Q&A

1. Do PM Refinables contain impurities?

Under REACH, an impurity is defined as an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance it was not intentionally added. [1]

PM Refinables are UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) because the number of constituents is relatively large and the variability of composition is relatively large. Due to the lack of differentiation between constituents and impurities, the terms "impurities" should not be regarded as relevant for UVCB substances. [1]

2. What is the difference/relationship between Strictly Controlled Conditions (SCC) and Rigorous Containment (RiCo)?

- The definition of SCC in Article 18(4) for transported isolated intermediates can also be used as a working basis for isolated on-site intermediates. Article 18(4) provides a wider definition of SCC than Article 17(3), the latter being limited to criteria (a) and (b) of the above list. Nevertheless criteria (c) to (f) are also considered appropriate for on-site isolated intermediates, in deciding whether SCC apply. [2] "*To assess if an intermediate is manufactured and used under **SCC** during its whole lifecycle, the registrant should evaluate if all conditions as set in Article 18(4) apply:*
  (a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
  (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."

  SCC should be seen as a combination of technical measures that are underpinned by operating procedures and management systems.

It should be emphasized that SCC must be achieved without taking into account the use of personal protective equipment (PPE) except when it aims at limiting exposure resulting from accidents, incidents, maintenance and cleaning. [2]

- **RiCo** is achieved by the technical design of a process and the equipment which aims at preventing releases (to prevent exposure of workers and to prevent releases to the environment). The physico-chemical properties of a substance are one factor to take into account in determining the right design to achieve rigorous containment, together with the process conditions if this is relevant. Rigorous containment is applicable to handling of intermediates at any scale. Release of the substance should be prevented through containment systems, such as combinations of suitable mechanical barriers (e.g. enclosures) and air dynamic barriers (e.g. Local Exhaust Ventilation (LEV) as integrated part of the containment and differential pressure). RiCo applies to the whole lifecycle of the substance including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage. [2]
- Thus, RiCo is an integral part of SCC: RiCo covers technical measures at the process level, while SCC include RiCo and further conditions addressed under b) to f) above.
  If RiCo for the workplace is demonstrated, and the other operational and organizational measures (training of workers etc.) are implemented, and adequate environmental risk management measures (RMM) are in place (in case environmental emissions occur from the site) - then all this together means criteria for SCC are met.

3. What are the specific aspects to be considered when assessing RiCo in the metals' industry?

According to the glossary of RiCoG, the following aspects are to be considered for an assessment of RiCo:

Concerning the handled intermediate and operational conditions:

- Physical form (state & emission potential, e.g. dustiness) of intermediate at process temperature;
- Vapour pressure at process temperature;
- Boiling point of intermediate in °C;
- Process temperature in °C;
- Quantity of intermediate handled per task/operation;
- Classification of the intermediate.

Concerning the containment strategy:

- Used equipment;
- Level of containment;
- Breaching incidents;
- Leakage prevention;
- Treatment of contaminated air;
- Maintenance scheme;
- Level of contact.

However, specific containment measures relevant for the substance/intermediate may apply (e.g. containment for heat).

4. How to determine whether a registration dossier needs to be updated or upgraded, and what is the difference between both?

Registrants of isolated intermediates can provide reduced registration information if they confirm that the substance is manufactured and used under SCC. Reduced registration dossiers were submitted for all PM refinables in 2010, based on the 2008 version of the ECHA Guidance on intermediates. However, in light of the change of interpretation of the concept of 'intermediate' and 'SCC' in the December 2010 version of the ECHA Guidance on intermediates [2], registration dossiers will need to be "updated" or "upgraded to a standard registration dossier" without undue delay.

First, companies registering refinables will have to check if they meet RiCo and SCC criteria according to the December 2010 ECHA Guidance (see also Table 3). The current ECHA guidance on intermediates leaves it up to the registrant to use measured exposure data to support his claim of RiCo/SCC. However, no further guidance is provided for this, except for: "*It is important to note that absence of rigorous containment or absence of minimisation of release cannot be justified with a risk characterisation ratio.*" [2]

Depending on whether RiCo and SCC are met, three possible approaches are available to companies registering refinables:

1) For those refinables where RiCo and SCC are met, a dossier **update** will be made. Full documentation of the SCC in place is not required in the registration dossier, however the registrant should give a basic indication on how the conclusion concerning SCC is reached. A format for documenting information on RMMs in a registration dossier is given in **Appendix 3** (available exposure data can also be included to support the conclusion of RiCo and SCC). Nevertheless, there should be detailed internal documentation within a company in order to demonstrate that SCC apply throughout the whole life cycle of the intermediate. The national enforcement authorities may request such information. An example of a general format to document how the substance is manufactured and used under strictly controlled conditions is provided in **Appendix 2**. [2]
2) If the SCC criteria are not met – because (a) RiCo is not demonstrated for the workplace (then SCC are not met whatever RMM exist for the environment) or (b) RiCo is demonstrated for the workplace, but there are insufficient RMMs in place to control emissions to the environment in the event that releases to air and/or water are taking place - then an **upgrade** will be required to a full intermediate registration dossier, with a data package depending on the tonnage level (see Table 1). This would require (in addition to data for various hazard endpoints) a full exposure assessment (for human health and the environment) demonstrating Risk Characterisation Ratios (RCR) below 1. Risk characterisation for an intermediate is limited to the workplace and a local environmental scenario for the manufacture and use of the intermediate.
3) If RiCo and SCC are borderline (will always be subject to some level of interpretation by local authorities), the cost/benefit of performing a dossier upgrade instead of an update should be checked. If a non-testing / read-across approach to fill in information requirements is accepted by ECHA the workload would be very similar for both updates and upgrades, with less likelihood of being challenged in the case of an upgrade (SCC no longer needs to be demonstrated and upgrades would be regarded as more complete dossiers).

TABLE 1: DIFFERENCE BETWEEN A DOSSIER UPDATE AND DOSSIER UPGRADE

	Update of a UVCB intermediate Registration Dossier submitted in Dec 2010	**Upgrade of a UVCB intermediate Registration Dossier submitted in Dec 2010**
Based on	SCC compliance according to Dec 2010 ECHA Guidance on intermediates	Non-SCC compliance according to Dec 2010 ECHA Guidance on intermediates (or business decision e.g.: if borderline situation)
Appendix 2 of Dec 2010 ECHA Guidance on intermediates	Required & to be kept in house	Not required
Appendix 3 of Dec 2010 ECHA Guidance on intermediates	Required & to be updated in IUCLID Can be developed at consortium level but requires in most cases refinement by companies on an individual basis	Not required
Sections 1-3 of IUCLID 5 (identification, composition, classification & labelling, manufacture & use)	Can be updated if needed	Can be updated if needed
Sections 4-7 of IUCLID 5 (physical & chemical properties, env fate & pathways, tox and ecotox data)	Information requirements reduced to already available data and only study summaries have to be submitted	Required - dependent on tonnage band
Section 8 of IUCLID 5 (Analytical methods)	Not required	Not required
Section 11 of IUCLID 5 (Guidance on safe use)	Required	Required
Section 12 of IUCLID 5	Not required	Not required

(Literature search)		
Section 13 of IUCLID 5 (CSR)	Not required	Required for > 10 t/a
Time	Approximately 2 months/file (FTE)	Approximately 3-4 months/file (FTE) assuming non-testing/read-across approach is accepted by authorities
Registration costs	None in addition to original submission (i.e. 1.200 € for joint submission)	Increased registration fee depending on tonnage level: • 10-100 t: 3.225 € • 100-1000 t: 8.625 € • > 1000 t: 23.250 € (fee for joint submissions)
Compliance check by ECHA	Likely	Likely
Evaluation by Member States	Possible	Possible
Authorisation and restriction	Exempted	Exempted

The metals sector prepared cases to demonstrate SCC conditions typical for the non-ferrous metals sector in Autumn 2011. These examples are under review by ECHA.

5. What are appendices 2 and 3 and when are they required?

TABLE 2: SIMILARITIES AND DIFFERENCES BETWEEN APPENDIX 2 AND APPENDIX 3 OF THE ECHA 2010 GUIDANCE ON INTERMEDIATES [2]

	Appendix 2	Appendix 3
Purpose	To be kept in-house to demonstrate SCC to national enforcement authorities in case of update	For inclusion in registration dossier to demonstrate SCC to ECHA (should be attached to the IUCLID section 13 with the file name 'RMM_details') in case of update
Should include	• Justification for considering that the substance is used as an intermediate and customers' statements concerning the use as an intermediate and the fulfillment of SCC in case of a transported isolated intermediate; • The physical chemical properties of the intermediate relevant for deciding on measures to ensure that SCC apply; • Documentation on the design of the process and the equipment, especially those aspects contributing to the RiCo of the substance by technical means; • The relevant operating conditions; • Measures corresponding to the requirements set out in article 18(4) (b) to (f) (see question 2) implemented by the manufacturer company and recommended to users; • Information on any residual release and resulting exposure that occurs in spite of the RiCo measures by technical means; and • Available relevant physico chemical toxicological and eco-toxicological information and any relevant	The format in Appendix 3 is recommended to explain the RMMs in the registration dossier. Existing legislative frameworks or industry standards can be referred to when documenting such RMMs. • Brief description of technological process applied in manufacture / use of the intermediate (may include overview scheme); • Means of RiCo and minimisation technologies applied by the registrant during the manufacturing and/or use process and recommended to the user of the intermediate: ○ Description of technical means for RiCo + management means & training; ○ Identification of residual emissions to workplace / environment; ○ Description of the procedural & control technologies in place to minimise emission / exposure to workplace / environment; • Special procedures applied before cleaning and maintenance; • Description of activity and type of PPE in case of accidents, incidents,

	reference or threshold value (e.g. community Occupational Exposure Limits (OELs). Note that any information produced for the purpose of other legislation (e.g. for worker protection) can also be used as an element to demonstrate that SCC apply.	maintenance and cleaning activities; • Waste information
Detail	Extensive (more detailed than appendix 3) but as helpful for other workplace obligations (chemicals or carcinogens at the workplace, Seveso, ...)	Extensive and requiring exposure assessment to complement statements
Workload	A couple of days	A couple of days + update of IUCLID
Company specific	Yes	Can be developed at "Consortium" level but requires in most cases refinement by company

In summary, Appendices 2 and 3 contain a lot of similar information, but with a different level of detail (and workload) and for different purposes.

6. When to perform an exposure assessment?

The aim of the exposure assessment for refinables is twofold:

1) Demonstrate rigorous containment for assessment of SCC: if there is no (significant) exposure, this would mean that there is no release and good containment can be assumed;
2) Prepare future dossier upgrade needs: if the criteria for SCC are not met, then a full intermediate dossier will be needed including risk characterisation (limited to the workplace and local environmental scenario for the manufacture and use of the intermediate).

7. What are the similarities and differences between human health and environmental exposure assessment and risk characterisation?

TABLE 3: SIMILARITIES AND DIFFERENCES BETWEEN HUMAN HEALTH AND ENVIRONMENTAL EXPOSURE ASSESSMENT AND RISK CHARACTERISATION

	Human health assessment	Environmental assessment
Type of assessment	Workplace specific	Site specific
Demonstration of RiCo / SCC (update)	Tiered approach for demonstration of RiCo: • Tier 0: Screening with RiCoG • Tier 1: Exposure assessment using MEASE (modeling exposure) • Tier 2: Exposure assessment using monitoring data (for inhalation exposure) • Tier 3: Further info / tests needed for refinements Next tiers will only need to be conducted if RiCo cannot be confirmed in previous tiers. For all occupational exposure assessments it has to be decided, to which benchmark the exposure estimates will be compared (see question 8). If RiCo is confirmed, SCC has to be further demonstrated by: • Trained and authorised personnel for	Aspects of RiCo have an environmental element e.g. ensuring containment during storage, but RiCo is primarily considered under worker exposure assessment. If an assessment of RiCo is made for all process stages including storage for occupational exposure there is no need to repeat for the environment. However, RiCo for storage (prevention of emissions to soil, surface water and air) is relevant in cases where environmental hazards are the only concern (e.g. Ag). If RiCo is confirmed, SCC has to be further demonstrated by: • Qualitative screening to establish sufficiently robust procedural and control technologies or RMMs are in

	substance handling; • Special procedures before entering the system (for cleaning & maintenance); • Well-documented & supervised procedures for substance handling. Note that SCC must be achieved without taking into account the use of PPE except when it aims at limiting exposure resulting from accidents, incidents, maintenance and cleaning.	place to minimise emission / exposure (residual emissions from RiCo; emissions from purification, cleaning & maintenance after accidents or where waste is generated) • Compliance with other regulatory schemes can be used as evidence (e.g. the Directive 2008/1/EC concerning integrated pollution prevention and control - the IPPC Directive); • Available monitoring data to support the conclusion of SCC (used qualitatively to demonstrate releases are negligible – not used to calculate RCR). (see question 8 and question 9)
Expected exposure and emission data collection tiers	>1	~1
Hazard characterisation	Collection of DNELs for all human health relevant constituents and identification of a 'decisive DNEL'	Collection of PNECs for all environmentally relevant constituents and local protection endpoints.
Exposure and risk assessment (upgrade)	Tiered approach to calculate RCR: • Tier 1: Exposure assessment using MEASE (modeling exposure) • Tier 2: Exposure assessment using monitoring data (data generation) • Tier 3: Further info / tests needed for refinements (particle size distributions, speciation analysis, …) Next tiers will only need to be conducted if the risk assessment (as summarised in the RCR) does not demonstrate safe use.	Tiered approach to calculate RCR for constituents that have an environmental classification: • Tier 1: Development of Generic Exposure Scenario (GES) for each constituent, using default emission values (ERC or general metal SPERCs) • Tier 2: Refinement of emission estimates using refined SPERC values • Tier 3: Refinement of emission estimates using site-specific data (confidential) EUSES will be used to model the environmental exposure and resulting concentrations in each environmental compartment. Next tiers will only need to be conducted if the risk assessment (as summarised in the RCR) does not demonstrate safe use. Monitoring will be needed where tier 3 modelling still identifies risk or where data are lacking.
Tools to support exposure assessment	Decisive DNEL, MEASE (See question 10)	EUSES, SPERCs (See question 10)
Risk characterisation	Compare exposure data with DNELs	Compare modelled or site specific exposure data with PNECs
Risk Characterisation Ratio (RCR) aimed at	To be clarified by ECHA	RCR <1 for upgrades To be clarified by ECHA for updates

8. **RCR < 0,1 or 1: What is the status of latest discussions regarding minimum RCR value accepted by authorities to support SCC compliance?**

   Authorities do not propose a fixed RCR level under which residual exposure levels can be considered as SCC compliant. However if SCC conditions are met, exposure data can be used to demonstrate the RiCo conditions. Authorities indicated that RCR levels "significantly below 1" will have to be achieved to demonstrate this. Without being defined such level may be in the order of < 0,1.

9. **If RCR values and quantitative risk assessment cannot be used to demonstrate or document SCC (in the environment), but only a qualitative assessment can, what would this qualitative assessment look like in practice?**

   The guidance states that the calculation of an RCR cannot be used to argue that SCC are met. Instead, compliance with SCC can be based on:
   - A description of the RMMs in place to limit releases to the environment.
   - Company's IPPC license or permit, as long as sufficient and adequate documentation of the compliance with the conditions of the permit are available.
   - Relevant IPPC (Directive 2008/1/EC) Best Available Technique Reference Document (BREF) to demonstrate the effectiveness of procedural and control technologies from the perspective of minimisation.
   - Compliance with other regulatory schemes e.g. WFD etc. can be used as additional evidence.
   - Monitoring data can also be used to support conclusion of SCC if used qualitatively to demonstrate releases are negligible.

10. **Tools to support exposure assessment (RiCoG, decisive DNEL, MEASE, SPERCs, etc.): how to use them for in-house determinations and demonstrations to authorities?**
    - **RiCoG**: EBRC and Eurométaux are developing RiCoG (Rigorous Containment Guide), an electronic, easy-to-use tool aimed at supporting companies / decision-makers to define whether or not the intermediate is rigorously contained. It brings together several elements, such as the Hirst containment scheme referred to in the ECHA guidance, hazard considerations, and exposure potential. While it would help to assess rigorous containment in a standardised, qualitative way, referring to both the October and the December versions of the ECHA guidance on intermediates, it leaves the final decision regarding compliance/non compliance to the companies. The use of RiCoG is voluntary (self assessment tool for companies allowing to compare different steps, intermediates and sites in an objective and comparable way), and there is no obligation to report the results of the RiCoG assessment, but they can be included in Appendix 3 (decision is up to PMC Members). PMC Members are reminded that it is their responsibility to prove they are REACH compliant (and compliant to national legislation). Tools like RiCoG can help but are only one tier. RiCoG gives guidance on where companies could make improvements to arrive at rigorous containment (e.g. improve containment measures).
      Because of its conservative nature, a confirmation of rigorous containment with RiCoG is currently assumed not to require to be supported by measured exposure data. If rigorous containment cannot be demonstrated with RiCoG, an exposure assessment for a dossier update or upgrade will be required.
    - **Decisive DNEL**: For each Refinable for which rigorous containment cannot be demonstrated with RiCoG, it is essential to define a single critical DNEL for each relevant health end-point, thereby identifying the most important risk driver and subsequently proposing measures for adequate protection of workers during the use of the refinable. It is currently assumed that a DNEL is available for each relevant health end-point and for each refinable constituent. From this complex multitude of DNELs, one decisive DNEL per health end-point can be identified. This approach takes into account the individual DNELs of each constituent as well as their specific percentage in the refinable to be assessed. This has to be identified for each exposure pathway (for occupational exposure, only the inhalation and dermal route are generally considered as being relevant), nature of effect (local or systemic) and exposure duration to which the effect refers (acute or repeated). The DNEL having the highest rank is designated as the 'decisive DNEL'.

If, for a specific decisive DNEL, both threshold- and non-threshold related effects are involved, a careful toxicological evaluation of the available information has to be performed. Such an evaluation should aim at checking whether the non-threshold effects may be considered as being covered by the decisive DNEL based on the DNELs of the other constituents.
Depending on the nature of the conducted processes (cold metal processes / hot-metallurgical processes), the ranking of DNELs is done differently.
For refinables for which RiCo cannot be demonstrated, decisive DNELs have to be determined to prioritise (define the most important risk driver) and proceed with the occupational exposure assessment (and risk characterisation in case of an upgrade). If it can be shown that a single decisive DNEL is sufficient for a refinable of variable composition (for a specific health endpoint), a consortia-wide exposure assessment could be sufficient in the form of a sector-wide exposure scenario. If the decisive DNEL of one refinable considerably varies between different companies, a company-specific assessment will be required.
It has to be further discussed how the decisive DNEL can be used for risk characterisation.

- **MEASE** – the metals' EASE - is a first tier screening tool developed by EBRC on behalf of Eurométaux for the estimation (modelling) of occupational inhalation and dermal exposure to metals and inorganic substances. MEASE combines approaches from the EASE expert system, from the TRA tool and from HERAG:
    - Estimation and Assessment of Substance Exposure (EASE) is a model to estimate worker exposure when exposure data are unavailable [3].
    - The ECETOC targeted risk assessment (TRA) tool has been developed to assess exposure to volatile and non-volatile substances [4]. It provides initial exposure estimates on a process category (PROC) specific basis. The initial estimates can be refined by several parameters (such as the frequency and duration of exposure, the presence of a local exhaust ventilation (LEV) etc.). Since the TRA tool aims on a very broad applicability, it fails to reflect some of the specific needs for the assessment of exposure to metals and inorganic substances.
    - The Health Risk Assessment Guidance for Metals (HERAG) has assembled a set of the most advanced and appropriate methods available for human-health based risk assessment of metals. HERAG is intended to address the specific properties of metals, metal compounds, alloys and other naturally occurring inorganic substances that sometimes warrant the application of a risk assessment methodology, which is different to that developed for and applicable to organic industrial chemicals. [5]

  For inhalation exposure, MEASE follows the PROC-specific approach of the TRA tool. In contrast to the TRA tool, the initial exposure estimates in MEASE are based on measured data from the metals industry. MEASE gives users the possibility to choose between several RMMs instead of just having an LEV as an implemented RMM. For dermal exposure, MEASE is based on the classification system of the broadly used EASE system. The exposure estimates are however based on real measured data for several metals (collated in the 'dermal factsheet' of the HERAG project). [6]
  The operational conditions (OC) under which a refinable is handled and the risk management measures (RMM) that are in place to manage workers' exposure can be entered into MEASE at a generic level to derive exposure estimates. Modelled exposure data obtained by MEASE could be used in some instances (for example, for closed processes or handling massive objects) to further confirm rigorous containment (no significant exposure → no release → good containment) and prepare dossier upgrades if rigorous containment is not demonstrated. The assessment of the data will initially be done per company/site.
  If the first tier exposure assessment concludes on exposure levels above the relevant DNEL (i.e. the associated RCR is at or above 1), a higher tier assessment based on monitoring data is needed to demonstrate safe use.
- **EUSES**: The European Union System for the Evaluation of Substances (EUSES) is a decision-support system for the evaluation of the risks of substances to man and the environment. EUSES is intended mainly for initial and refined risk assessments rather than for comprehensive assessments. The system is based on the EU Technical Guidance Documents (TGD) on Risk Assessment for New Notified Substances, Existing Substances and Biocides. [7]
  In the event of a dossier upgrade being required, environmental exposure modelling to calculate risk characterisation ratios (RCR) for each refinable constituent identified as relevant will be performed wherever possible. EUSES will be used to model the environmental exposure and resulting concentrations in each environmental compartment.
- **SPERCs**: Chapter R16 of the REACH Guidance on Information Requirements & Chemical Safety Assessment introduces Environmental Release Classes (ERCs) as generic, broadly applicable

emission scenarios. They define the fractions of a substance emitted during a process / application, and provide default assumptions for the local environmental properties. The guidance acknowledges that an 'ERC should be used as a starting point for emission estimation' and explicitly encourages the use of more refined or specific information for emissions. Therefore, SPERCs or specific ERCs for metals and metal compounds have been developed. [8]
SPERCs are used for refinement of emission estimates for the environmental exposure assessment.

11. **What does 'undue delay' mean?**
'Without undue delay' means not taking more time than reasonably required to fulfil the most up to date / validated information needs, as properly documented in a project work plan.

12. **What does 'due diligence' mean?**
In practice, REACH due diligence means a reasonable and well-documented reaction towards achieving REACH compliance.

13. **If you put the worst-case classification in the registration dossier, are you allowed / obliged to put the worst-case classification in the MSDS or you have to classify the Refinable as it is?**
TO BE FOLLOWED UP. Question will be sent to ECHA helpdesk.

References

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