

Challenges, Constraints and Opportunities In DU Communication

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► Introduction

- REACH introduced globally a new area of chemicals management.
- REACH applies to legal entities in the European Community only, companies located outside but exporting into the EU customs territory are not bound by REACH obligations. Authorities have no competence to enforce on operators outside EU.
- Responsibility for fulfilling REACH requirements is with EU-importers, jurisdiction is limited to EU territory.
- Non-EU Manufacturer (NEM) export into the EU via several importers, each importer shall make a separate (pre-)registration.
- If NEM prefers to register on behalf of his EU-importer, REACH allows appointing an Only Representative (OR) located in EU (REACH Article 8).
- OR takes over certain obligations on behalf of the exporter. This relieves (eventually) EU importers within same supply chain from their registration duties; hence they become downstream users.

► REACH Article 8

Article 8

Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.
2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, 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.
3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

▶ ORO – The **O**nly **R**epresentative **O**rganisation



Only Representative Organisation AISBL

Chaussée de Roodebeek 206
1200 Brussels, Belgium

www.onlyrepresentatives.org

- ORO's main objectives are to:
 - Set up OR quality standards
 - Develop a common understanding of REACH requirements for ORs
 - Represent the interests of ORs and Non-EU Manufacturers
 - Cooperate with regulators and other stakeholders in the process
 - Protect Non-EU Manufacturers from discrimination through REACH and EU against WTO claims

▶ ORO - Criteria for Full Membership

- **Be in compliance with REACH Article 8 requirements and ORO's Code-of-Conduct:**
 - ✓ **Have a clear understanding of REACH and applicable regulatory/administrative processes**
 - ✓ **Be competent in handling large amounts of data, including CBI**
 - ✓ **Employ competent people with relevant technical qualifications & experience**
 - ✓ **Have permanent physical presence of at least one competent person in the EU.
(There is no objection against the operation of a back-office in a non-EU country)**
 - ✓ **Have a Sustainability Process in place, which adequately addresses the risks for the non-EU Producer in case of bankruptcy or long lasting absence of key personnel**
 - ✓ **Have a professional liability/indemnity insurance specifically covering the OR activities**
 - ✓ **Promote the good reputation of ORs generally through proper behaviour, active communications with parties and professional execution of services**
 - ✓ **Actively strive to work in accordance with the ORO Best Practice Guide**
 - ✓ **Cooperate fully where Principal wishes to transfer to another OR or to move the REACH obligations to an importer, unless there are compelling circumstances to do otherwise.**
 - ✓ **No use of contact details of registrants, pre-registrants, notifiers or other submitters of information obtained from REACH IT for promotional or marketing purposes**

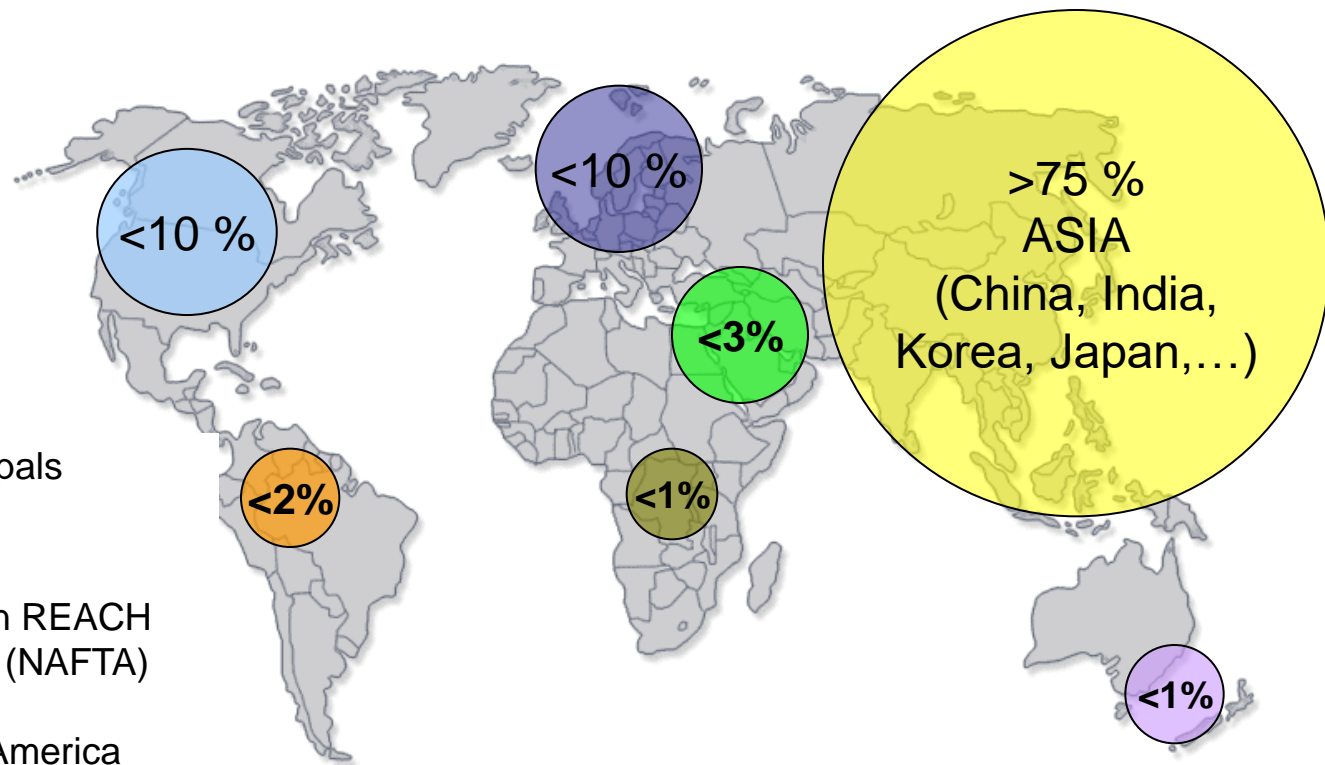
► ORO - Facts & Figures

- ORO has currently 32 Members (and further requests for joining)
- ORO Members:
 - are acting ORs (Service Providers)
 - serve >2.000 Non-EU Manufacturers
 - handle >10.000 chemical substances
 - cover >10.000 of importers all over the EU/EEA
 - pre-registered >15.000 substances
 - registered >3.200 substances



► ORO - Facts & Figures

Non-Community-Manufacturers from all over the world

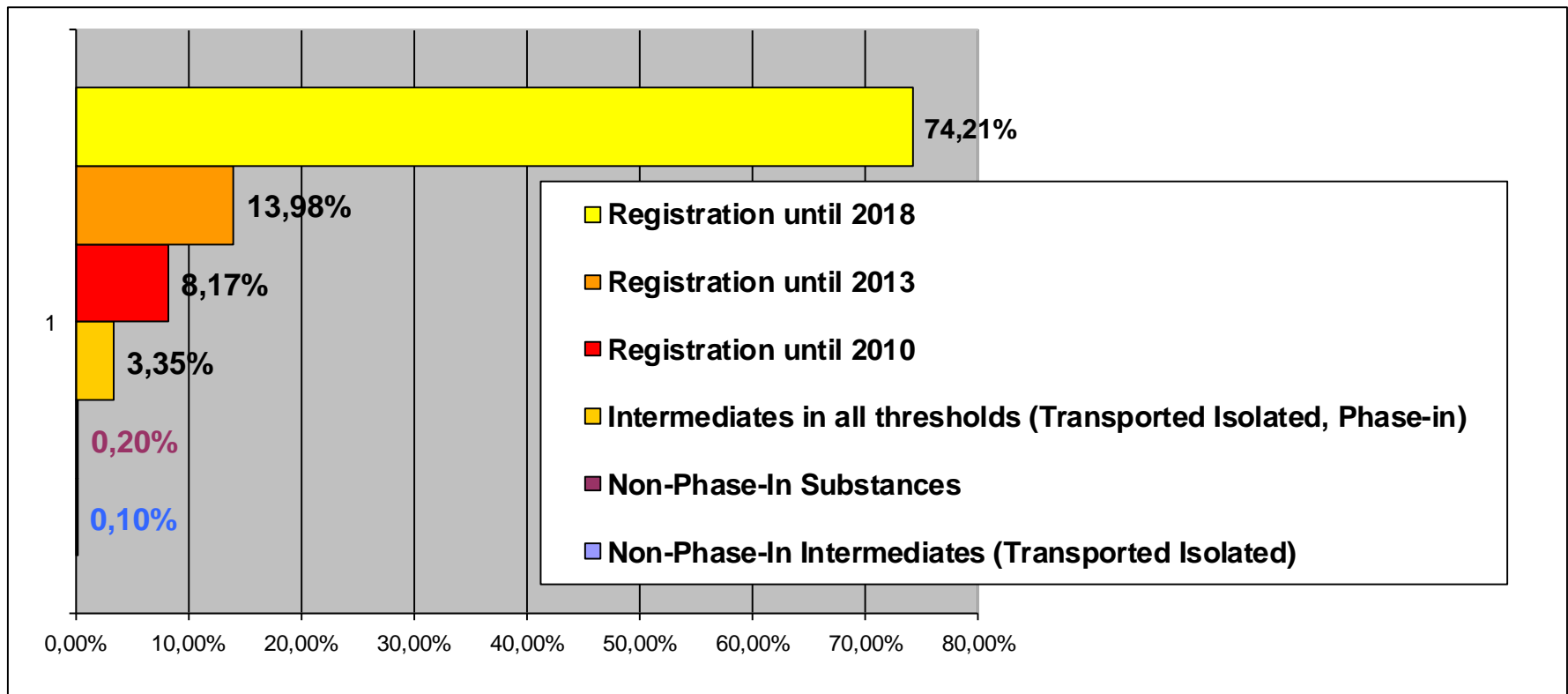


Distribution of Principals
by Region:

1. Asia
2. Europe – not in REACH
3. North America (NAFTA)
4. Middle East
5. South/Middle America
6. Africa
7. Oceania

► ORO - Facts & Figures

Substances of ORO Members by Type and Registration Deadline*



* According to ORO Surveys conducted from 2010 - 2014

► ORO Achievement

- Inauguration with 10 founding members in December 2008
- Registered as non-profit industry association in Brussels/Belgium (April 2009, 5 years anniversary to celebrate in May 2014)
- ORO has been recognized by Industry Associations, REACH Regulators, Missions from non-EU countries, Media....
- We participate in the REACH-Implementation debate and seek clarification of specific OR-topics to support our members and principals (e.g. SME verification, SDS-responsibilities, indirect imports, CLP)
 - ORO accomplished that ORs are eligible to submit Authorisation Applications
 - ORO achieved that ORs can act in the CLP Group Notification
 - ORO is an accredited stakeholder of ECHA
 - ORO participates as observer at the MSC-Meetings
 - ORO issued a Best Practice Guide (BPG) for Only Representatives
 - > 50% of ORO Members were inspected, no or just minor deficiencies were identified (in contrary to the REACH-ENFORCE-3 project findings)

- ▶ **Only Representatives only(!) can provide legally binding statements under REACH**
 - **Non-EU Manufacturers have no rights nor duties under REACH**
 - Statements are not legally binding for Importers or Downstream Users
 - Statements can be a fake documents leading to illegal imports
 - **OR is the legal representative of the Non-EU Manufacturer and the registrant on behalf of his principal**
 - **OR can legally confirm:**
 - Registration status of a substance (formulation or mixture)
 - Volume coverage
 - Uses coverage
 - Supplier of the substance

▶ **Import Certificate is a tool for legally binding Supply Chain and Authority communication**

- **Import Certificate specifies:**
 - **Only Representative**
 - **Supplier**
 - **Importer**
 - **Product and quantity**
 - **Registration status**
- **Import Certificates assist authorities (e.g. customs) to control illegal imports and avoid free-riders in the EU market**
- **Import Certificates should be part of the shipping documents to avoid problems at customs clearance**

► Importer Certificate Example

IMPORT CERTIFICATE OF REACH COMPLIANCE COVERAGE (EU)

Certificate No.: 20150133_010_151008

Validity period: Year 2014

As the appointed Only Representative of a NON-EU manufacturer, according to Article 8 of the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and/or Trustee of a NON-EU and/or EU manufacturer and/or Trustee of a NON-EU manufacturer's Only Representative, we herewith confirm that

The following product **Mulimix 25**

Supplied by **Mishmash Chemicals, Inc.**
 Uphil Road 1423
 Plastics Town, KL 72533
 USA

To **European Importer**
 P.O Box 53778
 F-31078 Toulouse
 France

With a delivery amount of **6.843 mt**

is covered within the supply chain of this product by a REACH Registration at the European Chemicals Agency (EChA) with the following Reference number:.

01-2119442288-35-0003

We are prepared to provide enforcement authorities within the EU with the necessary details upon request.

REACH ChemAdvice GmbH



Dr. Rudolf Staab
Managing Director

- ▶ **CLP Certificates facilitate customs clearance of non hazardous substances**
 - **Non hazardous substances don't need Safety Data Sheets**
 - **Customs authorities may ask for CLP Statement as a prerequisite for customs clearance**
 - **CLP Certificate specifies**
 - **Only Representative as the registrant of the substance**
 - **Supplier**
 - **Product**
 - **Registration status**
 - **Classification**
 - **CLP Certificates should be generated for registered substances only where all endpoints are known**

To whom it may concern

Products: Fertilizer NP 16-20-0
Fertilizer NPK T-15

manufactured by

Ferticompany S.A.
Farmers Boulevard 1234
4500 El Jadida
Maroc

Have been reviewed by REACH ChemAdvice GmbH (RCA) regarding CL notification obligations according to the REGULATION (EC) No 1272/2008 of the EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 (CLP Regulation).

These substances have been found to fall into following category;

These substances were registered by RCA in 2010 according to REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 (REACH Regulation) with the Reference numbers

01-2119552436-37-0001
01-2119488166-29-0019
01-2119455044-46-0156

Classification & Labelling information was included in the registration dossiers and therefore the substances are exempt of CL notification. As a conclusion, Fertilizer 16-20-0 and Fertilizer NPK T-15 don't need to be notified to the CL Inventory.

REACH ChemAdvice GmbH
Dr. Rudolf Staab
Managing Partner

▶ Confidential Business Information (CBI) is an issue in Supply Chain communication (1)

- **Non-EU Manufacturers are not willing to disclose their customers**
 - OR cannot fulfill its obligation to take record of Importers and their volumes
 - Downstream communication for OR is impossible
 - Upstream communication for Importers or Downstream Users is impossible
 - OR cannot pass inspections successfully
 - Result:
 - ❖ OR needs to terminate OR Agreement with its principal
 - ❖ Importers or Downstream Users have no longer REACH compliant imports

▶ Confidential Business Information (CBI) is an issue in Supply Chain communication (2)

- **Traders are not disclosing their customers to OR**
 - Transparency of the supply chain is more complex to understand by authorities
 - Data collection for Authorization dossiers is impossible
 - Downstream Users have no easy access to REACH compliant statements
- **REACH compliant certificates for formulations or mixtures**
 - Non-EU Manufacturer not willing to disclose the composition to Importers
 - Certificates impossible to generate for Traded goods if not all components are covered by the OR

▶ **OR cannot be responsible for the content of the SDS**

- **OR is not the manufacturer of the substance or formulation**
- **The Non-EU Manufacturer only can be responsible for the content of the SDS**
- **OR cannot take record of the composition of the imported substance**
 - **ORs represent hundreds or even thousands of substances**
 - **ORs are not allowed nor capable to import, store and analyze the products**
 - **ORs very often cover not all components of a product (e.g. formulations contain also substances covered by other ORs or other Manufacturers)**

► Guidance for Importers

- Integrate REACH responsibilities into sourcing agreements with suppliers
- Request Cover Statements/Import Certificates from the OR of the supplier
- If own (pre-)registration is not an option, source only verifiable REACH (pre-)registered chemicals
- Ask for REACH compliant SDS and coverage of uses
- OR can make the CLP-Group Notification for imported substances as OR, the responsibility is on the importer to document this!

► Conclusion

- **Supply Chain communication is complex but of highest importance for a REACH compliant Supply Chain**
- **Supply Chain communication provides legally binding documentation in case of inspections by authorities**
- **ORO Best Practice Guide helps to understand own role under REACH and gives recommendations for a REACH compliant supply chain**
- **Supply Chain communication can save cost under REACH**
 - **Change of REACH Role (from Importer to Downstream User)**
 - **REACH compliant SDS available through OR**
 - **Special Uses not yet covered by the registration can be added through a registration update**

Thank you for your attention



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