

REACH Lead Registrants Workshop

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Particular SIEF Challenges

Dealing with Only Representatives - SIEFs without an
EU Manufacturer

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

- 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-Community manufacturers (NCM);
 - Cooperate with regulators and other stakeholders in the REACH process
 - Protect NCM from discrimination through REACH and by that protecting EU against WTO/TBT claims.

▶ ORO – Membership Criteria for Full Membership

- Be in compliance with REACH Article 8 requirements;
- Have a clear understanding of REACH and concerned regulatory and administrative processes and provide evidence of experience of EU chemicals policy, legislation and management;
- Have competence in data and systems management, including handling of confidential information and confirm on request the Downstream User status to EU Importers for the REACH covered substances;
- Employ competent people with relevant technical qualifications and experience and have physical presence in the EU;
- Have a Sustainability Plan in place, which limits the risks of the non-EU-manufacturers - examples include fair OR contracts and succession planning;
- Have insurance coverage;
- Represent the interests of ORs and NCM.

► ORO Facts & Figures*

ORO has currently 15 full members
(and many requests for joining):

Located in:

Germany (8) / UK (2) / France (2) /
Belgium (1) / Netherlands (1) / Bulgaria (1)



All ORO Full Members:

- are acting ORs
- serve > 500 NCM
- cover > 5000 chemical substances

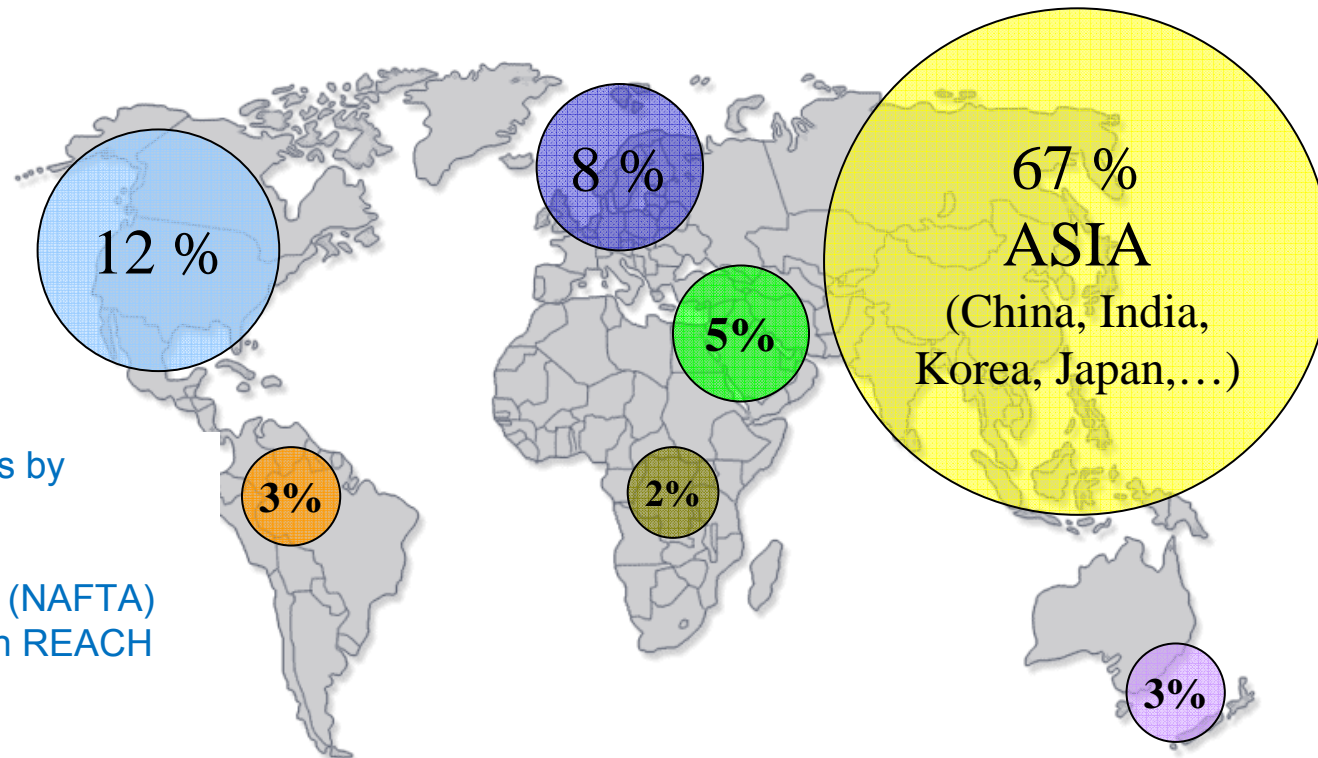
* Remark:

Date of the statistics July 2009

Statistic figures are approximates and where provided voluntary from the 10 ORO founding Members

► ORO Facts & Figures

Non-Community-Manufacturers from all over the world

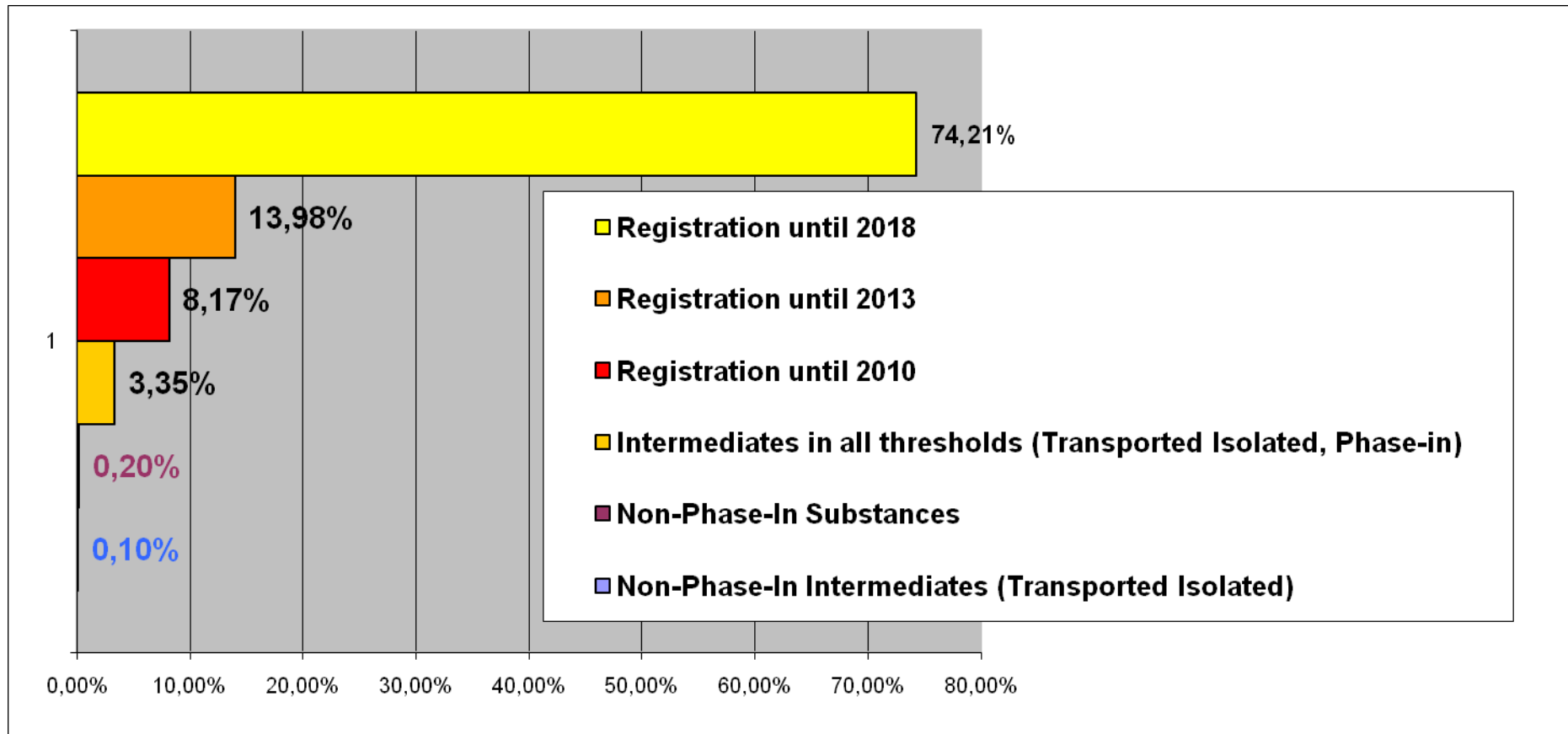


Distribution of Clients by World Region:

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

▶ ORO Facts & Figures

Substances according to Type and Registration Deadline



► Only Representatives in SIEFs and Registration Process

General Comments:

- “Reliable” ORs not less qualified in REACH process in comparison to EU-manufacturers/importers; but communication/decision making with NCM more complex
- Complexity and resources for SIEF Communication were underestimated
- ORs represent different NCM-types – varying from formulators, micro-enterprises to multinational market leaders (ca. 10% of ORO members’ substance portfolio is “Tier 1”)
 - Consequently the OR mandate differs depending on the client and ranges from “Dormant” to “Lead Registrant” in the SIEF or just as importer/volume tracker with no SIEF contact
 - The NCM knowledge about the REACH process has a broad range too, from uninformed to well informed
 - Competent ORs with uninformed NCM need to conduct a lot of education and communication, which might result in overloading NCM
- NCM are represented by different OR-types with different skills and expertise
 - Not every OR has the capacity to contribute actively in the SIEF or act as Lead Registrant
- Critical scenario: uninformed NCM with incompetent OR having registration deadline in 2010

▶ What should a competent OR do? 1/2

- Communicate with NCM well in advance (additionally to tracking of importers, volumes, SDS....)
 - which activity level to take in SIEF (and Consortia)
 - data ownership and data sharing
 - substance sameness requirements
- Check if “Tier 1 Substances” are covered
 - ...as a priority
 - ...by a serious SFF (not a “Cowboy”)
 - ...by a Lead Registrant
 - ...potentially by a Consortia

and investigate

 - ...what will not be submitted jointly (Guidance on Safe Use, CSR...)
 - ...if an individual dossier is in place
 - ...what the costs are

▶ What should a competent OR do? 2/2

- Communicate back any deficiency to the NCM
 - emphasis potential impact
 - propose corrective actions
- Provide appropriate documentation (e.g. “OR Cover Certificates”) for NCM’s EU-Importers, demonstrating that they qualify as “Downstream Users”

▶ What should a competent SFF do?

- ORs with serious intention can act as SFF
- Initiate and conduct discussions after pre-registration and facilitate the exchange of information & data required to form a SIEF
- Move the pre-SIEF to the SIEF (substance sameness agreed)
- Conduct and share SIEF Survey
- Facilitate the election of a Lead Registrant
 - In case no Lead Registrant is available (for a Tier 1 substance), SFF should communicate back to the SIEF impact and consequences (“The clock is ticking”)
 - Downstream User (as Importer) might need to pick-up Lead Registrant role

► Conclusion

- NCM with intention to register should select a reliable Only Representative, who can really participate in the REACH implementation and advice the NCM in a proper way
 - ORO is happy to provide guidance to NCM on reliability of OR
 - ORO welcomes membership of ORs, who apply the ORO standards
- Competent ORs can assume the role as SFF or Lead Registrant and should do so, if their NCM is in agreement.
- ORs should provide the appropriate documentation (e.g. Coverage Certificate) to NCM's customers (EU-importers) to demonstrate their Downstream User status. If no coverage is provided by OR, Importer is aware that he has lost DU status from this supplier and can react accordingly.
- In case no "active" SIEF participants can be found, an OR, an Importer or a Downstream User (as importer) might need to step up to the Lead Registrant role, as any other SIEF member with intention to register.

Thank You For Your Attention

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