

ChemicalWatch

ENFORCEMENT SUMMIT 2017

The Only Representative under REACH

Challenges, Opportunities & Enforcement

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President of the Only Representative Organisation (ORO)

Brussels, Belgium

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► Introduction

- REACH introduced globally 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.
- NCM (Non-Community Manufacturer) export into the EU via several importers, each importer shall make a separate (pre-)registration.
- If NCM 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 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.

► Non-Community Manufacturer (NCM)

“A natural or legal person that is manufacturing a substance, formulating a preparation or producing an article that is imported into the Community”
(REACH Legal Text)

- NCM appoints a natural or legal person in European Economic Area (EEA) as OR by mutual agreement.
- OR complies with obligations of importers under REACH and holds sufficient background in practical handling of substances and related information.
- NCM provides written confirmation of appointment to OR, needed in case of inspection by Member State's enforcement authority. No such letter has to be sent to ECHA.
- NCM should provide up-to-date information on EU-importers covered and quantities imported into EU to OR.
- NCM informs EU-importers in the supply chain about OR appointment, relieving importers from registration obligations.

- ▶ **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
 - 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 Coverage & Certificate

ONLY REPRESENTATIVE COVERAGE STATEMENT

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), we herewith confirm that

the following product(s) **Multimix 25**
Multimix 37

supplied by **Mishmash Chemicals**
Uphill Road 1423
Plastics Town, KL 72533
USA

to **European Importer**
P.O. Box 53778
D-09724 Nordhall
Germany

are included under our volume tracking obligations of REACH Article 8 (2) and are either exempt from the obligation to register according to REACH Article 2, or are covered by our (Pre-)Registration(s) at the European Chemicals Agency (ECHA).

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

The annual import volumes of each calendar year will be certified retroactively at the beginning of the following calendar year.

This statement is valid for the calendar year of issuance.

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May 27, 2011

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IMPORT CERTIFICATE OF REACH COMPLIANCE COVERAGE (EU)

Certificate No.: 88696CF80E1AF388F61EB2000B-2008

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 **Multimix 25**

supplied by **Mishmash Chemicals**
Uphill Road 1423
Plastics Town, KL 72533
USA

to **European Importer**
P.O. Box 53778
D-09724 Nordhall
Germany

with a delivery amount of **50 metric tons**

contains **100% (w/w)** of substances which are either exempt from the obligation to register, according to REACH Article 2, or are covered (within the supply chain of this product) by (Pre-)Registration(s) at the European Chemicals Agency (ECHA).

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

This certificate is valid for the year **2008**.

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December 15, 2008

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► Guidance for Importers

- Integrate REACH responsibilities into sourcing agreements with suppliers
- Request Cover Statements/Import Certificates of the OR through 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!

► ORs in the REACH Process

- OR tasks, duties and qualification not well defined under REACH & Guidelines
- Ca. 20 % of Tier 1 and 25% of Tier 2 Registrations submitted by ORs
- “Reliable” ORs not less qualified in REACH process compared to EU-manufacturers/importers, but communication/decision making with NCM is complex
- ORs represent different NCM-types: formulators, micro-enterprises, multinational market leaders
- OR mandate differs depending on the client and ranges from “Dormant” to “Lead Registrant” or just importer/volume tracker with no SIEF contact.
 - The NCM knowledge about REACH varies substantially, from uninformed to well informed
 - Competent ORs with uninformed NCM need to conduct a lot of training and communication, which might result in overloading NCM
- NCM are represented by various ORs with different level of expertise
- Not every OR is able to contribute actively in the scientific communication or in Dossier Preparation.
- Critical scenario: uninformed NCM with incompetent OR having registration deadline approaching.

▶ 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 and maintain OR quality standards
 - Develop a common understanding of REACH requirements for ORs
 - Represent the interests of ORs and NCM
 - Cooperate with regulators and other stakeholders in the process
 - Protect NCM from discrimination through REACH and EU against WTO/ TBT 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**

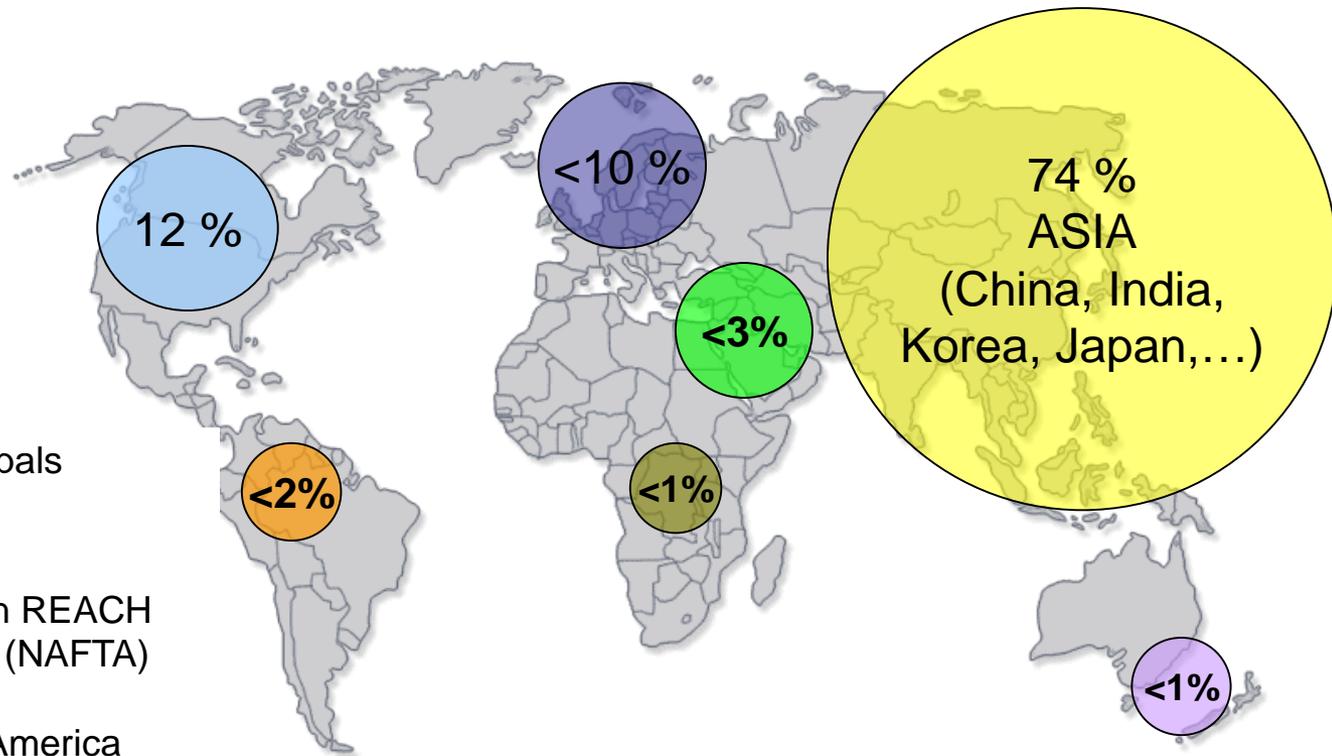
► ORO - Facts & Figures

- ORO has currently 35 Members
- ORO Members:
 - are acting ORs (Service Providers)
 - serve ca. 2.500 NCM
 - handle ca. 10.000 chemical substances
 - cover >18.000 of importers all over the EU/EEA
 - pre-registered ca.15.000 substances
 - registered ca. 3.500 substances



► ORO - Facts & Figures

Non-Community-Manufacturers from all over the world

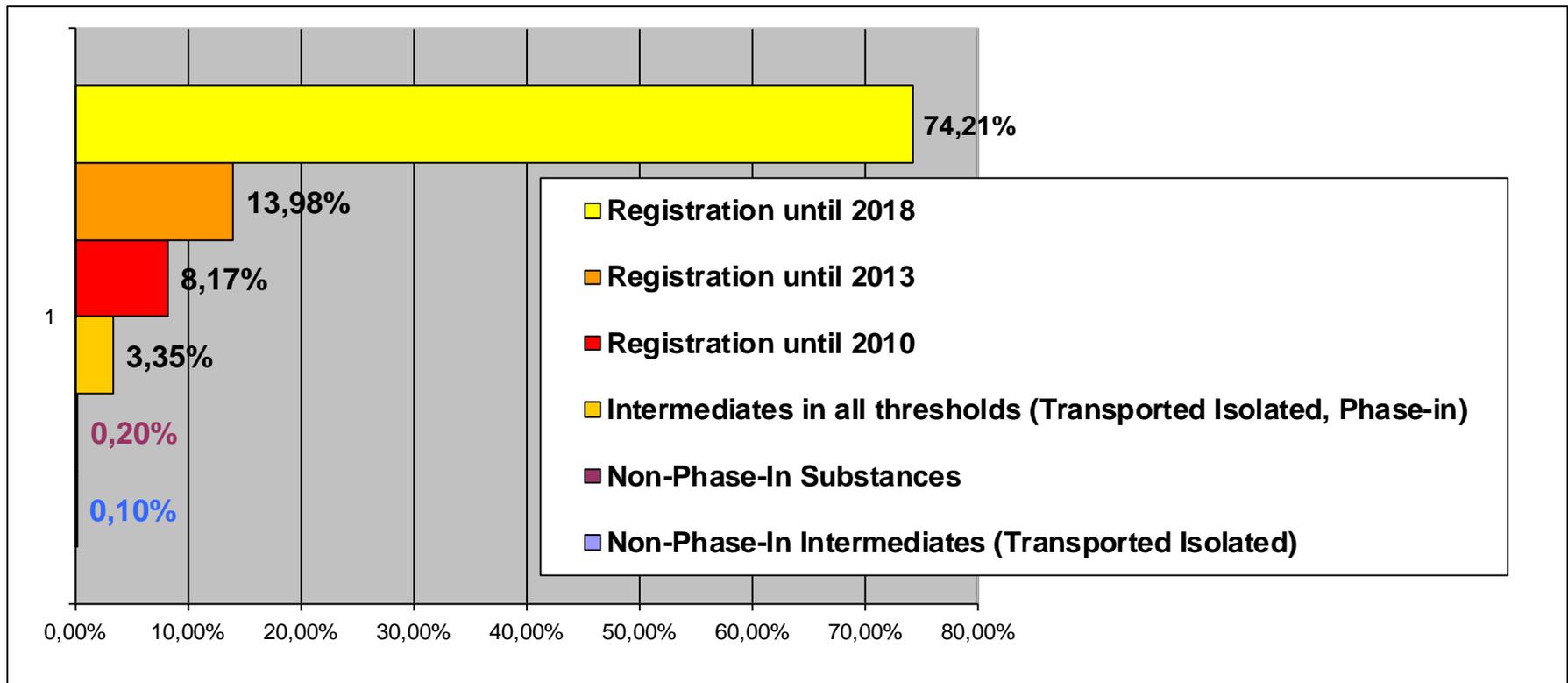


Distribution of Principals
by Region:

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 celebrated 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 Representative
 - Most ORO Members were inspected so far, no or just minor deficiencies were identified (in contrast to REACH-ENFORCE-3 project findings)

► REACH Enforce 3

- **Focus on Importers & Only Representatives**
- **Forum Report:**
 - ✓ **When analysing companies holding different (single/multiple) REACH roles, Only Representatives show the highest non-compliance rate (25%) compared to importers (15%) and manufacturers (7%).**
 - ✓ **The highest rate of non-compliance (43%) is found in the group of Only Representatives performing this one role only.**

▶ ORO Member Inspections

Pos.	Description	Number
1	ORO Members inspected in REF-3	19
2	Number of inspected ORO member	
	OR Compliance inspection in 2009	4
	OR Compliance inspection in 2010	4
	OR Compliance inspection in 2011	2
	OR Compliance inspection in 2012	1
	OR Compliance inspection in 2013	4
	OR Compliance inspection in 2014	17

In 2015: 2 Inspections

In 2016: 4 Inspections

► Inspections by Member States (2012 – 2016)

DE	7
FR	4
LU, BE, UK, FI	2
SE, ES, NL, IE, BG, IT	1
<u>n.a.</u>	<u>4</u>
Sum:	28

▶ REACH-ENFORCE-3 - OR Inspections

- REACH Enforce 3 Project (Part 2) had the aim to check in particular on ORs in order to review compliance from non-EU supply chains.
- Difficulties of ECHA & Enforcement Authorities locating ORs, identification through importer inspections (claiming downstream user status due to OR coverage) and customs.
- Information was entered into ECHA database, whenever OR was identified. ECHA communicated identified ORs (and related substance imports and importers) to Member States, who inspected the ORs.
- Rate of non-compliance of ORs in REACH Enforce 3 Project (Part 1) was 43% (not ORO Members).
- > 60% (19) of ORO Members were inspected within REF-3, no or just minor deficiencies were identified

-> contrary to the REACH-ENFORCE-3 Project findings

▶ ORO Member Inspections – Focus Areas

- Check qualifications & skills of staff to fulfil OR duties
- Check if system is in place for conducting OR duties
- **Substance specific volume and importer tracking**
- **Substance volumes match registration/pre-registration requirements**
- In case of late-pre-registrations: compliance with Article 28(6)
- **Are OR appointments in place**
- **Information on the supply of the latest update of the SDS**
- **SDS and eSDS availability and quality**
- Is „Strictly Controlled Conditions“ documentation in place
- Concern :
SDS responsibility (content and distribution) is inspected differently in different Member States!

► Conclusion I

- **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 and Enforcement 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**
 - **Uses not yet covered by the registration can be added through a registration update**

► Conclusion II

- **ORO supports Inspections of Only Representatives and Importers**
- **Comparing inspections on EU level shows that national authorities have different interpretation of REACH Art. 8.**
 - **In some cases even within Member States, where local inspecting authorities have different approaches.**
- **ORO Members followed the ORO Best Practice Guide and the vast majority of the ORO members had no or minor complaints, with no legal consequences.**
- **ORO considers the REF-3 a success for ORO members and a confirmation on sustainable support of the OR industry with robust guidance on compliance.**
- **ORs in general should follow ORO BPG.**
- **Importers should emphasise well documented REACH compliant imports.**

▶ ORO – Best Practice Guide

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Thank you for your attention



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