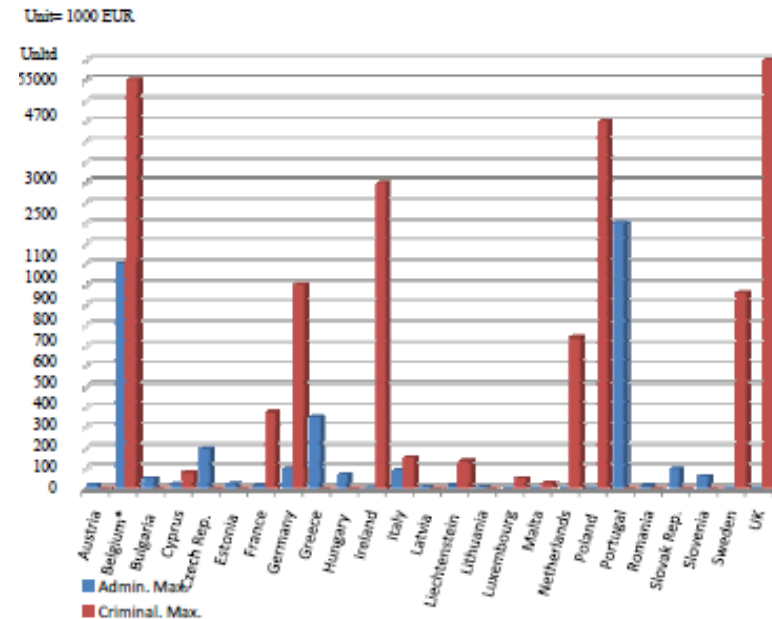
- REACH applies to goods brought into the EU's customs territory, except if:
 - They are in transit, in temporary storage, or in a free zone or a bonded warehouse; AND
 - are to be re-exported; AND
 - do **not** undergo any form of treatment or processing during their stay in the EU.
- **However: interpretation is not uniformly applied by Member State customs authorities (e.g. transfer of bulk fluids from ship to tank)**

Importer

- The **importer** is any natural or legal person established within the Community who is responsible for placing the product on the EU market
- *“The responsibility for import depends on many factors such as who orders, who pays, who is dealing with the customs formalities, but this might not be conclusive on its own.”*
- The entire ordering process and logistics must be clearly documented for each import
 - Strong **Management of Change** and **Workflows** procedures : Information Solutions must be commensurate with **Processes**

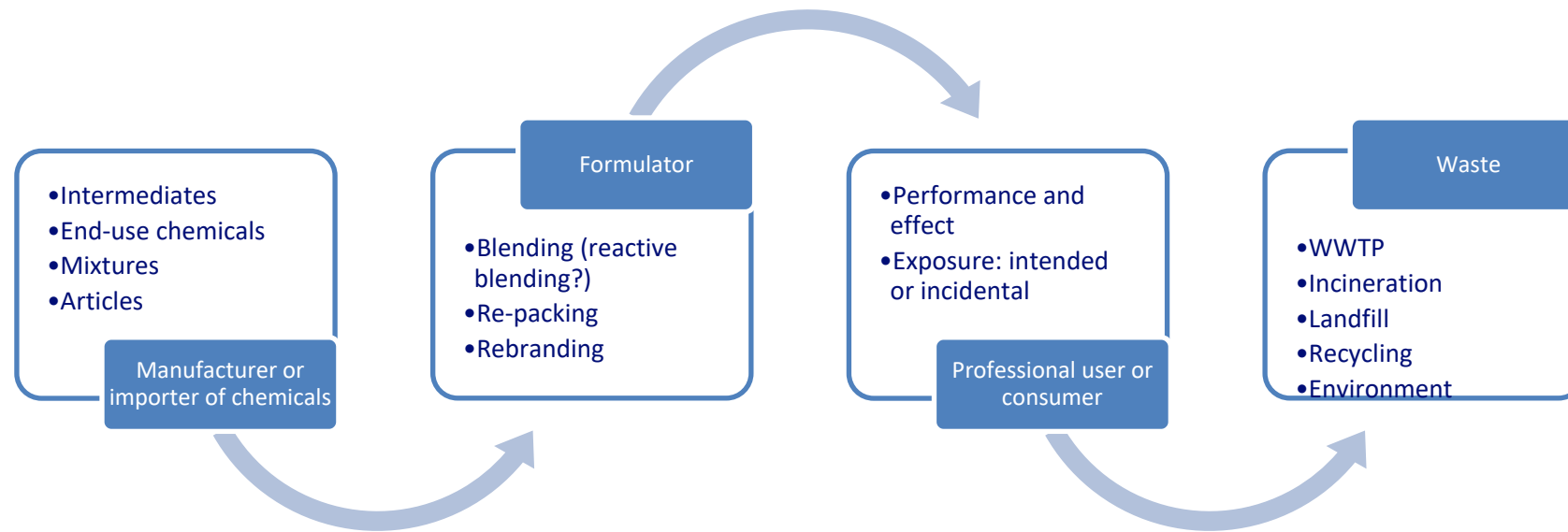
Penalties

- Each Member State implements a scheme of penalties under local legislation
- In some Member States, fines are disproportionately lower than compliance costs
- Incentive for supply chain engineering to avoid risk?
- Enforcement priorities evolve, at MS level, at EU level



Supply chain compliance

Supply Chains



Supply chains are always multilayered building complex networks with multiple actors driven by commercial optimization and supply security: procurement options, transport, storage, customs&duties, tax, insurance, packaging

Managing Supply Chains

- Mapping of functions and cross-functional interactions
- Identify critical processes
- Analyse compliance systematically
- Minimize cross functional interaction: refrain from duplication
- Mirror in functional software environment, define workflows, introduce customized sentinels and a tracking tool
- Product Approval Process: no entry without data
- Strict Management of Change
- Invest in people and the right support

Chemicals Imports in the EU

- Not only REACH but also BPR, PIC, RoHS, Detergents, Cosmetics, PPP, CLP, Transport of Dangerous Goods
- Customs have the duty to **verify** the *compliance* of goods imported and are **obliged** to suspend the release of non-compliant goods; specific enforcement powers on REACH authorities **does not supersede** the customs authorities' powers under Customs law.
 - Documents required by REACH (such as an authorisation) can be regarded as "documents which must be provided **before** the goods can be placed under, or released for, the customs procedure requested".
- **How to check chemical regulatory compliance at the borders of the EU?**

Proof of Compliance

- SDS is not sufficient to clear REACH Compliance
 - Must not be physically available upon the time of import or during transport.
 - Only hazardous substances when they exceed specific concentration limits
 - Band and type of registration is not listed: volume covered by registration?
 - Responsible for import not clear, but OR information may be included
- Transport Documents **may** give indications on the REACH responsible for import, but generally not.
- No official / standard transport document available to confirm regulatory compliance
- **In conclusion: there is nothing which can unambiguously show compliance**

Compliance Checks in Practice

- REACH enforcement authorities collect data at Customs and audit respective REACH importers (often!)
- Customs build comprehensive knowledge about REACH and develop key indicators which flag high probability of non-compliance
- Companies perform internal audits using smart screening methodologies to discover pain-points
 - Corporate governance: compliance is a **top-down** priority

Making compliance checks easier?

- Regulatory Compliance Declaration may or may not be a solution.....discussion necessary
 - Basic data needs covered
 - Contact information to a regulatory person



Compliance post- registration

Supply chain compliance post-registration

- REACH registration over
- Has REACH registration achieved its goal?
- Different possible cases of non-compliance with registration obligation
- What will the focus of ECHA/MS action be?
- How to ensure continued compliance in the supply chain?

REACH registration over

- Final registration deadline expired on 31 May 2018
 - Approx. 21,500 substances registered
 - Approx. 11,000 under the 2018 deadline
- Since 1 June 2018
 - Substances that were not registered cannot be manufactured/placed on the market
 - No more reliance on pre-registration?
 - No more SIEFs?

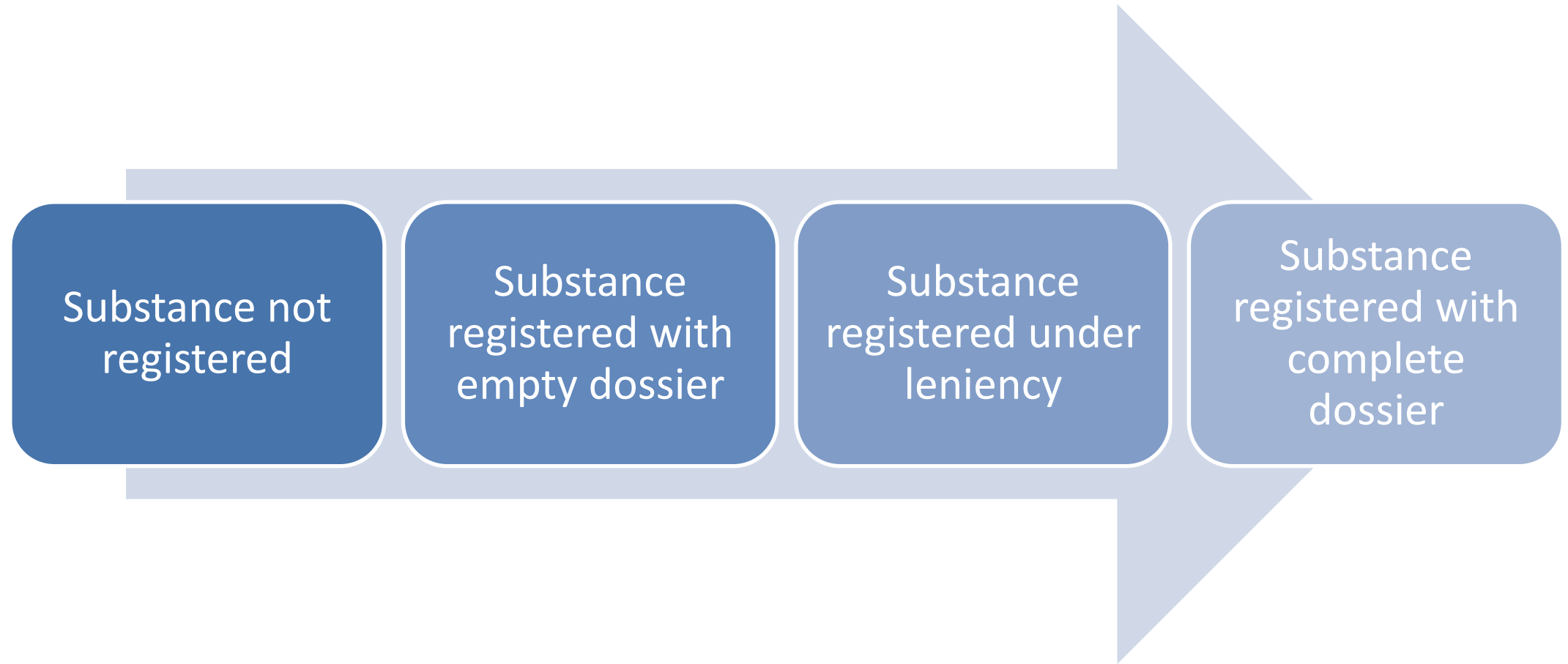
Post-registration events

- Changes in volumes
- Changes in information on substance
- Changes in regulation of substance
 - Other REACH processes
 - Other pieces of legislation (BPR, POP, PIC,...)
- Changes in the supply chain
- Changes in identity/number of registrants

 Contractual agreements must provide for post-registration events

 Continued communication in supply chain and “SIEF” is essential

Post-registration outlook



Post-registration outlook

- Focus of ECHA/MS compliance/enforcement action post-registration should be on most severe instances of non-compliance
 - Unregistered substances
 - Empty dossiers
 - Poor quality dossiers (e.g. “copy-paste”)
 - Leniency dossiers
- Need to ensure a genuine level playing field
 - Competitiveness objective of REACH
 - Participation in future costs

Inspections

Steps to prepare for/respond to inspections

1. Preparing for inspections
2. Handling inspections
3. Remedies

1. Preparing for inspections

- Identity substances and regulatory status
- Identify REACH roles and obligations
 - Per legal entity
 - Per plant
- Identify compliance measures taken and locate relevant documentation
 - Internal
 - External (e.g. OR certificates)
- Identify internal points of contact
- Instruct (reception) personnel

2. Handling inspections

- Reception of inspector
- Clarifying scope and legal basis of inspection
- Cooperation during the inspection
 - Documentation
 - Answering questions
 - Responding to claims of non-compliance
 - Dealing with confidential information
- Follow-up to the inspection

3. Remedies

- Procedural safeguards
- National administrative/civil/criminal courts
 - Compliance with national provisions
 - Compliance with EU provisions
- Interpretation of REACH obligations
 - ECHA guidance
 - CJEU/Board of Appeal case-law
 - Possible preliminary reference to the CJEU

Case Studies

Practical examples

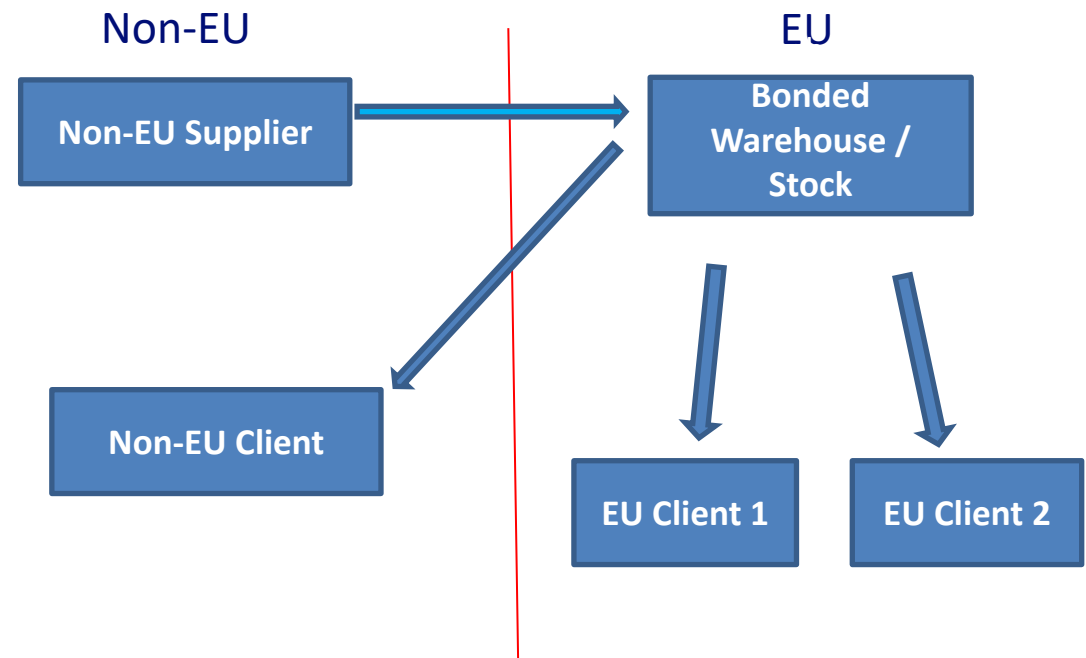
Regulatory forensic cases for customs

- No registration numbers for substances < 1MT/LE
- Rebranding and relabelling: wrong information on registration status (e.g. full and SCC registrations of the same substance): intertrading!
- OR Certificates issued to cover unregistered cargo
- Recycled materials / re-imports / exempted goods (polymers ---- monomers)
- Articles containing substances with the intention to be released (fragrance candles)
- Articles functioning as containers to hold mixtures (ink-cartridges)
- SVHC Substances (and the continuous updates of the candidate list)
- Restrictions: concentrations are necessary



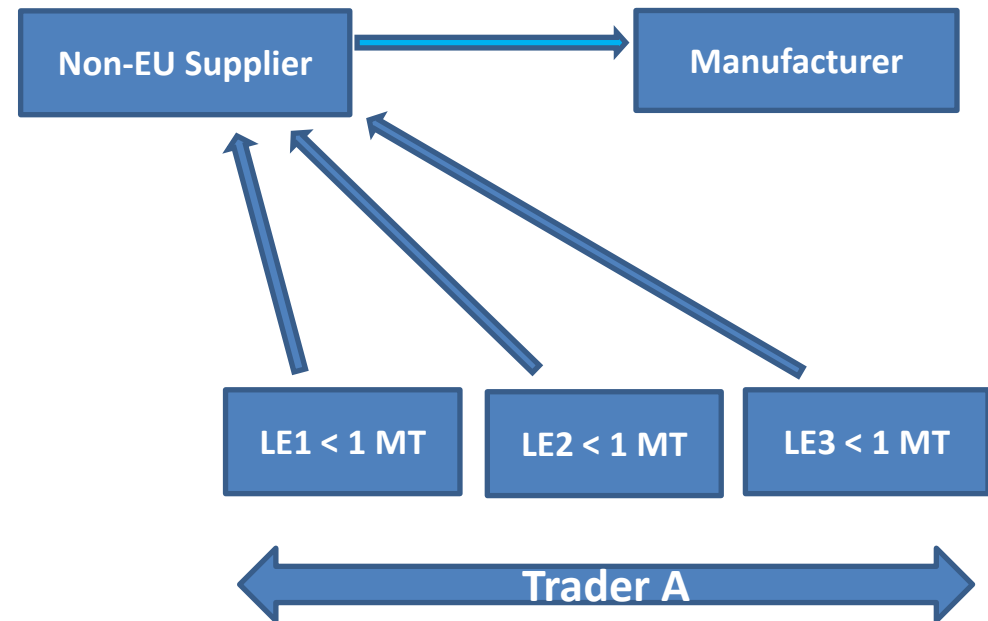
Consignment Stocks

- Agreement between supplier and client to keep stocks in bonded state
- Order / call-off / clearance by client; no call off obligation: stocks owned by supplier
- **Case A:** no handling (closed container):
 - REACH exempt until custom clearance
 - Client imports and registers
- **Case B:** handling (open storage tank / refilling):
 - REACH obligations
 - Supplier appoints OR and registers (client reserves, but has no obligation to call-off)
 - Client registers, no obligation to call off, but contract structure must be unambiguous on REACH responsibility
 - Considerations of corporate accounting rule scheme, insurance, customs, VAT and tax are necessary



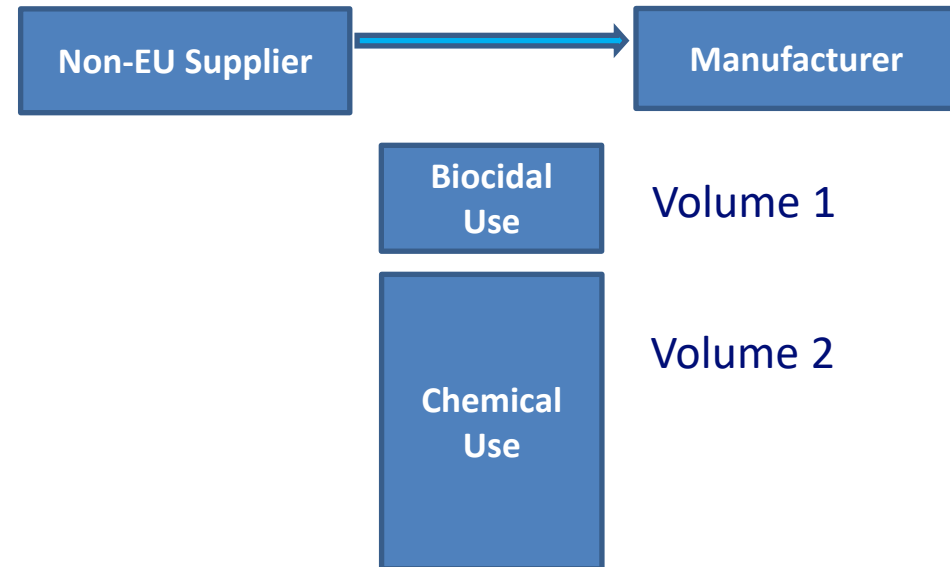
Accumulation of Volumes

- Situation has many variants; compliance is a matter of interpretation and intention
- Test volumes for a single client as part of an approval process
- No registration number available
- Documentation and quantity tracking proves bonafide intentions



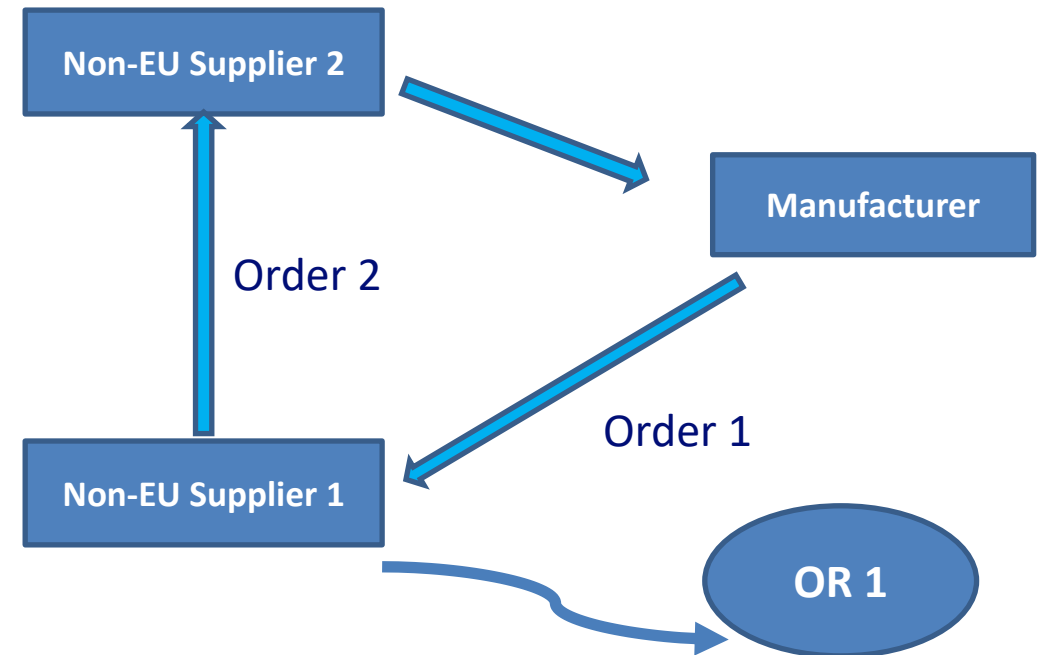
Dual Use Substance

- Biocidal Use is regulated under BPR
- Volume 2 = REACH Volume
- Use of 2 CAS Numbers and separation of volumes prevents difficulties to prove compliance



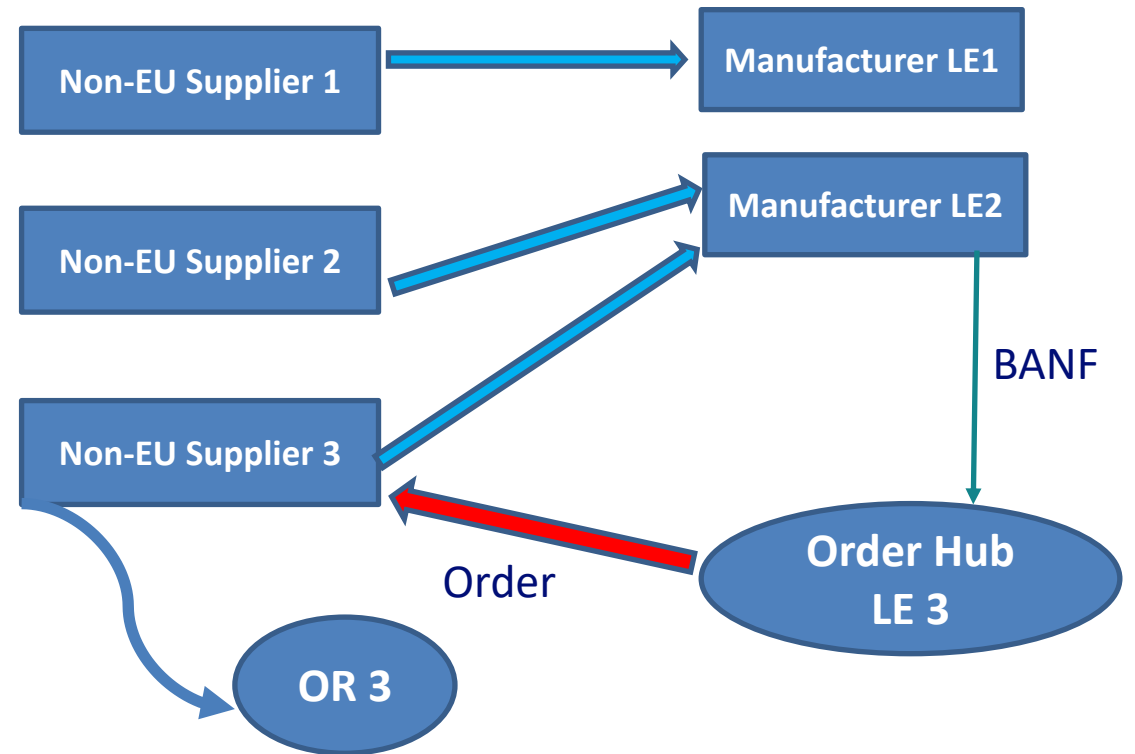
Triangular transactions

- Supplier 1 cascades order to supplier 2
- Supplier 2 direct delivery under brand of supplier 1
- Volumes accumulate under OR1 (appointed by supplier 1)
- Supplier 1 notifies volume to OR 1 and supplier 2 refers to OR1



Ordering Hub

- Manufacturer LE1 and LE2 hold registration
- Order Hub LE3 places order for direct delivery at LE1 and LE2
- LE3 has no registrations
- Ordering chain not Process may require LE3 to hold the registration
- Who covers otherwise the import the registration of LE2 or OR3? Must be fixed in advance!!



Thank you. Any questions?



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