Strictly Controlled Conditions (SCC)

Note: the objective of this factsheet is to clarify the conditions that need to be fulfilled by registrants in order to make use of the specific registration requirements covered by Articles 17 and 18 of the REACH Regulation.
For the circumstances under which a substance may or may not be regarded as an intermediate under REACH, please refer to the factsheet on REACH & intermediates.

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1. What is the difference / relationship between SCC and Rigorous Containment (RiCo)?

1.1. SCC definition

To assess if an intermediate is manufactured and used under **SCC** during its whole lifecycle, the registrant should evaluate if all conditions as set in Article 18(4) apply:

(a) the substance is **rigorously contained** by technical means during its **whole lifecycle** including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

(b) procedural and control technologies shall be used that **minimise emission and any resulting exposure**;
(c) only properly **trained and authorised personnel** handle the substance;
(d) in the case of **cleaning and maintenance works, special procedures** such as purging and washing are applied before the system is opened and entered;
(e) in cases of **accident and where waste is generated, procedural and/or control technologies** are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
(f) substance-handling **procedures are well documented and strictly supervised** by the site operator.

SCC should thus be seen as a combination of **technical measures** that are underpinned by **operating procedures and management systems**.

It should be emphasized that SCC must be achieved without taking into account the use of personal protective equipment (**PPE**) except when it aims at limiting exposure resulting from accidents, incidents, maintenance and cleaning.

SCC have to be demonstrated for the **whole lifecycle** of the isolated intermediate (on-site or transported) which begins with its manufacture (i.e. with its origin in the manufacturing process) and ends with the use of the substance in the synthesis process for the manufacture of another substance.

1.2. RiCo definition

RiCo is achieved by the **technical design** of a process and the equipment that aims at preventing releases (to prevent exposure of workers and to prevent releases to the environment). The **physico-chemical properties** of a substance are one factor to take into account in determining the right design to achieve RiCo, together with the process conditions (like temperature and pressure) if this is relevant.

Release of the substance should be prevented through **containment systems**, such as (combinations of) suitable mechanical barriers (e.g. enclosures) and air dynamic barriers (e.g. Local Exhaust Ventilation (LEV) as integrated part of the containment and differential pressure).

1.3. Relationship SCC-RiCo

SCC and RiCo are not independent concepts. RiCo is an integral part of SCC: RiCo covers technical measures at the process level, while SCC include RiCo and procedural and control techniques addressed under (b) to (f) above. RiCo has to be seen as one of several aspects of SCC.

2. How can RiCo be assessed?

RiCo in the **workplace** can be demonstrated in a tiered manner and taking into account several aspects:

1) Screening with **RiCoG** (Rigorous Containment Guide for Metals):
   - RiCoG is an Excel tool developed by EBRC and Eurométaux to provide guidance to registrants of isolated intermediates on how RiCo of their intermediates could be assessed and documented. It also gives guidance on where registrants could make improvements to arrive at RiCo.
   - RiCoG has been developed to address specific needs of an assessment of RiCo for metal intermediates and brings together several elements, such as the Hirst *et al.* (2002) containment scheme referred to in the ECHA guidance, hazard considerations, and exposure potential.
   - RiCoG is a voluntary tool, provided free of charge. There is no obligation to report the results of the RiCoG assessment in the Registration dossier, but they can be included in Appendix 2 and kept in-house in preparation of inspections by local competent authorities.
   - RiCoG is only part of the toolkit that can be used in the decision-making. It helps to assess RiCo in a standardised, qualitative way, but leaves the final decision regarding compliance/non compliance to the user of the tool. RiCoG is not aimed at becoming a reference tool for the assessment of RiCo.
   - RiCoG is intentionally designed in a precautionary way. Any conclusions drawn by RiCoG should therefore be interpreted with this built-in conservatism in mind, and negative results should not be seen as conclusive but instead should serve as an entry point for further (higher tier) assessments of RiCo. If RiCo cannot be demonstrated with RiCoG, an exposure assessment will be required.
   - In an integrated assessment of SCC for an entire process, RiCoG can be used to prioritise process steps requiring such higher tier assessments, and provides an easy and structured way to assess and to document RiCo for the remaining process steps.
   - Because of its conservative nature, a confirmation of RiCo with RiCoG is currently assumed not to require to be supported by measured exposure data; this data may however be of use to demonstrate RiCo where RiCoG does not achieve it due to the strictness of the tool (cf. item 2 below).

2) **Occupational exposure assessment** (excluding PPE):
   - If registrants cannot demonstrate fully with the containment system in place that release is prevented as far as technically possible, they can use their exposure data to demonstrate the prevention works. If there is no (significant) exposure, this would mean that there is no release and good containment can be assumed.
   - An RCR (based on measured or modelled exposure data) can be used as supportive evidence to supplement the demonstration of RiCo, but cannot be used to justify the lack or absence of RiCo (exposure data showing no exposure cannot be used to justify the non-existence of RiCo measures).
   - ECHA guidance does not propose a fixed RCR level under which residual exposure levels can be considered as SCC compliant. However if SCC conditions are met, exposure data can be used to demonstrate the RiCo conditions in place are effective. RCR levels "significantly below 1" will have to be achieved to demonstrate this. Without being defined such level may be in the order of < 0,1. The RCR should be as low as possible as a general principle[1].

3) **Expert judgement** / agreement with inspectors. Each registrant should include several parameters in the RiCo and SCC assessment, including the views of the local inspectors.

Aspects of RiCo have an **environmental** element e.g. ensuring containment during storage; but RiCo is primarily considered under worker exposure assessment. If an assessment of RiCo is made for all process stages including storage for occupational exposure there is no need to repeat the assessment of RiCo for the environment; it is assumed that if exposure to workers is prevented, none or very negligible emissions to the environment will occur. Performing a RiCo assessment for storage (prevention of emissions to soil, surface water and air) is however relevant in cases where the intermediate is or contains substances which are environmentally hazardous (e.g. Ag).

3. How can SCC be assessed when RiCo is demonstrated?

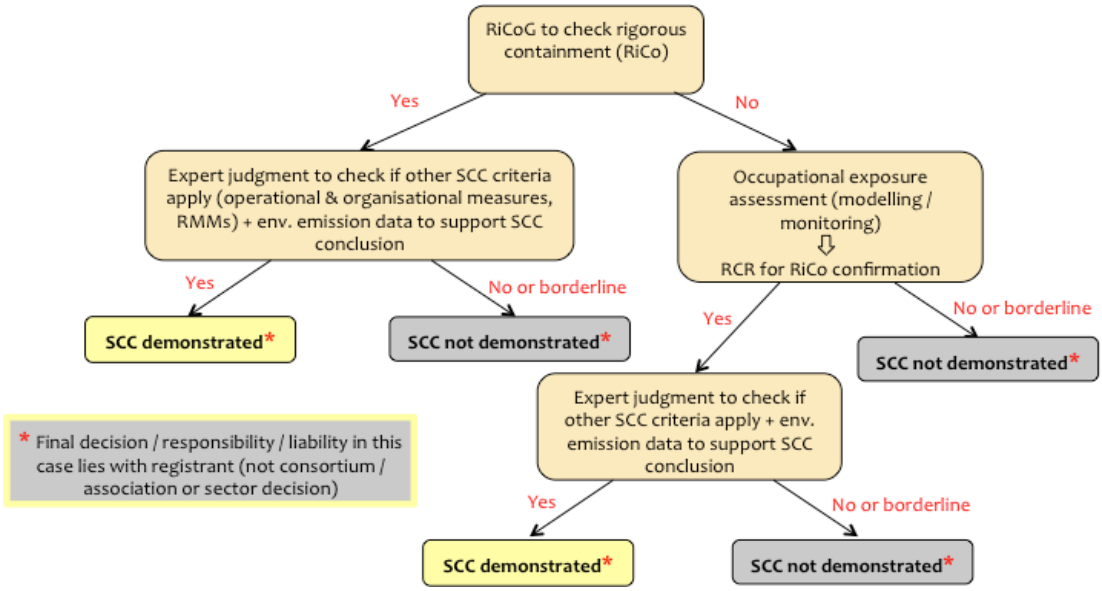
If RiCo is confirmed, SCC has to be further demonstrated by:

- Qualitative screening to establish sufficiently robust procedural and control technologies or RMMs are in place to minimise emission / exposure (residual emissions from RiCo, emissions from purification, cleaning & maintenance after accidents or where waste is generated). Compliance with other regulatory schemes can

[1] This is especially important for the PM Refinables project where the RCRs are calculated for each constituent of each complex UVCB substance. Indeed, ECHA may expect/request each constituent's RCR to be summed up to arrive at a total RCR for the Refinable and in doing so, in order to address combined toxicity/antagonism/synergism, there is a tendency to apply a correction factor for combined effects ensuring that none of the constituents would contribute more than 0,2 RCR to the overall risk of the Refinable.

be used as evidence (e.g. the Directive 2008/1/EC concerning integrated pollution prevention and control - the IPPC Directive);

- Trained and authorised personnel for substance handling;
- Special procedures before entering the system (for cleaning & maintenance);
- Well-documented & supervised procedures for substance handling;
- Available monitoring data to support the conclusion of SCC. This is considered to be especially important in a context of combined exposure (e.g. PM Refinables).



It is stressed that the **decision on SCC is a business one (per registrant), not a REACH consortium, trade association or industry sector one**. The registrant of an intermediate can choose between two registration routes:

1) Article 17/18 route if SCC (including RiCo) are in place, or
2) Article 10 route, if SCC cannot be demonstrated and control of risk is achieved by other means.

Each registrant can/must decide for its individual registration (not for the joint registration which is the consortia's responsibility).
If two or more registrants choose different registration routes for the same intermediate, joint registration still applies. The full Article 10 Dossier is then submitted by the lead registrant and individual registrants fulfilling SCC (including the lead registrant) attach Appendix 3 to their individual files.

It is noted that the 2010 ECHA guidance on intermediates does not contain metals examples. Advocacy actions were undertaken by Eurométaux to make the non-ferrous metals cases accepted by ECHA and Member States. Therefore, specific SCC examples, detailing non-ferrous metals specificities (e.g. availability of hazard data, forms with low emission potential, LEV) were submitted to ECHA to explain and support the non-ferrous metals SCC assessment. In March 2012 ECHA responded that the examples provided were not clear self-evident examples and referred back to the ECHA guidance for checking SCC. This ended the inquiry process towards ECHA on these topics: ECHA has in fact clearly indicated that it is industry's responsibility to apply the Regulation appropriately and judge whether the SCC requirements are fulfilled.

4. How to prepare for inspections on SCC compliance?

4.1. If SCC compliant: demonstrate SCC applied at the sites of manufacture and the use of the isolated intermediate

If an intermediate is manufactured and used under SCC, it is important to provide evidence and extensive documentation on SCC applied at the sites of manufacture and the use of the isolated intermediate. The information required on RMMs in **Appendix 3** of the 2010 ECHA Guidance on intermediates will have to be filled and attached to the REACH dossier. However, internal documentation has to be prepared by each legal entity that would need to demonstrate SCC over the substance's whole life cycle in order to provide such evidence to enforcement authorities. A general format to document how the substance is manufactured and used under strictly controlled conditions is provided in the Guidance of intermediates and referred to as **Appendix 2**. Additionally, documentation for compliance with other legislative frameworks can also be used. Examples of Appendix 2 and 3 for inorganic intermediates are available from Eurométaux.

The information provided in Appendix 2 should include information on:

a. **RiCo** of the substance in accordance with Article 18 (4)(a):
   i. A brief description (or flow chart) of the specific activities performed on each relevant site concerning the handling and use of the substance as an isolated intermediate (e.g. loading and unloading, maintenance of equipment, sampling, etc.);
   ii. For each specific activity, a brief description of the system and/or equipment that demonstrates how the substance is rigorously contained by technical means during its whole lifecycle (including waste disposal);
   iii. For each specific activity, information on consumption rate(s) of the isolated intermediate in the reactions, and explanation on how the unreacted substance is dealt with, demonstrating how the requirement for RiCo is dealt with;
   iv. Description of which circumstances in a closed area may require LEV and description of how the extracted substance is treated and/or removed;
   v. Description of the RMMs and OCs to avoid the release of the substance to the sewage treatment plant (STP) and aquatic compartment;
   vi. Presentation of the most recent worker monitoring data available.
b. **Procedural and control technologies** in accordance with Article 18 (4)(b):
   i. A list (or flow chart) of the activities and processes for which emissions may be expected and a brief description of the procedural and control technologies which you use to minimise emission and any resulting exposure to workers and to the environment;
   ii. A description of the role of PPE:
      - Indication if the use of PPE is strictly required to protect workers from exposure in typical OCs, or if the use is recommended as good practice, or if PPE is only to be used in the case of accident;
      - A list of activities where PPE is used/recommended to control/prevent the exposure of the substance;
c. **Training and authorised personnel** in accordance with Article 18 (4)(c): any documentation demonstrating that only properly trained and authorised personnel handle the substance, in relation to all tasks and identified uses, e.g. length, frequency and content of the training provided to the staff.
d. **Special procedures for cleaning and maintenance work** in accordance with Article 18 (4)(d): a description of special procedures applied in cleaning and maintenance, before the system is opened and entered into, including the assessment of residual potential for exposure following purging and washing.
e. **Procedural and/or control technologies in case of accident and where waste is generated,** in accordance with Article 18 (4)(e):
   i. A list (or flow chart) of activities and processes where waste is generated;
   ii. A brief description of procedural and/or control technologies applied:
      - to minimise emissions in case of accidents and in processes where waste is generated; and
      - to minimise resulting exposure during purification or cleaning and maintenance of equipment.
f. **Substance handling procedures and supervision** in accordance with Article 18 (4)(f):
   i. A description/list of the documentation related to work procedures and substance-handling procedures on each relevant site;
   ii. A description of supervision system on each relevant site related to substance handling.

In addition, registrants should have confirmed themselves or received confirmation(s) from the user(s) of the isolated intermediate that their use takes place under the above SCC. Registrants should provide either of the following:

- a copy of the confirmation(s) received from all the downstream users (DUs) that their use takes place under the SCC described above;
- a copy of all the letters sent to each of the DUs imposing the implementation of the SCC described above as a condition for the use of the isolated intermediate; or
- a copy of one of the letters sent to each of the DUs imposing the implementation of the SCC described above as a condition for the use of the isolated intermediate, as well as a list of the addressees of that letter.

It is important to note that ECHA and MS act jointly: following ECHA inquiries, there has been on-site verification by MS. Ideally, registrants should have all above information available at their premises for consultation by ECHA / MS upon inspections.

4.2. If not SCC compliant: demonstrate due diligence without undue delay

If it cannot be confirmed that an intermediate is manufactured and used under SCC, it is important to demonstrate due diligence (i.e. steps to prepare and proceed to Dossier update if relevant) without undue delay according to the December 2010 ECHA Guidance on intermediates. Registrants should then provide evidence of progress in the methodologies to risk assess intermediates and document steps taken as inorganic sector.

4.3. ECHA screening of intermediate Dossiers

In September 2012, ECHA conducted an IT-based screening to check whether REACH intermediate registration dossiers contain information that put into question the transformation of the substance during chemical processing and/or the SCC until its transformation. The tool screens the use descriptors (PROCs and ERCs) applied for the intermediate dossier submissions.

The following use descriptors have been identified by ECHA as not compatible with the requirement on SCC:

PROC number	Name
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
PROC22	Potentially closed processing operations with minerals/metals at elevated temperature in industrial setting

The following use descriptors have been identified by ECHA as unlikely to be compatible with the requirement on SCC without adequate justification explaining the applied technical process:

PROC number	Name
PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC26	Handling of solid inorganic substances at ambient temperature
PROC27a	Production of metal powders (hot processes)
PROC27b	Production of metal powders (wet processes)

In addition to above use descriptors, there are some PROCs and ERCs that ECHA considers not compatible with the definition of an intermediate under REACH (cf. factsheet on intermediates).

It should be noted that Eurométaux is currently in discussion with ECHA regarding the technical aspects related to metal PROCs and their compatibility with the intermediate definition / SCC.

Reference

Hirst, N., Brocklebank, M., Ryder, M. (2002): Containment Systems, A Design Guide, Institution of Chemical Engineers (IChemE), ISBN 0 7506 7612 4, 2002.