ATC

A SECTOR GROUP OF cefic

The Practical Working

of the ONLY REPRESENTATIVE Scheme

under REACH

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Paper on the Practical Working of the Only Representative (OR) Scheme
ATC REACH Working Group - October 2008

Abstract

This paper describes proposals for the practical working of the Only Representative (OR) scheme and simplified procedures for communicating information up and down the supply chain. These ideas are likely to be of particular value to those companies who are members of extended non EU supply chains. The paper suggests the use of a new document, a "Declaration of REACH Conformity (DRC)", to simplify the exchange of information along the supply chain whilst protecting the intellectual property of all stakeholders and providing an auditable trail that should be acceptable to the EU Authorities.

Current legislative position

In his speech to the FECC, in June of this year, Otto Linher, DG Enterprise indicated acceptance by the EU Authorities that members of a non EU supply chain could enjoy downstream user (DU) status for substances imported into the EU, provided that the substance had been registered by an Only Representative (OR) acting on behalf of another actor further up the supply chain, including non-community formulators. This has since been confirmed both verbally and in official documents.

An earlier amendment to the official guidance had made it clear that an Only Representative (OR) cannot combine the tonnages produced by different manufacturers but must submit a separate registration for each non-community legal entity organisation (manufacturer or formulator) he acts on behalf of.

These changes were generally welcomed by industry as they offered non EU companies the same status as EU companies and provided a much more level playing field. However, one unavoidable consequence is the need for more communication between members of the non EU supply chain and a greater exchange of information, some of it highly confidential (CBI).

In accordance with REACH it will be necessary for the non-community manufacturer's or formulator's substance pre-registration or registration (submitted by an Only Representative) to be communicated down the supply chain to the eventual EU importer and for information on the volumes imported to be reported back to the registrant (OR). In addition, the importer will probably require some form of proof that all substances in the product requiring registration have been registered whilst the registrant (OR) will need to ensure that the registration is in a volume band appropriate to the tonnage imported.

Consider the following scenario. A registered substance is sold to another company, blended with other substances into a product, which is sold as a functional component (e.g. antioxidant) for use in a second product (e.g. multifunctional lubricant additive). That product is sold for use in yet another product (e.g. finished lubricant), before being imported into the EU. Typically, each actor considers his/her product composition to be highly confidential business information and this information is rarely shared with downstream users.

In this example, the challenge is therefore to enable the importer to confirm that every substance in the lubricant requiring registration has been registered (by one or more ORs) without the release of confidential business information (CBI).

What follows, offers some reduction in the complexity of the task and better protection of CBI.

A Practical Solution to the Problem

Any proposal for the improved working of the Only Representative (OR) scheme must allow an importer to show that all substances in the product he is importing conform to REACH, in that they are registered or exempt from registration (e.g. substances in REACH Annexes IV and V). It must also ensure that the registrant (OR) for each of those substances is aware of the importer, that the importer is informed of the identity of the OR(s) and that each OR is informed of the imported volume of each substance that he/she is responsible for.

In addition, a practical scheme must be administratively simple, protect confidential business information (CBI) as much as possible and provide an auditable trail that will allow the EU Authorities to confirm that the scheme is being properly managed and that all substances in an imported product requiring registration have been registered in their correct tonnage bands.

ATC REACH Working Group proposes:

The non-community substance manufacturer or formulator appoints an OR, who will assume all responsibilities of the EU importer including pre-registration and registration of the substance(s) in his/her product. A simple document, a Declaration of REACH Conformity (DRC), is prepared by the manufacturer or formulator and is issued to all customers. This document confirms that each substance in the product is in conformity with REACH, identifies the manufacturer or formulator (or other actor) and the identity and contact details of each OR.

A formulator who then combines this product with other substances to form a different product would prepare his own DRC and issue that to each of his

customers[1]. This DRC would be based on the information received from all his/her non-community suppliers and would again confirm that all components in the product were in conformity with REACH. It would also identify the Only Representative(s) responsible for pre-registering and registering each of those substances.

[1] The DRC is the method for communicating this information in the supply chain favoured by ATC members. Other actors in the supply chain are free to choose their own method of communicating the same information to the next actor in the supply chain.

This process would be repeated at every level of the non-community supply chain with each actor in the supply chain issuing their own DRC (or equivalent communication) to their customers. It is envisaged that any DRC's received by an actor in the supply chain will not be passed onto the next actor; instead each actor in the supply chain collates the REACH conformity information on the DRCs received from their suppliers and prepares a new DRC (or equivalent) for the product they supply to their customers. This new document (DRC) should include the identity of an OR responsible for each substance in the product requiring registration (see Annexes 1 to 3 of this document).

Providing an actor in the non-community supply chain has their product formulation details they will be able to appoint an Only Representative for one or more substances in their product, even if other actors further upstream (e.g. component suppliers) have already appointed an OR for their substance or product. In this case, the actor (e.g. formulator) can choose which OR is communicated to the next actor down the supply chain.

The EU importer therefore receives a single document confirming that all the substances in the product he is importing into the EU conform to REACH, and listing the contact details of the registrant (OR) responsible for any substance requiring registration.

Only Representatives must ensure that the substance registrations they submit are in the correct tonnage band and therefore need to know how much of each substance is being imported into the EU. This information can only come from the importers.

One option would be for the importer to advise his/her immediate supplier of the annual tonnage of each product imported. The supplier would break that information down into annual tonnages of the components in his/her product(s) and communicate that data to the companies who provided those components. The identity of the importer or importers would also be given.

This process of passing information from one actor to the next up the supply chain would be repeated until it reaches the non-community manufacturer/formulator who appointed the Only Representative. Each actor in the chain would use their knowledge of the formulation to break down the data until the tonnage of individual substances was obtained. The OR would use that information to ensure that his/her registration was in the correct tonnage band. They might also advise the importer of receipt of this information.

Alternatively, importers might choose to contact each OR directly, give them the annual tonnage of the product imported and allow the OR(s) to calculate the tonnage of each substance for themselves. If desired, importers could seek confidentiality agreements from each OR in order to

protect their confidential business information. In order for this to work, each OR would need information on the formulation of the imported product and the disclosure of that data would have to be negotiated with the formulators.

It is important to understand that the DRC or equivalent will not identify, by name, the substance(s) for which the OR is responsible because this would necessitate disclosure of confidential business information (CBI) in the supply chain. To comply with the requirements of Article 8 the non-community manufacturer/formulator who appoints the OR should simply advise the EU importer that he/she is responsible for one or more substances in the product being imported. Clearly, for this communication to make sense the name of the exported product needs to be communicated to the OR(s), either by the EU importer(s) or the direct exporter(s). Again, if this is considered to be CBI, it can be provided under a secrecy agreement.

The process described above still necessitates the disclosure of some confidential information in the supply chain, specifically the identity of the EU importer(s), and the name and volume of the product (but not individual substances) being imported. However, this level of disclosure is far less than might otherwise be required if the REACH responsibilities were transferred downstream to the EU importer(s).

Clearly an EU importer does not have to follow this proposed scheme. They could, for example, choose to register for themselves, the substances in the products they import providing they had full compositional information. However, it is considered that the difficulties of obtaining formulation details from every actor in the supply chain, the legal complexity of setting up the necessary confidentiality agreements and the expense of registration, outweighs their loss of CBI described above.

Under this scheme, in the event of an audit by the European Authorities the importer will possess a document from their immediate non-community supplier confirming that all the substances in the imported product are in conformity with REACH and identifying a registrant (OR) for each substance in the product.

Should the Authorities want to confirm that all the substances in the product were registered and that the imported tonnage was covered by an appropriate registration then it is envisaged that they would do that by contacting each of the registrants (OR) listed on the DRC in the first instance.

Obligations

For this process to work there have to be some rules:

The DRC (or equivalent) from the actor appointing the OR must contain the trade name of the product together with their company name and address, and the name, telephone number and email address of their REACH contact

person. The identity and contact details of the Only Representative (OR) responsible for the importer(s) obligations including pre-registration and registration of the substance are also required.

Actors at each subsequent step down the supply chain are expected to create their own DRC (or equivalent communication format), including the trade name of their product, their company name and address, and the name, telephone number and email address of their REACH contact person.

The name and contact details of an Only Representative for every substance in their product requiring registration, must also be listed. Note that if a substance has been registered by more than one actor (OR), for example by the substance manufacturer's OR and also by a downstream formulator's OR, only the identity of one OR is required on the DRC. This would probably be the OR appointed by the formulator.

The DRC (or equivalent) should contain the date to which it's valid and a version number so that downstream actors can be certain that they hold the most up-to-date information concerning a product's REACH conformity. It is expected that a new DRC would be provided to the next actor in the supply chain if an update was made to this document (in much the same way that a revised Safety Data Sheet is provided to a downstream user after a significant change has been made).

Every DRC (or equivalent) could also indicate whether the document is for a substance or a preparation (mixture) or a polymer.

It is essential that the DRC includes the following conditions of issue:

This declaration covers only the stated substance, preparation or polymer, and only the stated supplier.

You are required to pass on the details of the Only Representative(s) stated on this declaration (or at least one OR for each substance in a preparation) to any EU legal entity of whom you are aware, who imports this substance/preparation/polymer into the European Union.

You are required to inform the Supplier(s) or the Only Representative(s) stated on this form of the identity of any EU legal entity that will use this Declaration to support their importation of the substance/preparation into the European Union.

On request, you will be required to inform the non-community Supplier or the Only Representative(s) stated on this form of the exact volume of product which is ultimately imported into the European Union. This data must be made available to ensure that all substances are covered by a registration in the correct volume band.

If you sell on to other customers outside the EU, who also export this substance or preparation to the European Union, either on its own, or as part of another preparation or article, then you or your customers are required to inform the Supplier or the Only Representative(s) stated on this form of the identity of the EU importer(s) and the volumes imported into the EU. This data must be made available to ensure compliance with REACH in the correct volume bands. Failure to communicate this information (EU importer identity and volumes) would result in the product being considered NOT to comply with REACH.

In addition, the company issuing this Declaration of REACH Compliance agrees to provide (in confidence) to the European Authorities, any information they might legitimately require to audit the REACH conformity of the substance or substances in the product covered by this document.

Summary

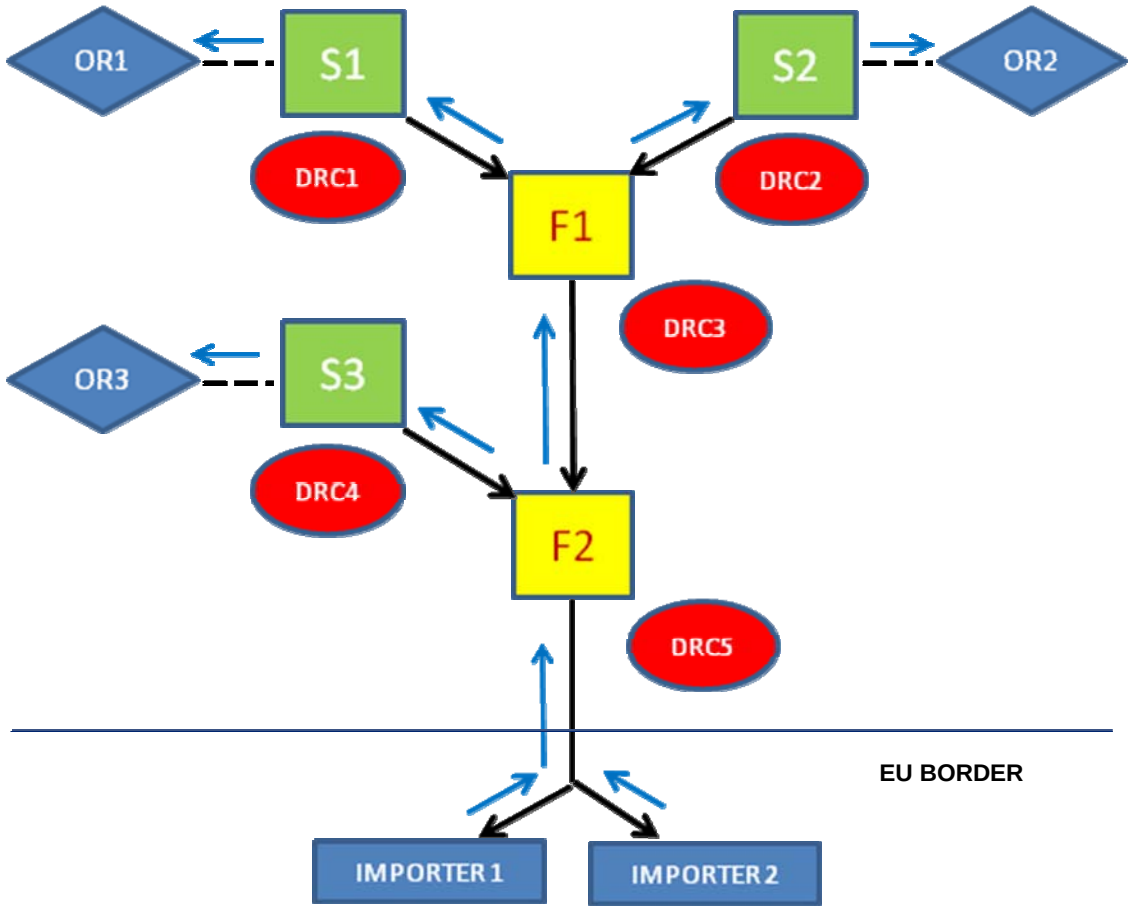
The ATC REACH WG believes that the proposals outlined in this paper constitute a simple and manageable approach to assuring REACH conformity among different actors in the non EU supply chain and for the EU importer, providing adequate protection of CBI for formulators, relieving downstream actors (including the EU importer) of any registration burden and ensuring the European Authorities have an auditable paper trail to follow if required.

It's not the ATC REACH WG's intention that this OR scheme should become an "official" procedure adopted into EU Registration guidance documents, or that this should be the only solution available to companies seeking to address these issues. Instead we offer this to the petroleum additive industry's supply chain as one possible solution to ensuring that product can continue to be traded between non-EU and EU countries.

Whilst this proposed scheme is widely endorsed amongst the member companies of ATC, it will not necessarily be followed by every member nor, as explained above, is it intended in any way as an "official" procedure for mandatory application. It is accepted that this is a complex issue, and that there may be other workable solutions which are now under active consideration.

Annex 1

Flow diagram showing the flow of information up and down the Supply Chain



1. In this example, two substance manufacturers (S1 & S2) have each appointed an Only Representative (OR1 & OR2, respectively) who will register their substance for REACH.
2. Each manufacturer prepares a Declaration of REACH Conformity for their substance (DRC1 & DRC2), identifying the registrant (OR) but not the substance. Each supplies this REACH declaration to Formulator F1.
3. Formulator F1 blends substances S1 & S2 together and sells the product. He prepares and issues his own REACH declaration (DRC3), identifying OR1 & OR2 as the registrants of the substances in the mixture.
4. Substance manufacturer (S3) has also appointed an OR to register his substance, which S3 sells to Formulator F2, providing the formulator with a REACH declaration (DRC4).
5. Formulator F2 blends this substance with the product obtained from Formulator F1 to make a new product. He supplies this to Importers 1 & 2, providing them with his own REACH declaration (DRC5), which identifies OR1, OR2 & OR3 as the registrants of the substances in the product, but does not disclose the identity of the substances as this is considered confidential business information (CBI).
6. Importers 1 & 2 advise Formulator F2 of the annual tonnage each import into the EU.
7. Formulator F2 breaks down the tonnage data into the tonnages of the substance (from S3) and product (from F1). He reports these figures to their respective suppliers together with the identity of the importers.
8. Manufacturer S3 gives the tonnage data of the substance to his OR, who checks that this imported volume is covered by his registration and may confirm that to the importers.
9. Formulator F1 breaks the tonnage data down into the tonnage of each substance in his product and gives that information to their respective manufacturers (S1 & S2), together with the identity of the importers.

Annex 1

Flow diagram showing the flow of information up and down the Supply Chain

10. Each substance manufacturer (S1 & S2) gives that data to their respective OR, who checks that the imported volumes are covered by their registration and may confirm that to the importers.

    Note that other scenarios are envisaged; for instance, DRC1 and DRC2 in this example MIGHT not be required if the Formulator F1 knows the exact chemical identity of the substances he purchases and has chosen to appoint an OR himself rather than rely on the OR appointed by S1 and S2

DECLARATION OF REACH CONFORMITY

Product Trade Name *My Substance*	Substance ✓ Preparation □ Polymer □

SUPPLIER DETAILS

Company Name:	*S1 Manufacturing Corporation*
Address:	*Chemical Road, Industrial Business Park, Anytown, USA*
REACH Contact Name:	*Jane Doe*
Telephone Number:	*001 222 333 4444*
Email:	*jane.doe@s1manufacturing.com*

FOR NON-EU SUPPLIERS – Details of Only Representatives are listed overleaf

SUBSTANCES

We declare that this substance conforms to the requirements of Regulation (EC) No. 1907/2006 (REACH)

PREPARATIONS & POLYMERS

We declare that all of the substances contained in this product conform to the requirements of Regulation (EC) No. 1907/2006 (REACH), and we confirm that we have obtained confirmation of conformity from any third parties supplying us with components contained in this product. In the event that the product is, or contains one or more polymers, we confirm that any monomers or other substances used in the manufacture of any polymer(s) and that are present at ≥ 2% in the polymer and imported at ≥ 1 MT/annum also conform to Regulation (EC) No. 1907/2006 (REACH).

Date created:	*1 October 2008*
Version number:	*1*
Expiry date:	*1 December 2008*

Conditions of Issue of Declaration of REACH Conformity

This declaration covers only the stated substance, preparation or polymer, and only the stated supplier.

You are required to pass on the details of the Only Representative(s) stated on this declaration to any EU legal entity of whom you are aware, who imports this substance/preparation/polymer into the European Union.

You are required to inform the Supplier or the Only Representative(s) stated on this form of the identity of any EU legal entity that will import this substance, preparation or polymer into the European Union.

You are also required on an annual basis to inform the Supplier or the Only Representative(s) stated on this form of the exact volume of product which is imported into the European Union that you are aware of. This data must be made available to ensure that all substances conform to REACH in the correct volume bands.

If you sell on to other customers outside the EU, who also export this substance, preparation or polymer to the European Union, either on its own, or as part of another preparation or article, then you or your customers are required to inform the Supplier or the Only Representative(s) stated on this form of the identity of the importer(s) and the volumes imported into the EU. This data must be made available to ensure conformity to REACH in the correct volume bands.

In addition, the company issuing this Declaration of REACH Conformity agrees to provide (in confidence) to the European Authorities, any information which is legitimately required and is available to the company in order to audit the REACH conformity of the substance(s) covered by this document.

Only Representative(s)

Substance(s) covered by this Declaration, are represented by the following Only Representatives:

Only Representative Name *S1 Europe Ltd.* Address *High Street, Up Town, England* Contact Name *Tom Pearse* Email *tom.pearse@s1europe.com* Telephone *+44 (0) 1234 56 7891*	Only Representative Name Address Contact Name Email Telephone
Only Representative Name Address Contact Name Email Telephone	Only Representative Name Address Contact Name Email Telephone
Only Representative Name Address Contact Name Email Telephone	Only Representative Name Address Contact Name Email Telephone

DECLARATION OF REACH CONFORMITY

Product Trade Name *My Formulation*	Substance □ Preparation ✓ Polymer □

SUPPLIER DETAILS

Company Name:	*F2 Formulation Corporation.*
Address:	*Product Lane, Heavy Industrial Estate, Somewhere, USA*
REACH Contact Name:	*Alice Spring*
Telephone Number:	*001 444 333 2222*
Email:	*aspring@f2formulation.com*

FOR NON-EU SUPPLIERS – Details of Only Representatives are listed overleaf

SUBSTANCES

We declare that this substance conforms to the requirements of Regulation (EC) No. 1907/2006 (REACH)

PREPARATIONS & POLYMERS

We declare that all of the substances contained in this product conform to the requirements of Regulation (EC) No. 1907/2006 (REACH), and we confirm that we have obtained confirmation of conformity from any third parties supplying us with components contained in this product. In the event that the product is, or contains one or more polymers, we confirm that any monomers or other substances used in the manufacture of any polymer(s) and that are present at ≥ 2% in the polymer and imported at ≥ 1 MT/annum also conform to Regulation (EC) No. 1907/2006 (REACH).

Date created:	*7 October 2008*
Version number:	*1*
Expiry date:	*1 December 2008*

Conditions of Issue of Declaration of REACH Conformity

This declaration covers only the stated substance, preparation or polymer, and only the stated supplier.

You are required to pass on the details of the Only Representative(s) stated on this declaration to any EU legal entity of whom you are aware, who imports this substance/preparation/polymer into the European Union.

You are required to inform the Supplier or the Only Representative(s) stated on this form of the identity of any EU legal entity that will import this substance, preparation or polymer into the European Union.

You are also required on an annual basis to inform the Supplier or the Only Representative(s) stated on this form of the exact volume of product which is imported into the European Union that you are aware of. This data must be made available to ensure that all substances conform to REACH in the correct volume bands.

If you sell on to other customers outside the EU, who also export this substance, preparation or polymer to the European Union, either on its own, or as part of another preparation or article, then you or your customers are required to inform the Supplier or the Only Representative(s) stated on this form of the identity of the importer(s) and the volumes imported into the EU. This data must be made available to ensure conformity to REACH in the correct volume bands.

In addition, the company issuing this Declaration of REACH Conformity agrees to provide (in confidence) to the European Authorities, any information which is legitimately required and is available to the company in order to audit the REACH conformity of the substance(s) covered by this document.

Only Representative(s)

Substance(s) covered by this Declaration, are represented by the following Only Representatives:

Only Representative	
Name	*S1 Europe Ltd.*
Address	*High Street, Up Town, England*
Contact Name	*Tom Pearse*
Email	*tom.pearse@s1europe.com*
Telephone	*+44 (0) 1234 56 7891*

Only Representative	
Name	*The OR Company.*
Address	*Nether Lane, Down Town, England*
Contact Name	*Bill Brewer*
Email	*bill.brewer@orco.com*
Telephone	*+44 (0) 345 67 8912*

Only Representative	
Name	*OR Legal Group.*
Address	*Centre Rd, Middleton, England*
Contact Name	*Jan Stewer*
Email	*jstewer@orlegal.com*
Telephone	*+44 (0) 456 78 9123*

Only Representative	
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