**Annex I. Form for documenting information on risk management in a registration dossier for isolated onsite and transported intermediates**

*This form can be used by the registrant of an isolated intermediate (the manufacturer or importer or user) to provide a basic indication to which conditions his conclusion refers that strictly controlled conditions are* *in place. If you are not sure whether your substance you use meets the criteria for intermediates under SCCs, please complete this form and send it to Dr Michael Chang([zxp@cirs-group.com](mailto:zxp@cirs-group.com)).*

|  |
| --- |
| 1. **Brief description of technological processes applied in use of the intermediate.** |
| *This section shall be provided by the user of intermediate.*   1. *Simple description of synthesis process.* 2. *Industry sectors or Sectors of use (SU)*   *Pharmaceutical industry  Yes*  *Petrochemical Industry  Yes*  *Fine chemicals industry  Yes*  *Others: Please give a brief description if not mentioned.*   1. *Choose all relevant activities (unit operations)*   *Synthesis*  *Yes  No*  *Purification steps  Yes  No*  *Cleaning and maintenance  Yes  No*  *Sampling and analysis  Yes  No*  *Loading and unloading  Yes  No*  *Storage and waste treatment  Yes  No*   1. *Description of the technical means to rigorously contain the substance*   *Synthesis:*  *Purification steps:*  *Cleaning and maintenance:*  *Sampling and analysis:*  *Loading and unloading:*  *Storage and waste treatment:*  *Example 1: Fine chemicals industry:*  *Synthesis: Reaction vessel held by under-pressure (negative pressure).*  *Loading and uploading:* *Material transfers via enclosed systems. Loading/unloading in a closed collection pan to prevent spillage into waste water.*  *Sampling and analysis:* *vented cabinets or sample bombs*  *Storage and waste treatment:* *Storage tanks have floating internal roofs with double mechanical sealing.* |
| 1. **Procedural and control technologies to minimize emission and any resulting exposure** |
| 1. *Some technical measures to control emissions to the environment*   *Waste gas incineration:  Yes  No*  *Condenser:  Yes  No*  *Scrubber:  Yes  No*  *HEPA-filter:  Yes  No*  *WWTP:  Yes  No*  *Cryogenic treatment:  Yes  No*  *Biofilter:  Yes  No*  *Others: Please give a brief description if not mentioned.*   1. *Description of the procedural and control techniques to minimize emissions from cleaning/maintenance.* |
| 1. **Handling of the substance by trained personnel** |
| 1. Description of training and information on appropriate precautions and working procedures (proper labelling of specific working places) at workplace. 2. Is the personnel provided with safety data sheet (SDS) of the substances handled?   *Yes  No*   1. Is it guaranteed that only trained personnel handles dangerous substances?   *Yes  No* |
| 1. **Cases of accident and where waste is generated** |
| 1. *Description of the procedural and control techniques to minimize emissions after accidents*: 2. *Description of the activity and type of PPE in case of accidents, incidents, maintenance and cleaning activities:* 3. *Declaration of compliance with relevant regulations:*   *Directive 96/82/EC*  *Yes  Not relevant*  *Directive 94/9/EC*  *Yes  No relevant*  Waste treatment operations：*BREF document*  *Yes  No relevant*  *Other local regulations:* |
| 1. **Management system** |
| Provide documents that occupational procedures have been assessed.（A management system should contain reference to procedures for accident prevention and response.） |

*Appendix 1*

Illustrative list of issues that may be taken into consideration for checking that the isolated intermediates are manufactured and used under strictly controlled conditions.

*This list can be used by*

* *the registrant of an isolated intermediate (the manufacturer or importer) and*
* *the user of the intermediate wishing to confirm to the registrant that his use takes place under strictly controlled conditions*

The documentation needs to contain a justification of the relevant issues listed below.

1. **Has the life cycle of the substance been accounted for?**
2. Manufacture of the intermediate? Continuous process or batch operation? Scale of operation?
3. Use of the intermediate? Continuous process or batch operation? Scale of the operation?
4. Final synthesis process?
5. Any purification step?
6. Sampling and analysis?
7. Loading and unloading from equipment or vessels and any other substance transfers?
8. Any relevant storage?

h) Waste treatment?

1. **Is rigorous containment by technical means in place?**

a) The substance is rigorously contained by the following means (refer to the life cycle steps and process steps under 1): …..

b) Procedures to ensure containment has been applied and maintained for all stages of production and processing.

c) Management system is in place

d) Implementation of existing EU legislation

e) Monitoring measurements to check on potential remaining emissions are being carried out. This includes: ……

**3. Are procedural and control technologies being used to minimise emissions?**

1. Residual emissions from rigorous containment occur at the following steps of the processes. ……. These emissions are minimised by the following procedural and control techniques (differentiation regarding work-places and environment required): …….
2. Emissions from purification, cleaning and maintenance after accidents are minimised by the following procedural and control techniques (differentiation regarding work-places and environment required): ……….
3. Emissions from purification, cleaning and maintenance are minimised by the following procedural and control techniques (differentiation regarding work-places and environment required): ……….
4. Emissions from waste handling is minimised by the following procedural and control techniques (differentiation regarding work-places and environment required):

**4. Are only properly trained and authorised personnel handling the substance?**

a) Relevant training or authorisation scheme covers this substance and/or process

b) A procedure ensures that only trained and authorised persons handle the substance

1. Other legislative frameworks that control the handling of the substance have been considered

**5. Are special procedures applied before the system is opened and entered during** **cleaning and maintenance works?**

a) Process procedures for containment during cleaning and maintenance have been accounted for in plant and engineering design as appropriate for the site

b) Operational procedure system checks include cleaning and maintenance of process equipment

c) Risk management measures are applied during cleaning and maintenance

d) Specific procedures before the system is opened. These include e.g. purging and washing and …… (further specify)

**6. Are substance-handling procedures well documented and supervised by the site** **operator?**

a) Occupational procedures have been assessed and are documented

1. **For transported isolated intermediates:**

Confirmation that the synthesis of (an) other substance(s) from that intermediate takes place under strictly controlled conditions on other sites has been documented.

**Background**

On 11 May 2011 ECHA announced that most (86%) of the more than 400 dossiers on intermediates it screened do not seem to meet the conditions imposed by REACH for them to benefit from the reduced information requirements. ECHA encourages registrants of intermediates to proactively reassess and, where necessary, update their registration dossiers.

According to REACH, two critical conditions need to be met for an on-site or transported isolated intermediate to benefit from the reduced data set provisions of articles 17 and 18 of REACH:

* the use of the substance must meet the definition of intermediates as described in article 3 (15) of REACH; and
* the substance must be manufactured and/or used under strictly controlled conditions (SCC).

In view of these conditions, ECHA is asking registrants to collect and send an extensive amount of information including a description of the chemical reactions that take place, and a description of all the measures taken to ensure strictly controlled conditions at all steps (See annex I), as well as copy of letters sent to, or received from all downstream users confirming that they use the substance as an intermediate under SCCs. It is recommended that annex I be completed by the downstream user of an intermediate to show compliance.

According to ECHA, compliance failures have mainly been due to the fact that the registration dossiers do not contain enough information to demonstrate that the above conditions are fulfilled, in particular the SCCs specified in the December 2010 version of the ECHA guidance on intermediates, a document revised after the first registration deadline of 30 November 2010.

**Q1. What shall registrants do now?**

Manufacturers and importers who have submitted reduced registration dossiers for isolated intermediates under SCCs are indeed advised to review their dossier to determine whether they are likely to face criticism from authorities on the fact that their substance either does not meet the definition of “intermediates” or is not manufactured or used under SCCs.

**Q2. What shall downstream users do next?**

Downstream users who are supplied intermediates for use under SCCs are also at risk and should review their position for two reasons:

* firstly, they face the risk of not being supplied these substances any more if the manufacturers, following a requalification of the substance as a normal substance decides not to continue producing it. They should therefore contact their suppliers to verify the status of their intermediates and their intentions and, if necessary, seek guarantees as to the continued supply of these substances;
* secondly, downstream users may already have confirmed in writing that they use the substance under SCCs but this may no longer be the case under the interpretation of the new guidance document. They should therefore verify whether the SCCs they committed to apply are in line with the new guidance document. If not, and if they have certified to suppliers that they will respect SCCs according to Article 18(4) of REACH, their responsibility may be engaged and they should review their position.

It is recommended that annex I be completed by the downstream user of an intermediate.

**Q3. 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?**

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.

It is recommended that annex I be completed by the downstream user of an intermediate to show compliance.

**Q4. I have registered a substance before 30 November 2010 as a transported isolated intermediate under SCCs as per Art. 18. The EU customer has confirmed he uses the substance as a transported isolated intermediate under SCCs 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 SCCs based on the December 2010 guidance?**

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.

A sample document is attached to this letter (Annex I).

**References:**

http://echa.europa.eu/web/guest/view-article/-/journal\_content/feebf4d2-42ba-439b-b9e8-009c30c60d00

http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/Final\_QA-SCC\_final%20for%20publication20110513.pdf