

Workshop Summary Report

Introduction

This report summarises the outcome of a workshop on Strictly Controlled Conditions held by ECHA at its premises in Helsinki on 24 May 2012. The workshop was held to clarify ECHA's understanding of the Guidance on Intermediates and the interpretation of the Strictly Controlled Conditions (SCCs).

Workshop Participants

The workshop was attended by the participants of the Forum Pilot Project on Intermediates (AT, BE, DE, FR, IT, NL, NO, SE, UK) and 14 members of ECHA staff.

Opening of workshop and the strategy to assess intermediates dossiers based on Article 36 letters

The workshop opened with introductory presentations on the history and background to the Workshop. ECHA clarified that the concept behind allowing registration of intermediates with reduced information requirements 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 release, i.e. without the need for a risk assessment; hence the standard data on the hazardous properties are not necessary.

A progress report on the Forum Pilot Project on Intermediates was given next. This was followed by presentations on the ECHA work to assess intermediates dossiers and results from the ECHA verification strategy based on using Article 36 letters to request information from registrants by means of templates to facilitate checking on Strictly Controlled Conditions (SCCs).

Article 36 letters were sent by ECHA last year to registrants of intermediates dossiers subject to intermediate verification. MSCAs were informed about the letters but not the National Enforcement Authorities (NEAs). These letters have the status of a Decision, and consequently they have a 'legal effect' that can be enforced. ECHA presented a summary of Article 36 letter responses received from registrants. The verification of SCCs aims at checking the general consideration as set out in Articles 17 and 18 of the REACH Regulation and the questions in the Article 36 letters follow the guidance on SCCs as given in the ECHA Guidance on Intermediates so that the responses can be used to check for SCCs. After ECHA assessed the responses received from the registrants, fifteen cases were chosen for further on-site verification by the NEAs within the Forum pilot project on intermediates.

An extensive discussion took place regarding verification of SCCs, in particular on how to judge SCCs and detect non-compliances, how to invite industry to devise solutions and implement them and how to give feedback to ECHA. There was also a debate on how to best support NEA inspectors through collaboration with

2(3)

ECHA. There was consensus that the Forum Pilot Project based on a small number of cases was a good way to identify the best way to carry out this activity.

It was noted that the follow-up on the Article 36 letters was already imbedded in the routines of inspections carried out by inspectors as part of their REACH responsibilities and that inspectors could support and instruct the registrants being inspected on how to comply with their Article 36 letters.

Discussions on three specific aspects of the strategy: Downstream Users, status of substances as intermediates and SCCs

There followed three separate presentations with subsequent discussions involving all participants at the workshop to openly exchange views and information on these key issues in the strategy on intermediates dossiers. The first was on downstream users and looked at how the template developed by ECHA to check intermediates dossiers was used, how the information was reported, what enforcement action could be taken and how enforcement action could be reported back to ECHA. The second discussion was on the definition and status of intermediates and the third discussion was on the understanding of SCCs. These two last discussions followed a similar format and specifically looked at how the template was used, how and when on site verification will be carried out, what inspectors/NEAs may expect to see on site and how verification feedback could be reported back to ECHA.

1. Downstream Users (DUs)

The main discussion concerned the different DUs along the supply chain and how to deal with them, as potentially the DUs could be in different Member States to the registrant or the substance could originate from outside the EU. A practical solution is to focus on the registrant and the confirmations they get from their customers regarding use under SCCs, leaving NEAs the option to follow up on DUs at different levels of the supply chain.

2. Status of substances as intermediates and the definition of intermediates

Participants discussed the legal definition of 'intermediate' under REACH, as well as potential misunderstandings and misinterpretation. ECHA clarified that an intermediate is a substance used in the manufacturing of another substance whereby the intermediate is transformed into that other substance. There was a short discussion about at what stage a new substance is produced: although this may not always be clear cut, this is not so important because verification of the substance as an 'intermediate' covers the point from which it is manufactured to the point that it no longer exists. During the presentation some examples of chemicals with intermediate status as well as non-intermediates were presented.

3. Strictly controlled conditions (SCCs)

A general discussion took place on the concept of SCCs, in particular on what is meant by 'rigorous containment', the concept of 'minimisation' of emission and resulting exposure and technical feasibility.

3(3)

The ECHA presentation set the scene for the discussions based on the definition of SCC in Article 18.4 and the current Guidance on Intermediates, whereby SCCs are considered to be technical measures underpinned by management systems. Rigorous containment is obtained by technical means to ensure virtual elimination of exposure and hence that risk is controlled. In particular a risk characterisation cannot be used to establish SCCs. The physico-chemical properties, as well as the process conditions, can be taken into account in the design of the measures for rigorous containment; indeed it is reasonable that all information on the known properties of the intermediate, including any known hazards, will be used by the professional designing the rigorous containment measures, although this is not specifically addressed in the Guidance.

Given the complexity of the issue inspectors may wish to receive a specific training as how to check SCCs and to judge whether they are adequate. There was a debate on whether it would be possible to have specific points (e.g. threshold levels) for inspectors to measure against.

The presentation emphasised the Article 36 letter and template as a tool to support inspectors, and it is expected that the majority of cases would not be too complicated. It was agreed that it was worth carrying out the Pilot Project on the 15 identified cases. ECHA explained that the documentation (processes, equipment, engineering controls, training records, procedures, etc) and SCCs (equipment, workplaces, procedures, use of PPE etc) can be checked by NEAs during on-site inspections.

At the end of the presentation some examples of compliance to SCCs were presented and discussed.

Final Remarks and Conclusions

The final discussion was led by the Forum Members and Experts. They firstly collected views on the workshop discussions and then discussed how the strategy could be embraced and implemented within the Member States, what they could do and how this could be done.

During the workshop, NEAs expressed their support for ECHA's Article 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 intermediates dossiers so that it will be more helpful for NEAs during inspection.

The participants appreciated the explanations ECHA had given to them, including the clarifications of the current Guidance on SCCs, in presentations at this workshop and expressed in the letter of 27 September 2011 from the Executive Director to CEFIC (see Annexes 1 and 2) that corrected possible misunderstanding of the Guidance. Those NEAs that were undertaking enforcement actions were aware of ECHA's understanding of these issues.

Annex 1: Letter to ECHA 18 July 2011

Annex 2: Reply to CEFIC 27 September 2011