

## Position Paper

Date: 10.Oct. 2010

# Only Representatives and Safety Data Sheets

## Summary

Where importers wish to be provided with Safety Data Sheets (SDS) by either their non-European Union (EU)-based supplier or its Only Representative, this will have to be agreed on a Business-to-Business basis. Neither the non-EU based supplier nor its Only Representative (OR) has a legal obligation under REACH to provide safety data sheets.

In practice, non-EU producers often provide SDS to their European customers. They may do this for reasons of efficiency, quality assurance, or to safeguard confidential business information. Only in this particular case the OR must keep the information on the dissemination of the SDS available and up-to-date.

Only Representatives also often provide a service with regard to SDS. They may prepare the SDS for their non-EU based customers and may even distribute these to the importers. This, however, does not imply an obligation under REACH to do so, let alone a responsibility for the content or liability in the case of non-compliant SDSs.

## The Issue

Where non-EU based producers of substances or formulations have appointed an OR, both importers and authorities often assume that the OR has the obligation to provide SDS for the imported products.

This assumption is thought to be substantiated by REACH Art. 8.2 and 8.3, which state that the Only Representative '*shall also comply with all other obligations of importers under this regulation*' and that the importers '*shall be regarded as Downstream Users*'. In addition, Art. 8.2 obliges the Only Representative to '*keep available and up to date ..... information on the supply of the latest update of the safety data sheet referred to in Art. 31.*'

## ***Legal analysis***

### **No Obligation for the Non-EU Producer**

- Art.31 obliges '*suppliers*' to provide '*recipients*' with a SDS. According to definition Art. 3 No. 32, a '*supplier*' is either '*a manufacturer, an importer, a downstream user or a distributor*'.
- Each of these four categories of REACH actors are defined as natural or legal persons '*established in the community*' (definitions Art. 3 Nos. 9, 11, 13 and 14). The non-EU based producer of substances, formulations or articles therefore is not, and cannot be, a '*supplier*' according to REACH.
- As a result, the non-EU based producer of the substance or preparation does not have the obligation to supply the importer with an SDS.

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It may be interesting to note that for similar reasons, an EU-based company that is exporting to non-EU countries also does not have an obligation to provide a SDS to its non-EU customer. In this case, the non-EU customer is not a 'recipient', since a 'recipient' must also be an EU-based legal entity.

### **No Obligations for the Only Representative**

- The first time that an obligation to supply a SDS exists in the supply chain is when one EU-based legal entity (the 'supplier') supplies the product to another EU-based legal entity; the 'recipient'.
- A downstream user who places a substance or preparation on the market is a 'supplier' and has all the obligations associated with this role.
- The fact that through the appointment of an OR the 'importer' has become a 'downstream user', does therefore not relieve him of this duty to provide an SDS to his customers.

## ***Discussion***

### **Transportation and Storage**

The safety of product transportation and storage en route from the non-EU producer to the importer does not fall within the scope of REACH. It is regulated elsewhere and special safety documents must be provided; also by the non-EU based producer.

### **Import Means Placing on the Market**

It could be argued that since according to definition Art. 3 No. 12, 'import shall be deemed to be placing on the market', the importer automatically becomes a 'supplier' according to definition 32. If at the same time he could also be called a 'recipient', he might, according to Art.32, have the obligation to provide himself with an SDS; however, only downstream users or distributors can be 'recipients' according to definition Art. 3 No. 34. An importer cannot be a 'recipient'. As a result, an importer does not need to provide himself with an SDS, and there is consequently also no such obligation for the OR.

This is analogous to the situation of the manufacturer, who also does not have to provide a SDS to himself. The obligation to provide an SDS arises as soon as the product is supplied to a recipient.

Where the importer has no obligation to provide himself with an SDS, there is also no obligation for the OR to take over any obligation from the importer.

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### **OR Obligation to Maintain Dissemination Records**

It is logical that if, in spite of the lack of any legal obligation, a non-EU producer or his OR disseminate SDSs, the OR is to keep the records associated to this dissemination. These records should be carefully maintained. The OR is the only-EU based legal entity eligible for this work.

An obligation to keep records in the case that there is a dissemination of SDSs may very well co-exist with a lack of a legal obligation to provide an SDS. The obligation to keep the records does not imply any legal obligation to provide the SDS in the first place.

### **REACH Annex II**

REACH Annex II, under 'Requirements for the Compilation of Safety Data Sheets', Part A, Section 1.3, mentions the Only Representative as a possible 'supplier'. This could be read as to mean that, in contradiction to the above, an Only Representative can be a supplier. The word supplier here however is not intended to be understood as the supplier of a product, but as the supplier of the Safety Data Sheet itself.

The title of this section makes this clear: 'Details of the supplier of the Safety Data Sheet'. As argued above, it is indeed possible that an Only Representative supplies Safety Data Sheets, even if he has no legal obligation to do so.

### ***ORO Support***

ORO is always prepared to support, contribute with its expertise and cooperate with ECHA, the European Commission and Member States in order to help find appropriate solutions for the implementation of REACH.

ORO is the professional industry association of Only Representatives, which represents the interest of non-EU manufacturers and ORs and has set-up quality standards for Only Representatives.