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## Cefic and FECC disappointed about the revised Guidance on Intermediates under REACH

In December 2010 the revised *Guidance on Intermediates* v. 2 was published by ECHA. The final version of the revised guidance has significantly restricted the criteria for Strictly Controlled Conditions (SCC) established in the previous guidance (February 2008). Companies have submitted registration dossiers for the December 2010 deadline and based their company's implementation of the SCC on the old guidance. The revised guidance will have a significant socio-economic impact, especially for SME's and fine chemicals industry. The most dramatic changes are:

- Deletion of the risk-based approach: risk-based approach is one of the core elements of the **REACH regulation** that allows this approach for intermediates.
- New definition of intermediates: the new definition goes beyond the definition of the REACH legal text.
- Introduction of containment strategies: the use of local exhaust ventilation (LEV) is now restricted beyond reason despite being an effective and well proven technology to ensure workers are protected.

As this is a very important matter for the chemical sector, industry provided significant contributions to the process of the draft guidance revision, by preparing multiple examples to demonstrate SCC and their technical experts to support the discussions. Industry also participated in several meetings including Partner Expert Group (PEG) meetings to discuss and agree the requirements of SCC. After the last PEG meeting (September 2010) there was an agreed proposal on two critical points:

- Use of hazard data as part of the containment strategy
- Use of local exhaust ventilation under specific conditions

Following the PEG consultation, these two points were however removed from the guidance text during the written procedure with Committees and CARACAL. The removal of these two critical points simply annihilate any flexibility in the implementation of SCC. The chemical industry calls for the guidance to be revised to integrate the proposal agreed at PEG level.

Without it, the revised guidance will have a considerable impact on the whole European manufacturing industry:

- Industry will be forced to handle non-harmful substances in exactly the same way as highly hazardous substances when they are used as intermediates under SCC in chemical processing.
- Intermediate registration dossiers may need updating to full art. 10 dossiers, with additional data generation (including many tests involving unnecessary animal testing, which contradicts ECHA's own commitment and the European Commission policy on the limitation of tests on vertebrate animals in REACH regulation and associated costs). It has to be emphasised that an update of an intermediate dossier to a full registration will not necessarily enhance the level of protection for workers and the environment.
- Technical installations may need to be re-engineered, even if the risk has been assessed as low. In these circumstances, where risk is low, further expenditure will have no tangible benefit on the protection of human health and the environment. In many cases these re-engineered installation will need to undergo a long and costly validation process before it can be applied.



- An additional report with detailed description of the SCC for such registered intermediates is now to be added to the IUCLID dossier. Such detailed information is not required in the legal text. Industry fully recognizes the importance of making this information available during REACH inspections in production plants. However as ECHA is not in charge of enforcement the reasoning behind providing this data to ECHA too is not obvious to industry.
- Downstream processors will have to re-examine whether their intermediates still fall under SCC according to the revised guidance and then potentially change to intermediate use under no SCC, with all the foreseeable commercial and adverse competitive consequences
- The requirements to switch to full containment also applies to pilot plants introducing an additional obstacle for innovation in Europe although another core objective of REACH.
- The costs for either updating an intermediate dossier or investing in modifications to the installation in line with the new guidance will not be a viable option for many companies, especially SME's. These companies may be forced to stop their production in the EU or to move their intermediate production outside the EU. Another consequence would be that the subsequent supply chain manufacturing operations would delocalise outside EU leading to significant jobs and business losses in the EU.

**The revised guidance on intermediates contains major changes from the earlier 2008 version, which is severely inhabiting the workability of the REACH legislation for intermediates. Industry is extremely disappointed that its significant contribution of expert knowledge done in the spirit of collaboration has been ignored in the final guidance development process. The consequences of the new guidance requirements are that this tremendously increase the financial burden on companies, this sadly without necessarily enhancing the level of health and environmental protection when handling these intermediates**

**The dire consequences for the whole of the EU economy, not just for chemical manufacturers, are unfortunately very real and predictable. This is especially true for the fine chemicals industry and the EU SME's which represent a major stake in European innovation and job creation.**

**We argue that a change of this guidance should be considered since the impact is such that the objective of REACH to enhance competitiveness of the industry is seriously endangered.**