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MSCA/15/2012

Ad-hoc Meeting of Competent Authorities for REACH

Open session

28 June 2012

12.00 – 16.30

ECHA conference centre

(Annankatu 18, Helsinki, Finland)

Concerns:	**Update on ECHA's activities on intermediates**
Agenda Item:	**For information – 4**
Action requested:	**The REACH and CLP Competent Authorities are invited to take note of this document and to provide comments where appropriate.**

Update on ECHA's activities on intermediates

1. Introduction

On-site isolated intermediates and transported isolated intermediates are exempted from "General obligation to register and information requirements" (chapter 1 of Title II of REACH - Registration of substances) with the exception of Articles 7 and 8. They benefit as well from the exemption from the authorisation obligations (Title VII – Authorisation)[1].

A "light" registration is required for certain isolated intermediates as long as they are being manufactured under strictly controlled conditions (SCCs). Intermediates are substances that are used in the manufacturing process but are consumed or transformed into another substance and therefore are not present in the final manufactured substance. For those intermediates that do not leave the site on which they are used and those that are transported between sites under strictly controlled conditions, only the following information needs to be submitted to the Agency: the hazard classification, any information on the properties of the substance that is already available to the registrants and information on the risk management measures applied, or recommended to meet the SCC requirements. If more than 1000 tonnes of an intermediate are transported under strictly controlled conditions, the risk of exposure is potentially higher, and therefore information which is required in Annex VII needs to be included in the registration dossier and submitted to the Agency.

Consequently, whether or not a chemical is considered as an intermediate will impact substantially on a company's obligations under REACH. This is the major reason why this subject triggers so much discussion. This paper gives an overview of ECHA's activities on intermediates, mainly, but not only, focussing on SCCs. At this moment in time there are not sufficient grounds to initiate an update of the Guidance on intermediates as additional clarifying examples and other related new information are not available.

2. Historical background

ECHA's first Guidance on intermediates (including the issue of SCCs) was published in February 2008. The guidance produced by CEFIC on this topic had already been objected to by MSCAs, the Commission and ECHA in May 2009. Industry's interpretation of the definition of an intermediate as well as their understanding of SCCs, were not in line with the legal provisions of REACH. As it became clear that Industry had interpreted ECHA's Guidance on intermediates differently, an update of ECHA's guidance on this topic was urgently needed.

[1] Article 2(8) of the REACH Regulation.

Industry provided substantial input before and during the consultation process. This led to a significant improvement of the Guidance on intermediates, e.g. example 2 of the guidance on containment strategies for handling of substances (example of technical measures) and the appendix dealing with an illustrative list of issues that may be taken into consideration for checking that the isolated intermediates are manufactured and used under strictly controlled conditions. However, industry did not manage to provide examples that clearly illustrated complete fulfilment of SCCs. Therefore the approach was shifted from demonstrating completely rigorous containment to demonstrating some of the technical means to achieve rigorous containment. Finally, ECHA's updated Guidance on intermediates (Version 2) was published in December 2010[2].

3. ECHA's approach

ECHA's guidance has not changed regarding the interpretation of the definition of intermediates and strictly controlled conditions (SCCs). Rigorous containment aims to prevent releases of a substance by technical design of the process or product. The physico-chemical properties of the substance may have an impact on the required level of rigorousness of the containment. Open handling of substances can however never be regarded as rigorous containment and there may be residual releases from rigorous containment. These have to be minimised by procedural and technical means. The means to achieve the required level of minimisation may vary depending on what is known about the physico-chemical properties of the substance. The Guidance on intermediates is silent on the fact that hazardous properties may be taken into account in the design of rigorous containment as explained earlier[3]. The registrant of an intermediate is required to provide details on risk management measures applied and recommended (Article 17 (2f) and Article 18 (2f)). Registrants are advised to have data available to justify that the strictly controlled conditions applied lead to minimised release and exposure. If a registrant can establish risk characterisation ratios for exposure resulting from not rigorously contained processes, he is advised to use the normal registration route according to Article 10 (see Article 17 (3) and 18 (4)).

4. Overview of activities

a. Dialogue with industry

Given the pertaining confusion regarding the understanding of the Guidance on intermediates, a meeting with several Industry associations took place within the ECHA premises on 26 August 2011. The meeting was useful for ECHA in analysing correctly both the practical implications and potential socio-economic impacts of the intermediates regime under REACH. From the meeting it became obvious that parts of the industry have understood the Guidance on intermediates differently despite all previous discussions on this matter.

As a follow-up from the meeting, ECHA invited industry to provide clear examples to demonstrate SCCs - i.e. clear cases where (a) it is justified to take into account known hazardous properties in designing SCCs (without using a risk assessment to justify SCCs), (b) Local Exhaust Ventilation (LEV) is legitimately part of the SCCs scenario and (c) Personal Protection Equipment (PPE) is used as a routine precaution (i.e. but is not part of the SCC justification). However none of these examples were,

[2] The Guidance on intermediates can be accessed via:
http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf

[3] See CA/55/2011, Follow-up of the 7th Meeting of the Competent Authorities for REACH and CLP, NL comments on Caracal document CA/18/2011 - Update on ECHA guidance activities.

in ECHA's view, suitable to demonstrate SCCs for the three circumstances that industry proposed.

b. Dialogue with MSCAs

At the March 2012 CARACAL meeting, some MSCAs expressed concern on the impact of the letter sent by ECHA to CEFIC[4]. This letter clarified the use of hazard data when considering how to put SCCs in place. The reason for their concern was that the wording expressed in the letter seemed to go beyond the principles detailed in the guidance and that it left room for interpretation. However, the response provided by this letter did not go beyond the principles explained in the Guidance on intermediates, although there is indeed an area for on-site and case-specific interpretation regarding the practical implementation of SCCs.

A few MSCAs expressed some concern regarding the current Guidance on intermediates as it may affect many SMEs as well as some big companies. It was questioned whether a risk based approach could be an option[5]. However such an interpretation is not in line with REACH and consequently MSCAs objected to such an approach.

MSCAs reiterated that the Guidance on intermediates should not be re-opened. ECHA agreed with this view and stated at the March 2012 CARACAL-meeting that it has currently no intention to reopen the Guidance on intermediates for an update of this issue.

c. Pilot project of the Forum

The Forum at its tenth meeting, decided to conduct a pilot project on the enforcement of intermediates. Several MSCAs had previously already emphasised that their National Enforcement Authorities (NEAs) intended to undertake enforcement actions in the context of the pilot project carried out by the Forum. The Forum decided to launch a small-scale project, limited to follow-up actions on the Article 36 decisions ECHA sent out to registrants in September 2011.

The objectives of the pilot project are to define the status quo of intermediates with regard to the pending Article 36 decisions of ECHA through coordinated enforcement actions and to collect information on the outcome of the enforcement actions, with a view to prepare a document identifying best practice.

The operational phase of the project will start in July 2012; by then the evaluation of registrants' responses to the Article 36 decisions will have taken place. ECHA will present the results of the evaluation to the participants of the pilot project at the end of June 2012, thus enabling them to conduct follow-up actions in those cases where the responses have been considered incomplete or insufficient.

During the preparatory phase, participants of the pilot project collected information on the enforcement of intermediates in the Member States. Fifteen Forum members provided information on their experience with, and their future plans for, the enforcement of intermediates. The results of the survey were presented at Forum-

[4] ECHA reply dd. 27/09/2011 to letter of CEFIC with reference GD/JN/ps D(2011)4193 addressing registration of intermediates.

[5] Italian position paper on the Guidance on Intermediates (ECHA 2010) for REACH Implementation dd. 28.12.2012 communicated via e-mail dd 29.12.2012.
E-mail exchange of the Polish MSCA to ECHA regarding the understanding of the Guidance on intermediates by a copper producer dd. 01.07.2011.

11. After Forum-11, project participants also provided comments on the evaluation templates developed by ECHA.

d. Workshop on SCCs with participants of the pilot project of the Forum

ECHA held a one-day workshop on 24 May 2012 with the NEAs involved in the pilot project on intermediates. ECHA took this opportunity to explain to NEAs how the requirements for SCC (as described in the Guidance on intermediates) should be understood regarding hazardous properties, the use of PPE and LEVs. At the end of the meeting there was a common understanding among the meeting participants regarding the principles to meet SCCs for intermediate uses.

During the meeting, NEAs expressed their support to ECHA's Art 36 approach and made suggestions for improving the communication amongst involved parties. Furthermore, NEAs gave advice on how to improve the template developed by ECHA for the evaluation of intermediate dossiers so that it will be more helpful for NEAs during inspection.

e. Screening of intermediate dossiers and follow-up of Art. 36 letters

Regarding the screening of intermediate dossiers, ECHA verifies whether the conditions of Articles 17 and 18 are met for such dossiers and, in a second step, ECHA may consider where necessary, to carry out a compliance check pursuant to Art 41. In a similar manner to the targeted compliance checks for full registration dossiers announced at the Stakeholders' Day, ECHA is also developing algorithms to automatically screen all the intermediate dossiers received.

Earlier, ECHA screened (manually) all 414 (on-site and transported) intermediate dossiers registered (i.e. having passed the technical completeness check) between 1.11.2009 and 22.6.2010[6] to check whether they met the conditions specified for intermediates in REACH Articles 17 and 18. Of the 414 dossiers, 115 were solely for on-site intermediate use[7]. Four of the dossiers appeared to be spontaneous updates of an intermediate dossier that had already been included in the screening. An overview of this exercise is given in Table 1.

Table 1. Outcome of the screening of intermediate dossiers[8]

	On-site isolated intermediates	Transported isolated intermediates*	All
Total number of screened dossiers	115	299	414
Meeting all the main requirements for intermediates	6	50	56
Missing, insufficient or doubtful information on RMM/SCC	106	231	337
Missing, insufficient or doubtful information 1) on RMM/SCC and 2) on intermediate status	3	14	17
Dossiers for which a spontaneous update was available	0	4	4

[6] The relatively high level of non-compliance is not related to the fact that current Guidance on intermediates is unclear as the updated guidance was only published on 16 December 2010 after the screening exercise, but rather due to the fact that companies have based their actions on the previous version of this guidance document where additional clarifications on this matter were still missing.

[7] As the on-site dossiers cannot be evaluated under a compliance check, the set of intermediate dossiers were divided to on-site and transported intermediates. For some transported intermediates the same dossier covered also on-site use. Dossiers including both on-site and transported intermediate use were classified as being "transported intermediate" dossiers.

[8] These dossiers may include also on-site isolated intermediate use as part of the registration dossier.

Article 36 allows ECHA and Member States to request from any registrant "all the information he requires to carry out his duties under this Regulation". Registrants of an intermediate are required to hold information confirming that the chemical is used as an intermediate, that SCCs are met and that downstream users are implementing those SCCs. In the Article 36 letters, ECHA asks registrants for detailed information on these three issues. Registrants are requested to provide details on the chemical reaction process for manufacturing another substance, a description of the technical role of the intermediate in this process and the chemical identity of the substance manufactured from the intermediate.

Regarding the Article 36 letters, so far ECHA has assessed 40 cases in September-October 2011. Within the two month deadline set in the decisions, ECHA received 35 responses on these letters. It seems that about half of the cases can be terminated without further action and in 15 of the cases ECHA would invite MSCA/NEA action in the form of on-site verifications. By the end of June 2012, ECHA will inform the participants of the pilot project on the individual cases, thus enabling them to start with follow-up actions as appropriate. A second wave of Article 36 letters focussing on SVHCs used as intermediates has also been sent out. The information provided by registrants in response to the Article 36 letters is currently being assessed.

5. Conclusions

ECHA's Guidance on intermediates helps in interpreting the REACH Regulation, but cannot cover all circumstances and possibilities. There are indeed some areas for on-site and case-specific interpretation regarding the practical implementation of SCCs. However, at this moment in time there are not sufficient grounds to initiate an update of the Guidance on intermediates as additional clarifying examples and other related new information are not available. At the same time, practical experience is evolving and instead of continuing theoretical discussions it is now time to collect the practical experience on this matter. Once sufficient practical experience is available, an assessment will be made on whether an update of the Guidance on intermediates providing additional clarifications is needed.

Action Requested: The REACH and CLP Competent Authorities are invited to take note of this document and to provide comments where appropriate.