Case Study Non-EU Manufacturers

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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.

Many Non-EU manufacturers are hesitating to finally register their products under REACH…

Some quotes from our clients after our recent survey:

- **"The business in Europe is too small to justify the investment…"**
- **"We don't have any commitment from our clients that they will continue buying from us…"**
- **"More and more clients are pushing us to register…"**
- **"The test cost for our small volumes do not justify a registration…"**
- **" We will discontinue our business in Europe…"**

Only Representatives (ORS) have several duties under REACH

- As a natural or legal person within the EU the OR is the legal representative for a Non-EU manufacturer
- An OR has to have the capabilities to handle huge amounts of substances and must have the skills to understand the REACH legislation
- OR acts as a trusty versus Importers, Non-EU manufacturer and authorities
- OR has to take record of all imported substances and importers
- OR has to have the latest update of the SDS on file.
- The content of the SDS stays with the Non-EU manufacturer
- OR manages the supply chain and authority communication as it pertains to REACH compliance

Only Representatives have to fulfil the obligations of an Importer but there are some differences…

Importer

- Gets ownership of all imported substances and has to take record of them
- Has the registration obligation according to the imported quantities and the resp. deadline
- Has to have the latest update of the SDS on file and is responsible for the content
- Can develop his business according to his strategy

Only Representative

- Has no ownership in the imported substances
- Is not involved in business development and day-to-day business
- On request of his Non-EU manufacturer the OR has registration obligations
- Through the registration the Importers become Downstream Users

Appointment of an Only Representative is a strategic decision of a Non-EU manufacturer…

- A Non-EU manufacturer depend on the Importers and cannot develop the business independently
- Through an OR the Non-EU manufacturer can export to whom he wants according to (pre-) registrations done by its OR
- Aim should be a long-term relationship between Non-EU manufacturer and OR; precondition for that is trust
- Non-EU manufacturer must provide all required data to the OR (quantities, client lists, updated SDS) otherwise OR needs to terminate the OR contract

The right choice of the OR is key for own business…

How to find my OR?

- ORO is a good place to find a reliable and capable OR
- Search on ECHA webpage whether the OR has successfully register substances
- Lead Registrations are a good indicator for the capabilities of an OR
- Talk to companies which have experience with ORs
- OR Fees should not be the main decision factor

The Registration Strategy is the key for a successful business development…

Non-EU manufacturer and OR should work intensively together.

- **Prioritize the product portfolio**
- **Define the own role for all substances**
- **Analyze the SIEF and find potential co-registrants**
- **Decide early to take the Lead Registrant role**
- **Prepare the budget for the registrations and register as early as possible**
- **Try to establish a strategic partnership with Importers for cost sharing or volume commitment**

The test cost are the biggest burden for SMEs and small volume registrations…

Example 1 (Lead Registrant;Tonnage band 1-10 t/a; Substance; SME)

- **Test cost:** ca. 25,000 € (Annex VII, Sameness, Literature search)
- **OR fees:** ca. 5,000 - 10,000 € (dossier preparation and submission)
- **ECHA fees:** 64 – 1,114 €

Example 2 (Lead Registrant;Tonnage band 10-100 t/a; Substance; SME)

- **Test cost:** ca. 250,000 € (Annex VII and VIII, Sameness, Literature search)
- **OR fees:** ca. 15,000 - 30,000 € (dossier preparation and submission)
- **ECHA fees:** 173 – 2,993 €

Joint Submissions diminish the cost

The lower the volume and the margin the less profitable is a registration …

Example 1 (SME; 5 t/a; Margin 2 €/kg; Lead Registrant)

- Total Margin: 10,000 €/a
- Registration cost: ca. 35,000 €
- Loss first year: ca. - 25,000 €

Example 2 (SME; 95 t/a; Margin 4 €/kg; Lead Registrant)

- Total Margin: 380,000 €/a
- Registration cost: ca. 270,000 €
- Profit first year: ca. 110,000 €

REACH can be a threat for many supply chains in Europe…

Conclusions

- SMEs are hesitating to register their substances and will stop business in Europe
- Importers may lose their supply of chemicals
- Downstream users may lose supply of chemicals and can no longer manufacture their own products
- A shift of supply chains to countries outside the EU may happen with all consequences for the economy

Thank you for your attention

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