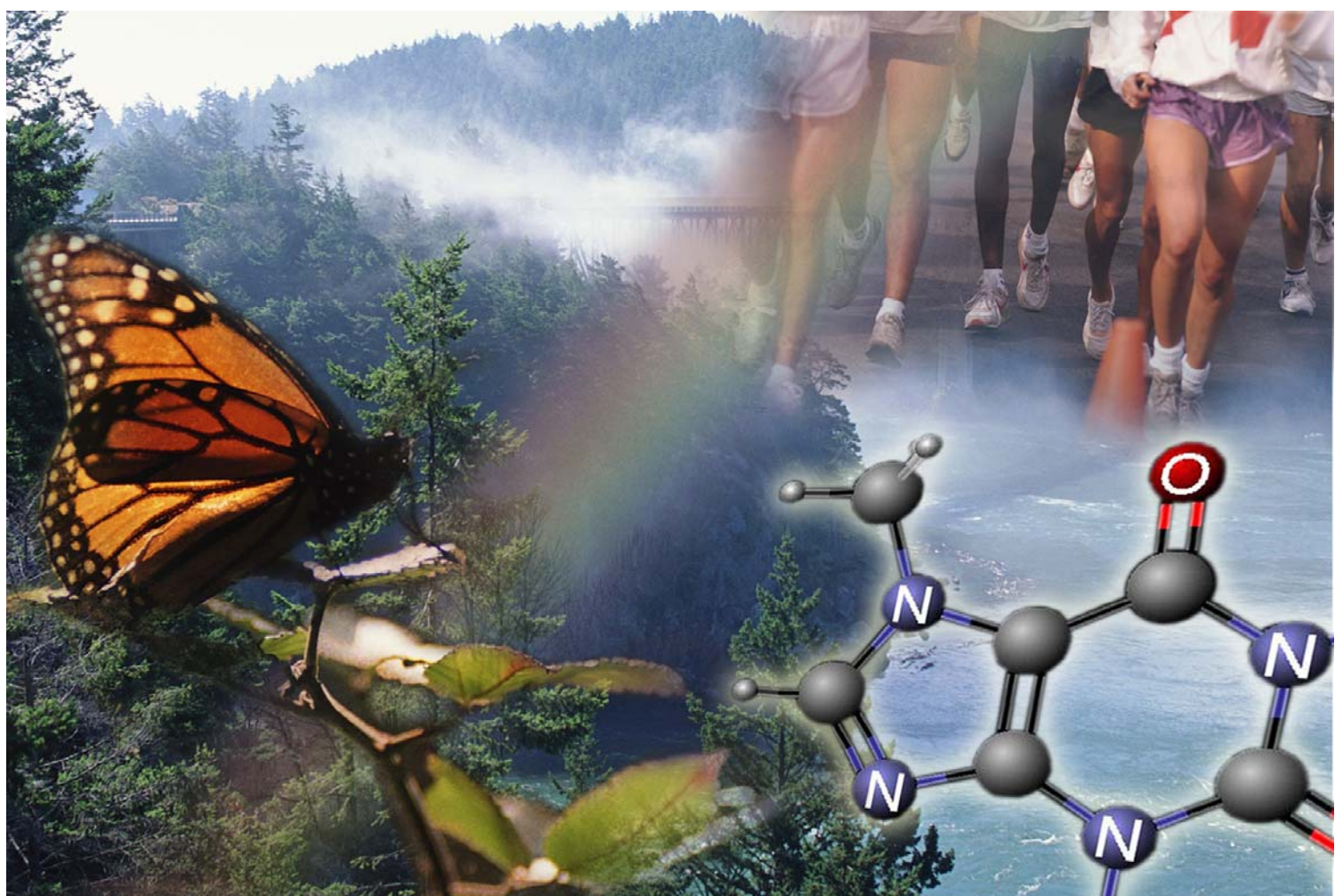


Guidance for intermediates



February 2008

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

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006¹

This is the first update of this guidance. The changes are tracked in Appendix 3.

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).

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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(s)* (Article 3 (15)). Therefore intermediates should not be present in the final manufactured substance (except possibly as an impurity).

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)).

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 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 obligation to register substances. 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 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*).
- In cases when an on-site isolated intermediate is a monomer (see [Guidance for polymers](#)) used for polymerisation, the reduced registration provisions for intermediates do not apply to the substance and the manufacturer has to proceed as for a "standard" substance (see [Guidance on registration](#)).
- If a notification under Directive 67/548/EEC covering the relevant use has already been submitted by the manufacturer/importer, no registration is required (*Article 24*); the substance will be considered as registered and a registration number will be 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 must notify to the Agency the information related to its classification and labelling if (*Article 113*):

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

This has to be done before 1st December 2010 for substances already on the market at that date or, for substances that were not yet on the market on 1st December 2010, as soon as the substance is put on the market (*Article 116*).

For on-site isolated intermediates registered before 1st December 2010 the classification and labelling will be reported in the registration dossier so that no separate notification is required.

If the on-site isolated intermediate is a phase-in substance manufactured at less than one tonne per year, the manufacturer must notify to the Agency the information related to its classification and labelling if (*Article 113*):

- he puts the substance 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 dangerous

This has to be done before 1st December 2010 for substances already on the market at that date or, for substances that were not yet on the market on 1st December 2010, as soon as the substance is put on the market (*Article 116*).

For non phase-in substances manufactured at 1 tonne or more per year a registration dossier has to be submitted in any case including the classification and labelling; in that case a notification is not necessary.

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 risk is not properly controlled (*Article 49*).

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 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 [section 1.6 of the Guidance on registration](#)). The information to be submitted for standard registration purposes (i.e. not reduced requirements due to strictly control conditions in place) 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 obligation to register substances. 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 available data (e.g. information he holds himself or that he can obtain from other sources) and only study summaries have to be submitted 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*).
- If the transported isolated intermediate is a monomer used for polymerisation, the reduced registration provisions for intermediates do not apply to the substance and the manufacturer has to proceed as for a "standard" substance (see the [Guidance on registration](#)).
- However, if a notification under Directive 67/548/EEC covering the relevant use has already been submitted by the manufacturer/importer, no registration is required (*Article 24*). The substance will be considered as registered and a registration number will be 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 if (*Article 113*):

- he puts 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.

This has to be done before 1st December 2010 for substances already on the market at that date or, for substances that were not yet on the market on 1st December 2010, as soon as the substance is put on the market (*Article 116*).

For transported isolated intermediates registered before 1st December 2010 the classification and labelling will be reported in the registration dossier so that no separate notification is required.

If the transported isolated intermediate is a phase-in substance manufactured at less than one tonne per year, the manufacturer must notify to the Agency the information related to its classification and labelling if (*Article 113*):

- he puts 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 dangerous

This has to be done before 1st December 2010 for substances already on the market at that date or, for substances that were not yet on the market on 1st December 2010, as soon as the substance is put on the market (*Article 116*)

For non phase-in substances manufactured at 1 tonne or more per year a registration dossier has to be submitted in any case including the classification and labelling; in that case a notification is not necessary.

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 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

This guidance is intended to support registrants to answer the question, whether a registration according to *articles 17 or 18* can be provided or whether a full registration is required for an intermediate.

Isolated intermediates (on-site as well as transported intermediates) are within the scope of REACH although specific requirements apply for their registration (*Articles 2(8), 17, 18, and 19*).

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.

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 use(s) are not 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 under strictly controlled conditions, the registrant can submit one registration dossier covering all

his tonnage. The information requirements for this registration dossier are 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 as 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 the use as intermediate under strictly controlled conditions (fees for intermediates) and for the other uses (standard fees).

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 *Article 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](#).

A fee must accompany any registration of an intermediate.

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](#) 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) without any additional 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 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 in that it is rigorously contained by technical means during its whole lifecycle (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 Article 18(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 uses. When filling his registration dossier using IUCLID²⁵ the registrant must report if the substance is manufactured and used under strictly controlled conditions or not and can provide the confirmation of this (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 the following conditions, as detailed in *Article 18(4)*, are in place:

- (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;*

² International Uniform Chemical Information Database

(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 control in *Article 18(4)* for transported isolated on-site intermediates can be used as a working basis for isolated on-site intermediates also. *Article 18(4)* provides a wider definition of strict control than *Article 17(3)* which is limited to criteria (a) and (b) of the above list. This does not mean that criteria (c) to (f) cannot also be appropriate criteria to determine strict control also for on-site isolated intermediates. This definition covers both: (i) normal operating conditions and (ii) non-routine operational circumstances such as maintenance and incidents.

For both types of intermediates, on the basis of the assessment and description of the conditions under which the substance is manufactured and/or handled on site(s) of both the manufacturer and the user in case of transported intermediates, the registrant has two possibilities:

- Submit a registration dossier containing the limited set of data requested for intermediates, provided that he concludes that the substance is manufactured and used under strictly controlled conditions.
- Submit a full registration dossier as described in *Article 10*, if he is not able to conclude that the substance is manufactured and used under strictly controlled conditions.

Strictly controlled conditions should be seen as a combination of technical measures that are underpinned by management systems. This approach to managing human health and environmental risks aligns with and acknowledges the existing regulatory obligations that impact on manufacturers of substances (e.g. control of accidents under Directive 96/82/EC³, Integrated Pollution Prevention and Control under Directive 96/61/EC⁴, occupational protection under the Chemical Agents Directive 98/24/EC⁵). This approach includes training, process controls, management systems, monitoring, personal protective equipment (PPE) where combinations of 'hardware' and 'software' measures (using, in some cases, a hierarchy of preferences) strictly control risks. However it should be kept in mind that the use of PPE, for example, should not have a prime role when determining whether workplace exposures to an intermediate are strictly controlled as the use of such measures alone generally cannot equate to strictly controlled conditions. It is recognised that PPE should be recommended and used especially in relation to sampling, maintenance and repair.

A full explanation of the strictly controlled conditions in place is not required in the registration dossier, however the assessment of the use(s) of any substance (or group of similar substances) as intermediate(s) should be documented within a company in order to show the adequacy of the measures as authorities may request such information which then must be made available. Where relevant, documentation for compliance with other legislative frameworks can also be referred to.

³ Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances.

⁴ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control

⁵ 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.

The documentation may include:

- justification for the assignment of use as an intermediate to the substance, including customers' statements if a transported isolated intermediate;
- the relevant operating conditions;
- the risk management measures implemented in the company and recommended to external customers;
- the corresponding exposure considerations and
- reference or derivation of any relevant threshold value (e.g. Derived No Effect Levels (DNELs), Predicted No Effect Concentrations (PNECs)) including the relevant physico-chemical, toxicological and ecotoxicological data, including data from substance grouping where available.

The details of the risk management measures applied and recommended to the user, which reflect the strictly controlled conditions, should be included in the registration dossier. Existing legislative frameworks or industry standards can be used when documenting the risk management.

To facilitate the process for assessing whether strict control is achieved, Appendix 1 presents an indicative and non-exhaustive list of issues that could be considered. This approach is only intended as a user-friendly tool to document the process of assessing the conditions of strict control. The actual process behind answering the questions involves considerable analyses by relevant people (e.g. site managers, engineers). Although transported isolated intermediates require communication through the supply chain for confirmation that strictly controlled conditions are achieved, the process for documenting strict control does not require the interchange of information that could be seen to constitute confidential business information (e.g. fine detail of process technology and/or engineering, etc).

An example of a general format to document how the substance is manufactured and used in strictly controlled conditions is also proposed in Appendix 2. This should contain information and justification on the relevant issues raised in Appendix 1. Please also note that any information produced for the purpose of other pieces of legislation (e.g. worker protection legislation) can of course be used as an element to demonstrate strictly controlled conditions.

2.1.1 Rigorous containment of the substance

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. It is applicable to handling of intermediates at any scale.

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.

The intermediate needs to be rigorously contained by technical means during its whole life cycle which includes the manufacture, the isolation of the intermediate out of the reaction mixture, if necessary further purification steps (e.g., distillation, re-crystallisation, filtration), cleaning and

maintenance, sampling, analysis, loading and unloading of equipment/vessels, waste disposal/purification and storage, and the use in synthesis.

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

The description of these technical means and conditions should allow the identification of potential exposure of workers and the environment to the substance. One way to do this is to assure the necessary level of leakproofness of the different functional elements (pressurised vessels, seals, sacks, containers, drums, etc.) involved during the different steps of the whole process such as manufacture, transfer (filling, emptying, etc.) or sampling of the substance when potential emission could be expected to the workplace or the environment.

For example, isolated intermediate packaging and containers should only 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 measures in place, which will be consistent with the characteristics and properties of the intermediate, e.g. efficient exhaust ventilation, to prevent any significant release of the substance into the immediate surroundings from the container. For companies operating batch processes in discontinuous equipment there may be other considerations, but the risk management adopted in these companies must also identify a suitable combination of technical measures.

Examples of technical measures that could be implemented in order to ensure rigorous containment are given in examples 2 to 4 for workers 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 2 Pharmaceutical industry: examples of technical measures for workers and environmental protection.

Wherever possible, design containment is implemented to prevent exposure of the worker. 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 unidirectionalised air flow booths. Examples include:
 - Engineered Airflow Device
 - Ventilated enclosures e.g. laminar flow/powder containment booth
 - Vertical process trains
 - Special valving such as split butterfly valves
 - 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
 - Specialised Vacuum transfer systems

Emissions and exposures of the environment are controlled by technical measures.

Examples of technical measures to control emissions to the environment may include:

- 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 system to which the aqueous wastestreams from a process and washing/cleaning solutions are sent. Microbes in the WWTP break down the organic constituents of the wastestreams to CO₂ and water before discharge into the environment.
- Cryogenic treatment is a 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.

Example 3 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 4 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 minimise potential for 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)
- Discharging arrangements designed to minimise emissions (e.g. into drums/kegs via pneumatic filling heads and continuous liners; vented booths with exhaust scrubbing)
- 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)

If the information available to determine whether the substance is rigorously contained during manufacture, use and handling, is not sufficient, then reliable model calculations and/or monitoring data could also be used to assess the exposure of workers or the environment to the substance.

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 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

Any significant release of the substance into the wider environment should be prevented through containment procedures, such as suitable physical barriers (e.g. bunds) and/or chemical barriers (e.g. membranes). Operations on site should be managed in order to ensure containment within the site premises wherever possible, including accident prevention, as specified under the section 2.1.5.

An additional way to minimise emissions and resulting exposure is to apply procedural and control technologies when emissions have been identified. Such technologies allow to still consider the substance to be rigorously contained. For example, in case of emissions to waste water (including during cleaning and maintenance processes), it will be considered that the substance is rigorously contained if the registrant can prove that techniques are used to minimise the emissions by, for example, incinerating the waste water or extracting the intermediate from it. The same applies to emissions to air or disposal of wastes where procedural and control technologies are used to minimise potential exposure of humans and environment. The efficiency of any methods applied to minimise emissions and resulting exposure should be described and documented in-house. Furthermore the details of these methods (e.g. efficiency) must be included and described 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 rigorous containment of the substance.

Following an assessment of containment, the selection and use of further risk management measures, equipment standards and safety procedures will vary considerably across industry and be dependent on the process and on the physico-chemical properties and the hazard of the substance, when sufficiently well known.

2.1.3 Handling of the substance by trained personnel

In order to minimise emissions and any resulting exposure, it is important that only trained and authorised personnel handle the substance (*Article 18(4)(c)*). As a minimum, the registrant should take care that the workers who handle intermediates are provided with:

- training and information on 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.
- access to a safety data sheet (SDS), which includes information on the hazardous 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.

2.1.5 Management Systems

Management systems are good options to ensure the proper application of risk management measures. A management system should include the relevant operational procedures to ensure that control measures are indeed applied⁶. Such a system may also define management responsibilities, authorisation procedures (e.g. for maintenance or opening of equipment, inspection and auditing requirements etc).

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 [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.

⁶ In practice management systems include the structure to respond to accidents and demonstrate compliance with relevant occupational and environmental legislation and/or standards.

- **The classification of the intermediate:** the registrant has to determine the classification of his substance with respect to physico-chemical 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 8.2.2.6 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:** the details of the risk management measures should be reported in section 11 of IUCLID (Guidance on safe use), in particular in the fields “Handling and storage” and “Exposure controls/personal protection”. The information has to include a description of the efficiency of the risk management measures applied sufficient to demonstrate that the substance is manufactured and used under strictly controlled conditions in that it is rigorously contained during its whole lifecycle. More information on how to describe the risk management measures applied and their efficiency is available under the [Guidance on Chemical Safety Report](#).

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 *Article 10* 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 physico-chemical 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:** the details of the risk management measures should be reported in section 11 of IUCLID (Guidance on safe use), in particular in the fields “Handling and storage” and “Exposure controls/personal protection”. The information must include a description of the efficiency of the risk management measures applied sufficient to demonstrate that the substance is manufactured and used under strictly controlled conditions in that it is rigorously contained during its whole lifecycle. More information on how to describe the risk management measures applied and their efficiency is available under the [Guidance on Chemical Safety Report](#).

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> for free 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 in 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 in 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 in the Guidance on registration](#).

2.7 Registration fee

A registration fee will be specified in a Commission Regulation at the latest one year after entry into force of the REACH Regulation.

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? Continuous process or batch operation? Scale of operation?
- b) Any relevant storage?
- c) Any processing?
- d) Final synthesis process?
- e) Disposal, waste treatment?

2. Are procedural and control technologies being used?

- a) The substance is rigorously contained
- b) Appropriate risk management measures are applied
- c) Management system is in place
- d) Implementation of existing EU legislation

3. 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

- 4. 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, e.g. purging and washing are applied before the system is opened.
- 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
 - b) Operating system checks include accident prevention and waste management
- 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.

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.

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?

Give a description of the information and training in place.

APPENDIX 3 : UPDATE OF THE DOCUMENT.**I. Update of the June 2007 version**

Section	Change made
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
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..
2	Clarification that the registration is only needed if the substance is not exempted from registration.
2	<p>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.</p> <p>At the end of the 4th paragraph a sentence has been added to explain how the fees will be calculated.</p>
2	In the 3 rd paragraph from bottom of page 12 some words have been added to clarify that the information requirements applies only to the transported intermediates.
2.1	In 2 nd bullet point the reference to EU or non EU sites has been deleted.
2.2	<p>In the classification section, some text has been added to clarify that only classification and no labeling is necessary for intermediates.</p> <p>In addition it has been specified where the risk management measures and the strictly controlled conditions should be reported.</p>
2.3	<p>In the classification section, some text has been added to clarify that only classification and no labeling is necessary for intermediates.</p> <p>In addition it has been specified where the risk management measures and the strictly controlled conditions should be reported.</p>
2.5	Another bullet point has been added to the 3 rd paragraph to specify what the lead registrant is recommended to submit.
2.7	Some words have been added to clarify when the registration fee will be specified.
Appendix 3	List of changes made during the update has been added.