

Brussels, March 2006

**European Association of Chemical Distributors (FECC)  
position on the  
Council political agreement on the REACH proposal**

The European Association of Chemical Distributors (FECC) acknowledges the progress made by the European Parliament in November 2005 and the EU Council in December 2005. FECC continues to support the original objectives and particularly welcomes some of the improvements, which will make REACH more workable such as the introduction of the OSOR approach (One Substance One Registration), an enhanced role for the Agency, the establishment of support for SMEs, and the CSA/CSR only required above 10t/y.

**However, there are still several improvements, which FECC believes are essential to enable SMEs to meet the goals of the REACH legislation, but in an affordable and sustainable way.**

FECC urges the Commission, Parliament and Council to give further consideration to the following issues:

1. The **Categories for the description of the Use and the Exposure** in the registration dossier should be the rule and not the exception. An individual description of the use and/or an individual determination of the diverse exposure scenarios would make REACH unworkable. In this context, we urge that the categories according to Appendix IV Section 6 (Industrial, Consumer and Professional) should be applicable to all tonnage bands, not just restricted to 1 to 10 tonnes.
2. No satisfactory solution for imported preparations has been put in place. We strongly urge that instead of the submission of individual registrations for all of the substances within a preparation, the manufacturers or importers of the preparations should be able to alternatively submit a **registration for the preparation as a whole**. For many preparations there is already a wealth of data and information available and registration of the preparation directly would be a less burdensome option. Many non-EU preparation producers would not continue to supply their products into the EU if they have to register each individual substance within the preparation, as this would be a resource intensive, financially burdensome procedure that could lead to the loss of Intellectual Property Rights (IPR). The FECC proposal would aid in the protection of IPR of formulators and the goals of REACH, "environmental, worker and consumer protection" would be achieved just as effectively.
3. The **extent of the data to be supplied for registration** must also be limited for the volume range between 10 and 100 t – as envisaged by the Parliament. A targeted approach on data requirements for this lower tonnage



band will reduce the economic burden of REACH on those areas identified by the impact assessment studies as having the highest negative impact for industry.

4. The **preparation of a CSA/CSR for preparations** should also be possible and simple. The Commission should formulate text to be included in Annex Ib that concentrates on the highest risk components of the preparation and should avoid the requirement to provide information on every substance in a preparation.
5. The legal entitlement acquired within the registration process should be both **transferable and divisible**. Corresponding notification to the Agency, as well as the declaration of the conscientious continuation of the registration should be adequate prerequisites.
6. The **study summaries** and **robust study summaries** required for registration will need expertise not usually available in SMEs. Therefore, simplified forms of these summaries should be developed and the complex summaries should only be demanded in exceptional cases, justified by the risk.
7. The requirement to have **Good Laboratory Practice** (GLP) for all data and volume ranges will result in unbearable financial burdens on industry, especially SMEs. Any data generated by recognised and accepted procedures from laboratories that could be independently verified should continue to be accepted, and the GLP requirement should only apply to newly generated animal data as envisaged by the European Parliament.
8. The **costs of substance data registration** in the consortia should be allocated in a way, which is **proportional** to each party's production/import volume. The costs of the supplementary company and application related information should be carried alone by each enterprise with a duty of notification. The rules concerning cost sharing must be clearly defined in the regulation.
9. There must be an open Internet consultation on the outcome of the **RIP projects**. The final guidance provided will be essential for SMEs to achieve cost effective compliance with REACH however, SMEs by their very nature do not have extensive resources and have not been fully engaged or adequately consulted to-date in the RIP project developmental work. Small and medium-sized importers and manufacturers will not be able to meet the registration requirements if the already extremely demanding specifications defined in the regulation are additionally complicated by thousands of pages of extra execution instructions and guidelines.

FECC will be glad to provide further information on the above. Please contact:

Hendrik Abma

Director General

European Association of Chemical Distributors (FECC)

Ch. de Wavre 1519. B - 1160 Brussels

Tel.: +32 2 679 02 60 ; Fax: +32 2 672 73 55

E-mail: [hab@fecc.org](mailto:hab@fecc.org)