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EUROPEAN ASSOCIATION OF METALS

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Disclaimer:

This draft document endeavours ~~tries~~ to describe when and how the specific provisions for the registration of intermediates under REACH can be used in our sector.
This draft focuses on intermediates, for which there is no exemption from Title II on Registration.

The author reserves the right not to be held responsible for the topicality, correctness, completeness or quality of the information provided. Liability claims regarding damage caused by the use of any information provided, including any kind of information that is incomplete or incorrect, will therefore be rejected.

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1. Introduction

How is an intermediate defined under REACH?

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)). Intermediates should therefore not be present in the final manufactured substance (except possibly as an impurity).

Definition of "manufacture" as well?

Different types of intermediates are defined under REACH (see also glossary)

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

1.b What is at stake?

- Substances that fulfilFor the conditions ~~for~~use of a substance as a–for non-isolated intermediates, there are out of the scope of no obligations under REACH *(Article 2(1)(c))*. *(See glossary for definition)*
- Existing REACH requirements for isolated intermediates:

	Registration	Classification	Evaluation	Authorisation
On-site isolated intermediates	*Article 2 (8)* exempts intermediates from the general obligation to register substances. A manufacturer of an on-site isolated intermediate has to register his substance in quantities of 1 tonne or more per year, as specified in chapter 3 of Title II of REACH.	If phase-in substance to be registered: the manufacturer must notify to the Agency the information related to its classification and labelling if 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. Timing: < 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	Dossier and substance evaluation do not apply. However, the Member State Competent Authority (MSCA) where the manufacturing site is located may request additional information if 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 that risk is not properly controlled	All Intermediates are not subject to authorisation (i.e. Title VII – Authorisation - does not apply). Any manufacturer/importer or downstream user must check whether an intermediate is covered by any restriction in Annex XVII of REACH

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	Registration	Classification	Evaluation	Authorisation
Transported isolated intermediate	*Article 2 (8)* exempts intermediates from the general obligation to register substances. A manufacturer of a transportedan on-site isolated intermediate has to register his substance in quantities of 1 tonne or more per year, as specified in chapter 3 of Title II of REACH.	If phase-in substance to be registered: the manufacturer, importer must notify to the Agency the information related to its classification and labelling if 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. Timing: < 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	Dossierdossier and substance evaluation apply to transported isolated intermediates. The Agency or, if there is no agreement between MSCA, the Commission may request additional information when it is conducting an evaluation.	Intermediates are not subject to authorisation (i.e. Title VII – Authorisation - does not apply). Any manufacturer/importer or downstream user must check whether an intermediate is covered by any restriction in Annex XVII of REACH

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Registration and data requirements

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.

Registrants of both on-site and transported isolated intermediates can, however, 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 Article 18(4):*

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- For on-site isolated intermediates, if 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)), 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)
  If strictly controlled conditions are not met, a full (standard) data package is required depending on the tonnage level (Articles 10 & 12).

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- For transported isolated intermediates, if 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 (Article18(4)) 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).
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 manufacturer or importer of a substance manufactures or imports the substance for other purposes than only 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*. If part of the tonnage manufactured or imported is for use as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirements of the full registration dossier and could, but it will nevertheless need to be registered separately as an intermediate.reflected in the ES/CSA where applicable. (?)

Main advantages of a lighter registration package: fewer data requirements, decreased costs

Suggestion to add this kind of decision tree (can be refined and discussed)

Main advantages of a lighter registration package: less data requirements, flexibility, possibility for read-across, decreased costs (?)

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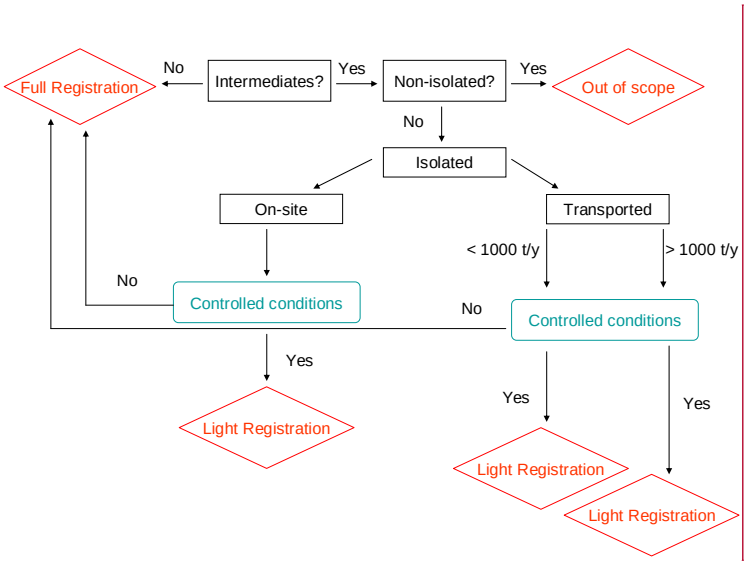

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Add "strictly" to "controlled conditions"
No point in distinguishing between <1000 and >1000 t/y unless different message given

~~**b.**~~
~~**c.**~~
~~**d.**~~

~~*c.*~~ ***1.c How are strictly controlled conditions defined?***

Guidance on strictly controlled conditions is available in the RIP 3.1 TGD.

Overall, strictly controlled conditions should be seen as a combination of technical measures that are underpinned by management systems.

Article 18(4) states that, in order to assess whether ~~if~~ the intermediate is manufactured and used under strictly controlled conditions during its whole lifecycle, the registrant should evaluate whether ~~if~~ the following conditions are met:

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
(b) procedural and control technologies shall be used that minimise emission and any resulting exposure;
(c) only properly trained and authorised personnel handle the substance;
(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
(e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures
(f) substance-handling procedures are well documented and strictly supervised by the site operator.

1.d Scope of this draft guidance document

The overall objective of this document is to ~~define~~ interpret the concepts of strictly controlled conditions in our sector and endeavour to ~~draft a registration approach~~~~approach~~enhance/improve the existing Intermediates Fact Sheet so that it could be of best use to the members.

2. ~~a~~A 'generic approach' to the registration of intermediates under strictly controlled conditions:

2.a Some basic principles

2. ~~a~~A a ~~'generic approach' to the registration of intermediates under strictly controlled conditions~~:

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~~2.~~a. ~~Some basic principles~~

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~~i.~~*ii. Main concept: knowledge of hazard to manage the risk management*

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The main concept at stake is the ***successful management of risk*** both for the environment and for workers. The way to achieve the status of strictly controlled conditions (and lighter registration requirements) will, in fact, depend upon the ability to demonstrate that risk is controlled. This will require knowledge of the properties of the substance, the exposure conditions and risk.

In RIP 3.1, it is stated that when no hazard and risk information is available, 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.

Should the phrase "adequate control" be incorporated somewhere here?

Data (hazard, risk, risk management) availability is therefore key!!

~~ii.~~*iii. Use of existing data and existing regulations to avoid further increase of workload*

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The process behind answering ~~the~~ questions on ~~a~~ successful risk management involves several actors (e.g. site managers, engineers) and significant analyses. Rather than starting from scratch it is proposed to use as far as possible existing information, registers, etc…and what has been documented in the context of existing legislation (IPPC, CAD etc.). The NFM BREF note should be used and referred to in order to strengthen the documentation and interpretation of strict control~~.~~. Any information produced for the purpose of other pieces of legislation (e.g. worker protection legislation) can be used as an element to demonstrate strictly controlled conditions.

~~viii.~~*iv. When data are missing?*

As data requirements will have to be fulfilled, when public data are not available (sufficient), the producer/importer of the intermediate will have to address the consortia of the relevant substances to be able to document its strictly controlled conditions. Agreement on the participation and input to the consortia will have to be discussed on a case-by-case basis. One concern is that this may generate disproportionate costs for the manufacturer/importer of the intermediate who is not part of the consortium. Costs /benefits shall be evaluated carefully, as the authorities might not consider disproportionate costs as an argument for not having data 'available'.
This interaction with consortia or other players in the SIEF can influence the status of the intermediate during the data collection phase of such consortia or SIEF. Please

explain this point more fully. Presumably the definition of intermediate never changes, so the status of the substance shouldn't change either.

v. Reality is a complex mix of metals and compounds within the boundaries set for the assessment

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It should be realised that, in practice, both workers and environment are not exposed ~~not~~ to a single substance (intermediate) but to a mix of metals and metal compounds, resulting from the presence of different substances in the same exposure area or the existence of different processes for a substance/intermediate. ~~Therefore, i~~It has therefore been proposed to approach the definition of strictly controlled conditions by considering the process as a unit rather than a substance and to focus on the assessment of the whole process with all inputs and outputs. To do this, a clear definition of the system boundaries will be required in the description of the exposure.

As data requirements will have to be fulfilled, when public data are not available (sufficient), the producer/importer of the intermediate will have to address the SIEF and/or consortia of the relevant substances to be able to document its strictly controlled conditions. Agreement on the participation and input to the SIEF and/or consortia will have to be discussed on a case-by-case basis. A concern is that this may generate disproportionate costs for the manufacturer/importer of the intermediate who is not part of the consortium (a manufacturer/importer automatically becomes a member of a SIEF by pre-registering). Costs /benefits shall be evaluated carefully as the authorities might not consider disproportionate costs as an argument for not having data 'available'.

viii. *Reality is a complex mix of metals and compounds*

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vi. A good communication system with customers/users is needed

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It should be realised that in practice both workers and environment are exposed not to a single substance (intermediate) but to a mix of metals and metal compounds, resulting from the presence of different substances in the same exposure area or the existence of different processes for a substance/intermediate. Therefore, it has been proposed to approach the definition of strictly controlled conditions by considering the process as a unit rather than per~~a~~ substance.

ix. *A good communication system with customers/users is needed*

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~~This interaction with consortia or other players in the SIEF can influence the status of the intermediate during the data collection phase of such consortia~~a ~~um or SIEF.~~

I am not sure what the last sentence means
Transported isolated intermediates require communication through the supply chain for confirmation that strictly controlled conditions are achieved. The initial intermediate producer must guarantee use under strictly controlled conditions along the chain. It is therefore crucial that the manufacturer/importer of the intermediate identifies and exchanges information with his users. 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). The question is however whether a letter would be sufficient to protect both the producer of the intermediate and its customer or if a summarised CSR shall be provided to the user.

x. *Measured data vs. modelled data*

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In the metals sector, clear preference is given to measured data over modelled data as available models generally overestimate exposure levels, in particular for occupational &consumer exposure. In case no measured data are available, it should be referred to models (EUSES, EASE, …) (~~,~~ however guidance for interpretation on the possible limitations of those models should be provided).

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~~*iv.Reality is a complex mix of metals and compounds within the boundaries set for the assessment*~~

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~~It should be realised that, in practice, both workers and environment are~~ not ~~exposed not to a single substance (intermediate) but to a mix of metals and metal compounds, resulting from the presence of different substances in the same exposure area or the existence of different processes for a substance/intermediate. Therefore, i~~It ~~has~~ therefore ~~been proposed to approach the definition of strictly controlled conditions by considering the process as a unit rather than a substance and to focus on the assessment of the whole process with all inputs and outputs. To do this, a clear definition of the system boundaries will be required in the description of the exposure.~~

xi. *CMR vs. non CMR containing intermediates*

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EU Member States will be the responsible body for assessing the 'strictly controlled conditions' at plant level. According to their own policy and other specificities, there may be some disharmony over the EU in approaching concepts like 'rigorous containment', "minimized exposure", "acceptable" and/or "residual risk" according to each Member State specificities. Some Member States may favor to use worst case scenarios (CMR-like scenarios) to define strictly controlled conditions in an overall precautionary attempt, even at plants where CMRs containing intermediates are not an issue.

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~~*v.A good communication system with customers/users is needed*~~

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It shall be recalled that for CMRs, the Carcinogens Directive is of application and constitutes law, considering that if risk cannot be accounted for, exposure should be zero. It would however be unfair to apply the same reasoning to non-CMRs: if you have a non-CMR you should be able to work with allowable emission factors and

suitable control conditions. A distinction needs to be made between CMR and non-CMR containing intermediates when defining strictly controlled conditions, as the descriptor of "no risk" is different.

Transported isolated intermediates require communication through the supply chain for confirmation that strictly controlled conditions are achieved. The initial intermediate producer must guarantee use under strictly controlled conditions along the chain. It is therefore crucial that the manufacturer/importer of the intermediate identifies and exchanges information with his users. 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 details of process technology and/or engineering, etc). A statement by the user that the synthesis from the intermediate takes place under strictly controlled conditions will require some basic hazard and risk data. Data availability will be key, and a sort of "mini-CSR"" could be required in the communication with the user in order to obtain confirmation from the user that ~~the~~ strictly controlled conditions apply.

~~xi.~~*vii. Some guidance on some technical points:*

- *Measured data vs. modelled data(what kind of data?)*

In the metals sector, clear preference is given to measured data over modelled data, as available models generally overestimate exposure levels, in particular for occupational & consumer exposure. In cases where no measured data are available, models ~~it~~ should be referred to ~~models~~ (EUSES, EASE, …), although ~~however~~ guidance for interpretation of ~~on~~ the possible limitations of those models should be provided??? (see HERAG, MERAG for example).

The Carcinogens Directive covers the production and the use of CMRs, however the status of the unloading activities ~~had~~ has to be clarified: is unloading to be considered as part of the manufacturing process or of the transportation? According to the Council Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rails, transport shall mean any operation for the transport of dangerous goods by rail, conducted wholly or partially within the territory of a Member State, including the activities of loading, unloading and transfer to or from another mode of transport and the stops necessitated by the circumstances of the transport, covered by the Annex to this Directive, without prejudice to the arrangements laid down by the laws of the Member States concerning liability in respect of such operations; it shall not include transport wholly performed within the perimeter of an undertaking.

Commented [u19]: By whom should this guidance be provided? And when? Is it a task for the "Implementation sub-group"?

xii. *Role of personal protective equipment (PPE)*

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RIP 3.1 notes that 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. PPE should be recommended and used especially in relation to sampling, maintenance and repair. The possibility to mention the use of PPE as a constitutive element of the strictly controlled conditions has still

to be clarified. In the meantime, it is recommended to assess whether PPE are indeed the most important requirement to have strictly controlled conditions.

- *CMR vs. non- CMR containing intermediates*

The EU Member States will be the responsible body for assessing ~~the~~ 'strictly controlled conditions' at plant level. According to their own policy and other specificities, there may be some disharmony within ~~over~~ the EU in approaching concepts like 'rigorous containment', "minimized exposure", "acceptable" and/or "residual risk" according to the specificities of each Member State ~~specificity~~. Some Member States may favour the use of ~~favor to use~~ worst- case scenarios ~~(CMR-like scenarios)~~ to define strictly controlled conditions in an overall precautionary attempt~~, even at plants where CMRs containing intermediates are not an issue.~~ .

xiii. *Fugitive emissions*

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~~It shall be recalled that for CMRs~~For example, the Carcinogens Directive ~~is of application and constitutes law, considering~~~~considering~~requires that if risk cannot be accounted for, exposure should be zero. It would, however be unfair to apply the same reasoning to non-CMRs: if you have a non-CMR you should be able to work with allowable emission factors and suitable control conditions. A distinction needs to be made between CMR and non-CMR containing intermediates when defining strictly controlled conditions, as the descriptor of "no risk~~"~~" is different.

- *Loading and unloading in the life cycle of intermediates?*

The Carcinogens Directive covers the production and the use of CMRs, although ~~however~~ the status of the unloading activities had to be clarified: is unloading to be considered as part of the manufacturing process or of the transportation?
According to ~~the~~ Council Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rails, transport ~~shall~~ means any operation for the transport of dangerous goods by rail, conducted wholly or partially within the territory of a Member State, including the activities of loading, unloading and transfer to or from another mode of transport and the stops necessitated by the circumstances of the transport, covered by the Annex to this Directive, without prejudice to the arrangements laid down by the laws of the Member States concerning liability in respect of such operations; it shall not include transport wholly performed within the perimeter of an undertaking.

- *Role of personal protective equipment (PPE)*

RIP 3.1 notes that 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. PPE should be recommended and used, especially in relation to sampling, maintenance and repair. The possibility to mention the use of PPE as a constitutive element of ~~the~~ strictly controlled conditions ~~has~~ still has to be clarified. In the meantime, it is recommended to assess whether PPE are indeed the most important requirement to have strictly controlled conditions.

Violaine: May I refer back to the UK COSHH Regulations ACOP which I previously sent you. Perhaps the paragraph could be rephrased in the light of what HSE had to say about PPE

- *Fugitive emissions*

The actual presence or absence of fugitive emissions in the life cycle of the intermediate has to be assessed. If present, the risks of these fugitive emissions has to be determined, and risk reduction measures should be applied if required.
This aspect is very much case-~~-~~specific and in most cases, real measured immission data will be the result of many different sources of (fugitive) emissions (including

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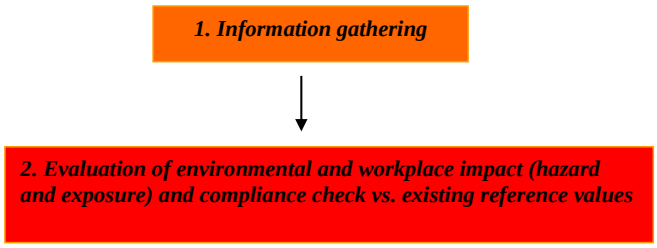
Commented [FC23]: This point is still unclear to me… unloading is part of the transport but as soon as the unloading is achieved you have to demonstrate the "strictly controlled conditions" no? therefore, it does not change a lot…

emissions caused by real substances as well as ~~of~~ other intermediate substances). Compliance with immission (emission) standards (if they are available and applicable) around a site or in a receiving water or soil should prove that fugitive emissions of all individual sources are strictly controlled.

2.b Stepwise generic approach



1. Information gathering

This is clearly the most resource-requiring step of the process, as all the information required so as to be able to demonstrate knowledge of the handled substance/intermediate and of the controlled management of the risk should be made available. This means that, besides information on the properties of the substance/intermediate (physico-chemical, environmental and human health hazard), the whole lifecycle of the intermediate should be documented, including the different steps of the process, the potential exposures and risks at each step, and the measures.

A flow sheet is provided in Annex 1 as an attempt to collect the information in a user-friendly, easy-to-complete excel sheet. This sheet has also been used in the examples provided.

Note: the 'Flow sheet' may be used for each individual intermediate (example…) or by process/combination of processes (example…). It is essential for a good description to accompany the flow sheet setting out the reasoning and arguments used!!

2. Evaluation of exposure and hazard both for the environment and human health:

A. Environment:

A quantitative and/or qualitative evaluation of the environmental impact can be carried out, based on the existing dataset (including substances fed into in the process, description of the process, risk management measures in place, etc.). Ideally, both evaluations should be performed.

- *Quantitative approach:*

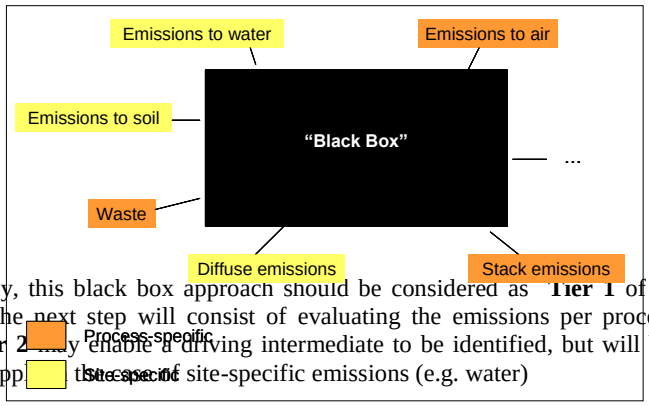
The idea is to consider the plant as a 'black box', considering the emissions of the *entire* site. Relevant evaluation parameters (e.g. Pb for the group of Pb compounds) should be selected and measured/modelledestimated, and outcomes (measured or modelled emission values) should be compared to existing ELVs:

- If you can demonstrate that the ~~operations~~you ~~–~~operations comply with existing limit values (ELVs), the intermediates used/produced in these operations should be considered toyou will be, as such, in strictly controlled conditions.
- If no ELV is available, emissions have to be compared to the PNECs for the different compartments. If the comparison exposure versus PNEC is satisfactory, then it can be concluded that the intermediates are produced/used in a way that does not affect the environment

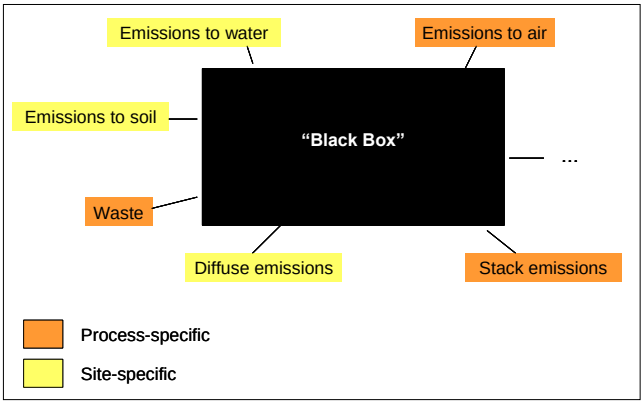
Limitations: This approach considers the processes performed at one plant altogether and all intermediates produced/used as a 'whole'. However:

- not all intermediates involved in site processes are responsible for (hazardous) emissions. One intermediate may also drive the emissions and require specific consideration
- this approach may work for the water and soil/sediment compartment where there is one point of (discharge)/measurement, but emissions to air and waste will require a more refined approach, as they are more specifically linked to processes and have several measurement points

Therefore, this black box approach should be considered as a **tier 1** of a tiered approach. The next step will consist in evaluating the emissions per process. The **refined Tier 2** may enable to identify a driving intermediate but will be more difficult to apply in case of site-specific emissions (e.g. water)



Consequently, this black box approach should be considered as **Tier 1** of a tiered approach. The next step will consist of evaluating the emissions per process. The **refined Tier 2** may enable a driving intermediate to be identified, but will be more difficult to apply in the case of site-specific emissions (e.g. water)



This approach requires emissionemissions data. In cases where case no exposure data are available, REACH-recognised models should be applied.. Models can also help to avoid the errors induced by the influence of historical pollution on monitoring data, but can be stringent and limited to "default" or "worst-case scenario" values.

Example:

- determine the *substances* (metals, metal compounds, other relevant elements, …) that are *fed* into each process, including handling and storage
- determine the *relevant parameters* to be measuredmeasure: Pb for all Pb compounds, …
- sample and analyse the discharge water
- ELV's for water are derived from the water EQS under the WFD

- *Qualitative approach:*

The oObjective is to list all the measures that are in place:

- IPPC and BAT (as IPCC plants have been evaluated by authorities)
- Measures taken at all process stagessteps: e.g. ISO14001 environmental aspects, workplace evaluation, etc
- Management system: e.g. ISO 14001, EMAS, procedures for control, training, accidents, etc.…

B. Workplace:

- *Quantitative approach:*

The sSuggestion is to consider the exposure control on a "logical process unit" basis and per job description/category (melting/smelting, mechanical handling, raw material handling, drying, etc.). The logical process unit groups grouping several related functions and operations ('same breathed air area') that create one common exposure area.).
The NnextNext step is then again to select the relevant evaluation parameters (e.g. Cu for Cu compounds), to measure/estimate exposure and compare the exposure values against reference values such as like OELs, when available, or DNELs. If the

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reference values are exceeded, there is a need to go for a more refined approach to assess which measures shall be put in place

Example:

Description of workplace: (e.g. tapping floor of blast furnace)
• sub-processes: tapping of lead
casting of lead in final form
tapping of matte
tapping of poor slags
• functions: furnace operators
fork-lift truck drivers
• *Measurements*: stationary measurements (Pb, Cu, Cd, …) and portable measurements (Pb, Cu, Cd, …)
• When measurements do *not comply* with TLV, MAC, …:
use of PPE
definition of improvement actions

- *Qualitative approach:*

This lists what is in place to:

- show that protection hierarchy is observed
- describe measures taken at all process stages
- ensure that the management system is in place: e.g. OSHAS18001, procedures for training, risk assessment, accidents,…

2.c how do you constitute your strictly controlled conditions SCC intermediate file? How to (pre-) register?

Overall, RIP 3.1 states that 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.**

Pre-registration:

There are two possibilities according to the possibility to refer to an EINECS number:
a) (pre-)register as a MCS (if EINECS number exists)
b) (pre-)register the ~~constituents~~ components of the intermediate. If the components of the intermediates are pre-registered, the producer/importer will appear on the radar screen and be part of the SIEF of the components of the intermediate. A joint dossier will have to be submitted with the people working with the substance.

If you pre-register the intermediate as UVCB, you will have two options to have the minimum dataset: minimal testing or preparation rule

Registration:

UVCB??
When filling his registration dossier using IUCLID5 the registrant must report if the substance is manufactured and used under strictly controlled conditions or not and can provide the confirmation of this

Include screen shots IUCLID 5

In-house file

The documentation may include:

- justification for the assignment of use as an intermediate to the substance, including suppliers' and customers' statements if it is a transported isolated intermediate;
- the relevant operating conditions;
- the risk management measures implemented in the company and recommended to external customers

Glossary

Overall, RIP 3.1 states that a full explanation of the strictly controlled conditions in place is not required in the registration dossier. ~~However t~~The assessment of the use(s) of any substance (or group of similar substances) as intermediate(s) should, however, be documented **within a company in order to show the adequacy of the measures, as authorities may request such information which ~~then~~ must then be made availablee**.

RIP 3.1 no longer exists: one should refer to the guidance by its actual title
The relevant section of the guidance should be cited here.

Pre-registration:

There are several possibilities, depending on ~~according to~~ the possibility to refer to an EINECS number:
a) (pre-)register as a mono-constituent substance (if EINECS number exists)
b) (pre-)register as a MCS (if EINECS number exists)
c) (pre-)register the constituents of the intermediate (if no EINECS number exists for the MCS). If the constituents of the intermediates are pre-registered, the producer/importer will appear on the radar screen and be part of the SIEF of these constituents of the intermediate. A joint dossier will have to be submitted with the companies working on the substance, even if ~~be it that~~ the data requirements for the intermediate are reduced (if under strictly controlled conditions)..
d) UVCB (if EINECS number exists): the (minimal) data set can be created by testing(??) or by applying the preparations rules.

The references to EINECS numbers are not accurate in the case of isolated intermediates which have not been put on the market for sale, since there was never a requirement to register them on EINECS. I am not sure that IUCLID 5 can cope with this.

Registration:

IUCLID 5 enables the registrant to identify the information requirements for each type of intermediate (e.g.: isolated on-site, isolated transported…). In each case, all available and relevant information needs to be reported in the Registration dossier. The report documenting the "strictly controlled conditions" will be kept in-house by the Company.

Include screen shots IUCLID 5

In-house file

The documentation may include:
- justification for the assignment of use as an intermediate to the substance, including customers' statements if this ~~it~~ is a transported isolated intermediate;
- the relevant operating conditions;

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Commented [FC28]: Add somewhere a "warning" explaining that the same rules apply for intermediates and substances. If you do not pre-register, you can not benefit of the interim period for registration and you have to stop the production of the substance until registration is completed!

Commented [FC29]: I am not sure that is feasible for the UVCB… It is relevant for MCS but not for UVCB following my understanding.

- the risk management measures implemented in the company and recommended to external customers

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Glossary and Abbreviations

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 pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after ~~the~~ manufacture (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)).

CAD: Chemicals Agent Directive (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)

CMR: Carcinogen Mutagen Reprotoxicant

DNELs: Derived No ~~e~~Effect Level: ~~It~~ This is the level of exposure to the substance below which no adverse effects are expected to occur. It is therefore the level of exposure to the substance above which humans should not be exposed. DNEL is a derived level of exposure because it is calculated on the basis of available dose descriptors such as No Observed Adverse Effect Levels (→NOAELs) or benchmark doses (BMDs).

ELV: Emission Limit Value

EQS: Environmental Quality Standards

IPPC: EU directive concerning Integrated Pollution and Prevention Control setting common rules for permitting and controlling industrial installations; technical standards are described in -BREF documents

MAK: Maximale Arbeitsplatzkonzentration) is the maximum concentration of a substance in the ambient air in the workplace which has no adverse effect on the workers' health

OEL: Occupational Exposure Limits

PNEC: Predicted No ~~e~~Effect Concentration: Concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur

PPE: Personal Protection Equipment Technical means (e.g. mask, gloves, goggles, respirator...) to protect workers and consumers against direct exposure

TLV: Threshold Limit Value

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WFD: Water Framework Directive

Annex **I**

Annexes: Flow sheet (generic)

Annexes: examples