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**MEMORANDUM**

**PRIVILEGED AND CONFIDENTIAL  
CLIENT-ATTORNEY PRIVILEGE**

**To : ICDA**

**From : Cyril Jacquet and Anne-Laure Saint-Girons**

**Date : 20 February 2008**

**Re : The Only Representative Mechanism; Our File N° IC09432/02**

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The process for compliance with REACH includes mostly individual obligations that must be met on a company-by-company basis. In relation to manufacturers established outside the European Union (EU), one such decision is whether or not to appoint an Only Representative to make the registration. If not already taken, this decision must be taken very soon, preferably before 1 June 2008 and in any case before 30 November 2008.

Indeed, potential registrants are compelled to pre-register between 1 June 2008 and 30 November 2008 if they want to take advantage of the special registration benefits afforded to existing chemicals, i.e. the phase-in registration. If a non EU manufacturer wants to appoint an Only Representative, that Only Representative will have to fulfil the pre-registration obligation before 30 November 2008.

This memorandum provides basic information as to enable members of ICDA to take informed decisions on the Only Representative issue under REACH.

**I) REGULATORY BACKGROUND ON ONLY REPRESENTATIVE**

Under REACH, each EU-based manufacturer, importer of a substance either in its own or in an article has to make an individual registration. Those that do not register will lose access to the market. An EU-based producer of a substance is required to make only one registration irrespective of the number of customers to whom the substance is sold. Any such entity that fails to make the necessary registration will not be permitted to place their product on the market.

As for importers, REACH sets forth a general principle according to which registration obligations of substances imported into the EU on their own, in preparations or in articles have to be carried out by the EU importer. This is justified by the fact that jurisdiction of the EU is limited to the territory of the Community, and the competent authorities have not competence to enforce the regulation on operators not established in the EU.

As a consequence, where a manufacturer based outside the EU is exporting into the Community via several different importers, each importer shall make a separate registration.

Article 8 of REACH allows manufacturers of substances, formulators of preparations or producers of articles, established outside the Community, who export their products to the EU, to nominate an Only Representative established within the EU to carry out the required registration of the relevant substances. Article 8 stipulates:

- 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 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 supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.*

The first paragraph provides non EU- manufacturers, formulators and article producers with the possibility to appoint a natural or legal person established within the EU to fulfil, as his Only Representative, the REACH obligations of importers in the EU.

Firstly, the notion of “non EU-manufacture” is to be understood in an extensive way. It extends to the manufacture of a substance to be used on its own, in preparations or in articles. The language is broad enough as to cover the import of the substance in any form and since substances are generally not “manufactured in preparations or in article, the provision seems to be intended to cover situations where the manufactured substance is manufactured into mixtures or incorporated into articles either by the manufacturer or by a third party outside the EU, such as a contract formulator or a non-EU customer. Secondly, there is nothing in Article 8 (1) that requires the non-EU operator appointing the Only Representative to be the actual person that

exports the substance into the EU, it is only required that the substance “is imported in the Community” as such, in a preparation or in an article

The second paragraph clearly sets the Only Representative obligations and qualifications. The Only Representative will have to comply with obligations of importers under the registration title of REACH, but “also comply with all other obligations of importers under this Regulation” (article 8.2 of REACH, emphasis added). It should also be noted that with respect to supply chain communications, the only representative is only requested to “keep available and up-to-date” “information of the latest update of the safety datasheet” but is not itself responsible of providing the safety datasheets up and down the supply chain. This is sensible because the Only Representative is not part of the commercial supply chain and the content and provision of supply chain communications should remain the responsibility of the commercial actors

The Only Representative as such can but does not necessarily need to be one of the actual importers of the substance and there is no requirement that an importer be located in the country where the registration will be made. Note that, if the appointed Only Representative is one of various EU importers competing with the other EU importers, such appointment might raise competition law compliance questions, in as much as the function of Only Representative should involve access to sensitive market information, including competitors ‘s importation volumes. The appointment in this case should therefore be considered carefully.

In any case, the natural or legal entity or person which serves as Only Representative must be established in the European Union and have a sufficient background in the practical handling of chemicals and the information related to them to discharge the responsibilities of an Only Representative. It must especially understand the way the substance is used in the supply chain in order to be able to fulfill all its duties under REACH.

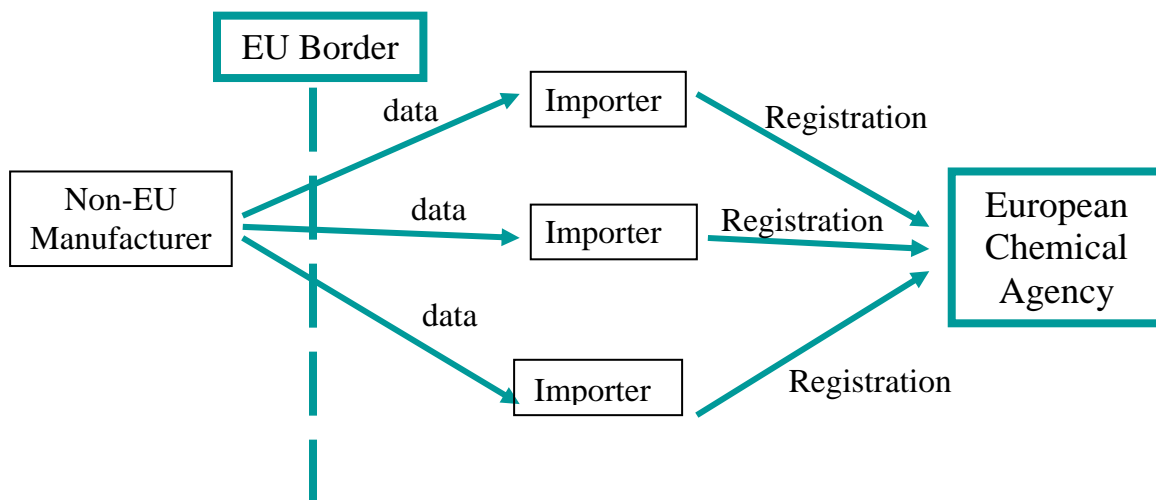
The third paragraph requires the non-EU operator to inform the importers in the “same supply chain” of the only representative appointment thereby moving these importers into the position of downstream users raises a number of issues. It is currently unclear as to whether the term “same supply chain” refers only to the supply chain of the substance in the EU, whether all of the tonnage supplied by the same non-EU manufacturer is considered within the same supply chain even if part of the tonnage is supplied by non-EU traders, or whether all importers in the same supply chain become downstream users or an importer can reject the Only Representative to register on their own.

## II. ADVANTAGES AND DISADVANTAGES OF APPOINTING AN ONLY REPRESENTATIVE

The decision for a non-EU manufacturer not to appoint an Only Representative and rely on its EU customers to comply with the REACH registration requirements will have some legal and commercial consequences.

The schemes below illustrate the cases where an Only Representative is appointed or not.

### Scheme 1 In case of registration by each EU Customer without Only Representative



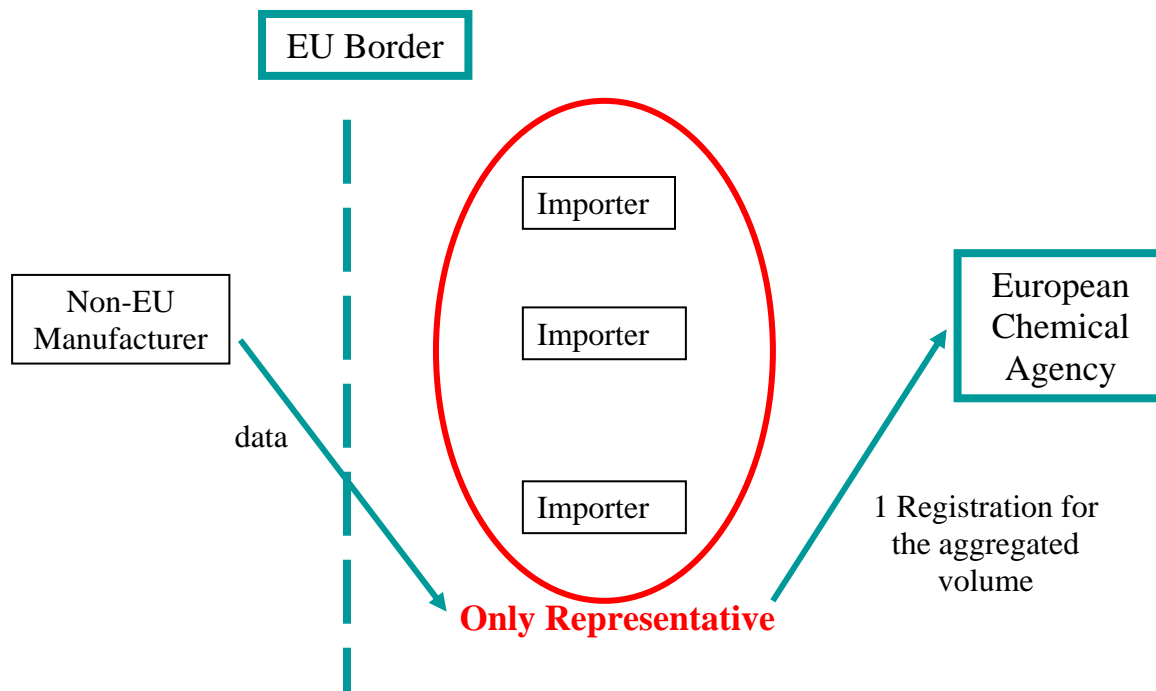
#### Advantages:

- The non-EU manufacturer involvement in the registration process will be limited to the provision of information on the product, unless it is required by its customer to provide human or financial resource to support the registration.
- The fact that volumes imported by each customer will not be aggregated under one registration. The distribution of the total volume between several importers might reduce the data requirements and fees applicable individually to each of them. However, this argument might not be valid in the metal industry given the imported volumes.

**Disadvantages:**

- The non-EU manufacturer, which will not hold the registration, will be dependent from its EU customers for the continuance of the supply chain. Indeed, the EU customers holding the registration will be entitled to import the volume of product covered by the registration, irrespective of the source of supply. They will be able to change non-EU suppliers at their own will, without further registration obligation, or without an obligation to find a non-EU supplier covered by its own registration through an Only Representative.
- Registration by EU importers implies a confidentiality break, in as much as the non-EU manufacturer of the product has to provide the necessary data to support the registration, including confidential business information.
- The EU customers might request the financial support of the non-EU manufacturer to prepare the registration and buy the necessary data. Otherwise, the EU customers may seek another non-EU supplier that has registered or that would agree to support financially the registration by that EU importer.

**Scheme 2     In case of registration by an Only Representative**



**Advantages:**

- The non-EU manufacturer will hold the registration through its representative and will keep control of its supply chain. If the importer want to change supplier, it will have to register the substance or find a supplier that is covered by a registration, whether an EU supplier or a non-EU supplier having registered through an Only Representative.
- He does not have to disclose confidential data.
- The Only Representative mechanism reduces the bureaucratic hurdle for importers and may provide competitive advantage to the non-EU manufacturer.

**Disadvantages:**

- The Non-EU manufacturer will, in principle, support the costs of registration.

**III) DUTIES OF THE ONLY REPRESENTATIVE UNDER THE REACH REGULATION AND IN PRACTICE**

For phase-in substances, the Only Representative will pre-register the substance and will subsequently become participant of the Substance Information Exchange Forum (SIEF). Consequently, he needs not be in-place prior to June 1, 2008, the beginning of the pre-registration phase. The Only Representative shall also submit the Registration by the applicable deadline.

Under REACH, the Only Representative technically is the entity that is legally responsibility for fulfilling the obligations of the EU importer.

The non-EU manufacturer has no formal legal responsibility under REACH because the European authorities can not impose liability on a non-EU entity. Instead, the interest of the non-EU manufacturer is to insure that the REACH obligations are carried out properly in order to prevent disruption in supply. Liability can be imposed on the non-EU manufacturer's European customers as well. Thus, if the non-EU manufacturer does not in practice take ownership of the REACH obligations, it is the non-EU manufacturer's market and its customers that will suffer.

In practice, many of the REACH tasks can be performed by the non-EU manufacturer and any consortium that this operator would join. The Only Representative need not be substantively involved in these tasks other than making the necessary submissions to the Authorities. These tasks will include:

- 1) Negotiating in good faith data sharing costs with data holders.
- 2) Joint submission of the technical part of the registration dossier through the lead registrant at the earliest deadline applicable to the SIEF members, unless opting out as duly justified under article 11.3.
- 3) Preparation of the individual company data portion of the registration dossier by the appropriate deadline applicable to the tonnage of the non-EU manufacturer.
- 4) Preparation and updating of the chemical safety report for substances imported in greater than 10 tonne per year.
- 5) Provision to downstream users of a properly compiled and updated safety data sheet that is consistent with the information in the Chemical Safety Report.
- 6) Performance of a risk assessment for uses newly identified after the registration dossier has been submitted before supplying the substance for the newly identified use.
- 7) Carrying out any test proposed by the authorities under Evaluation within the deadline specified by the authorities.

However, there are a number of REACH obligations that in practice will have to be carried out by the Only Representative. These tasks principally involve:

- 1) Obligation to 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.
- 2) Obligation to update the registration dossier in a timely manner in the following circumstances:
  - a. any change in the name or address of the Only Representative;
  - b. any change in the composition of the substance;
  - c. changes in the annual or total quantities imported
  - d. new identified uses and new uses advised against as for which the substance is imported;
  - e. new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report.
  - f. any change in the classification and labelling of the substance;
  - g. any update or amendment of the chemical safety report or the risk management measures recommended for safe use of the substance;
  - h. where the Only Representative identifies the need to perform a test listed in Annex IX or Annex X of REACH , in which cases a testing proposal shall be developed;
  - i. any change in the ownership or right of access granted to information in the registration dossier.

- 3) Obligation to maintain records of all required information for at least 10 years after the last date of importation of the substance.
- 4) Obligation to submit or make available the records to the authorities upon request.
- 5) Obligation to inform the authorities of cessation of import.

Because the Only Representative will not in fact be a part of the supply chain for the substance, it will need to rely on information from the supply chain in order to carry out the above reporting and dossier updating functions. The Only Representative should prepare periodic questionnaires for response by the non-EU manufacturer and its customers.

#### **IV) PENDING ISSUES REGARDING THE ONLY REPRESENTATIVE**

The REACH Regulation is silent on various aspects of the practical implementation of the concept of Only Representative. The EU institutions are currently reviewing these issues and have been urged by the industry to provide clarification. You will find below the pending issues which are the most relevant for your industry.

- As already mentioned, it is unclear from article 8.3 of REACH if all importers in the same supply chain become downstream users or if an importer can reject the Only Representative to register on their own
- Multiple appointments of the same Only Representative by different manufacturers of the same substance is also a pending issue, i.e., whether in that case the volume of these different manufacturers is aggregated and whether they are subject to only one Registration fee.
- The Commission is also discussing the status of indirect supply of a non-EU manufacturer's substance into the EU, i.e., whether the Only Representative of a non-EU manufacturer can register on behalf of all importers of the same substance irrespective of whether the non-EU manufacturer:
  - exports the substance directly into the EU,
  - exports indirectly through the use of non-EU distributors, or
  - exports indirectly through the use of non-EU formulators or article producers that themselves export preparations or articles containing the substance into the EU.
- The question of the timing of the transfer of importers' obligation to an Only Representative, i.e., whether Only Representative can be appointed after the pre-registration deadline has ended. In the absence of Only Representative at the time of pre-registration importers will be obliged to pre-register the substance themselves in order to avoid any disruption in supply. The competent authorities have to confirm whether they

allow importers to transfer the obligations to the Only Representative after pre-registration.

## **V) LIABILITY AND POSSIBLE SAFEGUARDS**

In so far as the competent authorities do not have jurisdiction over operators not established in the Community, under REACH, the Only Representative will be held personally liable for breaches of REACH obligations by the non-EU manufacturer or the EU importers of the relevant substances.

However, in practice, the Only Representative might not be an actor in the supply chain, and even if he is, he would not be in a position to review the channels of supply of the substance to all the various importers. He can therefore be held liable in relation to actions or omissions, which he would not be in practical position to prevent.

The Only Representative is only able to limit its liability through the adoption of appropriate indemnification contractual provisions for acts not attributable to the Only Representative's negligence.

Similarly, because the Only Representative in principle holds the responsibility for securing and maintaining the registration, he could require hold harmless agreements from the EU customers for any disruptions in the supply chain, again due to acts not attributable to the Only Representative's negligence. Additional protections of the Only Representative's personal liability for the acts of others outside the control of the Only Representative may be sought as appropriate.

## **VI) COMMUNICATION**

It is essential for each non-EU manufacturer to communicate its decision to all EU-based customers immediately so that they are properly informed of its intentions and can consequently decide whether or not to pre-register on their own to maintain their supply chain. Although most or all customers will welcome that decision, some may wish to register independently, if permitted under REACH. In any case, those who do so will not undermine the non-EU manufacturer decision to appoint an Only Representative.

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We trust that you will find this information useful, but please do not hesitate to contact us should you need any further clarification.