REACH compliance of EU importers

Thomas Schaefer and **Dr Dieter Drohmann** of Chemservice present the REACH-Code-Model for non-EU supply chains with final export to the EU

Reach introduced several new challenges for importers of chemicals into the EU. One is the compliance of imported confidential product formulations, especially in combination with indirect suppliers. As an EU Regulation, REACH cannot oblige non-EU companies to comply, but all substances being placed on the EU market at ≥1tonne/year are subject to registration, unless they are exempt, so it puts an obligation to register onto importers.

This could become a very costly burden for the importers and could require that every importer of the same substance would ultimately need to have his own registration. Additionally, non-EU manufacturers would only be able to place their substances on the EU market through certain importers and would thus become dependent on importers.

Role of the OR

For these reasons, REACH provided that any non-EU manufacturer or formulator may appoint an Only Representative (OR) - who must be established within the EU - as their legal representation, in order to relieve EU importers from their obligation to pre-register or register substances and to enable non-EU manufacturers to supply substances to any importer of their choice.

However, the OR is not automatically obliged to pre-register or register any substances. This is still down to the importers, unless they receive a written confirmation from one or more ORs that their imported volumes of certain products are fully covered by the substance pre-registrations or registrations of one or more ORs of non-EU manufacturers.

Thus it is in the hands of the non-EU manufacturers whether or not all or some importers within the same supply chain are relieved of their registration obligations by informing them of the OR appointment and by certifying to them in writing that their imported substance volumes within this supply chain are indeed covered.

This provides clear documentation to the importers, as otherwise they remain responsible for these specific imports and cannot be regarded as downstream users (DSUs). As a consequence of relieving EU importers from their registration obligations, the OR needs to keep records of importers being supplied and the relevant volumes they have actually imported.

Indirect imports

In multi-level, non-EU supply chains, the manufacturers of substances usually do not know through which channels and in which products

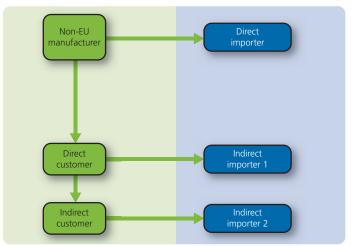


Figure 1 - Material flow in chemical supply chain

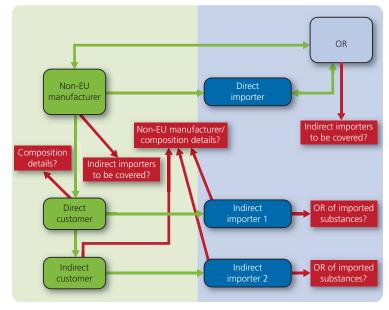


Figure 2 - Information flow in chemical supply chain

their substances are being imported into the EU. Thus they do not know the importers and their individually imported substance volumes.

In most cases, too, the EU importers do not know the detailed compositions of their imported products and who the substance manufacturers are. Additionally, what the components of their products are and who their suppliers and customers are form essential business secret of traders or formulators, and competition and anti-trust law needs to be followed.

Consequently, neither can the non-EU manufacturers (represented by ORs) relieve the importers of their obligations, nor can the importers themselves fulfill their substance registration and volume tracking obligations without disclosing confidential business information (CBI) through the supply chains, which could lead to a loss of business and the violation of competition/anti-trust rules! Figures 1 and 2 demonstrate a simple example of material flow and the associated difficulties with the required information flow.

Approaches & issues

So, what can EU importers do to ensure the REACH compliance of their imported products and prove this to the enforcement authorities? Different actors in the supply chain are taking different approaches, encouraging importers to believe that they are actually in compliance with REACH. Most of the common approaches are, however, coupled with issues that make watertight proof of compliance impossible.

One approach is the simple communication of substance pre-registration numbers through general REACH compliance statements from the non-EU manufacturers down to the importers. This depends strongly on successful communication between several DSUs and is vulnerable to error, since pre-registration numbers can get altered or even disappear on their way to the importers. Even if they make it, pre-registration numbers cannot be verified for their validity.

Additionally, there is no control on the actual supply chains and substance quantities supplied, which allows 'free riding' on third party pre-registrations. In the case of

exempted substances, preregistration numbers are not even being assigned and importers have no way to verify whether they have actually received all the preregistration numbers of all substances contained in their imported products, whose compositions are unknown to them.

However, the main issue is that there is no communication between ORs and importers on imported substances and volumes, so the ORs cannot fulfill their importer and volume tracking obligations. Thus, EU importers are not covered by the ORs' pre-registrations, which leaves them responsible for their registration obligations.

Another approach, which appears more reliable and inspires much confidence, is the communication of registration numbers through general REACH compliance statements or Safety Data Sheets (SDSs). The issues here are essentially the same as the ones raised with the pre-registration number communication, plus a few more.

Registration numbers identify substances through the ECHA website. Therefore communicating all of the registration numbers of a product may allow downstream suppliers (DSSs) and DSUs to find out detailed product compositions.

The existence of a registration number does not necessarily mean that an imported substance is in compliance with REACH. The total volume may exceed the registered volume band and many substances will not be registered before the 2013 and 2018 deadlines and so may not even have registration numbers yet. Even so, these substances may be REACH-compliant anyway, if they have been properly pre-registered and the respective registration deadlines have not been missed.

Relying on the communication of registration numbers through SDSs makes the situation even worse, since SDSs only have to be provided for hazardous products and only the hazardous components of a product have to be disclosed. Furthermore a hazardous substance on a SDS may not have a registration number yet, but may - or may not - be REACH-compliant anyway. Even wrong registration numbers copied from other SDSs may be provided. Importers can neither verify all of this nor prove anything to the authorities.

The main issue remains the same. In all cases, there is no

communication between ORs and EU importers on imported substances and quantities. Therefore, the ORs cannot fulfill their importer and substance volume tracking obligations, so EU importers are not covered by the ORs' (pre-)registrations, remain responsible for their registration obligations and will be importing illegally without their own (pre-) registrations.

A more sophisticated attempt to relieve importers from their registration obligations is the distribution of REACH compliance declarations up and down the various supply chains. In this case, non-EU manufacturers create declarations, including OR information, to confirm REACH compliance of their products to their direct non-EU customers.

In the next step, the respective customers are expected to create their own compliance declarations for their own products, which again may contain additional substances and additional OR information. These declarations are based on all declarations received and need to be provided to the next customers again, until finally the EU imports take place.

Then the EU importers are expected to report back their annually imported product volumes to their direct suppliers. The importers' suppliers need to break down these volumes into tonnages of the components of their products and then they need to continue to report this

information (including information on the importers!) further up their supply chains. This continues until the non-EU manufacturers receive the detailed information, so that their ORs can record all relevant data on importers and their imported substances and volumes.

With this model, the ORs of the non-EU manufacturers cannot ensure that all substances are in the correct volume band before all EU imported volumes have been reported back through the whole supply chain. Importers cannot prove REACH compliance of their imported products to the authorities before all the relevant ORs have finally confirmed this to them.

The system relies on all actors in the supply chains calculating all their component volumes properly and reporting this information in full, back and forth through all the supply chains involved. Due to the complexity of supply chains and product compositions, there is a very high chance that the final reported product volumes will be incorrect. Even if the calculations work, the importers never know if they will ever hold some kind of reliable document in their hands.

Another issue is that the supplied product volumes are not being controlled. Therefore formulators may be able to purchase the same material, for which they have a valid declaration of REACH compliance. from other non-REACH compliant sources and may use the existing declarations as a 'free ride'. In the end, more volumes might be reported back to the non-EU manufacturers than they have ever supplied to their customers. Moreover, with this system, information on importers needs to be disclosed and transferred through the involved supply chains. This may become a CBI and/or competition law issue.

REACH-Code-Model

The goal of the REACH-Code-Model is to address all of the shortcomings of the different approaches and provide a watertight documentation to the EU importers in order to make them become DUs under REACH. With it, an independent OR acts as a trustee of the non-EU manufacturers, traders, formulators and importers and for their respective substances or formulations in order to maintain confidentiality for all steps of the supply chains.

A coding system is used to exchange the relevant supplier, product and volume information between the different parties of the supply chains and the OR. The OR generates and provides unique, time- and volume-limited codes to all supply chain participants by means of certificates. This is done for all products containing material from non-EU manufacturers and intended to be imported into the EU.

The OR keeps track of all importers, substances and volumes through a central database and finally issues import certificates to the importers, related to their imported products and volumes covered. Thus all parties can continue their business without the need to disclose any CBI and can fulfill their REACH obligations

The basic principles are that the code process follows the supply chains and is a simple chain of certificates, up from the non-EU manufacturers, down to the

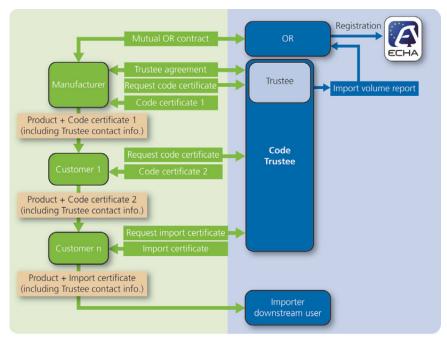


Figure 3 - Flow chart of the REACH-Code-Model

importers (Figure 3). No composition details of the products have to be provided to the trustee and ORs remain responsible for the correctness of all information provided to and certified by the trustee.

Only information which is known already is being exchanged between suppliers and customers. All certificates are immediately valid. All product volumes are controlled at every step of the supply chain in order to avoid free riding. No actor needs to do complicated and errorprone calculations. Certificates may be issued retroactively.

Volume reports are provided to non-EU manufacturers or their ORs on a regular basis. This allows them to monitor the actual coded and EU imported volumes of each substance and to fulfill their substance volume tracking obligations. Any information on suppliers, importers and products is kept only by the trustee. The system makes it possible to demonstrate REACH compliance to the authorities at the push of a button. Finally, no individual contracts between DSSs, DSUs and the trustee are required

Code procedure

The REACH-Code-Model works in this way. The non-EU manufacturer determines the total volume for each of the substances that he wants to 'enable' to be imported into the EU (= EU cleared volume). This information is based on coverage requests from the customers. His OR ensures that all substances are (pre-)registered in the appropriate volume bands.

The trustee records the data and generates a code for the non-EU manufacturer for every single product (substance or mixture) supplied to each non-EU customer who exports directly or indirectly to the EU. He may also record and code the data of all material being exported directly to the EU by the manufacturer. Finally the manufacturer pays a fixed fee for every code and receives a code or import certificate from the trustee.

A non-EU customer who directly exports products that contain EU-enabled material to the EU or who sells EU-enabled material to another non-EU customer. receives the assigned code certificate, including the trustee contact information, from the nonEU manufacturer, together with the covered product shipment. Then he contacts the trustee for each of his products that contain code material and that he wants either to export to the EU directly or to sell to the next non-EU customer, who needs EU-enabled material.

Again, the trustee records the data, generates a new code for the non-EU customer for every product supply to each EU or non-EU customer and provides an import certificate or code certificate. Every non-EU customer who requests an import or code certificate pays a fixed fee for each one issued.

The **importer** receives an import certificate from his non-EU supplier for the EU-enabled material exported to the EU, certifying the maximum covered product volume. The importer can demonstrate to the authorities that the substances contained in his products are covered by OR (pre-)registrations or are exempt. By demonstrating OR coverage for his imports, the importer becomes a DU and thus will be relieved from his (pre-) registration obligations for the imported substances

Conclusion

The REACH-Code-Model is a very straightforward system to provide REACH coverage along with the actual product streams.

The system can even be applied in case of reimported substances, since it is important to ensure that no more material is being reimported into the EU than has been exported before. Even combinations of different scenarios and multiple supply chains can easily be realised.

The administrative burden and costs for the participants are low. All control of coverage requests (verification of covered product volumes, validity of certificates, etc.) is done centrally through the trustee.

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