

MEMORANDUM

**PRIVILEGED AND CONFIDENTIAL
CLIENT-ATTORNEY PRIVILEGE**

To : Mrs. Marie-Solange Pollard, ICDA

From : Cyril Jacquet, Herb Estreicher and Anne-Laure Saint Girons, Keller and Heckman LLP

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Re : Update on pending issues regarding the Only Representative mechanism under REACH

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 (hereinafter the "OR") to make the registration.

Potential registrants are compelled to pre-register between 1 June 2008 and 1 December 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 OR, that OR will have to fulfill the pre-registration obligation before 1 December 2008.

However, the REACH Regulation is silent on various aspects of the practical implementation of the concept of OR. Several crucial questions on the nature of the OR mechanism are still pending, but some of them have been very recently resolved by the European institutions.

This memorandum provides an up date on the recent clarification brought by the European institutions on the OR mechanism (A) and identifies the issues that are still pending (B). This information will hopefully enable operators to take informed decisions regarding the appointment of OR in view of pre-registration.

I. RECENTLY RESOLVED ISSUES REGARDING THE ONLY REPRESENTATIVE

A) Multiple Appointments of the Same OR by Different Manufacturers of the Same Substance

1. Initial position of the European institutions: aggregation of volumes of several non-EU manufacturers into a single registration

According to the European Chemicals Agency (ECHA) helpdesk, a single OR may represent multiple non-EU manufacturers of the same substance. In addition, the European authorities initially considered that if more than one non-EU manufacturer shared the same Only Representative to register the same substance then the Only Representative could submit a single registration for that substance, thereby aggregating the volumes of the common substances of the non-EU manufacturers in a single registration dossier. This interpretation was inconsistent with the REACH principle of one registration and one fee per legal entity which is applied to EU manufacturers and appeared to place EU manufacturers at a competitive disadvantage vs. non-EU manufacturers.

Such interpretation was provided in one of the European Commission's Guidance documents now revised: "*As he is fulfilling the registration obligations of importers, the tonnage of the substance to be registered is the total of the tonnages of the same substance covered by the contractual agreements with him and all "non-Community manufacturers" represented by him. The information requirement for the registration dossier shall be determined according to this total tonnage.*"¹

However, the authorities recently reversed their position.

2. Final position: separate registration for each non EU-Manufacturer

On 16 April 2008, the European Commission, together with the European Chemicals Agency organised an important REACH Workshop in Brussels: "*Final Countdown to pre-registration and registration of Chemicals*". The aim of this meeting was to explain to companies the key elements of pre-registration and registration, provide up-to-date information on the REACH guidance documents and tools and discuss the strategy to raise awareness of these topics.

At the above mentioned meeting, the European Commission reversed its position and decided that the Only Representative would have to complete a separate registration for each non-EU manufacturer that he represents and thereby separately report the volumes of the individual companies.

¹ RIP 3.1 Guidance on Registration § 1.5.3.4. February 2008

On 26 May 2008, the Commission issued a new version of the Guidance on Registration confirming that change:

“The only representative can represent one or several “non-Community manufacturers”. If it acts on behalf of several “non-Community manufacturers” it must submit a separate registration for each of these substance manufacturers. The tonnage of the substance to be registered in each registration is the total of the tonnages of the substance covered by the contractual agreements with the only representative and the specific “non-Community manufacturer” represented by him. The information requirement for the registration dossier shall be determined according to this tonnage. [...]”²

B) OR in Relation to Indirect Supply Chain

One of the most important question with respect to the Only Representative arrangement concerns “indirect supply”, i.e., whether the OR of the non-EU substance manufacturer can register on behalf of all importers of the same substance irrespective of whether the non-EU substance manufacturer:

- exports the substance directly into the EU,
- exports indirectly through the use of non-EU formulators or article producers that themselves export preparations or articles containing the substance into the EU.

That question was first brought by the national competent authorities and was then raised to the Commission and the Agency which has recently taken a position in this regard that clarifies previously conflicting views.

1. Position of some Member State that an OR cannot cover indirect supply chains

The UK helpdesk advised, as an expression of their opinion, that the appointment of an OR by a non-EU substance manufacturer may not be used to cover the importer of a preparation containing that substance in any case, even if the non-EU formulator of a preparation sources the substance from the same non-EU manufacturer.

However, this approach appeared to provide a competitive disadvantage for non-EU preparation formulators versus EU preparation formulators insofar as, in the example described, the non-EU preparation formulator would be required to appoint an OR to register the components in the preparation whilst an EU preparation formulator importing the component substances could rely on the registration of the substance manufacturer’s OR. Additionally, the OR of the non-EU preparation formulator would be required to obtain confidential information from the substance manufacturer which might not be forthcoming.

² RIP 3.1 Guidance on Registration § 1.5.3.4. May 2008

The advice of the UK Helpdesk resulted in narrowing the options for the non-EU substance manufacturer and did so in a way that places a disproportionate burden on foreign sources of supply. The advice of the UK Helpdesk created a far greater degree of disparity between domestic and non-domestic supply than is justifiable by the goals of REACH.

These issues have been brought to the attention of the Commission and the European Chemicals Agency, which took position on them very recently.

2. European Commission's recent position allowing the OR to cover the indirect supply chain

At the Annual Congress of the European Association of Chemical Distributors (FECC) held in Budapest on 3 June 2008, Otto Linher of the European Commission, DG Enterprise, announced that the Commission had revised its position on whether the registration of a substance by a non-EU manufacturer's OR can cover the imports of that same substance in a preparation produced by a non-EU formulator that purchases the manufacturer's substance.

According to the Commission, if a non EU substance manufacturer appoints an OR, then importers of the substance in a preparation can refer to the registration of the substance by the non-EU manufacturer's OR, provided the OR maintains documentation to demonstrate to the authorities that the imported preparation is comprised of substances which have been registered by the non-EU manufacturer's OR.

This provision to allow the non-EU substance manufacturer's OR to cover the indirect supply of its substance as part of preparations imported into the EU has been an issue of great import to both non-EU and EU industries. Making provision for indirect supply chain coverage places imported goods on an equal footing with EU-manufactured goods and eliminates a potential trade barrier.

The exact details of this new decision are still awaited for and will soon be reflected in the Technical Guidance on Registration. It should be noted that the manufacturer's OR will need to track the import volumes of the substance as part of the imported preparations and maintain the list of the importers of the preparation. Also, for preparations containing multiple substances, the preparation importer will need to ensure that all of the substances subject to registration are covered by the non-EU manufacturer's OR. In some cases, the non-EU formulator (or its importers) may find it easier to undertake the pre-registration/ registration obligations themselves in order not to be tied to a particular substance supplier. It may also be prudent to pre-register in any event in case the non-EU substance manufacturer ultimately decides not to register. But this new decision provides added flexibility and allows non-EU preparation producers the choice of relying on their suppliers to cover the registration obligations of the importers of the preparation.

If the option of relying on the registration by the supplier's OR is selected by a non-EU formulator of a preparation, then strong contractual guarantees will be needed to ensure that the supplier actually pre-registers and registers and the importers of the preparation actually provide the OR with the necessary information.

C) Change of OR

The conditions under which non-EU operators may change OR might be discriminating if they would have imposed a new registration. This is particularly true in relation to OR services which are provided by natural person, which will eventually retire or pass away.

1. Initial position of the European Authorities requiring the submission of a new registration dossier in case of change of OR

The draft update to RIP 3.1 on Guidance on Registration (dated December 2007) states as follows:

If non-Community manufacturer decides to change his only representative, the successor will have to submit a new registration dossier, as there is no link between the two only representatives who are separate legal entities. It is nevertheless possible for the new only representative to agree with the former only representative and to reuse the data and dossier of the former only representative to prepare his registration dossier.

The suggestion in the draft update to the RIP that the change of an OR will require a new registration is troubling.

2. Issues arising from the European Commission's initial position

The REACH obligations extend well beyond 2018 when the last tonnage dossier is due and most ORs will be individuals who may well retire before their duties are completed.

There are also problems with the concept during the pre-registration period because the successor OR will only be able to pre-register late under Article 28(6) prior to the year before the registration dossier is due. After the phase-in period is over, there is a three week period to market delay for new registration dossiers and as such the suggestion in the draft update to the RIP could lead to market disruption. And, there is the question as to payment of an additional registration fee for the new registration.

The June 2007 version of the Guidance on Registration on the ECHA website provides a much more sensible solution. At page 14 of the Guidance it is noted:

If a non EU manufacturer decides to change his only representative, the newly appointed only representative can, in agreement with the former only representative, update the registration dossier, by changing the registrant identity, and if necessary any other issues (e.g. change of tonnage band).

Allowing updating of the existing dossier to reflect the successor OR is consistent with the approach taken in the case of mergers and acquisitions as well as the procedure under the former chemicals legislation in the case of a change in the sole representative.

3. European Commission's recent decision not to require a new registration in case of change of OR

At the Annual Congress of the European Association of Chemical Distributors (FECC) held in Budapest on 3 June 2008, Otto Linher of the European Commission DG Enterprise also confirmed that in the event that a non-EU manufacturer decides to change its OR, it will NOT be necessary to submit a new registration as is currently stated in the Guidance on Registration. It will only be necessary to pay an administrative fee to update the name of the OR in the REACH-IT system.

This change was urged by the industry in order to allow non-EU companies greater flexibility in their arrangements with ORs. It should be noted that the fee for changing the identity of the registrant is 1500 Euro per substance according to the REACH fee legislation so care must still be taken in the selection of an OR.

II. ISSUES STILL PENDING REGARDING THE ONLY REPRESENTATIVE

A) Non-EU Distributors

Article 8 of REACH provides a list of non-EU operators, which may appoint an OR (substance manufacturer, preparation formulator or article producer). This list does not include non-EU distributors.

The ECHA has already conceded that a non-EU substance that is exported indirectly in the EU via a non-EU trader should be registered by the initial non-EU manufacturer of the substance. In a Q&A dated October 11, 2007 the ECHA stated:

[A] non-Community company cannot appoint an only representative in the case where they are only a trader or distributor. However if the non-Community manufacturer appoints an only representative, the registration by that only representative may cover the total amount of the substance imported to the EU. It does not matter if the substance is purchased via traders or exported directly from the non-Community manufacturer”

This approach confirms that non-EU distributors of substances and preparations may only rely on the OR appointed by the substance manufacturer or formulator of a preparation. This may, however, raise competition law compliance issues, as the non-EU distributor will not only be dependent on its supplier's OR registration, but he will also have to make available sensitive market data, including the list of its customers and exported volumes.

Although not addressed yet, it will most probably pose problems at the time of the practical implementation of REACH.

To date, the only possible solution would be to appoint an independent third party as OR, which makes implementation of REACH even more complicated and create further discrimination for non-EU manufacturers or distributors.

B) Issue of the Timing of Transfer

A question arose on the timing of the transfer of importers' obligation to an OR, i.e., whether an OR can be appointed after the pre-registration deadline has ended. In the absence of OR 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 OR after pre-registration.

It is likely that many ORs will only be appointed after the pre-registration deadline has ended and Importers will therefore be obliged to pre-register the substance themselves in order to avoid any disruption in supply. There should be a vehicle to allow the non-EU manufacturer's OR to assume ownership of the pre-registration of the Importer prior to registration or alternatively, Importers should have the possibility to transfer the obligations to an OR after pre-registration.

There is nothing in Article 8 that imposes a deadline for the appointment of an OR. There is no particular reason why the OR should file the pre-registration papers. The Importers can certainly provide the necessary information and the OR can assume the responsibilities at a later time. Once appointed the OR would simply operate in the SIEF on the basis of an aggregation of the volumes of the Importers. Also, because the OR is not in principle an owner of data but in most cases simply a consultant, he would not be expected to play an active role in the early data sharing stages of the SIEF. As such, the participants in the SIEF would not be disadvantaged by the OR joining the SIEF at a later stage. In any event, all of the consortia agreements of which we are aware envision the active participation of the non-EU producer rather than his OR because the non-EU producer is the entity that is likely to hold data and will be paying the costs of registration.

The issue is still pending and we will keep you informed of this outcome as soon as possible.

C) Possibility to Reject an Only Representative

Article 8(3) of REACH stipulates:

“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.”

However, it is unclear from that article if all importers in the same supply chain become downstream users or if an importer can decline the OR in order to register the substance on his own. By doing so, that importer would be the holder of the registration and secure its own right to import the substance from any source.

The issue is still pending and we will keep you informed of this outcome as soon as possible.