ORGALIME

Comments

Brussels, 16 August 2007

Final draft RIP 3.4: Orgalime comments

In the context of the ongoing stakeholder's consultation on the final draft guidance document on pre-registration and data sharing (RIP 3.4), Orgalime wishes to provide the following comments.

Orgalime is concerned with the ambiguous wording of the last sentence of point 3.7 of the above mentioned RIP, which reads as follows:

> ***"What if the deadline for pre-registration is not met?***
> *If a company fails (or does not wish) to pre-register within the applicable deadline (i.e.in most cases 1 December 2008), it will have to suspend its activities involving the substances concerned and register them without delay. In addition it should be remembered that in this case the registrant will also have to enquire at the ECHA if a registration for the substance has been made.* ***All manufacturing, placing on the market and use of such substances between the start of the pre-registration deadline (i.e. in most cases 1 June 2008) and the date of suspension of activities may be subject to penalties according to national law[1]****."*

This wording in our view is misleading as well as going beyond the legal requirements of the REACH Regulation for the following reasons:

1. The present text could be understood that the penalties mentioned in the last sentence of the quoted paragraph would not only refer to the company that fails or does not wish to pre-register, but also to a potential client (i.e.: downstream user or article producer) to such a company failing or unwilling to pre-register. Such an understanding, however, would clearly contradict with the REACH Regulation since the legal requirements for a client industry are specifically –and differently- determined in the REACH Regulation, i.e.:

   - For downstream users, Article 3.7 REACH (and subsequently pages 18 and 111 of RIP 3.4) rules that downstream users are not considered as potential registrants and therefore are not authorised to pre-register a substance. The above-mentioned wording, however, gives the erroneous hint that downstream users would have to pre-register the substances they use in order to be able to continue using these substances during the registration transition period.
   - While downstream users should of course communicate as early and continuously as possible with their chemical suppliers to ensure that the substances supplied to them will be pre-registered/registered, REACH only allows the downstream user -after the publication of the pre-registered substances on the ECHA website by 1 January 2009- to notify his interest in a substance not appearing on the list to ECHA (see Article 28.5 REACH). ECHA shall publish on its website the name of that substance and, on request, provide details of the downstream user to a potential registrant.

[1] Final draft guidance document RIP 3.4 (pre-registration and data sharing), 10 July 2007, p. 20 (our emphasis)

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- From a time perspective, downstream users will only know by 1 January 2009, and in any case after 1 December 2008 when the pre-registration period has already expired, whether or not the substance they use has been pre-registered, with the publication of the list of pre-registered substances on the ECHA website according to Article 28.4 REACH. Prior to the publication of this list by ECHA however, downstream users have no legal means to get to know whether or not the substances they use have been pre-registered. It would therefore be wrong if RIP 3.4 penalised downstream users for an act they are neither obliged nor mandated to fulfill.
- The responsibility of article producers as further client industries to a company that is obliged to pre-register are equally determined in the REACH Regulation. In more detail, Article 7.1 REACH requires the registration of substances intentionally released from articles under certain conditions only. Article 7.1 *inter alia* shall not apply if the substance has already been registered for that use (Article 7.6 REACH). The pre-registration and registration duties by the article producer would therefore "only" occur if the substance supplier would not carry them out. This clearly determines the scope of REACH with regards registration and pre-registration requirements for substances in articles.

2. Article 5 REACH requires that "*Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required".* The use of a substance, however, is <u>not</u> explicitly mentioned in Article 5 REACH. We therefore doubt that point 3.7 of RIP 3.4 should include a reference to "the use" of a substance.
   Moreover, if REACH is to work properly, the issue of use of substances would be irrelevant in the context of pre-registration since non (pre-)registered substances should no longer be delivered to our industry according to the enshrined REACH principle "no data - no market". In case of stocks of substances delivered before 1 June 2008, downstream users would be entitled to continue using such substances in line with preceding legislation to REACH that had to be applied at the time when the substance supply occurred.

Consequently, Orgalime proposes that the point 3.7 of RIP 3.4 should be modified to clarify that the penalties mentioned in the last sentence of the quoted paragraph refers to the same company that fails or does not wish to pre-register, but does <u>not</u> refer to a potential client company.
We also suggest removing the term "use" from the present text since going beyond Article 5 REACH.

Orgalime has further pronounced on the issue of pre-registration in the Orgalime practical guide for understanding REACH. The guide is available for download free of charge at the following address: http://publications.orgalime.org.

In terms of REACH, Orgalime represents a major downstream user, with annual imports of some 33 billion euros of electronic components, for manufacturing activities in Europe. Orgalime represents the major industry branch that will be required to implement provisions related to substances in articles in REACH. The industry is characterized by highly complex global supply chains that operate under highly competitive conditions with "just in time" flows of most components. We are the supplier of technology to all other industry sectors, including automotive, aerospace or chemical industries.

Orgalime, the European Engineering Industries Association, speaks for 35 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.6 million people in the EU and in 2006 accounted for some €1,779 billion of annual output. The industry not only represents more than one quarter of the output of manufactured products but also a third of the manufactured exports of the European Union.

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