9. Exposure assessment (and related risk characterisation)

9.0. Introduction

The current document includes all relevant occupational exposure scenarios (ES) for the manufacture and use of the substance as required under the REACH regulation (Regulation (EC) No 1907/2006). The ES were developed according to the REACH Regulation and the relevant REACH Guidance documents where appropriate (Source: European Chemicals Agency, http://echa.europa.eu/):

- "R.12 – Use descriptor system" guidance (version 2, March 2010, ECHA-2010-G-05-EN) for the description of the covered uses and processes.
- "R.13 – Risk management measures" guidance (version 1.2, October 2012, ECHA-12-G-19-EN) for the description and implementation of risk management measures.
- "R.14 – Occupational Exposure Assessment" (version 2.1, November 2012, ECHA-2010-G-09-EN) for the actual occupational exposure assessment.

The precious metals refinables are so-called UVCB substances (Substance of Unknown or Variable composition, Complex reaction products or Biological materials) for which explicit guidance is however not yet available. The followed approach for the occupational exposure and risk assessment of the substance is therefore described in this section.

Generally, according to the REACH Guidance R.14, different methodologies may be used for occupational exposure assessment. Preference should be given to monitoring data measured under the same operational conditions (OC) and with the same risk management measures (RMM) in place when compared to the OC and RMM described in the ES. If such data are not available, analogous data can be used given that OCs and RMMs are similar to an extent which justifies such read-across. If monitoring data are not available, occupational exposure can be assessed by the aid of exposure assessment tools. By definition an ES has to describe under which OC and RMM the substance can be handled safely. This is demonstrated if the estimated exposure level is below the respective derived no-effect level(s) (DNEL(s)), which is expressed by a risk characterisation ratio (RCR = Exposure/DNEL) below 1. Please refer to Chapter 5 of the CSR for further information on relevant DNELs.

9.0.1. Specific considerations for UVCB substances

UVCB substances are characterised by a high variability in content of individual constituents, whereas the constituents as such are known. It is noted that the content range of individual constituents could also include zero as lower limit. Such variation in composition requires specific adoptions of the standard exposure assessment as required under REACH.

9.0.1.1. UVCB implications on hazard assessment

For the hazard assessment, one normally has to conduct testing by defining a sample being representative for all marketed specifications as well as being reflective of the entire life cycle. For a substance which is produced from various input materials and which is exclusively produced for the purpose of being refined (i.e. for the purpose of altering the composition), defining a representative sample and, consequently, conducting meaningful tests is impossible. Since all constituents are known, the hazard assessment is instead based on the hazard assessment of the individual constituents. As a consequence, the hazard assessment will not conclude on a single DNEL for a specific combination of route and exposure duration (e.g. "chronic inhalation") but instead has to consider all DNELs for each of the individual constituents classified for human health.

9.0.1.2. UVCB implications on exposure assessment

As a consequence of the hazard assessment, the exposure assessment has therefore to consider all constituents identified in the hazard assessment as being classified for human health. These are displayed below in the so-called generic exposure assessment (GEA). Since the UVCB substance is exclusively manufactured for its direct use in further refining, exclusively industrial workers are exposed to the UVCB. As part of good industrial hygiene practice in the metals' industry and additionally as a requirement from parallel legislation on the protection of workers' health, the identified hazardous constituents are often monitored on a regular basis in the relevant

workplaces. Such monitoring is normally only conducted for inhalation exposure and dermal exposure is commonly assessed by the aid of exposure modelling tools. Additionally, bio-monitoring is often conducted for specific constituents, which is particular relevant if workers are exposed to lead or lead compounds.
When analysing inhalation monitoring data, obtained in workplaces, in which the substance is manufactured or handled, the following aspects are to be considered:

1. The impact of varying content of any constituent in the substance on exposure to that constituent is automatically reflected. The impact of varying process conditions and risk management measures are also directly reflected in any sample.
2. Other substances (including UVCBs) handled in parallel having the same constituent(s) as the substance and contributing to overall exposure, are automatically included in the sample.
3. The generic dust is analysed for individual elements. Further chemical speciation is normally not done and in most cases even not possible.

The first point is the main reason why monitoring data is commonly the preferred basis for occupational exposure assessments as the introduction of uncertainties by assuming the impact of variation in composition, process conditions and risk management measures is omitted.
The contribution of other substances to workers' exposure to an individual constituent as listed under the second point is normally not to be addressed under REACH since substance-specific assessments are required under the REACH regulation. By the inclusion of such contribution from other substances, the assessment for the substance is therefore intrinsically conservative (i.e. pre-cautionary) with respect to legal REACH requirements. As being anyway good industrial hygiene practice, the exposure assessment is however based on these "aggregated exposure levels" and could be seen as an "intrinsic combined exposure assessment" to an individual constituent.
The third point is of high relevance if the hazard profile of a constituent varies with its chemical speciation. In such cases, the worst-case chemical species (i.e. the most hazardous) is therefore always assumed as a pre-cautionary measure unless this species can be excluded based on plausibility considerations.
In summary, the exposure assessment to the substance therefore:

- reflects current good industrial hygiene practice in terms of monitoring,
- reflects variations of the substance composition during its use,
- covers all classified constituents,
- already includes a "combined exposure assessment" to individual constituents, and
- is sufficiently pre-cautionary to protect workers' health even in unrealistic worst-case conditions.

9.0.1.3. UVCB implications on risk assessment

Modification of both, the hazard and exposure assessment as described above, is to be reflected with an adapted risk assessment. Several DNELs are to be compared with multiple exposure estimates resulting in a generic risk characterisation for all combinations of exposure settings and (classified) constituents that is annexed to this document. Depending on initial exposure estimates for specific exposure settings, the use of respiratory protective equipment (RPE) has to be taken into account in the exposure assessment. It has to be guaranteed that RPE is assigned appropriately to protect workers' health, e.g. by showing that exposure levels are below the relevant DNELs in consideration of PPE. However, exemptions from this approach are substances for which an exposure assessment is based on internal exposure levels, such as lead. The uncertainty of the exposure assessment is less compared to substances for which internal exposure levels are not available. In addition, internal exposure levels already take any PPE as worn by the worker under surveillance into account.

9.0.1.5. Inclusion of bio-monitoring data for lead in UVCB risk assessment

In Europe, DNELs that have been developed under the REACH regulation have to be observed when manufacturing or using lead metal or inorganic lead compounds. With respect to the substance containing a significant proportion of lead, these DNELs do also apply. It is noted that bio-monitoring data already reflect uptake through all routes of exposure and all sources of lead present in the workplace atmosphere. Since also data for external exposure via inhalation were submitted for lead, the risk assessment was conducted on the basis of external and internal

exposure data. It is noted that the reported exposure assessment based on external data is exclusively included for information purposes.

9.0.2. Exposure assessment based on monitoring data

9.0.2.1. Dermal exposure data
Dermal exposure data representing actual workplace measurements were not provided.

9.0.2.2. Oral exposure data
For workers, oral exposure is assumed to be sufficiently controlled by strict occupational hygiene practices (e.g. not eating and smoking in the workplace, wash hands before eating, etc.) and is therefore not considered in the assessment of workplace exposure.

9.0.2.3. Bio-monitoring data
Since bio-monitoring of exposure to lead in the form of blood measurements is a standard procedure in the EU, the availability of such data is accordingly high at the company level (given that specific medical confidentiality requirements are met). It is recognised that depending on national legislation and/or company-specific policies, blood lead levels of individual workers may be repeatedly measured on an annual basis. In particular, if high blood lead levels have been measured, additional monitoring of the same worker is common practice. Consequently, any database consisting of individual measurements would be biased by high exposed workers simply by their over-representation in the database. Thus, in analogy to the EU risk assessment report on lead (ILA Europe, 2009), repeated measurements of a specific worker have been consolidated into a single median value on an annual basis.

9.0.2.4. Inhalation exposure data
All data considered in the data base and subsequently used for the exposure assessment outlined in this document had to fulfil strict quality criteria. A detailed description of the quality criteria applied to the measured inhalation exposure data can be found in several risk assessment reports as conducted under 793/93/EEC (e.g. the RA of diantimony trioxide). For the sake of brevity, only the most important qualifiers are listed below:

- In general, only personal measurements of inhalation exposure data have been used.
- Depending on the exposure duration, these values have to be either full-shift-representative (at minimum of 120 minutes measurement duration) or must have been obtained during the entire task duration. If the latter is the case and in addition it could be shown that exposure is negligible for the remaining shift, values have been weighted accordingly to obtain time weighted averages (TWA). If applicable, the corresponding task durations can be found under Section 2.1, “Frequency and duration of use/exposure”.
- The measured fraction must be “inhalable” according to EN 481.
- All measurements have to be assigned to a specific workplace, process or task.
- The measurement date has to be reported.
- Additional information such as sampling equipment and method of analysis has to be provided for individual data sets.

In addition, measured data can only be used for the purpose of REACH ES if the operational conditions and risk management measures which prevail during the measurements are reported.
For the sake of brevity, only measurements which comply with the above mentioned quality criteria have been taken into account in further data analysis below.

9.0.2.5. Inhalation exposure data - Assessment of data quality and percentiles to be used
Whenever measured data are used in exposure scenarios they have been checked for their quality by applying the quality criteria as outlined above. According to REACH Guidance R.14, the percentile to reflect the exposure level for workers has to be determined according to the specificity of the data to the ES of interest and the variability of the data (Table 14-2) as reflected by the geometric standard deviation (GSD). Additionally, the REACH Guidance requires a minimum number of measurements based on the GSD.

9.0.2.6. Analysis of air monitoring data

An analysis of all inhalation monitoring data that were submitted to EBRC and that fulfilled the requirements with regard to quality and applicability is provided in APPENDIX XX. Please note that these data apply to all precious metals refinables that are subject to standard registration under REACH. A subset of the data is used for the generic risk assessment provided in APPENDIX XY and of these data, a subset is used for the company-specific exposure scenarios provided in the corresponding company-specific CSR.

It has to be noted that all inhalation monitoring data described above were measured outside any RPE. If applicable, such equipment was taken into account by dividing the calculated exposure level by the so-called assigned protection factor (APF) as reported in the exposure scenario below. These APFs have been set according to BS EN 529:2005 and can also be consulted in the glossary of MEASE (available on http://www.ebrc.de/mease.html).

9.0.3. Analogous data

For scenarios for which measured data were not available, analogous data have been used to estimate exposure. APPENDIX XZ summarises for which ES analogous data were used, from which sources the analogous data were taken, the specific justification for such a read-across and the mode of extrapolation applied.

9.0.4. Modelled exposure

In cases where neither measured data were made available to EBRC nor an assessment based on analogous data could be established, occupational exposure was assessed with the aid of a modelling tool. At the first tier screening level, the MEASE tool (http://www.ebrc.de/mease.html) was used according to the ECHA Guidance (R.14). All parameters needed to run the tool are provided in the ESs below. In cases in which multiple PROCs and/or physical forms have been assigned to a specific workplace, the corresponding exposure assessment for that specific workplace was made by using the PROC and/or physical form leading to the highest exposure estimate for precautionary reasons.

9.0.5. Definition: Overall composition profile

The exposure assessment for the precious metals refinables is in large part based on monitoring data obtained in workplaces, which are characterised by their combined exposure settings. In addition, the concerned inorganic UVCB substances consist of many constituents of which most have hazardous properties to human health. The proposed constituent-based approach (please refer to CHAPTER 9.0.1.1. above), recognises these settings by simultaneously conducting risk assessments for all classified constituents on a workplace-by-workplace basis, instead of trying to conduct a substance-specific assessment, which is non-compliant with industry practice. For example, if one knows that in a given workplace several substances containing arsenic are being processed, one would try to conduct a risk assessment for arsenic instead of three substance-specific assessments for the individual substances. The constituent-based approach is however “data-hungry” by nature: the guidance requires a minimum number of data points for individual assessments. These requirements can in most cases only be met if monitoring data were pooled for multiple companies (e.g. Company A and Company B have similar operational conditions and risk management measures so that a combined analysis of their monitoring data to increase the number of data points is justified). Such pooling however requires that also the processed materials are similar enough: pooling arsenic data for a specific workplace from multiple companies could only be justified if all processed materials at the associated workplace for all companies contain similar amounts of arsenic. Data from companies with totally different materials cannot be pooled, for example, if Company A only processes materials at the workplace of interest which contain very low levels of arsenic whereas Company B has significant arsenic levels in the processed materials. The result of an exposure assessment on a pooled data set (Company A + Company B) would consequently be meaningless for both companies. In order to avoid such artificial and unrealistic assessments, companies provided an approximate indication of the amount of specific constituents present in the processed materials in relation to the overall mass of materials being processed in the individual workplaces. The term “processed materials” thereby

includes non-REACH substances such as waste and by-products as well as already registered substances if relevant for the workplaces in which monitoring data were obtained.

9.0.6. Assignment of activity classes

Although the refinable's sector is a very complex industry sector, there are some processes required to refine precious metals that are (with respect to occupational exposure assessment) very similar between all companies. It is therefore assumed, that the development of activity classes describing common tasks/operations in industry represents a simplification of relevant processes but still provides an adequate level of detail to reflect customer's needs. Therefore, a list of common workplaces (activity classes, ACs) was developed for all reported activities/processes during handling of refinables. Information provided with measured data, i.e. information on tasks that were conducted by the worker during the measurement and information on assigned workplaces for these measurements according to occupational exposure questionnaires that were circulated was used as a basis for the definition of these common workplaces. Each inhalation exposure monitoring measurement was subsequently assigned to one of the activity classes. By also assigning workplaces of data submitters and non-data submitters as nominated in the occupational exposure questionnaires, (see Figure 1 below) it is possible to derive exposure estimates on a task/operation basis.

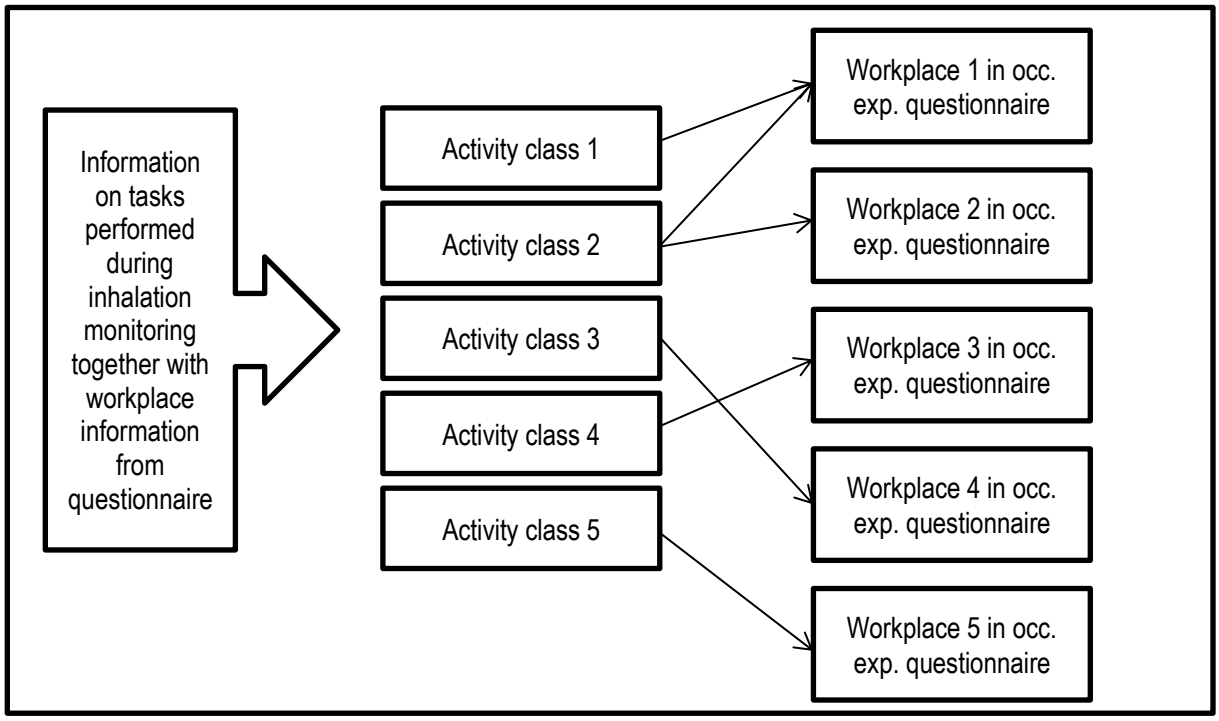

Figure 1: Development of activity classes and subsequent assignment of these to nominated workplaces

For the development of these common workplaces/ACs, performed tasks (as indicated during the submission of measurements and as indicated in the occ. exp. questionnaire) were taken into account, together with information on the handled physical form of substances and information on exposure modifying parameters such as enclosure of processes and separation of workers (see TABLE XX below). The rightmost column of below table indicates which of the activity classes are relevant for below “test-case”.

Overview of activity classes

Activity Class # (AC)	short description of AC	involved tasks	significant exposure modifier	Relevant for "test-case"
AC1	handling of dusty materials			X
AC2	handling of materials with varying dustiness potential			
AC3	handling of very low to low dusty materials			X
AC4	obsolete			
AC5	smelting, no separation of workers			X
AC6	smelting, separation of workers			X
AC7	melting, open processes			X
AC8	roasting			
AC9	drying			
AC10	hydrometallurgical processes			X
AC11	obsolete			
AC12	mechanical operations			
AC13	obsolete			
AC14	cleaning & maintenance			X
AC15	sampling & evaluation			
AC16	obsolete			
AC17	obsolete			
AC18	obsolete			
AC19	obsolete			
AC20	not applicable			

The above described approach facilitates grouping of data from different data submitters for similar tasks and enables analysis of these data on a task-specific basis. Since inhalation monitoring data were already assigned to workplaces of data-submitting companies, further information such as operational conditions (OCs) and risk management measures (RMMs) are available for these data and consequently also for activity classes. Considering data submissions from different companies with potentially different sets of OCs and RMMs, a specific AC may be sub-divided on the basis of these different conditions. To already have an indication on the feasibility of grouping of monitoring data from different companies into the same activity classes, interim analyses with the programme R[1] were performed. If these indicated that grouping of different data sets resulted in a high geometric standard deviation (GSD), indicating high variability of data in a specific activity class, grouping was reconsidered taking into account all available information.

Statistical analysis

The software package R was used to perform statistical analyses of the quality-assured inhalation monitoring and bio-monitoring data. To be amended.

[1] R Core Team (2012). R: A language and environment for statistical computing. R Foundation for Statistical computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/.

9.1. Exposure scenario for the manufacture of the substance

9.1.1. Environmental contributing scenario (placeholder)

9.1.2. Title Workplace 1 (to be adapted for individual registrants)

9.1.2.1. Conditions of use

Composition profile (overall content)		
Element	upper limit value	assumed species
Ag	%	
Au	%	
…	%	
…	%	
…	%	
AC X1	Title Activity Class X1	
Physical form and emission potential	physical form	substance- or process-intrinsic emission potential
Process temperature	°C	
Exposure duration	min/shift	
Level of separation		
Localised controls	Type of localised controls	Effectiveness of localised controls
Level of containment		
Level of segregation		
Personal protective equipment		
Type of respiratory protective equipment	Type of respiratory protective equipment	Assigned protection factor
Type of dermal protection		
Type of eye protection		
Type of further PPE		
AC X2	Title Activity Class X2	
Physical form and emission potential	physical form	substance- or process-intrinsic emission potential
Process temperature	°C	
Exposure duration	min/shift	
Level of separation		
Localised controls	Type of localised controls	Effectiveness of localised controls
Level of containment		
Level of segregation		
Personal protective equipment		
Type of respiratory protective equipment	Type of respiratory protective equipment	Assigned protection factor
Type of dermal protection		
Type of eye protection		
Type of further PPE		

General good occupational hygiene practices: Required good occupational hygiene practices to ensure a safe handling of the substance involve measures (e.g. shower and change clothes at end of work shift) to avoid any contamination of private households via the work-home-interface and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no eating and smoking in the workplace. In general, inhalation and ingestion should be avoided. Unless otherwise stated below, certified working clothing and shoes should be worn during work. Any contaminated clothing should not be taken home. Good general ventilation in the workplace should be ensured. Dust should not be blown off (e.g. from dried splashes) with compressed air. Regular

training in workplace hygiene practice and proper use of personal protective equipment (if relevant) is required.

9.1.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Activity	Substance	Route of exposure	Type of effects	Duration of exposure	Exposure concentration (source of information)	Risk characterisation
Title Activity Class 1	Ag	Inhalation	local	long-term	µg/m³ (source of information)	RCR =
		Inhalation	local	acute		
		Inhalation	systemic	long-term		
		Inhalation	systemic	acute		
		Dermal	local	long-term		
		Dermal	local	acute		
		Dermal	systemic	long-term		
		Dermal	systemic	acute		
		Eye	local	acute		
	Au	Inhalation	local	long-term	µg/m³ (source of information)	RCR =
		Inhalation	local	acute		
		Inhalation	systemic	long-term		
		Inhalation	systemic	acute		
		Dermal	local	long-term		
		Dermal	local	acute		
		Dermal	systemic	long-term		
		Dermal	systemic	acute		
		Eye	local	acute		
	…	…	…	…	…	…
Title Activity Class 2	Ag	Inhalation, local, long-term	Inhalation, local, long-term	Inhalation, local, long-term	µg/m³ (source of information)	RCR =
		Inhalation, local, acute	Inhalation, local, acute	Inhalation, local, acute		
		Dermal, local, long-term	Dermal, local, long-term	Dermal, local, long-term		
		Dermal, local, acute	Dermal, local, acute	Dermal, local, acute		
	Au	Inhalation, local, long-term	Inhalation, local, long-term	Inhalation, local, long-term	µg/m³	RCR =
		Inhalation, local, acute	Inhalation, local, acute	Inhalation, local, acute		
		Dermal, local, long-term	Dermal, local, long-term	Dermal, local, long-term		
		Dermal, local, acute	Dermal, local, acute	Dermal, local, acute		
	…	…	…	…	…	…

9.1.3. Title Workplace 2

9.1.3.1. Conditions of use

…to be amended…

9.2. Exposure scenario for the intermediate use of the substance

9.2.1. Environmental contributing scenario

9.2.2. Use Title
The same workplaces and corresponding activities as already defined for the contributing occupational exposure scenarios under 9.1. also apply for the use of the substance as an intermediate. Thus, all relevant information regarding operational conditions and risk management measures is provided above and is not duplicated here.

9.2.2.2. Exposure and risks for workers
The same workplaces and corresponding activities as already defined for the contributing occupational exposure scenarios under 9.1. also apply for the use of the substance as an intermediate including all relevant information regarding operational conditions and risk management measures. Thus, the exposure and risks for worker as provided under 9.1. also apply for the use of the substance as an intermediate and is not duplicated here.

10. Risk characterisation related to combined exposure/toxicity

10.1. Human health

10.1.1. Workers

…to be amended…