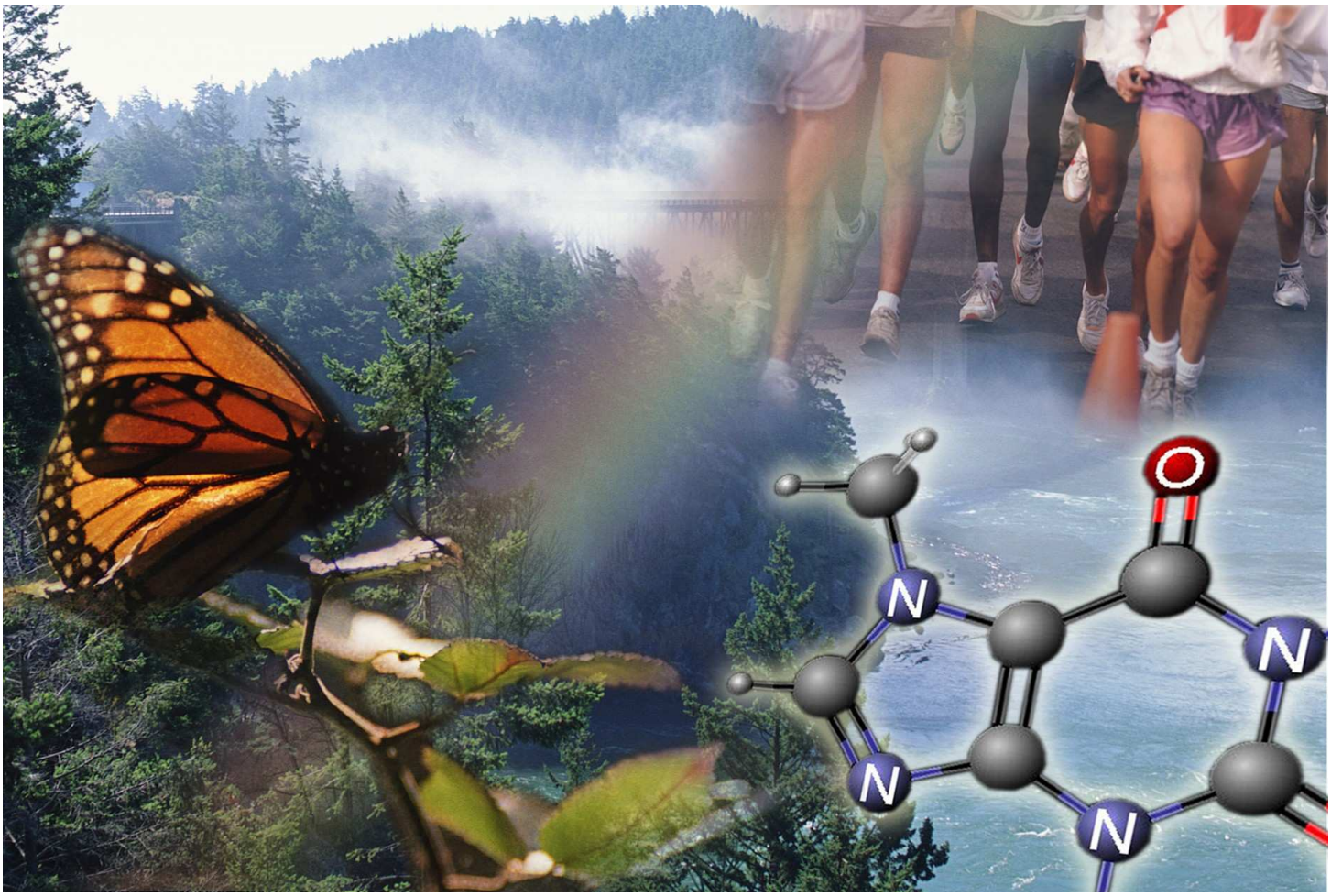
Guidance for intermediates



August 2010

Draft Update V.02

Guidance for the implementation of REACH

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This document describes when and how the specific provisions for the registration of intermediates under REACH can be used. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. After acceptance by the Member States Competent Authorities the guidance documents had been handed over to ECHA for publication and further maintenance. Any updates of the guidance are drafted by ECHA and are then subject to a consultation procedure, involving stakeholders from Member States, industry and non-governmental organisations. For details of the consultation procedure, please see:
http://echa.europa.eu/doc/FINAL_MB_30_2007_Consultation_procedure_on_guidance.pdf

The guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalized or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

Document History

Version	Section	Change made	Date
1			June 2007
1.1	1.2.3	Wording has been changed for more consistency with section 1.2.2 and for clarification that the registrant can only rely on the confirmation from his customer that the substance is used under strictly controlled conditions	February 2008
1.1	1.2.3	A sentence has been added at the end of the last paragraph to give advice to inform non-EU costumers on the RMM.	February 2008
1.1	2	Clarification that the registration is only needed if the substance is not exempted from registration.	February 2008
1.1	2	In the 4th paragraph a sentence has been added to clarify how registration dossier can be submitted in case a substance is manufactured or imported also for other purposes than only the use as intermediate, or if the manufacture or use(s) are not under strictly controlled conditions. At the end of the 4th paragraph a sentence has been added to explain how the fees will be calculated.	February 2008
1.1	2	In the 3rd paragraph from bottom of page 12 some words have been added to clarify that the information requirements applies only to the transported intermediates.	February 2008
1.1	2.1	In 2nd bullet point the reference to EU or non EU sites has been deleted.	February 2008
1.1	2.2	In the classification section, some text has been added to clarify that only classification and no labeling is necessary for intermediates. In addition it has been specified where the risk management measures and the strictly controlled conditions should be reported.	February 2008
1.1	2.3	In the classification section, some text has been added to clarify that only classification and no labeling is necessary for intermediates. In addition it has been specified where the risk management measures and the strictly controlled conditions should be reported.	February 2008

Version	Section	Change made	Date
1.1	2.5	Another bullet point has been added to the 3rd paragraph to specify what the lead registrant is recommended to submit.	February 2008
1.1	2.7	Some words have been added to clarify when the registration fee will be specified.	February 2008
1.2	2.1	Footnote 4: Update of reference to IPPC Directive	June 2010
1.2		Addition to list of items for documentation: design of process and rigorousness of containment	June 2010
1.2	2.1.1	It has been clarified that "rigorous containment" according to Article 18 (4a) means the technical hardware designed for preventing releases, taking into account the physica-chemical properties of the substance.	June 2010
1.2	Examples	Consequently the examples which in fact refer to procedural and control techniques (Article 18 (4b)) have been moved to section 2.1.2. The example box for the fine chemicals industry has been updated. An additional example has been added for the metal industry.	June 2010
	2.1.2	It has been clarified that procedural and control techniques are to be applied on top to rigorous containment in order to minimize residual releases, taking into account the available knowledge on the substance' hazards. A reference to the relevant BREF document has been added.	June 2010
	Examples	The example box on technical measures to control releases to the environment has been shifted from 2.1.1 to 2.1.2.	June 2010
	2.2	Editorial modification under "Details of RMM applied"	June 2010
	2.2	Editorial modification under "Details of RMM applied"	June 2010
	2.3	Editorial modification under "Details of RMM applied"	June 2010
	Appendix 1 Point 2	Point 2: Rigorous containment has been added to the headline	June 2010

Version	Section	Change made	Date
	Appendix		

CONTENTS

1 INTRODUCTION

1.1 Definition of the different categories of intermediates

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* (Article 3(15)).

Different types of intermediates are defined under REACH:

- Non-isolated intermediates
- Isolated intermediates
  - On-site (non transported) isolated intermediates
  - Transported isolated intermediates

A non-isolated intermediate is 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 pipework 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* (*Article 3(15)(a)*).

On-site isolated intermediate means *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 take place on the same site, operated by one or more legal entities (Article 3(15)(b)).*

A site means *a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared (Article 3(16)).*

A transported isolated intermediate is *an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites (Article 3(15)(c)).*

The circumstances under which a substance may or not be regarded as an intermediate under REACH are clarified in document' Definition of intermediates as agreed by the Commission, Member States and ECHA on 4 May 2010'[2].

Depending on the identified intermediates different obligations and information requirements apply.

The lifecycle of an isolated intermediate begins with its manufacture (in practical terms, with its removal from the manufacturing process). This lifecycle ends with the use of the substance in the synthesis process for the manufacture of another substance.

Residues of the isolated intermediate, which are not transformed into another substance in a manufacturing process, will be typically discarded or disposed of as waste and channelled into waste management when not recycled as a non-isolated or isolated intermediate. Consequently, they

[2] http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC

no longer fall in the scope of REACH. Where residues of the intermediate are found in the synthesised substance, they are covered – as an impurity - by the registration and evaluation of that other substance.

1.2 Tasks and obligations

1.2.1 Non isolated intermediates

For the use of a substance as a non-isolated intermediate, there are no obligations under REACH *(Article 2(1)(c)).*

1.2.2 On-site isolated intermediates

Manufacturers of on-site isolated intermediates in quantities of 1 tonne or more per year need to submit a registration dossier unless the substance is exempted from the registration provisions (see further information on the scope of REACH in section 1.6 of the Guidance on registration. The information to be submitted for standard registration purposes (other than registration as an intermediate) is listed under *Article 10* and detailed in section 1.8.1 of the Guidance on registration. However registrants of on-site isolated intermediates can provide reduced registration information according to *Article 17(2)* if they confirm that the substance is manufactured and used under strictly controlled conditions as described under *Article 17(3)* and section 2.1 of this guidance.

Registration obligations and exemptions

- *Article 2(8)* exempts intermediates from the general registration regime in chapter 1 of Title II of REACH. Instead a manufacturer of an on-site isolated intermediate has to register his substance in quantities of 1 tonne or more per year under a different regime, as specified in chapter 3 of Title II of REACH.
- If the manufacturer confirms that the on-site isolated intermediate is manufactured and used under strictly controlled conditions (see section 2.1), the information requirements on the substance intrinsic properties (physicochemical, human health and environment properties) are reduced to already available data (e.g. information he holds himself or that he can obtain from other sources) and only study summaries have to be submitted even if a full study report is available (*Article 17*) (see 2.2).
- If strictly controlled conditions are not met, a full (standard) data package is required depending on the tonnage level (*Articles 10 & 12*), and above 10 t/a a chemical safety assessment is required
- For monomers that are used as on-site isolated intermediate in the production of polymers the reduced registration provisions for intermediates do not apply, and the manufacturer has to proceed as for a "standard" substance (see Guidance on registration).
- In the unusual case that a notification under Directive 67/548/EEC had been submitted by the manufacturer/importer of an onsite intermediate, no registration is required; the substance is considered as registered and a registration number is assigned by the Agency (*Article 24*).

Classification and labelling

If the on-site isolated intermediate is a phase-in substance to be registered the manufacturer or importer must notify to the Classification & Labelling Inventory established at the Agency the information related to its classification and labelling in accordance with Article 39 (a) and Article 40 of *Regulation (EC) No 1272/2008* if he places the intermediate on the market (i.e. he makes it available to another legal entity on the same site)..

Notification can be done either by sending a separate notification to the Inventory or through inclusion of the relevant information, i.e. the CLP classification and labelling elements, in a registration dossier where this is required. In general, a separate notification will always have to be submitted where the notification is legally due before the registration is submitted. Once a registration dossier is submitted, a separate notification is no longer possible. Where that registration dossier still contains the DSD classifications, the manufacturer or importer would have to update it with the CLP information without undue delay, in accordance with REACH Article 22.

If the on-site isolated intermediate is a phase-in substance manufactured at less than one ton per year, the manufacturer must notify to the Agency the information related to its classification and labelling in accordance with Article 39 (b) if:

- he places the intermediate on the market (i.e. he makes it available to another legal entity on the same site), and
- the substance meets the criteria for classification as hazardous

Notification to the Inventory has to be done by 3rd January 2011 for on-site isolated intermediates that had been placed on the market on 1 December 2010 or, for intermediates that are placed on the market only later than 1 December 2010, within one month of placing them on the market (Article 40 (3)).

Further clarification in relation to notification of the classification and labelling can be found in ECHA's Practical Guide 7 'How to notify substances to the Classification and Labelling Inventory[3]. In addition one can consult ECHA's 'Introductory Guidance on the CLP Regulation'[4].

Dossier and substance evaluation

- For on-site isolated intermediates, dossier and substance evaluation do not apply. However the Member State Competent Authority (MSCA) where the manufacturing site is located may request additional information when it considers that:
  - there is a risk to human health or the environment equivalent to the level of concern arising from the use of a substance of very high concern (as defined in *Article 57*) and
  - that the risk is not properly controlled (*Article 49*).

Authorisation/Restriction

[3] http://echa.europa.eu/doc/publications/practical_guides/pg_7_clp_notif_en.pdf

[4] http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC

- Intermediates are not subject to authorisation (i.e. Title VII – Authorisation - does not apply). This is also valid for intermediates used as monomers for the synthesis of polymers.
- Any manufacturer or downstream user must check whether an intermediate is covered by any restriction in Annex XVII of REACH (*Article 67*).

1.2.3 Transported isolated intermediates

Manufacturers or importers of transported isolated intermediates in quantities of 1 tonne or more per year need to submit a registration dossier unless the substance is exempted from the registration provisions (see further information on the scope of REACH in 1.6 of the Guidance on registration. The information to be submitted for standard registration purposes (i.e. reduced requirements due to strictly control conditions being in place do not apply) is listed under *Article 10* and detailed in section 1.8.1 of the Guidance on registration. However, a registrant of transported isolated intermediates can provide reduced registration information according to *Article 18(2)* if he confirms that he is manufacturing and/or using the substance under strictly controlled conditions and if he confirms himself or states that he has received confirmation from the user that the substance is used under strictly controlled conditions as described under *Article 18(4)* and section 2.1 of this guidance. In that case both the registrant and the users are each liable for their own statement regarding the strictly controlled conditions.

Registration obligations and exemptions

- *Article 2(8)* exempts intermediates from the general registration regime in chapter 1 of Title II of REACH. Instead, a manufacturer or importer of a transported isolated intermediate has to register his substance in quantities of 1 tonne or more per year under a different regime, as specified in chapter 3 of Title II of REACH.
- If the manufacturer or importer confirms that he is manufacturing and/or using the substance under strictly controlled conditions and he confirms himself or states that he has received confirmation from the users that the substance is used under strictly controlled conditions (section 2.1) and the annual quantity of substance is less than 1000 tonnes, the information requirements on the substance's intrinsic properties (physicochemical, human health and environment properties) are reduced to existing available data (e.g. information he holds himself or that he can obtain from other sources) and only study summaries have to be submitted even if a full study report is available (*Article 18*) (see 2.3).
- When manufactured and used under strictly controlled conditions and the annual quantity of substance is 1000 tonnes or more, the data requirements on the substance's intrinsic properties (physicochemical, human health and environment properties) as specified in Annex VII must be included in addition to the information required under chapter 3 of title II of REACH.
- Where strictly controlled conditions are not met, a full (standard) data package is required depending on the tonnage level (*Articles 10 & 12*), and above 10 t/a a chemical safety assessment is required.
- For monomers that are used as transported isolated intermediate for the production of polymers the reduced registration provisions for intermediates do not apply, and the manufacturer has to proceed as for a "standard" substance (see Guidance on registration) [5].

[5] http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm?time=1271257385

- However, if a notification under Directive 67/548/EEC covering manufacture and the relevant use has already been submitted by the manufacturer/importer, no registration is required. The substance is considered as registered and a registration number is assigned by the Agency (*Article 24*).
- If the transported intermediate passes the 1000 t/y threshold, then the manufacturer/importer has to update the registration dossier and submit as a minimum the information required under Annex VII.

Classification and labelling

If the transported isolated intermediate is a phase-in substance to be registered the manufacturer/ importer must notify to the Agency the information related to its classification and labelling in accordance with Article 39(a) and Article 40 of *Regulation (EC) No 1272/2008 if*:

- he places the substance on the market (i.e. he makes it available to another legal entity on the same site or on another site), and
- he has not already submitted a registration.

Notification can be done either by sending a separate notification to the Inventory or through inclusion of the relevant information, i.e. the CLP classification and labelling elements, in a registration dossier where this is required. In general, a separate notification will always have to be submitted where the notification is legally due before the registration is submitted. Once a registration dossier is submitted, a separate notification is no longer possible. Where that registration dossier still contains the DSD classifications, the manufacturer or importer would have to update it with the CLP information without undue delay, in accordance with REACH Article 22.

If the transported isolated intermediate is a phase-in substance manufactured at less than one ton per year, the manufacturer must notify to the Agency the information related to its classification and labelling in accordance with Article 39(b) if:

- he places the substance on the market (i.e. he makes it available to another legal entity on the same site or on another site), and
- the substance meets the criteria for classification as hazardous.

Notification to the Inventory has to be done by 3rd January 2011 for transported isolated intermediates that had been placed on the market on 1 December 2010 or, for intermediates that are placed on the market only later than 1 December 2010, within one month of placing them on the market (Article 40 (3)).

Further clarification in relation to notification of the classification and labelling can be found in ECHA's Practical Guide 7 'How to notify substances to the Classification and Labelling Inventory[6]. In addition one can consult ECHA's 'Introductory Guidance on the CLP Regulation'[7].

Dossier and substance evaluation

- Manufacturer / importer must be aware that dossier and substance evaluation apply to transported isolated intermediates. Therefore, the Agency or, if there is no agreement

[6] http://echa.europa.eu/doc/publications/practical_guides/pg_7_clp_notif_en.pdf

[7] http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC

between MSCA, the Commission may request additional information when it is conducting an evaluation. The manufacturer/importer must comply with any such request within the deadline set (see the Guidance on evaluation).

Authorisation/Restriction

- Intermediates are not subject to authorisation (i.e. Title VII – Authorisation - does not apply). This is also valid for intermediates used as monomers for the synthesis of polymers.
- Any manufacturer/importer or downstream user must check whether an intermediate is covered by any restriction in Annex XVII of REACH (*Article 67*).

2 REGISTRATION OF ISOLATED INTERMEDIATES

Manufacturers of on site isolated intermediates and manufacturers or importers of transported isolated intermediates in quantities of 1 tonne or more per year need to submit a registration dossier unless the substance is exempted from the registration provisions. However specific rules apply for their registration (*Articles 2(8), 17, 18 and 19*). If the isolated intermediate is manufactured and used under strictly controlled conditions, the registration requirements are lighter than for non-intermediates. Otherwise the registration for the isolated intermediate shall include the information specified in Article 10.

This guidance is intended to support registrants of isolated intermediates in assessing whether the conditions of manufacture and use fulfill the requirements for an isolated intermediate registration set out in *Articles 17(3) or 18 (4*). Also, the guidance includes three annexes describing the content and the format for documenting that strictly controlled conditions apply.

If the manufacturer or importer of a substance manufactures or imports the substance for other purposes than only the use as an intermediate, or if the manufacture or certain use(s) cannot be demonstrated as being carried out under strictly controlled conditions, then the manufacturer or importer needs to submit a “standard” registration dossier according to Article 10. In this situation, if part of the tonnage is manufactured and used as an intermediate under strictly controlled conditions, the registrant can submit one registration dossier covering all his tonnage.

- The information requirements for this registration dossier are then based on the tonnage for non-intermediate uses and for intermediates not used under strictly controlled conditions. The part of the tonnage manufactured or imported for use an intermediate under strictly controlled conditions will not need to be taken into account for the information requirements of the registration dossier.

- Nevertheless the use as intermediate should be documented in the dossier, including the volume manufactured or imported for this purpose.

- The fees will be calculated independently for i) the use as intermediate under strictly controlled conditions (fees for intermediates pursuant to Article 4 of Regulation (EC) No 340/2008) and ii) for the other uses (standard fees pursuant to Article 3 of Regulation (EC) No 340/2008).

Example 1 Tonnage to consider for the registration dossier of a substance both used as isolated intermediate and non-intermediate

A company manufactures 2300 tonnes of substance A, of which 1700 tonnes are used as intermediate in strictly controlled conditions. This company will submit a standard registration dossier for substance A, where the volume of the remaining 600 tonnes not used as intermediate is used to determine the information requirements. This means that the information requirements for 100-1000t substances will be used as a basis for this standard dossier. The fact that the substance is also used as an intermediate should be indicated in the dossier and the volume of 1700 tonnes used as intermediates will need to be documented in the dossier.

If the manufacturer or importer of the substance manufactures or imports it only for the use as an isolated intermediate under strictly controlled conditions (see 2.1), then the manufacturer or importer can submit a registration dossier with reduced information requirements (according to *Articles 17 and 18*) as described in section 2.2 and section 2.3. However, this registration dossier has to contain all available existing information on the intrinsic properties of the substance.

More guidance on how to calculate the tonnage is given in the Guidance on registration.

The data requirements for the registration of isolated intermediates manufactured in quantities of 1 tonne or more per year depend on whether they are transported or not. For transported intermediates, those requirements depend on the manufactured or imported volume which is transported. Compared to the data requirements for the registration of a "standard" substance, there are reduced information requirements for isolated intermediates, as long as the registrant confirms that strictly controlled conditions are applied during manufacture and use of the substance on-site but also, in case of transported intermediates, that he has received confirmation from the user that strictly controlled conditions are applied on other sites (*Articles 17(3)* and *18(4)*). In case of a transported isolated intermediate in quantities of more than 1000 tonnes per year, also the information specified in Annex VII of REACH should be included (*Article 18(3)*).

It should be noted, though, that **monomers** used as on-site isolated intermediates or transported isolated intermediates do not benefit from the exemption from standard registration requirements which normally applies to intermediates and have to be registered following the registration requirements described in *Article 10* (*Article 6(2)*). Therefore for the registration of monomers the Guidance on registration[8] has to be used.

For **on-site isolated intermediates** the information requirements on physicochemical, human health and environmental properties are limited to the data that is available to the manufacturer (e.g. information he holds himself or that he can obtain from other sources, including literature data) without any new testing. The registrant shall therefore gather all existing available information on physicochemical, human health or environmental properties of the substance for which he submits a registration dossier as required under REACH.

For **transported isolated intermediates** available existing information needs to be submitted as for on-site isolated intermediates, but a limited set of additional information needs to be generated, if not already available, if the annual tonnage exceeds 1000 tonnes/year as referred to in *Article 18* and developed under section 2.3 of this guidance.

The first task for the registrant is therefore to determine if the substance under investigation is an isolated intermediate manufactured and used under strictly controlled conditions and whether it is

[8] http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm?time=1271257385

transported or not, in order to identify the information he has to provide in a registration dossier to fulfil his obligations.

2.1 Strictly controlled conditions

For both on-site and transported isolated intermediates the possibility to provide a reduced set of information for their registration applies when:

- *For on-site isolated intermediates, the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions (Article 17(3)).*
- *For transported isolated intermediates, the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under strictly controlled conditions* detailed in *Article18(4)*. For transported isolated intermediates that are manufactured in the EU the strictly controlled conditions shall apply both to the manufacture and use of the substance.

Therefore, in order to benefit from the reduced registration requirements the registrants have to first assess if their intermediates are handled under strictly controlled conditions on the sites of manufacture and use. When compiling the registration dossier using IUCLID5[9], the registrant must confirm whether the substance is manufactured and used under strictly controlled conditions (see section 2.4).

To assess if the intermediate is manufactured and used under strictly controlled conditions during its whole lifecycle, the registrant should evaluate if all the *Article 18(4)* conditions 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;* (see chapter 2.1.1)

(b) procedural and control technologies shall be used that minimise emission and any resulting exposure; (see chapter 2.1.2)

(c) only properly trained and authorised personnel handle the substance; (see chapter 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 chapter 2.1.4)

(f) substance-handling procedures are well documented and strictly supervised by the site operator.

The definition of strict controlled conditions in *Article 18(4)* for transported isolated intermediates can also be used as a working basis for isolated on-site intermediates. *Article 18(4)* provides a wider

9 International Uniform Chemical Information Database

definition of strictly controlled conditions than *Article 17(3)*, the latter being limited to criteria (a) and (b) of the above list. Nevertheless criteria (c) to (f) can also be appropriate for on-site isolated intermediates in deciding whether strictly controlled conditions apply.

For both types of isolated intermediate, the registrant has two possibilities based on the assessment and description of the conditions under which the substance is manufactured and/or used:

- Submit a full registration dossier as described in *Article 10*, if he is not able to demonstrate that the substance is manufactured and used under strictly controlled conditions.
- Submit a registration dossier containing the limited set of data requested for intermediates, provided that he concludes that the substance is manufactured (and used for transported intermediates) under strictly controlled conditions. In this case, the dossier must contain details on risk management measures applied by the manufacturer (Article 17.2(f) and Article 18.2 (f)) and information on risk management measures recommended to the user (for transported isolated intermediates art 18.2 (f)).

Strictly controlled conditions should be seen as a combination of technical measures that are underpinned by operating procedures and management systems. This approach to managing potential risks to human health and the environment aligns with, and also acknowledges, the existing regulatory obligations that impact on manufacturers of substances (e.g. control of accidents under Directive 96/82/EC[10], Integrated Pollution Prevention and Control under Directive 2008/1/EC[11], occupational protection under the Chemical Agents Directive 98/24/EC[12]).

Rigorous containment by technical means aims to prevent releases by technical design of the process or product. The physico-chemical properties of the substance and the processing conditions (such as temperature and pressure) may have an impact on the level and type of containment measures that are required.

Open handling of a substance would normally not be in line with the rigorous containment requirement, unless the physico-chemical properties of the substance in combination with the process conditions ensure that no releases and exposure can occur.

It should be emphasized that the use only of PPE in an activity, without other measures, would not be sufficient to ensure strictly controlled conditions. Nevertheless PPE can be part of the strictly controlled concept as far as it aims at limiting exposure resulting from:

- Accidents and incidents that occur despite appropriate management systems and operational procedures to prevent such incidents and accidents.
- Maintenance and cleaning works, providing that special procedures such as purging and washing are applied before the system is opened or entered.

10 Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances.

11 Council Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control).

12 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

- Procedural and control technologies being used to minimise emission and the resulting exposure. For example, LEV types of measures are control techniques, which can be used to minimise exposure but cannot be used to claim rigorous containment.

Full documentation of the strictly controlled conditions in place is not required in the registration dossier (Article 17 (2); Article 18 (2)). However there should be detailed internal documentation within a company in order to show the adequacy of the measures taken to ensure strictly controlled conditions apply. The national enforcement authorities may request such information. Note that where relevant, documentation for compliance with other legislative frameworks can also be referred to. The detailed documentation may include (but is not limited to):

- justification for considering that the substance is used as an intermediate and customers' statements in case of a transported isolated intermediate;
- the physical chemical properties of the intermediate relevant for deciding on measures to ensure strictly controlled conditions apply
- documentation on the design of the process and the equipment, especially those aspects contributing to the rigorously containing the substance by technical means
- 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;
- available data on any residual release and resulting exposure that occurs in spite of the rigorous containment measures by technical means; and
- any relevant reference or threshold value (e.g. Derived No Effect Levels (DNELs), Predicted No Effect Concentrations (PNECs), community Occupational Exposure Limits (OELs)) and available relevant physico-chemical, toxicological and ecotoxicological information… **Please note:,** DNEL and PNEC derivation is not required for substances registered under Article 17 and 18, and thus it is not foreseen to provide quantitative risk characterizations in the corresponding registration dossiers.

To facilitate the process for assessing whether strictly controlled conditions are achieved, Appendix 1 presents an indicative and non-exhaustive list of issues that could be considered. This list is intended to support a structured assessment and documentation by the registrant to decide if strictly controlled conditions apply. For this considerable input by experts (e.g. site managers, engineers) will be needed.

It should be noted that the registrant of a transported isolated intermediate does not need to get access to confidential business information (e.g. fine detail of process technology and/or engineering, etc) from the user(s). This is because the user is responsible for ensuring that they use the intermediate under strictly controlled conditions and to confirm this to the registrant.

An example of a general format to document how the substance is manufactured and used under strictly controlled conditions is provided in Appendix 2. This would contain information and justifications for the issues addressed in Appendix 1. Note that any information produced for the purpose of other legislation (e.g. for worker protection) can also be used as an element to demonstrate strictly controlled conditions apply.

Information on details of the risk management measures applied at the manufacturing site and recommended to the user in order to achieve strictly controlled conditions, ~~should~~ have to be included in the registration dossier. Existing legislative frameworks or industry standards can be

referred to when documenting such risk management measures. The format in Appendix 3 is recommended to explain the risk management measures in the registration dossier. It should be attached to the IUCLID section 13 with the file name 'RMM_details'.

2.1.1 Rigorous containment of the substance by technical means

Rigorous containment is achieved by the technical design of a process and the equipment which aims at preventing releases. The physico-chemical properties of a substance is one factor to take into account in determining the right design to achieve rigorous containment, together with the process conditions if this is relevant. Rigorous containment is applicable to handling of intermediates at any scale. Release of the substance should be prevented through containment systems, such as suitable physical barriers (e.g. enclosures, bunds) and/or chemical barriers (e.g. membranes).

According to Article 18 (4):

" 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".

To be able to confirm and document the rigorous containment of the substance, the registrant should characterise the processes and equipment used during the whole life-cycle of the substance, taking into account the physico-chemical properties of the substance.

The description of these technical means and conditions should allow the identification of potential residual exposure of workers and the environment to the substance. It should for instance specify the means of rigorous containment for the different functional elements (pressurised vessels, seals, sacks, containers, drums, etc.) involved during the whole process such as manufacture, transfer (filling, emptying, etc.) or sampling of the substance when potential residual emission could be expected to the workplace or the environment.

Within a rigorously contained process some open processing steps may occur. For example, packaging and containers of isolated intermediate may remain open for short periods during equipment filling and emptying (via hose lines, pipe joints), during sampling (transfer from one container to another container via closed sampler) and when performing cleaning and maintenance. Consideration should be given to the transfer and management of the isolated intermediate in bulk through pipelines and dedicated bulk storage facilities. Containers or equipment open for any extended period of time should have suitable technical measures in place, which will be consistent with the characteristics and properties of the intermediate, e.g. local exhaust ventilation with subsequent waste gas treatment, to minimise release of the substance into the immediate surroundings from the container.

Examples of technical measures that could be implemented in order to ensure rigorous containment are given in examples 1 to 4 for worker and environmental protection in different industrial sectors. Those examples are in no way binding or exhaustive but illustrate the types of measures that can be applied.

Example 1 Pharmaceutical industry: examples of technical measures for workers and environmental protection.

Wherever possible, design containment is implemented to prevent exposure of the worker and the environment. The

design and selection of control technologies and equipment is based upon a set of performance based criteria. The selection of control measures that aim to control and prevent emissions at source is prioritised. Examples of technical measures may include:

Transfers using direct coupling and closed systems, also selected use of laminar air flow booths. Examples include:

- Vertical process trains
- Special valves such as split butterfly type
- Vacuum transfer
- Intermediate bulk containers

Totally enclosed processes; transfers using direct coupling; barrier/isolator technology. Examples include:

- Isolation technology e.g. isolators
- Intermediate bulk containers with split butterfly valves
- Soft Wall Isolators (Glove bags)
- Alpha Beta Rapid Transfer systems on enclosures
- Specialized vacuum transfer systems

Example 2 Petrochemical Industry: example of technical measures for workers and environmental protection.

Bulk petrochemical intermediates will invariably be handled in a chemical plant of a high integrity that is designed to minimise potential for emissions to air and water. Typical examples of control measures and systems in place to deliver such strictly controlled conditions include:

- Enclosed transfers designed to prevent leaks e.g. self-draining transfer lines
- High integrity methods of material loading and unloading (e.g dry lock couplings, vapour capture and recovery)
- Plant designed to facilitate the draining and flushing of plant equipment items prior to maintenance, with recycle and/or suitable disposal of wastes
- High integrity (low emission) valve packings and flange seals
- In-line process controls and/or contained systems for process sampling
- Low emission pumps e.g. canned, magnetic, mechanical seals
- Routine monitoring and inspection for leaks to reduce fugitive emissions

Example 3 Fine chemicals industry: examples of technical measures for workers and environmental protection.

Handling intermediates in batch fine chemicals facilities will require that the plant engineering and systems are designed to prevent emissions to air and water. Typical examples of control measures and systems which might be encountered to deliver such strictly controlled conditions include:

- Material transfers via enclosed systems (e.g. semi-bulk containers such as IBCs)
- Enclosed and vented charging systems (e.g. bag slitters with integral package disposal)
- Reaction vessel held by under-pressure (negative pressure). Exhaust air filtered and subsequently incinerated. Vessels connected via fixed pipes.
- Discharging arrangements designed to minimise emissions (e.g. into drums/kegs via pneumatic filling heads and continuous liners; vented booths with exhaust scrubbing, connection of big bags done in a full enclosure (e.g. glove box.)
- Use of containers fitted with inliners for intermediate packaging and transport.
- Plant designed to facilitate the draining and flushing (and detoxification) of equipment items prior to maintenance
- Maximal use made of automated process control systems to minimise manual interventions
- Contained process sample systems (e.g. vented cabinets or sample bombs)
- For batch processes in discontinuous equipment techniques, such as localized extraction, coupled with strict observation of operating procedures, can be appropriate for substance handling

- Loading/unloading in a closed collection pan to prevent spillage into waste water

Example 4 Fine chemicals Industry: charging a dusty substance to a reactor including cleaning and maintenance of the system

Processing of a powder of medium/high dustiness and high hazard properties both for human health and the environment.(substance classified harmful for human health and dangerous for the environment. Risk phrases R50-52, R22 and R68)

The following risk management measures contribute to the rigorousness of containment:

- Unloading of raw materials in dedicated filling station from big bags using a crane equipped with a closed cabin with filtered ventilation.
- All exhaust ventilation passes a bag filter before release. The filter is equipped with monitoring and alarm/halt system that detects leakages. Exhaust air is incinerated
- Dedicated unloading area with restricted access and kept under negative air pressure.
- Closed reaction vessels with dust collection system and filters.
- Automated process operated from a physically separated control room. Manual interventions under PPE, including respitarory protective equipment.
- Emptied and closed big bags are detached, re-encapsulated into PE foil and stored for incineration
- All transport processes are automated and enclosed.

Cleaning, maintenance and repair work will be done only after residues in the system are removed e.g. by rinsing with organic solvents and using appropriate protective equipment. The organic solvent is recycled or incinerated.

Example 5 Chemical industry: railway car loading and unloading of liquid products

Loading and unloading of railway car of liquid, volatile, products. Substance is classified dangerous for human health and the environment (risk phrases R20, R36/38)

The substance is stored into storage tanks and loaded into railway cars in order to be transported to another production site.

- Railway cars are loaded through connection arms.
- Informatic control system exists in order that loading can start only when the arm is well connected.
- At the end before disconnection, purge of arms is performed with N2 and gaseous substance is sent back to the tank as well as liquid phase in order to be recycled.
- Arm in aval is purged into a container which is reinjected into the unit through flexibles.
- Flexibles are cleaned and water is collected for treatment.

OC & SCC implemented to protect workers & environment

- Loading of wagon is done through an automated connection arm equipped with recommended diameter (DN 80 for liquid and DN 50 for gas)
- All couplings are equipped of ONIS lineblind system, avoiding exposure to residual hazardous chemicals

Example 6 Chemical and petrochemical industry: examples of technical measures for workers and environmental protection

Sampling of liquids via “CLIC adapter” and purging of sampling bottle and sampling line. This technique allows operators to take samples of liquid substances from distribution lines in complete absence of exposure.

- Distribution and storage of Heavy vacuum gas oil
- Enclosed transfers designed to prevent leaks (self-draining transfer lines).
- Plant design to facilitate draining and flushing prior to maintenance.
- High integrity (low emission) valve packings and flange seals (The rating of the
- valve type is in accordance to Fugitive Emission Tightness Class, Flange gaskets specified and the intermediate properties)
- Routine monitoring and inspection for leaks to reduce fugitive emissions.
- Storage tanks have floating internal roofs with double mechanical sealing
- systems are situated on concrete bases within a bund of a capacity required by the environmental permit. The tank floor and base sections of the walls are also painted to prevent corrosion. The tanks are cathodically protected. Storage tanks are installed with level controls incorporating High and High-High level alarms and an independent High level alarm.

Loading and unloading of tanks / truck tanks and railway tanks

- Top loading through dome with cone and with vapor recovery
- Top loading with dip tube and with vapor recovery
- Top loading with dip tube and with inert gas blanketing
- Bottom loading with closed manhole and with vapor recovery
- Bottom loading with closed manhole and with blanketing
- Bottom unloading by compressed air or inert gas
- Bottom unloading by pump with closed manhole and with intake of air
- Bottom unloading by gravity with closed manhole and with vapor return
- Bottom unloading by pump with closed manhole and with vapor return
- Bottom unloading by pump with closed manhole and with inert gas
- Top unloading by pump with closed manhole and with vapor return

Release and exposure data is a useful element to demonstrate that rigorous containment is achieved. Also reliable exposure model calculations can be used for this purpose.

Product-based containment procedures depend on the form and use of the substance, e.g. some degree of containment is inherent in a liquid or a pasty substance with a very low vapour pressure or for a solid that does not release dust in repacking/decanting or processing activities. Where a substance is in a matrix used for synthesis (e.g. masterbatch, glass, plastic), containment depends on the potential migration of the substance from the matrix.

2.1.2 Procedural and control technologies to minimise emission and any resulting exposure

Releases and any resulting exposure occurring despite rigorous containment by technical means of the process are to be minimised by procedural and control technologies. For example, in case of releases to waste water (including during cleaning and maintenance processes), strictly controlled conditions include techniques to minimise the emissions by, for example, incinerating the waste water or removal of substances by onsite treatment. before discharging the waste water. The same approach applies to emissions to air.

The effectiveness of any methods applied to minimise emissions and resulting exposure would be described in the detailed documentation kept in-house. Furthermore some details of these methods (e.g. efficiency) may need to be included in the registration dossier.

The documentation and description of methods applied can be based on the company's IPPC licence or permit, as long as sufficient and adequate documentation of the compliance with the conditions of the permit are available, and demonstrate strictly controlled conditions. In general, the relevant IPPC (Directive 2008/1/EC) Best Available Technique Reference Document (BREF) e.g. “Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector” can be used as a starting point to demonstrate effectiveness of procedural and control technologies.

Available information on the physico-chemical properties of the intermediate, human health and environmental hazards as well as information on the environmental distribution and fate can be used to put into perspective the minimization of residual emissions (generated although rigorous containment is in place). The registrant may include a qualitative justification for the level on minimization to be achieved.

In case there is largely incomplete or no information available on the toxicological and ecotoxicological properties, the intermediates are best treated as highly hazardous substances, with the consequence that virtually any emissions and exposure should be prevented.

Example 5: Technical measures to control emissions to the environment

- Waste gas incineration: complete destruction of waste gases at high temperatures for a specified minimum residence time, as calculated by an engineer.
- Condenser: low temperature devices through which waste vapours are sent causing them to liquefy and be collected.
- Scrubber: number of types available. Usually packed columns around which an appropriate scrubbing solution circulates, as specified by an engineer. The waste vapours from a process and/or area are passed through the scrubber causing the fumes to be trapped in the scrubbing solution. The waste scrubber solution is then disposed of by incineration.
- Hepa-filter: a filter designed to trap small particles. The general air from an area or a piece of equipment

passes through the filter before discharge to atmosphere. The contaminated filter is then disposed of by incineration.

- WWTP: a wastewater treatment plant is a biological and/or physical/chemical system to which the aqueous wastestreams from a process and washing/cleaning solutions are sent. Traces of the substance are removed from the water before discharge into the environment.
- Cryogenic treatment: very low temperature condenser which traps all the condensable materials as a liquid or a solid. This liquid or solid is then disposed of by incineration.
- Biofilter: a biofilter is a biological system where certain substances in vent streams are degraded by mico organisms

2.1.3 Handling of the substance by trained personnel

In order to minimise emissions and any resulting exposure, only trained and authorised personnel can handle the substance (*Article 18(4)(c)*). As a minimum, the workers who handle intermediates would be provided with:

- training and information on process and task specific operating procedures, appropriate precautions, working procedures during the malfunctioning of the process and in accidental situations, and actions to be taken in order to safeguard themselves and other workers at the workplace. Note that there would be
- appropriate filing and documentation of training.
- access to a safety data sheet (SDS), which includes information on the hazardous properties and on PBT/vPvB properties of the substance, such as its identity, the risks to safety and health, relevant occupational exposure limit values (EU and national ones) and other relevant legislative provisions.

These procedures should apply to all personnel handling the substance including during cleaning and maintenance works.

2.1.4 Cases of accident and where waste is generated

There must be procedural and/or control technologies in place that are used in cases of accidents and in cases where waste is generated (*Article 18(4)(e)*). In this, the clarifications according to Directive 96/82/EC on the control of major-accident hazards involving dangerous substances and Directive 94/9/EC concerning equipment and protective systems intended for use in potentially explosive atmospheres might usefully be consulted and the requirements implemented. Management Systems

Management systems are good options to ensure the proper application of risk management measures. A management system includes appropriate operational procedures to ensure that control measures are indeed applied[13]. Such a system may also define management responsibilities, authorisation procedures (e.g. for maintenance or opening of equipment), inspection and auditing requirements etc.

[13] In practice management systems include the structure to respond to accidents and demonstrate compliance with relevant occupational and environmental legislation and/or standards.

On any given site, a management system should contain reference to procedures for accident prevention and response. It may be appropriate to link this system to operational engineering control systems. In case of a transported intermediate, the various parties involved (supplier and customer) each will need a management system in order to ensure rigorous containment and controlled conditions over the life cycle of the intermediate.

2.2 Registration requirements for on-site isolated intermediates.

On-site isolated intermediates manufactured in quantities of 1 tonne or more per year have to be registered to the Agency. In order to benefit from the reduced registration requirements for on-site isolated intermediates, the manufacturer must confirm that the substance is used and manufactured only under strictly controlled conditions during its whole lifecycle as defined in *Article 17(3)* (see also section 2.1).

The information required under *Article 17(2)* is the following:

- **The identity of the manufacturer**: the information to be submitted is detailed in section 8.2.2.3 of the Guidance on registration.
- **The identity of the intermediate**: the information to be submitted to identify the substance is the same as that to be submitted for a full registration (see 8.2.2.3 of the Guidance on registration) with the exception of analytical methods descriptions (section 2.3.5 to 2.3.7 of Annex VI) which are not required.
- **The classification of the intermediate:** the registrant has to determine the classification of his substance with respect to physicochemical properties, environment and human health. This classification has to be documented in section 2 of IUCLID 5, under the heading "classification". More guidance on classification and labelling is available in section 8.2.2.4 of the Guidance on registration.
- **Any available existing information on physicochemical, human health or environmental properties of the intermediate:** when the registrant is in legitimate possession or has the permission to refer to a full study report (a full study report or study summary can be used freely after at least 12 years after its submission in the framework of a registration (*Article 25(3)*), he shall submit a study summary within his registration, unless in case of joint registration when the lead registrant submits the information (see section 2.5). How to prepare a study summary is described in section 8.2.2.4 of the Guidance on registration.
- **A brief general description of the use:** only a brief general description of the identified use(s) of the substance as described in section 3.5 of Annex VI is required for isolated intermediates. More details can be found on what needs to be reported in section 8.2.2.5 of the Guidance on registration.
- **Details of the risk management measures applied**: the details of the risk management measures should be reported in section 13 of IUCLID (stand alone RMM report, format see Appendix 3) The information has to include a description of the efficiency of the risk management measures applied, sufficient to demonstrate that the substance is rigorously contained during its whole lifecycle and that it is manufactured and used under strictly controlled conditions. More information on how to describe the risk management measures applied and their efficiency is available under Appendix 3..

If from the available information and knowledge of the process the registrant is not able to conclude that the substance is manufactured and used under strictly controlled conditions, a full registration in accordance with *Article10* has to be submitted as described under the Guidance on registration.

2.3 Registration requirements for transported isolated intermediates

Transported isolated intermediates have to be registered to the Agency if they are manufactured or imported in quantities of 1 tonne or more per year. In order to benefit from the reduced registration requirements for transported isolated intermediates, the manufacturer or importer must confirm himself or state that he has received confirmation from user(s) that the substance is used and manufactured only under strictly controlled conditions during its whole lifecycle as defined in *Article 18(4)* (see also section 2.1).

Therefore the registrant of a transported intermediate should first get the necessary confirmation from the different users to whom the substance is supplied whether the substance is used under strictly controlled conditions or not.

For transported isolated intermediates below 1000 t/a, the information required under *Article 18(2)* is the following:

- **The identity of the manufacturer or importer**: the information to be submitted is detailed in section 8.2.2.3 of the Guidance on registration.
- **The identity of the intermediate**: the information to be submitted to identify the substance is the same as that to be submitted for a full registration (see section 8.2.2.3 of the Guidance on registration) with the exception of analytical methods descriptions (section 2.3.5 to 2.3.7 of Annex VI) which are not required.
- **The classification of the intermediate:** the registrant has to determine the classification of his substance with respect to physicochemical properties, environment and human health. This classification has to be documented in section 2 of IUCLID 5, under the heading "classification". More guidance on classification and labelling is available in section 8.2.2.4 of the Guidance on registration.
- **Any available existing information on physicochemical, human health or environmental properties of the intermediate:** when the registrant is in legitimate possession or has the permission to refer to a full study report (a full study report or study summary can be used freely after at least 12 years after its submission in the framework of a registration (*Article 25(3)*), he shall submit a study summary within their registration, unless in case of joint registration when the lead registrant submits the information (see section 2.5). How to prepare a study summary is described in section 8.2.2.6 of the Guidance on registration.
- **A brief general description of the use:** only a brief general description of the identified use(s) of the substance as described in section 3.5 of Annex VI is required for isolated intermediates. More details can be found on what needs to be reported in section 8.2.2.5 of the Guidance on registration.
- **Details of the risk management measures applied and recommended to the user, making reference to Article 18(4)**: the details of the risk management measures should be reported in section 13 of IUCLID (stand alone RMM report, format see Appendix 3) The

information must include a description of the effectiveness of the risk management measures applied, sufficient to demonstrate that the substance is rigorously contained during its whole lifecycle and that it is manufactured and used under strictly controlled conditions. More information on how to describe the risk management measures applied and their effectiveness is available in Appendix 3t.

For transported isolated intermediates in quantities of 1000 tonnes or more per year per manufacturer or importer the registrant shall include in addition information specified in Annex VII of the Regulation. More details can be found on what needs to be reported in the Guidance on registration.

From the available information and knowledge of the process on the different sites, or if no confirmation is available, the registrant may not be able to conclude that the substance is used under strictly controlled conditions. In that case, a full registration (including the complete set of information as requested for "standard" substances and described in the Guidance on registration has to be submitted taking into account the manufactured or imported tonnage of the substance.

2.4 Preparation of a registration dossier for isolated intermediates

Article 111 requires that the format of the technical dossier must be IUCLID (International Uniform Chemical Information Database). This means that also other IT tools could be used to prepare the dossiers as long as they produce the exact same format. In this document only the preparation of registration dossier using IUCLID is described. The last version of this software is IUCLID 5 which will be used as the reference in this document and for which a specific guidance is available Guidance on IUCLID. The IUCLID 5 software will be downloadable from the IUCLID website at http://iuclid.eu free of charge by all parties, if used for non-commercial purposes.

The full registration dossier should be submitted via REACH IT to the Agency as described in section 8.2 of the Guidance on registration.

For intermediates, IUCLID 5 enables the registrant to identify the information requirements for either on-site isolated intermediates, transported isolated intermediates produced at up to 1000 tonnes and transported isolated intermediates produced at 1000 tonnes or more per year. In each case, all available and relevant information need to be reported in the registration dossier. Depending on the selection of the registrant the fields to be filled in IUCLID 5 are clearly identified.

2.5 Joint submission of data on isolated intermediates by multiple registrants.

A substance being used as an isolated intermediate (on-site or transported) may be manufactured or imported by several different registrants, for intermediate or non intermediate uses. In such situation joint registration needs to be submitted. The registrants have to follow the general guidance developed for joint registration (See section 1.8.4 of the Guidance on registration).

Specific rules apply to registrants of intermediates as specified in *Article 19*.

Once the lead registrant has been identified, he has to submit first the following joint information with the agreement of the other manufacturer(s) or importer(s):

- the classification of the intermediate, and
- any available existing information on physicochemical, human health and environmental properties of the intermediate.
- In case one of the registrant manufactures or imports isolated transported intermediates at or above 1000 tonnes, it is recommended that the lead registrant provides the information in Annex VII, in accordance with article 18(3).

Each registrant shall then submit separately specific information:

- identity of manufacturer
- identity of intermediate
- a brief general description of the use (i.e. intermediate for chemical synthesis)
- details of the risk management measures

If one registrant does not want to submit information on the classification or on the physicochemical, human health and environmental properties jointly, it is possible for him to do it separately, as far as there is a clear and justified rationale of separate submission according to the reasons set in *Article 19(2)*. These reasons are:

- *it would be disproportionately costly for him to submit them jointly, or*
- *submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment, or*
- *he disagrees with the lead registrant on the selection of this information.*

A general guidance on how to document reasons for submitted data separately for joint registration is developed under the full Guidance on registration.

2.6 Time lines

The same rules apply for the registration of intermediates and the registration of non intermediates. Section 1.7 of the Guidance on registration describes those rules in detail.

Substances already notified under Directive 67/548/EEC, are considered as registered. Nevertheless some provisions apply and details can be found in section 1.6.5.3 of the Guidance on registration.

2.7 Registration fee

Registration fees are specified in Regulation (EC) 340/2008. .

APPENDIX 1: ILLUSTRATIVE LIST OF ISSUES THAT MAY BE TAKEN INTO CONSIDERATION FOR CHECKING THAT THE ISOLATED INTERMEDIATES ARE MANUFACTURED UNDER STRICTLY CONTROLLED CONDITIONS

This list can be used by

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

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

1. Has the life cycle of the substance been accounted for

a) Manufacture of the intermediate? Continuous process or batch operation? Scale of operation?

b) Use of the intermediate? Continuous process or batch operation? Scale of the operation?

c) Final synthesis process?

d) Any purification step?

e) Sampling and analysis?

f) Loading and unloading from equipment or vessels and any other substance transfers?

g) Any relevant storage?

h)

i) Waste treatment?

2. Is rigorous containment by technical means in place?,

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

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

c) Management system is in place

d) Implementation of existing EU legislation

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

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

a) Residual emissions from rigorous containment occur at the following steps of the processes. ……. These emissions are minimised by the following procedural and control techniques (differentiation regarding work-places and environment required): …….

b) Emissions from purification, cleaning and maintenance after accidents are minimised by the following procedural and control techniques (differentiation regarding work-places and environment required): …….

c) Emissions from purification, cleaning and maintenance are minimised by the following procedural and control techniques (differentiation regarding work-places and environment required): …….

d) Emissions from waste handling is minimised by the following procedural and control techniques (differentiation regarding work-places and environment required):

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

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

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

c) Other legislative frameworks that control the handling of the substance have been considered

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

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

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

c) Risk management measures are applied during cleaning and maintenance

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

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

a) Occupational procedures have been assessed and are documented

7. For transported isolated intermediates:

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

APPENDIX 2: EXAMPLE OF FORMAT FOR DOCUMENTING IN-HOUSE INFORMATION ON STRICTLY CONTROLLED CONDITIONS OF ISOLATED INTERMEDIATES

This format can be used by

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

1. **Description of technological process used in manufacture**
2. **Description of the uses of the substance.**

Give a description of the uses of the substance on the different sites.

Check that any relevant storage, processing and the synthesis process of the final substance have been accounted for.

3. **Is the substance rigorously contained:**

a. During the manufacturing process?

- Description of the process and technical means to contain the substance.
- Identification of potential emissions to:
  - Workplace
  - Environment
- Modelling estimations or available monitoring data if needed
- Procedure and systems in place to comply with existing health, safety and environmental legislation.

b. During the use?

- Description of the process and technical means to contain the substance.
- Identification of potential emissions to:
  - Workplace
  - Environment (air, wastewater, soil, etc.)
- Modelling estimations or available monitoring data if needed.

c. During substance transfers before and after transport?

- . Description of the process and technical means to contain the substance.

- Identification of potential emissions to:
  - Workplace
  - Environment (air, wastewater, soil, etc.)
- Modelling estimations or available monitoring data if needed.

4. If emissions have been identified on sites of manufacture or uses, are there procedural and control technologies to minimise emission and resulting exposure?

Give a description of these procedural and control technologies in place, including those applied after accidents and for waste collection and treatment.

5. Is the substance handled by trained and authorised personnel?

- Is the personnel provided with safety data sheet (SDS) of the substances handled?
- Is there sufficient training and information on appropriate precautions and working procedures (proper labelling of specific working places) at workplace?
- Is it guaranteed that only trained personnel handles dangerous substances?

Give a description of the information and training in place.

APPENDIX 3: FORMAT FOR DOCUMENTING INFORMATION ON RISK MANAGEMENT IN A REGISTRATION DOSSIER FOR ISOLATED AND TRANSPORTED INTERMEDIATES

This format can be used by the registrant of an isolated intermediate (the manufacturer or importer). To be attached into 13 of the IUCLID dossier with the file name _RMM details(In case the M/I has DUs using the intermediate: We have communicated the specifications presented below to our DUs and received confirmation that their conditions meet the specifications)

1. **Brief description of technological process applied in manufacture of the intermediate.**

Include a process flow chart if available. Ensure that all relevant activities (unit operations) are covered in this description, such as synthesis as such, purification steps, cleaning and maintenance, sampling and analysis, loading and unloading, storage and waste treatment

2. **Brief description of technological processes applied in use of the intermediate.**

Include a process flow chart if available. Ensure that all relevant activities (unit operations) are covered in this description, such as synthesis as such, purification steps, cleaning and maintenance, sampling and analysis, loading and unloading, storage and waste treatment

3. **Means of rigorous containment and minimisation technologies applied by the registrant during the manufacturing and/or use process**
    - Description of the technical means to rigorously contain the substance. *Make reference to different activities (unit operations) and life cycle stages as appropriate (see Appendix 1)*
    - Identification of residual emissions to:
        - Workplace
        - Environment (air, onsite water streams)
    - Description of the procedural and control technologies in place to minimise emission and resulting exposure. *Include quantification of releases and information on effectiveness of control techniques as appropriate*.
        - Workplace
        - Environment (air, waste water, discharge from site)
    - Specify the management means and training that particularly contribute to the functioning of the technical means described above.
4. **Means of rigorous containment and minimisation technologies recommended to the user of the intermediate:**

- Description of the technical means to rigorously contain the substance. *Make reference to the different life cycle stages and activities (unit operations) as appropriate (see Appendix 1)*
- Identification of residual emissions to:
  - Workplace
  - Environment (air, onsite water streams)
- Description of the procedural and control technologies in place to minimize emission and resulting exposure? *Include quantification of releases and information on effectiveness of control techniques as appropriate*.
  - Workplace
  - Environment (air, waste water discharge from site)
- Specify the management means and training that particularly contribute to the functioning of the technical means described above.

In the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered

5. Special procedures applied before cleaning and maintenance

- Description of the special procedures (such as purging and washing) applied before the system (any contained operation units within the life cycle of the substance) is opened and entered for cleaning and maintenance work.

6. **Specific activities with the intermediate at the registrant's site where PPE is required to limit exposure of workers to levels that no adverse health effects can occur. *Specify the activity and the type of PPE both for normal conditions of use, and to accidents and incidents.***

7. Waste information

- Identify the process stages where waste is generated (e.g. purification, maintenance, emission controls).
- Quantify the amount for each of this waste streams
- Briefly describe the type of treatment applied onsite
- Briefly describe the type of treatment applied offsite. .