



Confirmation of Strictly Controlled Conditions for Intermediates under REACH: Supporting guidance on the extent of documentation required

concaawe



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Please be advised that the update of the ECHA *Guidance for Intermediates* is still under consultation and is expected after Dec 2010. The content of this industry guidance might be updated after the release of the updated ECHA guidance.

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1. Introduction

This document has been prepared by an industry working group representing CONCAWE, CEFIC and EFCG. It represents recommended advice for confirming strictly controlled conditions for on-site and transported isolated intermediates under REACH Article 17(3) and 18(4). The basis for the confirmation of strictly controlled conditions lies with the availability of appropriate documentation on an individual company basis.

Content of this guidance is based on the ECHA Guidance for Intermediates (Feb 2008). This guidance is at the moment in a revision process and the new release may result in an update of this industry guidance.

This document focuses on those considerations appropriate to the confirmation of SCC for Intermediates.

Release 2 of this document includes improved wording in several places, to emphasize to the readers that SCC can be applied to obtain reduced registration requirements for intermediates, but that the starting condition in the SCC assessment is full technical containment and depending on the hazard and risk profile of the substance other levels of rigorous containment can be accepted.

This release also includes reference to illustrative industry examples of SCC intermediates for different combinations of hazard and exposure profiles.

1.1. Background

Intermediates need a full registration dossier including a CSR. In the case the intermediates is manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole life cycle, reduced registration requirements are permitted. For substance tailored exposure driven testing reduced registration requirements also are permitted in that certain tests can be waived if for a relevant scenario if the substance is under SCC for its lifecycle (Section 3, Annex XI). When supporting exposure based waiving, SCC is used in conjunction with demonstration of safe use as part of the Chemical Safety Assessment and requires development of an Exposure Scenario. When used in conjunction with an isolated on-site or transported intermediate the development of an Exposure Scenario is not required. For additional details, the reader is referred to those references that are noted in this document.

The lifecycle of an isolated intermediate begins with its manufacture which, in practical terms, is its removal from the manufacturing process. The lifecycle ends with the use of the substance in the synthesis process for the manufacture of another substance. Reduced REACH requirements for intermediates for which SCC can be confirmed include:

- Exemption from the general obligation to register substances; a different registration regime applies, as detailed in REACH, Chapter 3 of Title II and includes the fact that the development of Exposure Scenarios is not required.
- Limiting data regarding the substance intrinsic properties (physicochemical, human health and environment properties) to those data already available for on-site isolated intermediates and full Annex VII information in case of transported intermediates and volume > 1000 t/a
- Limited need for animal test data

Guidance on the interpretation of SCC is provided in the European Chemicals Agency (ECHA) document "Guidance for Intermediates", February 2008; an update of this guidance is under preparation and is expected later this year.

It should be noted that the chemical industry in Europe safely handles very high tonnages of hydrocarbon and chemical products every year. The hazardous properties of some of these products makes it important that attention is given to safety and risk reduction by ensuring that

emissions are maintained as low as reasonably practicable. For this reason good engineering practices, safe working conditions and safe working practices have been developed on an industry basis.

Chemicals produced in high tonnages are mostly manufactured in large manufacturing facilities of high integrity, and it is necessary to control inherent properties of some chemicals such as flammability and explosivity by operating continuous processes under strictly controlled conditions. This is true especially for the manufacture of hydrocarbons by the petrochemical industry, but also for many basic chemicals, e.g., sulphuric acid. Such production plants are designed to minimize emissions to the environment and exposure to workers.

In addition, there are processes that are operated more in a batch mode and sometimes in a multi-purpose production facility, like for instance in fine chemicals production. Because of the very nature of the fine chemicals business, it would be expected that a wide range of substances would be produced in relatively small volumes, usually for products with very specific applications, for example, in pharmaceutical/healthcare and other similar areas. In parallel, it must be borne in mind that a high proportion of companies involved in this business sector are SMEs. For various reasons, therefore, it will be less likely that process installations will be specifically designed for a specific product and it will be more common that fine chemicals will be produced using aggregates of reaction equipment which are multi-purpose. Going from continuous via semi-continuous to multi-purpose batch process installations, the degree of containment will shift from purely technical to a combination of various technical control measures with an appropriate management systems which takes full account of the circumstances..

1.2. Purpose

This document sets out a proposal for the extent of documentation required for chemicals production along the supply chain to support confirmation of SCC within Industry based on the ECHA “Guidance for Intermediates” document. It is intended as a reference for processors of isolated and transported Intermediates seeking to demonstrate SCC, and may also be used for substances in relation to REACH Annex XI on Exposure Based Waiving.

Building on the ECHA guidance, it draws on the application of existing management systems and supporting work processes at manufacturing site level to confirm SCC for each of the relevant elements identified as defining SCC within REACH Article 18(4) and reproduced in Section 2.2 of this document. In support, this document provides:

- A. Example templates for use in mapping the relevant elements of management systems and processes to underwrite the confirmation of SCC – see Appendix 1.a. to 1.d.
- B. Example content of communications for confirmation of the need for and application of SCC within the supply chain – see Appendix 3
- C. Advice on strategies available for determining SCC depending on available hazard and exposure information for the affected intermediates – see Appendix 4

2. Definitions

2.1. Intermediate

REACH defines an intermediate as “*a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance*” – see REACH Article 3 (15)

On-site Isolated or Transported Isolated Intermediates are defined under REACH, and SCC must be confirmed if the reduced registration requirements are to apply. Non-isolated Intermediates are exempt from REACH. Please also see Figure 1 “Flow chart to determine the Registration status of an Intermediate”.

2.1.1 Non-isolated intermediate

An intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture – see REACH Article 3 (15)(a).

The following considerations help guide where an intermediate should be considered to be non-isolated:

1. Applies to both a continuous flow and/or a batch process reaction step, including holding in tanks and vessels between reaction steps.
2. When the non-isolated intermediate is held in the process equipment for a limited period during the manufacturing process. For example, when the holding step is less than the mean batch period, or the batch period is interrupted to accommodate a weekend or holiday period. Note: during production shutdowns, such holding tanks/vessels are empty.
3. Mechanical or gravity transfer through a closed system is not considered to be intentional removal.

2.1.2. On-site isolated intermediate

An intermediate, not meeting the criteria of a non-isolated intermediate, and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate takes place on the same site, operated by one or more legal entities – see REACH Article 3 (15)(b).

2.1.3. Transported isolated intermediate

An intermediate, not meeting the criteria of a non-isolated intermediate, and transported between or supplied to other sites – see REACH Article 3 (15)(c).

2.2. Strictly Controlled Conditions

2.2.1. ON-SITE ISOLATED INTERMEDIATE

Strictly Controlled Conditions (SCC) for on-site intermediates are defined under REACH Article 17(3) and are detailed below.

- (a) The substance is rigorously contained by technical means during its whole lifecycle
- (b) Procedural and control technologies shall be used to minimise emission and any resulting exposure

2.2.2. TRANSPORTED ISOLATED INTERMEDIATE

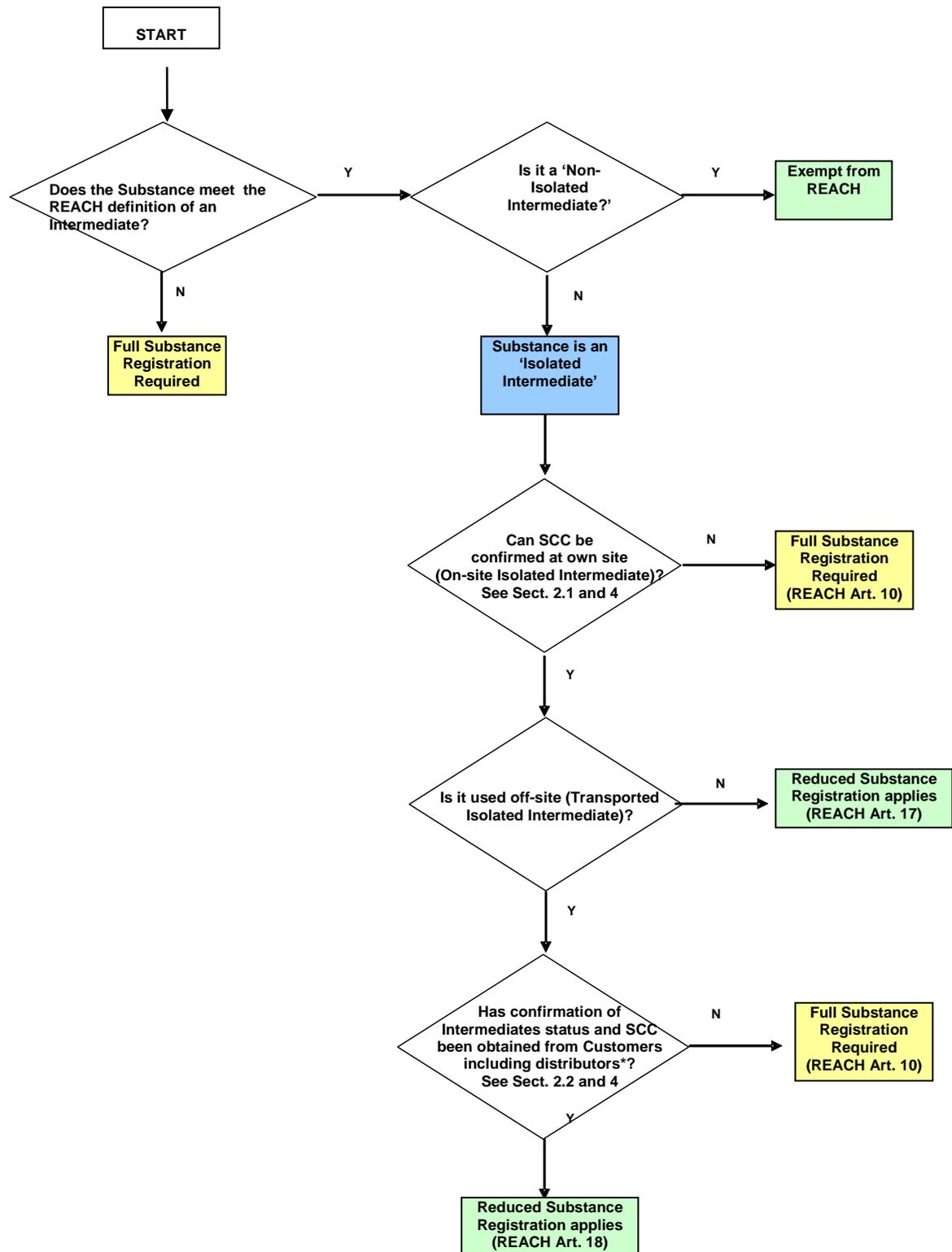
Strictly Controlled Conditions (SCC) are defined under REACH Article 18(4) and are detailed below. Further guidance on the interpretation of SCC is provided in the ECHA “Guidance for Intermediates”, February 2008.

- (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; (see also ECHA “Guidance for Intermediates” Sec. 2.1.1)

- (b) Procedural and control technologies shall be used that minimise emission and any resulting exposure; (see also ECHA “Guidance for Intermediates” Sec. 2.1.2)
- (c) Only properly trained and authorised personnel handle the substance; (see also ECHA “Guidance for Intermediates” Sec. 2.1.3)
- (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; (see also ECHA “Guidance for Intermediates” Sec. 2.1.4)
- (f) Substance-handling procedures are well documented and strictly supervised by the site operator.

The supporting guidance from ECHA clarifies that the required level of rigorous containment and minimization (and corresponding amount of residual releases) will depend on the knowledge on the substance properties (risk based considerations); additionally Management Systems play an important role in the delivery of SCC.

Figure 1: Flow chart to determine the Registration status of an Intermediate



3. Rigorous containment strategy

The responsibility to determine whether a substance is an intermediate under SCC lays within industry. The ECHA “Guidance for Intermediates” gives information on what are the key principles of strict control and rigorous containment you must follow, whereby “*Rigorous containment is the combination of technical and procedural measures that ensure that exposure (whether to man or the environment) is reduced so that risks are strictly controlled.*”

In every case, the successful management of risk is central to the concept of rigorous containment: when no hazard and risk information is available, then intermediates have to be treated as hazardous substances, with the accompanying need to ensure (and demonstrate) that emissions and exposure are minimised. When information on hazard is available for an intermediate, then the intermediate will be handled under appropriate conditions that ensure that any risks rising from handling the substance are strictly managed. Consequently, the way that rigorous containment can be achieved may vary according to the knowledge of an intermediate's physicochemical and hazard properties.”

It follows, therefore, that the documented confirmation of SCC will show that everything is done by the company to minimise human and environmental exposure and that risks are strictly managed according to the hazard properties of the substance.

While this would be achieved ideally by total enclosure of the process and handling systems, there are many cases where this is not reasonably practicable or justified. In these cases, the extent to which data are available for a substance will influence the strategies that will be applied to deliver strictly controlled conditions.

An indication of the types of strategy that could be applied, depending on the knowledge of the physicochemical and hazard properties of the substance, are given in Appendix 4 that shows commitment to the hierarchy of rigorous control. The strategy shall, therefore, also take into account the use of facilities, processes and risk management measures that minimise the emissions to the environment and in the workplace.

Companies are responsible for demonstration of SCC. In the documentation reference may be made to other management systems, databases and technical control measures, which may have been put in place to ensure compliance with other legislation, such as the following Directives: Chemical Agents Directive 98/24/EC, IPPC 96/61/EC and Control of Major Accidents (Seveso) 96/82/EC.

Examples developed by industry of intermediates under strictly controlled conditions can be found on the following websites:

Insert link to web.

These examples have been provided by the chemical industry to show the technical, operational and management measures to illustrate SCC for different combinations of hazard level, physicochemical properties (such as volatility and dustiness) and process. These examples are not intended to suggest a standard format be used to build up a file, but simply to show which elements are involved in each SCC assessment.

4. Documentation to confirm compliance with SCC

The following sets out a proposal for confirmation of SCC. It draws on the application of existing management systems and supporting work processes at each manufacturing site to confirm SCC. This has been compiled taking account of the following general principles drawn from the ECHA “Guidance for Intermediates”:

- a complete and detailed description of all implemented measures to deliver the SCC is not required in the registration dossier;
- Have available documentation of workplaces/activities in your processes including assessments for residual risk.
- management systems play an important role;

- rigorous containment may vary depending on the physicochemical and hazard properties of the intermediate supporting risk based analyses;
- documentation for compliance with other relevant legislative frameworks are applicable;
- The list of illustrative issues supporting SCC included in Appendix 1 of the ECHA “Guidance for Intermediates”.

4.1. On-site Isolated Intermediates

On-site documentation to cover:

- a. An inventory of the on-site isolated intermediates to be registered identifying the relevant production/process unit(s) in which they are present including the potential emission points and the control measures taken. In addition a mapping of relevant intermediate streams to the site’s own risk management system(s).

- b. Consideration and completion by each site or production unit of:

- A summary of site processes and systems to provide an overview of the site risk management controls supporting confirmation of SCC throughout the substance life cycle. See Appendix 1.a. for an example.
- For semi-continuous production processes: specific site documentation to support confirmation of SCC mapped to the individual SCC elements. See Appendix 1.b for an example template to assist in this mapping process. In completing the template it should be noted that the SCC elements identified within REACH Article 18(4) are not sequential. There is significant overlap between each element, which may result in repetition of the systems, processes and associated documentation relevant for the confirmation of SCC.

Examples of site documentation include:

- HSE management systems and associated documentation
 - Production specific documentation like:
 - Standard Operating Procedures
 - Documentation of the process with the control measures
 - Batch records
 - Loading and off-loading procedures
 - Training records
 - Maintenance procedures
 - Waste handling procedures
- For batch production processes typically found in fine chemicals operations:
 - i) Appendix 1c gives examples of general Risk Assessment and Management Measures by organisational topic or manufacturing step. Fine chemicals production may differ significantly from high volume production. These are worked examples to support the confirmation of SCC and can be exchanged, expanded or developed as necessary to be fit for purpose.
 - ii) Appendix 1d includes an example of an inventory for use in compiling the documented confirmation of SCC for a wide range of intermediates that are subject to regular change in accordance with the current business situation as is common in the fine chemicals production.
 - Examples of technical measures supporting SCC for different types of industry can be found within the ECHA “Guidance for Intermediates”.

- c. A statement of the Risk Management Measures applied for SCC (see Appendix 2 for an example). This needs to be included within each registration dossier and reported in IUCLID under Section 11 ‘Guidance on Safe Use’ in the fields ‘Handling and storage’

and 'Exposure controls/personal protection'. This is specified in the ECHA "Guidance on Intermediates" in Sections 2.2 and 2.3

4.2. Transported Isolated Intermediates

The requirement to confirm SCC also applies to transported isolated intermediates so that the complete lifecycle of the intermediate is addressed from its manufacture to processing into another substance, including repacking/refilling under strictly controlled conditions by Downstream Processors/Distributors in the supply chain. This processing into another substance or repacking/refilling may be by a third party purchasing the intermediate for processing or another site within the same company.

It should be noted that the management of risks during the transportation of intermediates between sites is outside the scope of REACH and this document.

Documented confirmation is proposed as follows:

- a. For manufacture and storage:
 - site documentation as outlined in Section 3.1
- b. For storage, repacking/refilling, further processing and equipment maintenance by the recipients of the transported isolated intermediate (Downstream Processors):
 - receipt by the registrant from the distributor of written confirmation for a specified intermediate that SCC applies to their operations, including repacking/refilling and maintenance, and to any further recipients in the supply chain
 - receipt by the registrant from Downstream Processors of written confirmation for a specified intermediate that SCC applies to their operation
 - documentation as described in section 4.1 must be available at the manufacturing site of the recipient and made available on request to the enforcement authorities

Appendix 3 includes a suggested form of words for use in letters/contractual arrangements/Safety Data Sheets for issue to Downstream Processors/Distributors

If confirmation of SCC is not received for transported isolated intermediates, then a normal registration for the intermediate will be required to be able to continue its delivery

Note: REACH Article 18(4) also indicates that a manufacturer/importer may '*confirm himself*' that SCC applies for transported intermediates. However, it is difficult to see how a manufacturer/importer will do this in reality for both practical and liability reasons and specific advice on this is not included in this guidance.

- c. In addition, a statement of the risk management measures recommended for SCC is also required as outlined in Section 3.1.c above and Appendix 2.

To allow continued delivery after registration of an isolated transported intermediate that is subject to SCC, it is advised that before submitting their registration files, suppliers should obtain written SCC confirmation from their first line customers and inform them that they are also required to confirm SCC if the intermediate is subsequently sold to another party. This is recommended to be on the basis of statements incorporated within existing sales documentation, as per examples given in Appendix 3.

Note: It is emphasized that the responsibility lies with the registrant (i.e., the original manufacturer/importer) to submit the registration and include the necessary confirmation that SCC are applied. Registrants have to confirm if their intermediates are handled under SCC on the site(s) of manufacture and also as intermediate on sites of use. For sites of use as intermediate, a declaration from the customer that SCCs are applied is sufficient. The customer needs to have on-site documentation describing sufficiently the implemented SCC

The recommendation to apply the principles of SCC to customers who reside outside of the EU is a company decision.¹ However, other legal requirements and/or company voluntary commitments for the communication of safe use of chemicals still apply.

The confirmation needs to be included in IUCLID section 11.

5. References

- REACH Article 17: Registration of on-site isolated intermediates
- REACH Article 18: Registration of transported isolated intermediates
- European Chemicals Agency: Guidance for Intermediates, February 2008
- Response comments CA Intermediates December 2007 final.doc
- Annex XI (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:046:0003:0005:EN:PDF>)

6. List of acronyms

ANSI	American National Standards Institute
ATEX	ATmosphère EXplosible
BAT	Best Available Techniques
BREF	BAT REFERENCE document
BS	British Standard
BSI	British Standards Institution
CA	Competent Authority
CEFIC	European Chemical Industry Council
CEN	European Committee for Standardization
CONCAWE	the oil companies' european organization for environment, health and safety
COSHH	Control of Substances Hazardous to Health Regulations
DIN	Deutsches Institut für Normung
DNEL	Derived-No-Effect-Levels
EBW	Exposure Based Waiving
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECFG	European Fine Chemicals Group
ECHA	European Chemicals Agency
EKMG	
EMAS	Eco-Management and Audit Scheme
ERP	Emergency Response Planning
ETNC	Environmental Threshold of No Concern
EU	European Union
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
GMP	Good Manufacturing Practice
HSE	Health, Safety and Environment
HSEMS	Health, Safety and Environment Management System
HSSE	Health Safety Security Environment
IBC	Intermediate Bulk Container
IPPC	Integrated Pollution Prevention and Control
ILO	International Labour Organization
ILO-OSH	ILO Guidelines on Occupational Safety and Health Management Systems
ISO	International Standardization Organization
IUCLID	International Uniform Chemical Information Database
LFI	Learning From Incidents
OEL	Occupational Exposure Limit
OSHA	Occupational Safety & Health Administration
PEC	Predicted Environmental Concentration
PNEC	Predicted No-Effect Concentration
PPC	Pollution Prevention and Control

¹ See response comments CA Intermediates Dec 2007 final

PPE	Personal Protective Equipment
PTW	Permit to Work
QC	Quality Control
QSAR	Quantitative Structure-Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances
RMMs	Risk Management Measures
SCC	Strictly Controlled Conditions
SDS	Safety Data Sheets
SME	Small and Medium-sized Enterprises
SOP	Standard Operating Procedure
STW	Sewage Treatment Work
TGD	Technical Guidance Document
WET	Whole Effluent Toxicity

APPENDICES

APPENDIX 1.A.

SITE PROCESSES AND SYSTEMS – MAPPING OF SITE RISK MANAGEMENT CONTROLS.

The following table illustrates many of the systems and processes that are typically encountered at refining and chemical manufacturing facilities and which, when taken together, serve to support the assertion that strictly controlled conditions are being adopted. The list is not intended to serve as a checklist; in practice, the size, location and nature of any facility will affect the extent to which such systems would be considered relevant.

Site Example: Strictly Controlled Conditions - Mapping of Site Controls			
Stage of Substance in Lifecycle	Management Processes	Management Systems	Legislation & Standards
PROCUREMENT			
Procurement of feedstock's, raw materials and process materials (catalysts, additives, mol sieves etc.)	<u>Procurement Procedures for Supplier</u> Pre-qualification SCC requires two way documentation flow	<u>Materials flow:</u> - Oil Movements Management System (feedstock management) - Materials flow system, ERP - Inventory Management Systems	

Continued overleaf

MANUFACTURE			
<p>Safe Operation and Maintenance of Process Plant & Equipment</p> <p>Processing of feedstock's, and use of raw materials, process materials (catalysts, additives, mol sieves etc.)</p> <p>Sampling and analysis of process streams, wastes and discharges</p> <p>Loading & Offloading of materials (Charging and discharging)</p> <p>Management of residual process materials & wastes</p> <p>Management of discharges to air, water and ground</p> <p>Control & Recovery from spillage</p>	<p><u>Hazard Identification, Risk Assessment and Control (identification of Risk Management Measures)</u> Common for whole Process of Risk Assessment: - HSE Hazard Register - External Safety Reports - Health, Safety & Environmental Risk Assessments and identification of Risk Management Measures - Material Safety Data Sheet Inventory</p> <p>Compliance Assurance: - env. emissions monitoring - personal exposure monitoring - health surveillance - see also audit and review</p> <p>See also Section 4 of this guidance</p> <p><u>Integrity & Reliability</u> - Design Engineering Standards - Asset Management System - Alarms, Safeguarding, Inspection, Plant Operating Windows Management etc. - Engineering & Inspection Procedures - Plant Local Operating Procedures - Routine maintenance of controls</p> <p><u>Competence Development Process</u> - Qualified, educated personnel - In-company job specific training Competence Assurance for example - External certification of competence process - Regulatory Training Matrix - Operations Training Plans - Maintenance Technician Competency Training Matrix - HSSE Competency Assessment</p> <p><u>Sample Management & Labeling</u> - Sampling plan - SOP in place</p> <p><u>Audit & Review</u> - Monitoring of Key Performance Indicators - Legislative Review - Process Safety Audit - HSSE Management System Audits - Regulator /Authorities Audits - Internal Systems Audits - Annual Management System Self Assessment & Review - Auditing of 3rd Parties</p> <p><u>Incident Management & Investigation</u> - Emergency Response - Incident Management System Incident & Event Reporting, Tracking and Action Management - Incident Investigation, Root Cause Analysis, Causal Learning - Learning From Incidents (LFI) - Spill control monitoring</p>	<p><u>Site (Quality) Management System</u> e.g. - Procurement, Production scheduling - Production Unit Management & Quality procedures - Projects Management & Quality procedures - Engineering Maintenance System Waste Management System - Volume tracking</p> <p><u>HSSE Management System</u> e.g. - Policies, Roles & Responsibilities, Audit & Review - Site HSE Rules - Permit to Work, Safe Isolation of Plant & Equipment, PTW Signatory Roles & Responsibilities - Risk Assessment and Incident Investigation - Environment Management - Health Management - Plant Change - Contractor Management - Safety Guidance - Electrical Rules & Regulations - Turnaround Safety Manual - Oil Spill Response - ATEX</p>	<p><u>Legislation & Industry Guidance</u> - Legislative requirements - Codes of Practice - GMP</p> <p><u>Global Company Standards & Good Practice</u></p> <p><u>National Company Standards</u> e.g. HSE Rules</p> <p><u>Industry Standards & Good Practice</u> - e.g. Permit to Work Systems, Safe Isolation of Plant & Equipment - Europa - CONCAWE - Industry Standards e.g. ANSI, ISO, CEN, DIN, BSI, GMP</p> <p><u>External Body Membership</u> - Chemical Industry Associations e.g. - Cefic - Europa - CONCAWE - EFCG</p>
DISTRIBUTION			
<p>Distribution and sale of products used as intermediates by Downstream Processor</p>	<p><u>Product Stewardship</u> - Responsible Care Programme - Material Safety Data Sheet - Membership of Industry Associations</p>		

**APPENDIX 1.B. EXAMPLE SITE TEMPLATE FOR DOCUMENTING THE CONFIRMATION OF SCC
FOR (SEMI-) CONTINUOUS PRODUCTION PROCESSES**

The following table illustrates how a site handling isolated intermediates might develop a system of documentation that confirms how the site's systems and processes for managing safety, health and environmental risks serve to secure and maintain strictly controlled conditions. The format is not intended to be mandatory, but rather an example of how such an exercise could be accomplished. In practice, the size, location and nature of any facility will affect the extent to which such systems would be considered relevant.

Appendix 1b:
DRAFT EXAMPLE

Manufacturing Site Template for Confirmation of 'Strictly Controlled Conditions' (SCC) for Intermediates			
Site name:	A Manufacturing Complex		
Site address:			
Contact name:			
Telephone:			
Email:			
	Green background and blue text indicates completion by specific sites		
SCC Requirement	General example of documentation/processes	Local site confirmation/reference. These columns include an example of types of site documentation/processes to illustrate SCC for sites handling Intermediates on a large or small scale. Complete for each site	
SCC Requirement - (Reference ECHA guidance Appendix 1)	Examples of general documentation/processes applicable to all intermediates to support confirmation of SCC Requirement	Site-specific example - Large Scale	Site-specific example - Small Scale
0 Intermediate Hazard Evaluation			
a	Are physico-chemical properties available?	Availability of suitable physicochemical data to enable hazard assessment	Information should be available sufficient to enable the appropriate evaluation of physical hazards (flammability, oxidizing effects, dust explosion properties, etc.).
b	Are toxicological and ecotoxicological properties available?	Availability of suitable toxicological and ecotoxicological data to enable hazard assessment	Information should be available sufficient to enable the appropriate evaluation of human health and environmental hazards. Refer to Section 4 of this guidance.
1 Has the lifecycle of the Intermediate been accounted for?			
a	Manufacture?	Outline how life cycle is accounted for in local systems, e.g. identify relevant management system; stock level tracking system(s), tank gauging arrangements	Management system of the company / specified for workplace safety / environmental safety. Central / decentral controlling of the substances flow in the process (central control center), documentation of the process in the central control center (historical operating data). Implemented Environmental Management System e.g. based on or derived from the ISO 14001 standard. Key element in lifecycle of the intermediate is a material balance based on accurate process and materials flow overviews and (electronic or procedural) inventory system and monitoring systems for import, storage, transfers, export, spills and emissions of chemicals. Manufacturing processes and emission control based on guidelines and/or techniques like BREF, BAT, IPPC, etc.
b	Any relevant storage?	Outline how life cycle is accounted for in local systems	As a) plus: Process flow documentation included in, e.g. Electronic tank inventory systems, Major Accident Hazards Legislation (Seveso II) Safety Reports, Pollution Prevention and Control Permit Applications, Process descriptions in Plant Operating Manuals. Storage in line with or exceeding national or European legislative requirements as reflected in Environmental Permits. Electronic tank level monitoring systems in combination with inventory system for amounts of storage in vessels, drums, IBCs.
c	Any processing?	Outline how life cycle is accounted for in local systems	As a) and b). As in a) and b)
d	Final synthesis process?	Outline how life cycle is accounted for in local systems	As a), b) and c) plus deliveries and receipts detailed in Procurement system. Products dispatched detailed in electronic As in a) and b). Material balance in synthesis processes based on (electronic and/or manual) production planning and

			distribution system.	monitoring system, combined with quality control activities.
e	Disposal, waste treatment?	Outline how life cycle is accounted for in local systems	Waste Management Quality procedures. Pollution Prevention and Control Permit for waste water treatment. Emissions monitoring. In the event that waste streams are formed they are allocated a unique identifying number for tracking purposes and identification of appropriate waste disposal methods.	Disposal and waste treatment in line with or exceeding national or European legislative requirements as reflected in Environmental Permits. Emissions monitoring programs and procedures in place to identify loss of control and take corrective action.
2 Are procedural and control technologies being used?				
a	The substance is rigorously contained (for example via automated process control)	Design and engineering standards defined. Ongoing assurance via e.g. formal engineering inspections, technical safety audits, monitoring of plant parameters (e.g. alarms), formal reporting and investigation of leaks, monitoring of waste effluent.	Standards: Process design in accordance with internal company Design and Engineering Manuals and external regulatory requirements. Other standards referenced in the site Engineering Quality System. Assurance: Process Safety Audits, monitoring of plant parameters by operations personnel and Process Engineers. Monitoring and investigation of leaks reported in site incident management system and investigated by site personnel with larger spills investigated by central organisation. Monitoring of waste effluent to ensure compliance with PPC permit limits.	Same text as for large scale operations. Standards like TGRS 500 and BauA 300 are applied.
b	Appropriate risk management measures (RMMs) are applied?	Formal risk assessment processes to identify appropriate RMMs for the control of Health, Safety and Environmental risks. Permit to Work and Job Hazard Analysis for non-routine activities. Ongoing assurance of controls including, where appropriate, inspection and audit, health surveillance, exposure measurement, incident investigation. Refer also to Sections 2d and 3c below.	HSEMS Manual Section XX - Risk Management Processes: a. Routine Operations: Process Safety assessment (Hazard analyses - in external safety report and hazard registers), Health Risk Assessment and associated procedures (HSEMS Section XX), Environmental Guidelines and procedures (HSEMS Section XX); b. Non-routine and maintenance Operations: Permit to Work (HSEMS Section XX), Job Hazard Analysis (HSEMS Section XX). c. Ongoing assurance: Regime for inspection and audit PTW audits; Health Surveillance (HSEMS Section XX). Exposure Measurement linked to Risk Assessment processes (HSEMS Section XX); Incident Investigation (HSEMS Section XX). Supporting standards/guidance: Company local rules contained within local Safety Regulations - Including guidance on risk assessment of specific activities, Permit to Work Systems, Isolation, preparation & gas freeing of equipment incorporating national regulations and standards that apply.	Documented Risk Assessment of all process steps and identified RMM are implemented. Task Risk analyses done for non-routine jobs (including maintenance).

c	Management system is in place?	HSE Management System (HSEMS). External ISO certification e.g. ISO9001 & 14001. Integration of HSE within Management of Change processes. Assurance provided by Internal and External audit and review processes.	HSEMS Manual latest revision. Section 1 describes the policies, organisations and arrangements for the management of HSE matters on this site. ISO9001 (Certificate number) & 14001 certification (Certificate number). Integrated Audit Schedule maintained. Annual internal management review of the suitability and effectiveness of the HSEMS. Management of Change incorporated within site Management System.	Same text as for large scale operations.
d	Implementation of existing EU legislation?	HSE MS defines process for compliance with regulations including EU legislation. Relevant Directives include: Seveso Directive for the control of major accident hazards 96/82/EC2; Protection of workers potentially at risk from explosive atmospheres (ATEX) 1999/92/EC; Equipment and Protective Systems intended for use in potentially explosive atmospheres 94/9/EC; Integrated Pollution Prevention and Control (IPPC) 96/61/EC3, Chemical Agents Directive 98/24/EC4. Health and Safety Framework Directive. List relevant national legislation.	Local country legislation - Major Accidents and Hazards Legislation. Explosive Atmospheres Regulations and associated regulations; Pollution Prevention and Control Regulations (PPC); Hazardous Substances Regulations; Carcinogens Directive. Tracking of existing relevant national legislation maintained. See also 3.c for examples of national legislation.	Same text as for large scale operations.
3 Are only properly trained and authorized personnel handling the substance?				
a	Relevant training or authorisation scheme covers this substance and/or process?	HSSE critical activities and positions are determined via risk based analyses. Job competencies for the identified critical positions are defined and individuals assessed against the required profiles. Training in substance hazards and exposure controls addressed. A program is in place to manage identified competence gaps.	Formal competency development schemes for Plant Operators and Mechanical Fitters addressing critical HSE activities. Supporting records. Oversight and coordination via Training Department. Covers general and hazard specific training. Supported by Competence Development procedures for critical task analysis inputting to training plans. This supports application of best practice across all shifts; associated method statements are documented and undergo regular review.	Training record for SOPs available. Operating instructions near the work place. Batch records show SCC requirements, OC and RMM. Well trained and qualified operators. Maintenance Task Descriptors include SCC requirements.
b	A procedure ensures that only trained and authorized persons handle the substance?	Plant personnel are trained in the process and the hazards of substances involved. Only competent operators are authorized to operate the plant. Maintenance is only carried out on drained and flushed/ isolated and cleaned equipment managed via a Permit to Work System.	Competence Assurance addressed via various schemes underwritten by job HSE competency requirements and site HSE risk assessment processes. Additional competence assurance/development activities include: External certification of competence development processes, Regulatory Training Matrix, Operator Training Plans, Maintenance Technician Competency Training Matrix, Staff HSE Competency Assessments	Batch records signing off procedure by supervisor. Procedures incorporating applicable HSE measures.

c	Other legislative frameworks that control the handling of the substance have been considered?	In addition to legislation referenced under Section 2.d. other relevant regulations are applied, e.g. supply and transport of dangerous goods regulations, substance specific regulation, and control specific regulation.	Example of additional relevant legislation: UK - Chemicals (Hazard Information and Packaging for Supply) Regulations, substance and control specific requirements incorporated in Control of Substances Hazardous to Health Regulations; Personal Protective Equipment Regulations; Equipment and Protective Systems intended for use in potentially explosive atmosphere Regulations (ATEX). Supporting national guidance and Codes of Practice, Industry good practice, e.g. Oil Industry Advisory Council, Concawe, Energy Institute, BSI, ANSI. Germany: Gefahrstoffverordnung, Berufsgenossenschaftliche Vorschriften/ Leitfaden)	GMP (e.g. pharmaceuticals, food etc), ISO 14001, ISO 9000
4 Are special procedures applied before the system is opened and entered during cleaning and maintenance works?				
a	Process procedures for the containment during cleaning and maintenance have been accounted for in plant and engineering design?	Design and Engineering standards. Operational instructions for routine maintenance; non-routine maintenance require a method statement. Integrated into the Operations and Maintenance Management Systems. All instructions and method statements are documented and audited. Inclusion of health and environmental aspects within Permit to Work and Job Hazard Analyses or similar.	Purging, flushing, venting procedures to prepare plant for intrusive maintenance HSEMS Section XX. Permit to Work (PTW) Regulations, Safe Isolation of Plant & Equipment procedure. Method statements prepared to accompany PTW documentation.	Preliminary risk analysis for process Purging, venting, control of atmosphere, electrical blocking, analytical Procedures prepared to accompany Permit to Work procedure.
b	Operational procedure system checks include cleaning and maintenance of process equipment?	Standard operating procedure. In case of presence of residual product, equipment transfer certificates specify potential contamination and include reference to the Material Safety Data Sheet and relevant Personal Protective Equipment.	Company Safety Regulations - Include guidance on the procedures to be adopted for Isolation, preparation & gas freeing of equipment and any regulations and standards that apply. Equipment Transfer procedure. Permit to Work procedure.	Isolation, preparation, purging & gas freeing of equipment procedures. Analytical control/validation, control of atmosphere, certificate of decontamination. Permit to Work procedure.
c	Risk management measures are applied during cleaning and maintenance?	Managed via HSE MS procedure and Permit to Work/Job Hazard Analysis. For non-routine work tools such as Job Hazard Analysis used to determine the precautions to minimize exposure.	HSEMS Section XX. Permit to Work Regulations, item XX. Safe Isolation of Plant and Equipment procedure applied and integrates Risk Management Measures from standard control sheets and risk assessment activities.	Same text as for large scale operations.
d	Procedures are applied such as purging and washing are applied before the system is opened?	Standard practice to drain and flush/isolate and clean equipment prior to opening lines/vessels. Other reasonably practicable alternatives to entering a confined space to have been considered.	HSEMS Section XX. Permit to Work Regulations, item XX. Safe Isolation of Plant and Equipment procedure applied and integrates Risk Management Measures from standard control sheets and risk assessment activities.	Purging & gas freeing of equipment procedures. Analytical control/validation, control of atmosphere, certificate of decontamination. Permit to Work. Same text as for large scale operations.

5	Are procedural and/or control technologies used during purification or cleaning and maintenance procedures, including in case of accident or waste generation?			
a	Procedures to ensure containment have been applied for all stages of production and processing?	Ongoing assurance of containment via e.g. monitoring of plant parameters (e.g. alarms, workers exposure monitoring), formal reporting and investigation of leaks, monitoring of waste effluent. Emergency procedures specify recovery measures in case of a safety, health or environmental impact.	Examples of site processes in support of plant integrity and reliability assurance and include site Key Performance Indicators are: - Maintenance, inspection and integrity processes - Alarms, Safeguarding, Inspection, Plant Operating Windows etc. - Plant Local Operating Procedures - Emergency Procedures - Supported by Company design standards	Provision of PPE in support of other mechanisms of control
b	Operating system checks include accident prevention and waste management?	Requirements specified within the HSE Management System.	HSEMS Section XX Site Rules. Safety critical equipment checked for integrity to mitigate incident. Product containment following opening of lines specified in Safe Isolation of Plant & Equipment; hazardous activity risk assessment and control sheets. Fugitive emissions monitoring and mass balance tracking. Additional: a system to ensure Duty of Care management for control of wastes. Waste should go to an Authorized waste Disposal contractor and there should be an auditable paper trail	Same text as for large scale operations.
6	Are substance-handling procedures well documented and strictly supervised by the site operator?			
a	Operational procedures and work instructions have been assessed and are documented?	Risk Assessment processes feed into standard operating instructions and competency development requirements. Chemical Substance Inventory and Material Safety Data Sheets accessible.	Process Unit Health Risk Assessments and specific plant procedures. Site Hazard Inventories and system for availability of Material Safety Data Sheets	Operating procedures taking into account risk assessment results
b	Strict supervision	Design of high-integrity plant; Monitored emission controls; Routine visual inspections of critical equipment and operations; Personnel competence assurance; Effective clean-out of equipment prior to maintenance; Regular inspection of management systems adherence	Project review records; Process logs; Shift logs; Training record inspections; Equipment inspection records; Audit and inspection reports; follow-up action close-out logs.	Same text as for large scale operations.

**APPENDIX 1.C. EXAMPLE OF GENERAL RISK ASSESSMENT AND MANAGEMENT MEASURES
BY ORGANIZATIONAL TOPIC OR MANUFACTURING STEP FOR THE PRODUCTION OF FINE
CHEMICALS.**

This is provided as a set of worked examples, modeled on cases suggested by the European Fine Chemicals Group (EFCG), but can be exchanged, expanded or developed as is fit-for-purpose.

Organizational Topic or Manufacturing Step	Management Measures and technical Controls in Place to Confirm Compliance with SCC	Some Examples, Details and References
Systems Management and Review	Includes provision for regular update, review and independent audit. Systems also include a requirement to take into account any new legislation to document all controls and changes. Management of change procedure in place	ISO 9000/14000/EMAS/HSE Management System control manuals. Compliance checks, including ongoing maintenance of controls. Audit reports. Incident reporting and data files.
Occupational Health and Safety/Hygiene	Documented procedures covering health surveillance and monitoring of chemical substances directive.	Pre-employment and annual medical screening. Risk assessments. Work place monitoring procedures
Manufacture 1: Handling, Storage and Charging/Loading of Intermediates to Chemical reaction Vessels	Quality control procedures on incoming raw materials. Sampling procedures which shall contain the relevant instructions for personal protection. Warehouse controls and procedures. Internal transport procedures, batch process controls, technical measures for charging of substance in flammable atmospheres, use of specialized equipment. Where possible handling in a segregated area with appropriate ventilation and use of designated PPE.	HSEMS: SMS/production/warehousing; charging of solids in flammable atmospheres. Standard Operating Procedure (SOP): specialized charging equipment. Documented risk assessments.
Manufacture 2: Reaction Systems	All reaction systems sealed and to operate in a closed state with venting only in accordance with IPPC permit or equivalent. Regular checks on equipment. Preventative maintenance to detect and repair leaks. Screening procedures for introduction of new substances and procedures.	Manufacturing batch sheet controls, SOPs. EU/national/company technical standards and codes of practice. Equipment files and drawings. Risk assessment in advance of new production. Process design data and equipment drawings. Distributed control system for batch process control, where appropriate. Emergency planning.
Emission to the Environment from processes using or producing intermediates	All reactions systems vented to specific emission points in accordance with IPPC permit conditions. All aqueous discharges balanced and discharged within license condition limits to well managed sewage treatment works (STW). All waste solvent and solids disposed of by incineration (using a licensed contractor) and managed within the conditions set down by the European waste regulations.	IPPC Permit. Other environmental operating permits and licenses. ISO 14000/EMAS systems. Detailed operating procedures in place.
Sampling and Analysis	Samples taken in accordance with control procedures at specific sample	Process batch sheets, SOPs, Safety data Sheet (SDS),

	<p>points, according to risk assessment measures as appropriate. Samples brought in closed containers to QC laboratory for analysis.</p> <p>Where it is not possible to do this under completely closed systems and conditions designated local ventilation is available.</p>	<p>specified PPE, analytical procedures. Risk assessment as appropriate. Internal audit procedures.</p>
Separation 1: Filtration/Centrifugation	<p>Closed system feed to separation device. Operation under inert pressure, atmosphere or under vacuum. Where top opening equipment is used, this operation is carried out (within a segregated area) with forced ventilation, or otherwise with separate local ventilation,.</p>	<p>Batch sheets, SOPs. Equipment logs, risk assessments.</p>
Separation 2: Distillation/Evaporation	<p>All distillation and evaporation operations are carried out in closed systems, unless otherwise justified by risk assessment.</p>	<p>Batch sheets, SOPs. Engineering controls. Technical control measures.</p>
Separation 3: Drying	<p>As completely closed systems are inappropriate for batch drying operations on relatively small product volumes, transport of material to be dried is effected using designated containers which are charged to and from drying equipment using local ventilation, engineering controls All drying operations are carried out under inert/reduced pressure.</p>	<p>SMS/SOPs/Batch Sheets. Engineering design and layout files. Preventative maintenance.</p>
Storage and Dispatch of finished products	<p>Packaging and labeling is carried out in segregated area with appropriate ventilation, and with use of the designated PPE. Product containers are classified and the containers labeled in accordance with EU and GHS regulations. All products dispatched from the Company with standard documentation, which includes the Safety Data Sheet (SDS), in the working language of that member state to which material is dispatched. Only qualified transport undertaking used.</p>	<p>Batch sheets, SOPs, classification and labeling procedures, dispatch documentation.</p>

APPENDIX 1.D. EXAMPLE OF AN INVENTORY OF INTERMEDIATES TO DOCUMENT THE CONTROL REGIME IN SUPPORT OF SCC FOR FINE CHEMICAL PROCESSING WHERE INTERMEDIATES ARE SUBJECT TO REGULAR CHANGE IN ACCORDANCE WITH THE CURRENT BUSINESS SITUATION.

It is a feature of the fine chemicals sector in the EU that manufacturers, and especially SMEs, will be using and manufacturing a wide range of intermediates. The fine chemicals sector typically manufactures a wide range of products, usually in multi-product batch facilities. Thus the range of intermediates in use can be subject to regular change as a response to the dynamic nature of this segment of the chemicals market. The inventory may be updated at regular intervals in line with production schedules. The following Table illustrates (part of) an inventory of handled intermediates that might be developed.

Intermediate	CAS No.	EC No.	Type of Intermediate	Process	Manufacturing Area	Manufacturing Step	Type of Approach (see Appendix 4. from core CEFIC Document)	Risk Assessment Summary	Specific Control measures
Acetic Acid	64-19-7	200-580-7	Transported	CNBN	Plant A	Charging Vessel	- Full containment - No significant emission - OEL published - Hazard data available - data limited substances		
Diethyl Oxalate	95-92-1	202-464-1	Transported	ECP					
Hydrogen Chloride	7647-01-0	231-597-0	Transported	DMPC					
NPG	103-01-5	203-070-2	Transported	NPG					
4-Bromobenzyl Bromide	589-15-1	209-636-5	Transported	4- Bromobenzyl Bromide					

It is suggested that the classification, and related risk assessment procedures, would correspond to, or draw on, other inventories or master lists which a company may already have put in place in compliance with other legislation. Suitable models could include those measures adopted by the company to ensure compliance with national legislation putting in place the requirements of Directive 98/24/EC (Chemical Substances Directive), or 96/61/EC (IPPC), or other appropriate guidelines. Reference can be made also to the websites of the national Competent Authorities and to the Cefic and EFCG websites.

APPENDIX 2: EXAMPLE ENTRY INTO IUCLID5 SUMMARIZING RISK MANAGEMENT MEASURES APPLIED FOR SCC

A statement referring to measures in place addressing strictly controlled conditions is required to be included within IUCLID5, Section 11 'Guidance on Safe Use' as part of the Registration documentation. ECHA guidance indicates that such statements should be included within the fields 'Handling and storage' and 'Exposure controls/personal protection'.

The following general statement is suggested:

'This substance is handled under Strictly Controlled Conditions in accordance with REACH regulation Article 17(3) for on-site isolated intermediates and, in case the substance is transported to other sites for further processing, the substance should be handled at these sites under the Strictly Controlled Conditions as specified in REACH regulation Article 18(4). Site documentation to support safe handling arrangements including the selection of engineering, administrative and personal protective equipment controls in accordance with risk-based management systems is available at each manufacturing site.

Written confirmation of application of Strictly Controlled Conditions has been received from every affected Distributor and Downstream Processor/User of the Registrant's intermediate.

APPENDIX 3: SUGGESTED FORM OF WORDS FOR USE IN LETTERS/CONTRACTUAL ARRANGEMENTS/MATERIAL SAFETY DATA SHEETS FOR ISSUE TO DOWNSTREAM PROCESSORS SUPPORTING CONFIRMATION OF SCC

a. Letter of Exchange

Confirmation that strictly controlled conditions are applied by Downstream Processors/Distributors is required. This may be in the form of a letter, or some other mechanism such as a response via a web questionnaire, so long as the response can be tracked and comprises an auditable record.

Example statement:

Specify the relevant product name(s):

We, [Company name], hereby confirm that:

- We are aware of Regulation (EC) No. 1907/2006 (REACH Regulation) which outlines the new framework for chemicals management in the European Union
- we understand the definition of 'transported isolated intermediate' (as defined in Chapter 2 Article 3 (15) of the above regulation)
- We use the above product(s) in accordance with 'strictly controlled conditions' as defined in Chapter 2, Article 18(4) of the above regulation and can confirm control. [Note: it is recommended that the details of Article 18(4) Sections a. to f. defining the elements of SCC are also listed. You will also find reference to these in Section 2.2.3 of this document.]
- We understand that the same confirmation needs to be obtained from our customers in case the product is being sold to third parties.

Please refer to industry guidance on confirming control to meet 'Strictly Controlled Conditions' for intermediates (provide web link to this guidance document).

b. Contract of Sale

It is recommended to include a statement within the contract of sale documentation for intermediates that stipulates that:

- *'this [item sold which may often be referred to as 'Product'] is registered by Seller as an intermediate under REACH and is subject to reduced registration requirements. Buyer represents and warrants that the substance will be handled and used at all times only under strictly controlled conditions as defined in Article 18(4) of Regulation (EC) No. 1907/2006 (REACH Regulation) and shall indemnify Seller and hold Seller harmless against any losses, costs, damages or claims arising from Buyer's failure to do so. Buyer understands that in case the Product is sold to a third party a confirmation of strictly controlled conditions needs to be obtained from each third party.'*

These statements should be supported by reference to the relevant REACH Article as follows:

- *'in accordance with Articles 18 and/or 19 of REACH 1907/2006'*

A more detailed provision on liability may be developed on a case-by-case basis in order to set up specific penalties for breach by the buyer of the requirement of use under SCC.

c. Safety Data Sheet (SDS)

The SDS shall provide all of the relevant available information to enable the user to understand and apply efficient risk management procedures.

A statement shall be included within Section 8.2 of the SDS for the intermediate that indicates to the user/customer that:

- *'the substance/product is registered with strictly controlled conditions as defined in Article 18(4) of Regulation (EC) No. 1907/2006 (REACH Regulation) and must therefore be handled as such. Refer to the industry guidance prepared by Concawe/Cefic/EFCG'*

for advice on the confirmation of strictly controlled conditions available from:
<http://cefic.org/Templates/shwStory.asp?NID=719&HID=714>

Similarly, in the part of the SDS where uses are advised against, to include a statement that indicates (e.g., within Section 16):

- *'the substance/product is registered with strictly controlled conditions as defined in Article 18(4) of Regulation (EC) No. 1907/2006 (REACH Regulation) and must therefore be handled as such.'*

APPENDIX 4: STRATEGIES AVAILABLE FOR DETERMINING THE STRICT CONTROL OF ISOLATED INTERMEDIATES DEPENDING ON AVAILABLE HAZARD AND EXPOSURE INFORMATION

As indicated in Section 3, it is clear from the REACH regulation and from the ECHA “Guidance for Intermediates” that the principle of strict control/rigorous containment must be applied to the management of an intermediate, and all management systems and technical control measures must ensure compliance with this concept. Following the ECHA guidance, and other appropriate guidance, each company must develop its own system to document its compliance with the principle of rigorous control, and be prepared to justify its approach to the regulatory authority.

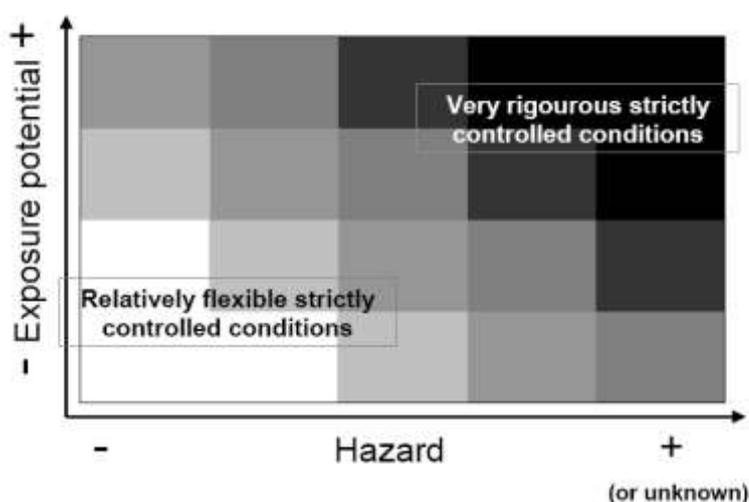
Appendices 4.1 and 4.2 illustrate the types of strategy that can be applied.

Based on the knowledge about the physicochemical and hazard properties of the substance, suitable technical and procedural measures can be implemented to ensure that exposure to the substance to humans and the environment is minimised at all times. Different approaches can be defined according to available information in which measures directed to control at source are generally believed to be the most effective.

The extent to which data are available influences the confidence that can be invested in the integrity of the measures used to deliver strictly controlled conditions (SCC) and hence the strategies that may need to be applied to justify that a substance is handled under SCC.

The following graph summarizes the widely accepted approach to assess the level of hazard and exposure potential to support alternative approaches/strategies identified in this Annex:

Modulation of rigourousness of containment depending hazardous & physchem data and potential exposure



The exposure potential of a substance (intermediate) in a particular use is dependent on the following factors:

- Substance properties related to the tendency to become airborne (i.e. volatility of liquids at operating temperature, dustiness of solids) or other propensity of the substance to disperse into the (work) environment, and
- Process operational conditions such as quantities in use, frequency and duration of use.

This definition of potential exposure is based on well-established control banding schemes such as the German EKMG.

The proper choice of the appropriate approach/strategy (described hereafter) should be clearly identified and documented in order to give evidence that implemented technical and procedural measures will ensure that exposure to the intermediate (whether to man or the environment) is reduced so that risks are strictly controlled.

APPENDIX 4.1: OCCUPATIONAL HEALTH

Starting from full technical containment, the following distinct hierarchy of approaches to managing occupational health risk can be applied to intermediates when determining whether they are handled under strictly controlled conditions.

Conformity with any approach in isolation does not necessarily reflect the fact that Strictly Controlled Conditions have been achieved. However, conformity to one or more elements serves to strengthen the basis for any justification of SCC for affected intermediates.

1. Full containment

Independent of the degree of hazard, whether known or not, use in a closed system, as described in the TGD, or examples 2, 3, and 4 provided in the ECHA “Guidance for Intermediates”, would correspond to conditions of strict control for an intermediate;

2. No significant emission / occupational exposure

Independent of the degree of hazard, whether known or not, the physicochemical properties, physical state of the intermediate, appropriate measures to prevent skin exposure, and/or inclusion in a matrix, may exclude any possible exposure under normal handling and use. In this case conditions of strict control for an intermediate can be achieved;

In case SCC following above two points is not reasonably feasible, the following alternatives could be considered:

3. Occupational Exposure Limit published or DNEL available

If a European or health-based National OEL has been published or if a worker DNEL has been derived according to the REACH TGD then a rigorous strategy for demonstration of strict compliance of occupational exposures with the appropriate OEL or DNEL has to be applied for example as described in EN standard EN689.

4. Hazard data available

Where a formal DNEL is not available for the registration of an intermediate but an appropriate OEL can be derived from available data considering the respective use conditions (e.g. frequency of exposure), then a rigorous strategy for demonstration of strict compliance of occupational exposures with this OEL has to be applied as described in EN standard EN689..

If partial hazard data is available (partially complete data set, QSAR, and/or read across), then these data may be used to identify the required level of control in order to help determine where the BAuA workplace control scheme, COSHH Essentials, or UIC DT80 provide relevant information that enable the user to identify appropriate steps for such a risk assessment and control process. A “hazard banding” assessment in such cases, has to correspond to a sound review of all the available data (partially complete data set, QSAR, dose response relationship, occupational health observations, read across, etc.). A hazard profile derived from R-phrases / CLP classification may be considered as one of the criteria for hazard banding, but not necessarily the only one depending on frequencies and durations of residual exposures.

5. Data-limited substances

When available hazard data are not sufficient to derive an OEL and the substance does not possess properties that would suggest it could be a substance of high concern, then a conservative hazard assessment and a standard process of risk assessment may be applied to determine an appropriate control strategy for the confirmation of SCC. For example:

- Hazard class n° C for substances of unknown toxicity as defined in COSHH Essentials (<http://www.coshh-essentials.org.uk/>).
- Default Generic Exposure Values (Medium Hazard Category) as defined in ECETOC TRA Technical Report 93 (www.ecetoc-tra.org/public/login/index.asp)
- Hazard Band n°4 for substances of unknown toxicity as defined in UIC DT80 (<http://www.uic.fr/mediatheque.asp?card=2540>)

An accepted conservative default OEL value of recognized local authorities.

With such a conservative approach, the resulting containment and associated RMM are likely to be comparable to the rigorousness of cases 1 and 2.

APPENDIX 4.2: ENVIRONMENT

Starting from full technical containment, the following distinct hierarchy of approaches to managing environmental risk can be applied to intermediates when determining whether they are handled under strictly controlled conditions.

Conformity with any approach in isolation does not necessarily reflect the fact that strictly controlled conditions (SCC) have been achieved. However, conformity to one or more elements serves to strengthen the basis for any justification of SCC for affected intermediates.

1. Full containment

Independent of the degree of ecotoxicological hazard, whether known or not, then a closed system, as described in the TGD, or examples 2, 3 and 4 provided in ECHA “Guidance for Intermediates”, page 16 and 17, correspond typically to acceptable conditions of strict control for an intermediate;

2. No emission in the environment

Independent of the degree of ecotoxicological hazard, whether known or not, then certain physicochemical properties, physical states of the intermediate, leading to the absence of release or effluent, and/or appropriate removal techniques using treatment facilities may result in no significant exposure of the environment. In this case, conditions of strict control can be achieved;

In case SCC following above two points is not reasonably feasible, the following alternatives could be considered:

3. Operations compliant with IPPC licence or other national environmental permits

Where a company is subject to IPPC licence and/or other national environmental permits with defined limits, full compliance with the IPPC licence or permit limits might correspond to acceptable conditions of strict control for an intermediate, especially where they are set by the competent environmental authority with reference to a suitable national standard; material

changes in operations and introduction of new processes are subject to risk assessment and compliance is enforced by the relevant inspectorate;

4. PEC/PNEC assessment

If a PNEC can be calculated on the basis of the TGD, or if a regulatory environmental quality standard exists (water quality standard, for example), or if any conservative default PNEC may be justified, then a strict process of environmental risk assessment can be undertaken for the confirmation of the SCC, based on an assessment of environmental exposure (PEC) to be below PNEC.

A "hazard banding" assessment in such cases, has to correspond to a sound review of all the available data (partially complete data set, QSAR. A hazard profile derived from R-phrases / CLP classification, may be considered as one of the criteria for hazard banding but not necessarily the only one;

5. Effluent assessment

The delivery of SCC may be achieved by using a complementary approach to #3 based upon the whole effluent assessment approach (Whole Effluent Toxicity (WET) for example);

6. Data-limited substances

When available hazard data are not sufficient for the derivation of a PNEC, use may be made of accepted conservative default environmental discharge values of recognized local authorities (for example, the Environmental Threshold of No Concern, ETNC).

With such a conservative approach, the resulting containment and associated RMM are likely to be comparable to the rigorousness of cases 1 and 2.

APPENDIX 4.3: INDUSTRY EXAMPLES

Several examples have been prepared by industry, illustrating the strict control of intermediates, depending on the available hazard and exposure information. These examples can be downloaded from the Cefic website:

<http://cefic.org/templates/shwPublications.asp?HID=750>

These examples use a template that was developed by the working group to facilitate the collection information by the working group from different companies and sectors.. This template should not be regarded as obligatory and companies are free to use their own form of justification.