

Discussion on Strictly Controlled Conditions and the guidance on intermediates

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Intermediates and SCC

- Special derogations (Art 17 and Art 18 of REACH) apply to intermediates manufactured and used under ***Strictly Controlled Conditions (SCC)***
- SCC are defined in Art 18.4 (a to d)
- *ECHA Guidance on intermediates* defines SCC as technical measures underpinned by management systems.
- This approach includes:
 - process controls,
 - management systems,
 - training
 - monitoring,
 - role of personal protective equipment (PPE)

Strictly Controlled Conditions

All conditions must apply

- ✓ rigorous containment by technical means
- ✓ procedural and control technologies for exposure and emission minimization
- ✓ handling only by properly trained and authorised personnel
- ✓ Special procedures for cleaning and maintenance (purging and washing before opening the system)
- ✓ Procedural and control technologies to minimize emissions in case of accident and if waste is generated
- ✓ Documentation of procedures and supervision.

REACH art 18.4 a) to f)

Main Principles of SCC*

- Rigorous containment is obtained by technical means to ensure that exposure (whether to humans or the environment) is reduced so that risks are strictly controlled;
- Risk Characterization cannot be used to *justify a lack or absence* of rigorous containment and emission minimisation technologies;
- Most efficient rigorous containment strategy has to be identified for each specific process step, taking into account the process conditions and the physico-chemical properties of the intermediate. The containment strategy may consist of a combination of mechanical and air dynamic barriers;
- The technical means of containment and the control technologies are always to be considered in context with procedural control and training of workers. Thus rigorous containment and procedural control (including training) together are the elements of a strictly controlled conditions strategy;
- Release and exposure data is an additional useful element to verify that rigorous containment is achieved. Reliable exposure model calculations may also be used for this purpose.

*see section 2.1.6 of the ECHA guidance on Intermediates – Dec 2010

Documenting the SCC

Documentation to be available on site*

- Description of the use of the substance as intermediate (process)
- Customers' statements concerning the use as an intermediate and the fulfilment of SCC (for Transported Isolated Intermediate)
- The physical chemical properties of the intermediate relevant for deciding on measures to ensure that strictly controlled conditions apply;
- Documentation on process design and equipment to justify rigorous containment and the relevant operating conditions;
- Measures corresponding to the requirements set out in article 18(4) (b) to (f) implemented by the manufacturer company and recommended to users;
- Information on any residual release and resulting exposure that occurs in spite of the rigorous containment measures by technical means;
- Any other available information on the substance (e.g. hazard data, OELs. Other threshold values)
- *see ECHA Guidance on Intermediates Dec 2010 par 2.1

The Art 36 letter: SCC

Requested information

- ❖ Addressing SCC
 - ❖ Details on rigorous containment
 - ❖ Procedural and control techniques
 - ❖ Role of PPEs,
 - ❖ Training
- ❖ Addressing Uses Downstream
 - ❖ List of DU users of the substance
 - ❖ Evidence that the registrant has received confirmation from them that substance is used under SCC

- ❖ Information submitted via REACH iT (secure platform)

The template: addressing SCC

ECHA

- Information requested addressed?
- Clear evidence that the requirements are not met?
- Need for clarification onsite?

POINTS ADDRESSED

- Rigorous containment of the substance
- Procedural and control technologies
- Training and authorised personnel
- Special procedures for cleaning and maintenance work
- Procedural and/or control technologies in case of accident and where waste is generated
- Substance handling procedures and supervision

Enforcement Authorities

- What can be checked onsite?
 - Documentation (processes, equipments, engineering controls, training records, procedures etc)
 - SCCs (equipments, workplaces, procedures, use of PPE etc)
 - exposure and release data (workers and the environment)
- What can be fed back to ECHA?
 - Check that information is available at the site
 - Inform the registrant to update dossier with required information

ECHA Verification of SCC

ECHA verifies the application of SCC based on information provided by the registrant. Doubtful situation may be related to:

- particular use of the substance (e.g. wide disperse use) not compatible with intermediate use under SCC
- technical description of the process leaving serious concerns on SCC (e.g. handling of dusty solids by crane in open or partially open environment with crane operator isolated from the substance)
- use of PPE as key measure to guarantee protection from exposure
- focus put in assuring minimization of exposure to workers but not releases to the environment (or vice-versa)
- lack of containment based on control of risks (e.g. exposure below OELs or local discharge limits)
- Other considerations on a case by case basis

Example 1 – compliance to SCC

Substance : A- filtered cake (solid with high water content)
 Use Covered: manufacturing and use (synthesis of substance B)
 Info available No
 Packaging big bags
 Reaction obtained from reaction between a solid and liquid acid solution at high temperature

Rigorous containment

Loading/unloading : semi automatic charging / discharging system with LEV
 Reaction : closed vessel closed distribution pipelines
 Cleaning/mainten. : washing and purging before cleaning. PPE are used in maintenance operation. Trained personnel. Special procedures
 worker exp : changing big bags (LEV is used) - maintenance
 environment exp. : manufacturing stage: crude product washed with warm water. Washing water is treated to internal STP
 discharge limits and aquatic toxicity are taken into account.

Conclusion

Compliance issue : Environment - washing water (containing the substance) is treated in internal STP and discharged to water. Exposure to environment is controlled (kept below legal limits; risk based approach) but it is not minimized.

Example 2 – compliance to SCC

Substance : B- liquid
Use Covered: manufacturing . The intermediate is used by other
DUs (declarations of use under SCC provided)
Info available No
Reaction multi step reaction with formation of non-isolated I
intermediates (process flow provided)

Rigorous containment

Loading/unloading : automatic charging / discharging system closed with LEV
Reaction : closed vessels, closed distribution pipelines
Maintenance: washing of reaction vessel with water and solvent and
purging before opening
Worker exp : limited to maintenance
environment exp. : exhaust gas: incineration
: waste water: no substance in waste water
: solvent and water used for cleaning : recycled or
incinerated as hazardous waste

Conclusion OK

Example 3 – loading in open system

NOT SCC



cutting the bag



Emptying the bag

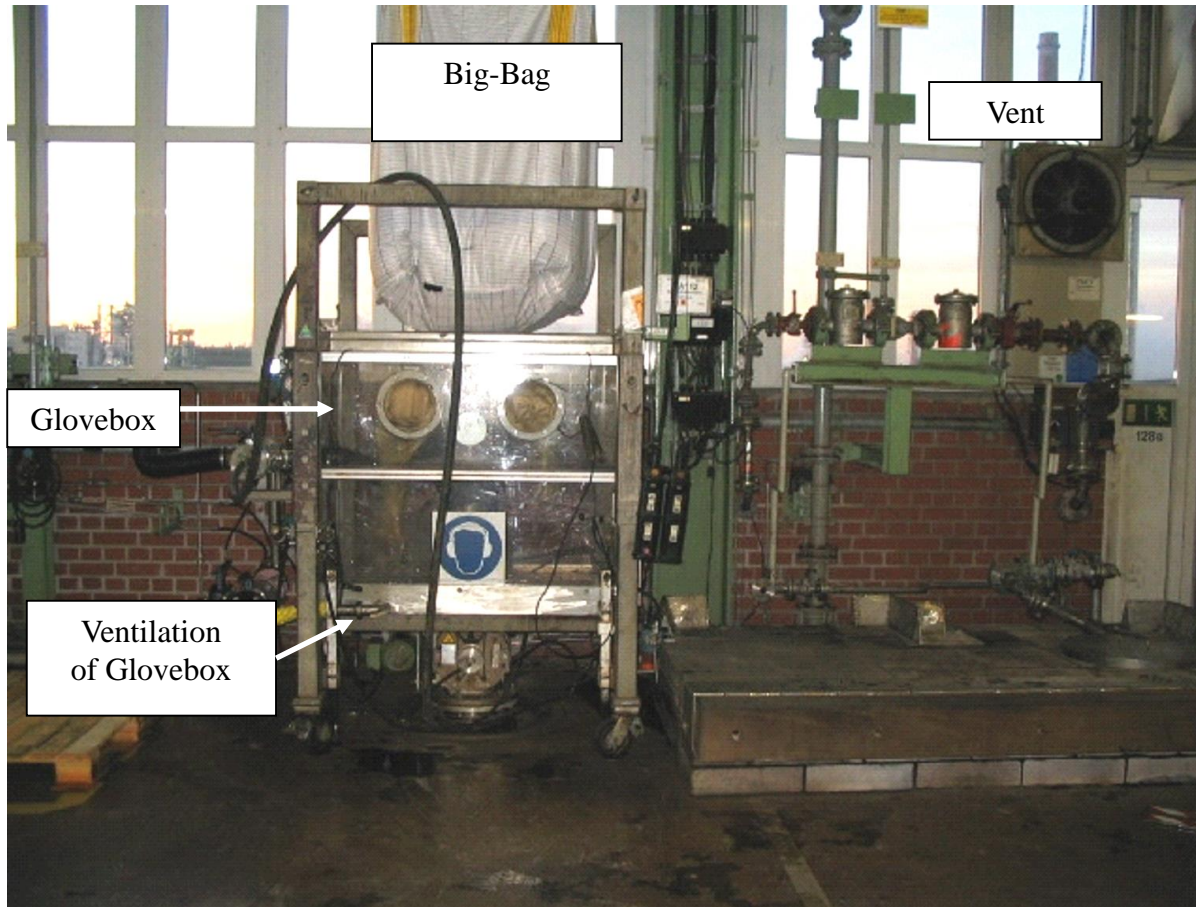


Compact roll of the bag



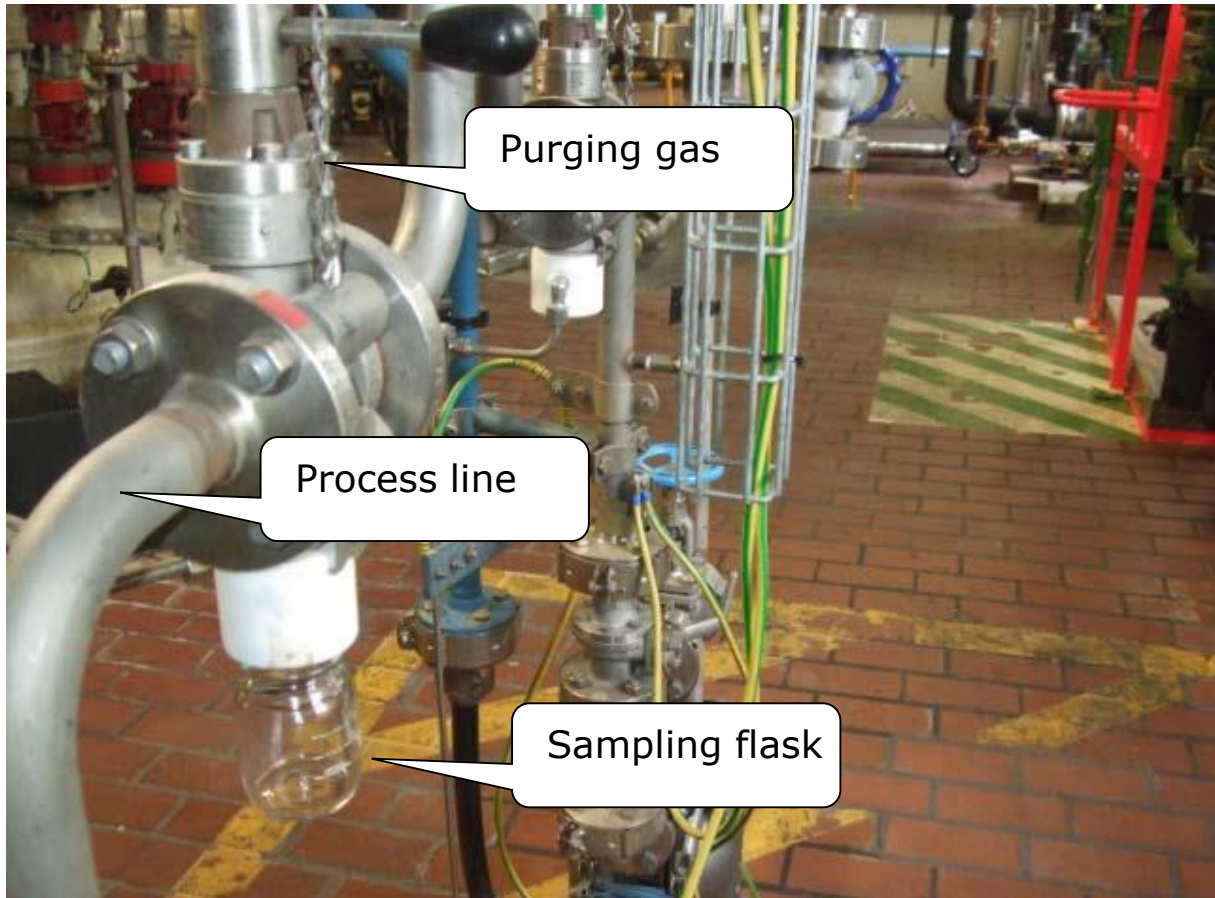
disposing the bag

Example 4 - Loading in contained system



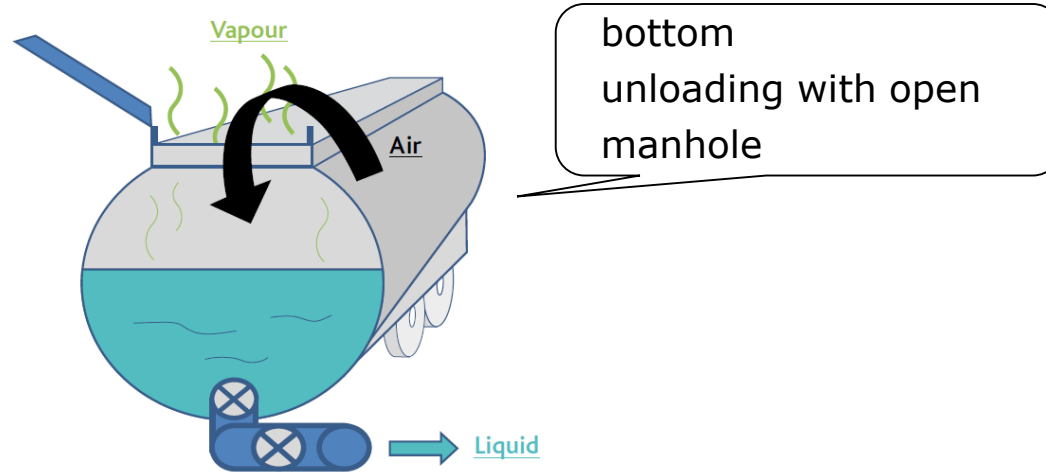
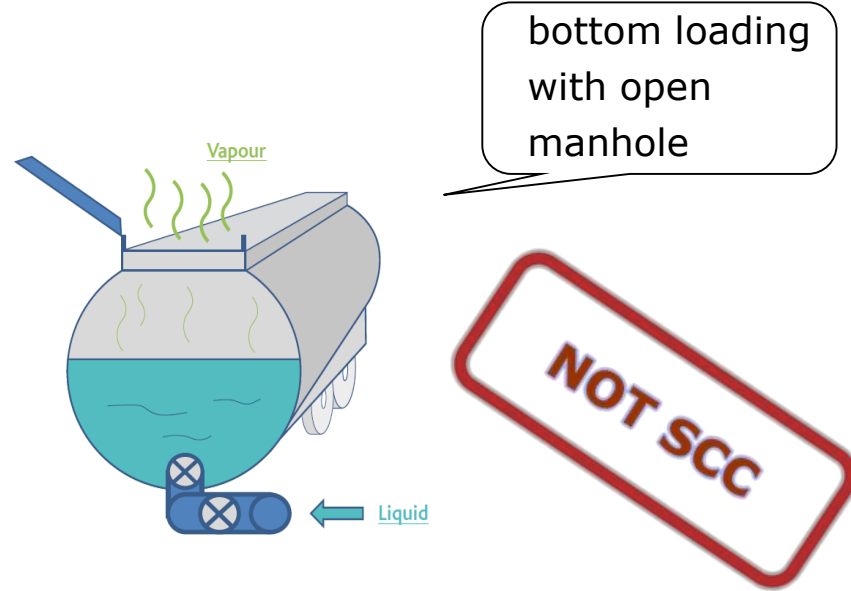
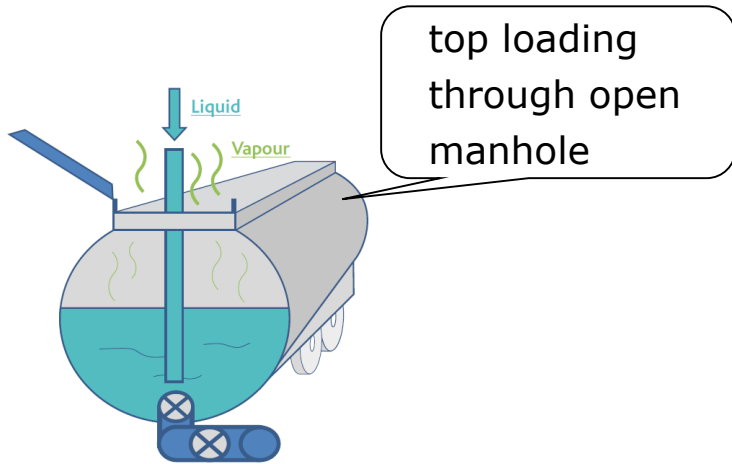
SCC OK

Example 5 - sampling in contained system



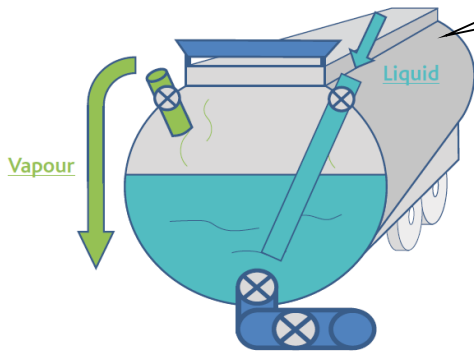
SCC OK

Example 6 - Loading /unloading open systems

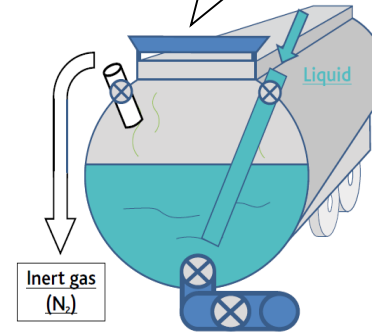


Example 7–Loading/unloading contained sys.

top loading
with deep tube
and vapour recovery

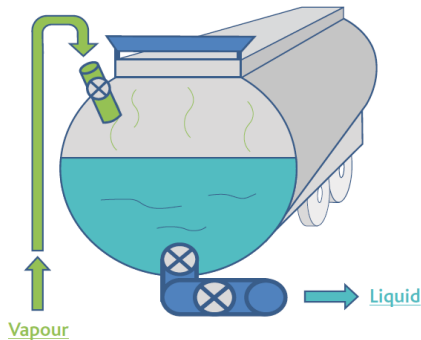


top loading
with deep tube
and gas blanketing

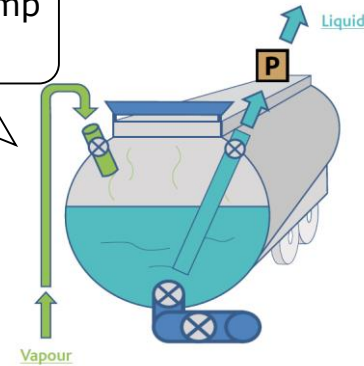


SCC OK

bottom unloading
with vapour recovery



top unloading with pump
and vapour recovery



Summary

- Intermediate use of a substance and Strictly Controlled Conditions go together and have to be both assessed. In implementing SCC exposure has to be minimized for humans and the environment
- SCC apply to the intermediate, but not to the substance produced by it (unless this is itself another substance registered as intermediate under SCC)
- Rigorous containment by technical means plays a primary role in the definition of SCC. Containment and control technologies have to be associated to training and special working procedures in order to guarantee implementation of SCC. Risk based approach cannot be used to justify lack of rigorous containment.
- The control strategy for SCC is dependent on substance properties and process conditions. Different control strategies may apply to different process steps
- ECHA verifies the application of SCC based on information provided by the registrant. In some cases on-site verification may be needed

Thank you

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