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Mr Hubert Mandery
Director General
CEFIC – European Chemical Industry Council
Avenue E. van Nieuwenhuyse 4
1160 Brussels
Belgium

Email: mail@cefic.be

Subject: **Your letter of 18 July 2011 – "registration of intermediates"**
ECHA/A(2011)3278 – registered on 25 July 2011

Dear Mr Mandery,

Thank you for your letter regarding the registration of chemical substances used as intermediates under the REACH Regulation (EC) No 1907/2006.

Let me assure you that we are taking the industry concerns related to intermediates very seriously and want to understand in more detail what exactly is causing these concerns. A useful first step to help develop a better common understanding was taken at the meeting at ECHA on 26 August with CEFIC, Eurometaux and FECC; hence to some extent the issues raised in your letter are already being addressed. At the meeting it became evident that parts of industry may have misunderstood the Guidance on intermediates, and as a follow-up to this meeting, industry has been invited to provide by the end of September 2011 examples illustrating strictly controlled conditions for further discussions.

Nevertheless I will respond briefly to the main issues in your letter.

Firstly, it is important to remember that industry is responsible for deciding if substances are used as chemical intermediates and if they are produced and used under strictly controlled conditions (SCCs) and hence for making the appropriate REACH registration. The concept behind allowing registration of intermediates with no new test data (or only Annex VII data for transported isolated intermediates at above 1,000 tonnes per annum) if they are produced and used under SCCs, is that it can be concluded that there is no unacceptable risk to human health or the environment in view of the virtual elimination of the release of the substance without the need for a risk assessment; hence the standard data on the hazardous properties are not necessary.

Secondly, it should be noted that there are several elements in establishing SCCs (i.e. (a) to (f) of Article 18(4)), so it is implicit that in spite of 'rigorous containment by technical means' (item (a)), emission must nevertheless be minimised (item (b)) using 'procedural and control technologies', together with the other four aspects of SCCs of Article 18(4). Therefore, according to ECHA, in practice there is flexibility in how

industry designs SCC processes. The ECHA guidance helps in interpreting the REACH text, but it is neither possible nor desirable to cover all circumstances and possibilities for production and use of intermediates. Indeed the fine and speciality chemicals industry (as you note some of which are SMEs) may have particular approaches in producing and using intermediates under SCCs. We hope that the above-mentioned discussion on the examples will provide further information if this sector would indeed have specific problems that need further attention. Please note that the input from industry during the guidance consultation process was taken on board to every extent possible. Notable progress was made on a number of issues, for example, containment strategies for handling substances and the illustrative list for checking that the isolated intermediates are manufactured and used under SSCs. These contributions led to a substantial improvement of the Guidance for intermediates and are highly appreciated.

To address your specific point about using information on the properties of substances in designing SCCs, it should be noted that the published Guidance (version 2 of December 2010) clarifies that indeed physicochemical properties can be taken into account in the design of rigorous containment. Although the Guidance does not refer to other properties of the substance, such as known hazards, it is reasonable to assume that professional industrial hygienists and chemical engineers will use all the relevant information in designing rigorous containment measures to ensure SCCs are met. ECHA considers that the Guidance does not advise against this, instead it is left to the discretion of the reader. Of course, the status of the intermediate, the known properties of the substance and the applied risk management measures to meet SCC should be presented in detail in the dossier to ensure that the justification is appropriate. Nevertheless, it should be self evident from the principles behind registration of intermediates produced and used under SCCs without the full standard data set that arguments based on a risk characterisation or compliance with occupational exposure limits are not adequate in themselves.

Please note also that the findings of ECHA resulting from screening of registration dossiers for intermediates (ECHA new alert 11 May 2011[1]) and the discussion on the revised guidance are two separate issues. The results of the screening are addressing very basic shortcomings in the dossiers, such as no documentation of the SCC at all, or very obvious discrepancies within the dossier (such as indication of wide dispersive use in an intermediate dossier). The results of this screening would have been the same even under the previous version of guidance.

I would like to particularly stress that, in ECHA's view, neither the basic concept nor definition of 'intermediates' is changed by the updated Guidance on intermediates. The industry input during discussions on the use of intermediates under SCCs was taken into account during our re-drafting of the document. However it emerged that some of the industry arguments were not in line with the definition of intermediates in the REACH Regulation itself as well as the interpretation of this in the earlier version of the guidance on intermediates. Consequently, we considered that further clarification of the text of the Guidance on intermediates was needed. This clarification, like all ECHA guidance, aims to clarify what we believe is the most correct interpretation of the legal text. The guidance underlines that an intermediate is a substance used in the manufacturing of another substance whereby the intermediate is itself transformed into that other substance. It also clarifies that substances used in the production of articles cannot be regarded as intermediates. The document contains a number of clear examples aimed at helping industry to determine whether their substances are

[1] http://echa.europa.eu/news/na/201105/na_11_21_intermidiates_en.asp

intermediates. This definition is coherent with the approach taken on intermediates under the previous European chemicals legislation.

In conclusion, as Executive Director, I want to emphasise that ECHA is open for further discussions with industry on this issue. I believe that such discussions will also help us in analysing correctly both the practical implications and socio-economic impacts of the intermediates regime under REACH.

Yours sincerely,

Geert DANCET
Executive Director

European Chemicals Agency
Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland
Tel.: +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | info@echa.europa.eu