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Briefing note revised ECHA guidance Intermediates under Strictly Controlled Conditions

Introduction:

The purpose of this document is to provide recommendations to those member companies of CEFIC that wish to follow the recently revised ECHA guidance, published in December 2010, for intermediates, in particular with respect to expectations for strictly controlled conditions (SCC) (http://guidance.echa.europa.eu/docs/guidance_document/intermediates_en.pdf). The first version of this guidance was published in 2007, the first revision of the guidance was issued by ECHA in February 2008.

It should be noted that CEFIC and FECC have issued a public statement of disagreement with the revised ECHA guidance (see http://www.cefic.org/Industry-support/Implementing-reach/Documents-and-Tools1/).

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The document provides interim guidance in the form of Questions and Answers (Q&A's) in anticipation of the revision of the existing industry guidance for the chemical and petroleum refining sectors.

Q1: Why did ECHA revise its guidance?

A1: Under REACH, ECHA has a mandate to revise and update its guidance periodically in the light of experiences gained. This is the third version of the guidance on intermediates (initially published as a RIP document, now a second version controlled by ECHA). One of the reasons to revise the previous version of the guidance (dated February 2008) was the amendment of REACH Annex XI , Section 3, Substance-tailored exposure-driven testing (Commission Regulation 134/2009 of 16 February 2009), which introduced reference to Article 18 (4) (a) to (f) of REACH (definition of strictly controlled conditions for transported isolated intermediates). In addition, during the Caracal meeting of December 2009 Member States questioned the industry interpretation of Strictly Controlled Conditions (as published by Cefic, Concawe and EFCG) and asked for more clear guidance.

Q2: How did industry participate in the revision?

A2: Industry participated in the guidance update process by preparing many examples on SCC, working directly with ECHA-appointed consultants, making experts available for discussions with ECHA, Commission and Member States, making major contribution in the Partner Expert Group (PEG) meetings and submitting comments during the formal stakeholder review procedure. However, many of the above mentioned industry contributions have been ignored during finalization of ECHA guidance.

Q3: When was the revised guidance published?

A3: It was published in December 2010, after closure of the first REACH registration timeline.

The revision process had started mid-2009 with the appointment of a group of contractors charged with the exemplification of SCC. As part of the moratorium published in May 2010, it had been agreed between ECHA, Commission and Industry Associations (via the Directors Contact Group) to postpone the update of the guidance until after the first registration deadline in order to allow registering companies to complete their 2010 dossiers on the basis of existing guidance.

Q4: What are the main differences in the new ECHA guidance (December 2010) compared with the previous version (February 2008)?

A4: The first point of note refers to the role of hazard data. The REACH legislative framework for intermediates under SCC (Articles 17 and 18) presents the concept of SCC as a combination of the substance being 'rigorously contained by technical means during its whole life cycle', and procedural and control arrangements for residual emissions and exposures from waste handling, cleaning and maintenance of equipment, and accidents. The February 2008 guidance specified that substance hazard data on health and environment could be taken into account for the specification of rigorous containment / emission minimisation techniques. The December 2010 guidance now excludes this option, only allowing taking account of physical-chemical properties. One paragraph in the summary of principles of the December 2010 guidance reads: "If SCC conditions are declared, Risk Characterization cannot be used to justify a lack or absence of rigorous containment and emission minimisation technologies". The new guidance separates more explicitly rigorous containment by technical means from minimization of residual emissions/exposure by procedural and control approaches. There is a new section that describes how in certain cases an equipment-integrated local exhaust ventilation arrangement can be considered part of rigorous containment.

A further point is the introduction of a template (in a new Appendix 3) for the description of the SCC's, to be included in the registration dossier (inserted electronically in IUCLID section 13). This is intended to satisfy the requirement of Articles 17(2) and 18(2) where details of the risk management measures applied are requested.

The final point relates to a new Appendix 4 which contains a document from ECHA, the European Commission and the Member States about the definition of an intermediate. Two different independent advisory legal opinions concluded that the definitions and restrictions on intermediate definitions made in the document go far beyond the legal text. (link) http://www.cefic.eu/Documents/IndustrySupport/Cefic%20concept%20of%20intermediates%20letter%20(2).pdf),

Neither the legal opinions nor industry input have been considered in an earlier discussion and this aspect was not debated as part of the guidance revision. Keeping the use of a substance within the definition of an intermediate as per Appendix 4 is of critical importance in order to be able to rely on REACH Art 2 (8) b, which exempts substances used as intermediates from the authorization requirements of Title VII. This exemption from Authorisation is still valid for substances used as intermediates under non-strictly controlled conditions that were registered as per Art 10.

Q5: Will the CEFIC/Concawe/EFCG guidance of June 2010 be updated?

A5: Yes. Sections that make reference to the ECHA guidance of February 2008 will be examined. Furthermore, the main differences as described in A4 will be addressed.

Q6: Should companies that registered in 2010 prepare an update of their dossier to address the new guidance? And if so, by when? See also Q11.

A6: It is the company's responsibility to decide if and when to update his dossier. According to Art. 22, the registrant has to update his dossier without undue delay if certain explicitly listed circumstances occur, inter alia, if the registrant becomes aware of new knowledge of the risks of a substance. The fact that a – legally non-binding – new guidance document has been published is not a circumstance that per se triggers an update obligation under Art. 22. The registrations of the intermediates prior to the first registration deadline were done before the new guidance was published and were based on the preceding guidance. Despite that, Cefic advises its member companies to have a close look at their registration dossiers on intermediates of the first registration deadline, in order to verify that the intermediate status is justified and the status of strictly controlled conditions verified and well documented. It is the responsibility of each company to assess whether an update of the dossier is necessary.

Q7: How and what to communicate to downstream processors of intermediates under SCC?

A7: This updated guidance does not require new communication to downstream processors who have previously confirmed SCC. When a substance is supplied as an intermediate under SCC, this should have been communicated to the downstream processor. Recommendations for risk management measures are also to be communicated to downstream users via the SDS. The downstream processor should have confirmed to his supplier that the substance is used as intermediate under SCC. It is not recommended that suppliers now contact their DU's again for this confirmation. Downstream processors

of intermediates are responsible for the compliance with the strictly controlled conditions derived from Art. 18 (4).

Q8: The ECHA guidance suggests that measurement data for exposure and emissions may support the demonstration of SCC. How can this be done?

A8: The guidance suggests that 'residual' emissions and exposures from a rigorously contained process can be monitored and documented as part of the demonstration of the effective containment or the efficiency of emission minimization techniques that are applied. Conceptually, where SCC apply, then exposures/emissions should be 'low'. However, for the purpose of estimating the effectiveness of the emission minimisation techniques applied, measurements of emissions are indicated as helpful. In the experience of successful environment, health and safety management in industry it is strongly recommended to set an *a priori* objective for any monitoring effort, for example comparison against a benchmark figure or analysis of a trend over time. Without such a yardstick there is a risk that the analytical detection limit of the monitoring method becomes the *de facto* decision criterion. Considering the resource implications of monitoring programmes, companies should carefully consider the benefits of such programmes and develop clear protocols before undertaking any monitoring efforts.

Q9: We have submitted a registration dossier for an imported transported isolated intermediate (TII) according to Art. 18. In-house evaluation of SCC was based on the ECHA guidance 2008 including risk based considerations. We use the imported intermediate (1) to manufacture a new substance (2). Is our registration of the intermediate (1) still valid under the new ECHA guidance December 2010?

A9: Yes it is because it is a valid registration number. Company could check that the in-house criteria for SCC are in line with the new ECHA guidance. Hence you need to evaluate your process to see if you still can claim SCC for all process steps:

Q10: I am a downstream user of a transported isolated intermediate. I confirmed to my supplier that I applied strictly controlled conditions according to Art. 18 in 2010 and earlier. Do I have to re-confirm to my supplier after the new guidance document is available.

A10: No, not necessarily. Company could check if the use of the intermediates still complies with the SCC given in the new guidance. Only if he is not sure he might contact his supplier in order to discuss possible options (update registration, discussion about upgrade of technical installation). If a full registration might become necessary and your supplier is not able to do so, you could search for an alternative EU supplier. Another option is to become an importer of the substance and to do a full registration yourself.

Q 11 I have registered a substance before 30 November 2010 as a transported isolated intermediate (TII) under strictly controlled conditions (SCC) as per Art. 18. The EU customer has confirmed he uses the substance as a transported isolated intermediate under strictly controlled conditions according to Art. 18. Do I have to contact my customer and ask for a confirmation that his use still qualifies as a transported isolated intermediate under non-strictly controlled conditions based on the December 2010 guidance?

A 11 No, the user of the intermediate itself has the responsibility to comply with the SCC according to Art. 18 (4). It could help to develop a document demonstrating that strictly controlled conditions are applied. This document should be kept available for the purpose of being shown to an inspector of the enforcement authorities.

In the event that he says that his use is not strictly controlled according to the new interpretation he will probably ask you to proceed as per question 11 above and you should be prepared to answer the DU's question as to whether the supplier (you) intend to expand the registration done according to Art 18 to an Art. 10 registration (intermediate use). If you decide not to update your dossier to an Art. 10 registration, you should no longer supply your customer with that substance. In this context, good communication and interaction with your customers is essential to avoid supply chain's disruption as much as possible.

Q12. The ECHA guidance states that rigorous containment is to be achieved by technical means during the whole substance lifecycle, including manufacture, equipment cleaning and maintenance, sampling, loading/unloading, etc. The aspects that can be taken into account when defining the level and type of containment measures that are required include substance physico-chemical properties and processing conditions. How can this be interpreted?

A12: Important physico-chemical properties are related to a substance's 'tendency to become airborne'; for liquid substances this is driven by the volatility (at process temperature), for solid substances by the degree of 'dustiness'. Further reference to such a scheme can be found in the German EMKG tool (www.reach-helpdesk.de/de/Themen/Expositionen/Expositionen.html?__nnn=true). Regarding process conditions, factors such as frequency, duration and quantities involved determine level and type of containment measures. For example, for process or tank sampling of a low volatility liquid substance, assuming this is done once a shift by a trained operator who takes care not to incur dermal exposure for a duration of 1 minute at a dedicated sampling point and in proper sample bottles which are capped directly after filling, this set of conditions could be regarded as strict control.