

**GENERIC ENVIRONMENTAL EXPOSURE SCENARIO
ADDENDUM TO CSR**

4 April 2014

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9 Exposure assessment (and related risk characterisation)

9.0 Methodology – environmental exposure

Representative exposure information from the precious metals refinables sector in Europe has been used to develop generic environmental exposure scenarios (environmental GESs). Assessment has been undertaken of the risks posed to all relevant environmental compartments by releases of selected environmental driving constituents during the production and use of the refinable substances. GES describe the general conditions under which the risks associated with the production and/or use of a substance can be controlled. The environmental GES describe appropriate risk management measures and the exposure assessment that has been developed based on a combination of reasonable worst case values from the sector, SpERCs¹ and default assumptions from ECHA technical guidance (ECHA 2012, REACH Chapter R16²).

9.0.1 Methodology – Constituent approach

In order to address the large variability in the composition of UVCBs such as refinables, both constituent-based and realistic worst case approaches are followed to ensure a scientifically-based, reliable and conservative assessment. Since significant differences between constituents and concentration ranges exist for the refinable substances, the constituent-approach was assumed to be sufficiently protective for all of the environmentally hazardous constituents present in the UVCB. Environmental modelling was conducted for each driving constituent using the 90th percentile tonnage of that constituent calculated from the sector data received from companies processing refinables³. Therefore, the results of such a constituent-based approach can be considered as being conservative with respect to the constituents considered in the exposure assessment.

For the purpose of the environmental risk assessment of the refinables, the selection of driving constituents is based on the following criteria⁴:

- Classified as hazardous to the environment
- Availability of PNEC for risk characterisation
- Availability of monitoring data to enable exposure assessment.

Exposure assessment has been undertaken separately for each of the seven driving constituents identified as relevant to the refinables substances. It is assumed that for constituents discharged to the aquatic environment that following waste water treatment the metal or metalloid will be in soluble form that any observable effects will be due to the metal/metalloid ion.

- Arsenic
- Cadmium
- Copper
- Lead

¹ Industry **S**pecific **E**nvironmental **R**elease **C**ategories

² ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R16: Environmental exposure estimation (Version 2.1, October 2012)

³ The tonnage of each driving constituent in all refinables processed at each site was calculated on the basis of mean % composition for each refinable and the volume of refinables produced or used on the site (a comparison was made between production and use of refinables in order to avoid double-counting).

⁴ There is an absence of exposure monitoring data for some constituents and for these metals and metalloids an evaluation has been made as to whether any potential risk could be adequately predicted using hazard and exposure data for other constituents. For example are there are no monitoring data for a specific constituent, evaluation was made to whether any potential risk could be predicted by assessment of another constituent on the basis that it occurs at higher concentrations and has a lower PNEC. Monitoring data for these constituents will be incorporated in subsequent updates to the CSR.

- Nickel
- Silver
- Zinc

The refinable substances have variable composition and may not contain all of the seven driving constituents so the GES for each refinable substance only considers the relevant constituents.

9.0.1.1 Consideration of risk characterisation for combined effects of UVCB constituents

The proposed risk assessment approach for refinables (inorganic UVCB substances) is based on the hazard and exposure assessment of its individual constituents, for which the risk assessment is conducted separately. These separate risk assessments do however not include a combined risk assessment for various constituents which may in conjunction form antagonistic, additive or even synergistic effects. It is noted that, ideally, the risk assessment should address how different UVCB constituents act together when the local environment is exposed to several constituents in parallel and how to consider this in the risk assessment of UVCBs such as the refinables.

It is worth noting that how to address co-exposure from several chemicals, the potentially associated combined effects -and the resulting risk- ("combined toxicity") is not a metal-specific issue but generic to all chemicals. Approaches are currently under discussion in several regulatory bodies like, for example, the WHO, EPA and NIOSH as well as in EU Scientific Committees. The methods currently proposed to assess mixtures can take account of additive actions, such as dose/concentration addition or response/effect addition. With these methods, effects of chemical mixtures composed of either dissimilarly or similarly acting substances can be predicted. Interactions between substances are, however, generally more difficult to assess and require expert judgment on a case-by-case basis.

In the EU, the risk assessment on the combined effects of chemicals is currently not commonly carried out and not required by REACH. In addition, clear guidelines on how to derive an overall estimation of the risk in case of combined exposure/combined effects are not yet available. Simply adding RCRs does not seem to lead to realistic estimates and efficient solutions in terms of risk management.

This generic issue, which will require a generic solution, is further complicated by the limited amount of literature data on combined toxicity of metals and metal compounds and the huge number of possible permutations of combinations of metals. It is known that effects of metals may be additive, less-than-additive, or more-than-additive but further research is needed to at least cover the spectrum of the main constituents in the inorganic UVCBs.

In the absence of a clear framework for consideration of risk from co-exposure to multiple chemicals, and until more metal data have become available, it is proposed by EUROMETAUX, the registrants of inorganic UVCBs and their respective consultants to apply the approach described below -as a temporary solution- and to update their dossiers as soon as more evidence has become available. This will allow at least the key information on risk management measures to be brought forward in the supply chain without delay and to already distinguish areas of concern from obvious low risk situations.

This strategy has been taken up as short-, medium and long-term actions on the combined toxicity issue which have been proposed to ECHA in the "roadmap" sent early February 2014 in follow-up of the January 22 meeting.

On a short-term basis (before the submission end of April):

- Registrants include considerations/information on combined toxicity on their UVCB constituents in their dossiers where possible.
- If information on combined toxicity is not available, the registrant includes in his dossier this 'placeholder' document, which summarises both the current thinking and includes references to on-going scientific research/ approaches under development in the metals sector.

On a medium- and long -term basis:

- Further improve dossiers with information on combined toxicity as becoming available from scientific progress
 - Develop a paper on tiered approach for the environment combined effects that can be consistently referred to in the different dossiers
- Research on combined toxicity to improve combined toxicity knowledge for further updates/validation of the methodology
 - E.g. by means of a literature review on existing (metal) studies (e.g. epidemiological studies and environmental studies) in order to better understand the magnitude of the issues (if any) in the metal sector and identify/clarify research gaps.

It is also recommended to the registrants to carefully follow up both the progress made by EU authorities and by the metal scientists on the issue and *to assess on a regular basis whether the registration dossiers shall not be further adapted in line with the state of the art.*

"Current thinking"

For ecotoxicity, combined toxicity effects are not clear at present. The available data are mostly obtained at high concentrations, while for risk assessment the interactions at low concentrations are relevant. Unfortunately, this information is not generally available for most metal combinations.

As a Tier 0, *by default*, it has been suggested to use the sum of PEC/PNEC values as a conservative, precautionary approach and to compare it with the value of 1.

This reasoning however immediately faces two important concerns for inorganic UVCBs and metals:

- First of all, because of the natural occurrence of metals and the conservatism built in the PNECs derivation, the simple sum up of the RCRs values of the different constituents of the UVCB even at *background* levels may already result in a sum >1, and this before any possible UVCB production/use. This is illustrated in the table below, showing that RCRs ≥ 1 are obtained already by considering the median ambient background for only a limited number of metals:

Table 1. Regional background RCRs

	Fresh Aq.	Fresh Sed.	Marine Aq.	Marine Sed.	Soil
Silver	0.15	0.022	0.0022	0.0048	0.094
Nickel	0.82 ^D	NA ^A	0.035	NA ^A	0.48
Lead	0.20	0.58 ^D	0.013	0.33	0.13
Zinc	0.17	0.39	0.49	0.61 ^D	1.3 ^C
Arsenic	0.048	0.046	1.6 ^C	0.00 ^B	13 ^C
Cadmium	0.58 ^D	6.9 ^C	0.13	13 ^C	0.46
Copper	0.37	0.79 ^D	0.21	0.026	0.38
TOTAL^E	2.3	0.8	0.2	0.02	1.5

^A: No PNECs are available for these compartments for these metals

^B: No regional background concentrations are available for these compartments for these metals

^C: The regional background concentration results in an RCR of greater than 1 (exposure assessment is conducted on

the basis of added risk)

^D: The regional background concentration contributes a significant portion of the RCR derived (i.e. regional background RCR is greater than 0.5)

^E; Excluding RCR of metals addressed by added risk approach (highlighted in italics)

- Secondly, the simple sum up entails that the considered toxicity values refer to the same species and endpoint. For metals, however, the most sensitive species may differ from one metal to the other (e.g. fish for Ag, bacteria for Ni...) or from one compartment to the other and one will need to consider this species sensitivity as well as the compartment specificity.

A number of research projects are ongoing to increase the knowledge on mechanisms of action and available data:

- 1) Desktop study on existing literature data is ongoing under the supervision of an international panel of environmental experts. The study comprises the assessment of 1800 mixture exposures, usually characterized by relatively high metal concentrations. Results will be published as a 12-manuscript Special Section in *Environmental Toxicology & Chemistry* in 2014.
- 2) As indicated above, most of the studies on mixture ecotoxicity of metals have been performed at relatively high metal concentrations. These studies are of less relevance for risk assessment, where combinations of more realistic (lower) concentrations should be considered. Key is thus to perform mixture toxicity studies at environmentally relevant concentrations. This approach has been followed by a modelling study in which the combined effects of Cu, Zn, Ni, Cd and Co were modelled at their respective HC5. For 125 simulated waters with conditions of pH, Ca, and DOC relevant for the EU. Theoretical modelling with 4 different models indicated potential levels of combined risks and conservatism related to each of them. The underlying modelling assumptions still need experimental testing and validation. This could be done in a next phase of the project, which is currently under discussion.

9.0.2 Methodology – environmental exposure scenarios

Sites concerned with production and use of refinables as chemical intermediates discharge waste water both directly to the aquatic environment and via sewage treatment plants (STPs) so GESs have been developed for both of these scenarios (ES1 for discharge to freshwater and marine water via STP and ES 2 for direct discharge to freshwater or marine water). The GES are based on total emissions of environmental driving constituents during production and use of a variety of refinable substances. Due to the difficulty of assigning emissions of each constituent to a specific refinable substance or process, the GES considers total emissions at a representative site and uses this to assess the acceptability of risk to environmental compartments. A summary of the site emission data used to quantify the environmental aspects of the GES for production of refinables and their use as chemical intermediates is detailed in the GES.

9.0.2.1 Data gathering

Descriptive information was collected during 2011 to 2013 on uses and processes from companies across Europe concerned with the production and use of precious metal refinables. This information included production facility details, tonnage of materials, general description of use, manufacturing processes and risk management measures (RMMs). Site visits were also undertaken to a selection of sites processing precious metal refinables

Data on environmental emissions, the occurrence of environmentally hazardous constituents in refinables and the quantities in which they are processed have been collected from twelve sites processing refinables across Europe. Statistical analysis of this dataset has been used to quantify the GES and to

verify the use of emission factors (EFs) detailed in relevant SpERC documents (SpERCs for metal compounds, ARCHE 2013⁵). For example, the tonnage value of each driving constituent used as the basis of the environmental GES (for both ES1 and ES2) has been taken as the 90th percentile value of the quantities of each driving constituent processed at the twelve sites in Europe. Details of how values from the refinables sector dataset have been used to quantify other parameters in environmental exposure assessment are provided in the description of the exposure scenarios (ES1 and ES2).

9.0.2.2 Emission factors

The emission dataset provided by the refinables sector has been used to verify the use of EFs detailed by SpERCs for the 'manufacture of metal compounds' (ARCHE 2013) to estimate emissions to water and air. Releases to wastewater and air during the manufacture of refinables and their use as chemical intermediates are estimated based on the application of SpERC EFs to the 90th percentile tonnage of each constituent.

The use of SpERCs EFs is considered to be appropriate based on comparison with the EFs derived from the refinables sector dataset. The 90th percentile EF(air) for refinables is 0.039% based on 37 values from 8 sites compared to the SpERC EF(air) of 0.03% based on the 90th percentile for data from 145 sites. EF(waste water) for the refinables sector in Europe ranges from 0.00002% to 1.0% based on 37 values for 7 metals at 8 sites (showing variation with Kd of metal constituents) compared to the SpERC EFs(water) of 0.001-0.2% calculated from Kd and based on the 90th percentile of data from 201 sites. The relationship between Kd (solid-water partition coefficient) and EF to water is justified because Kd expresses the distribution between the aqueous phase and suspended matter and this is a key factor in the removal efficiency of industrial waste water treatment. SpERC EFs are preferred due to their derivation from a much larger dataset than that available for the refinables sector and they are based on monitoring data taken from a directly comparable industry.

Other exposure model inputs are based on default assumptions for dilution taken from ECHA technical guidance (ECHA 2012, REACH Chapter R16). Risk characterisation is performed by comparison of the 'predicted environmental concentrations' (PECs) to appropriate 'predicted no effect concentrations' PNECs.

The environmental exposure scenarios for precious metal refinables are considered to be a 'reasonable worst case' scenario based on the use of the 90th percentile tonnages, SpERCs and median values for other parameters such as flow rate, the STP conditions and other modelling inputs. In order to make the assessment clearer, where appropriate, values, such as the STP flow rate, have been rounded to useful significant figures following the reasonable worst case approach outlined.

⁵ ARCHE (2013) Manufacture of metal compounds. SpERC code Eurometaux 1.2.v2.1. Available online at <http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/>

9.1. Exposure scenarios

9.1.1. Conditions of use

The conditions of use are as described in the generic exposure scenarios (GES) below.

9.1.2. Releases

The GES and associated risk assessment are concerned with releases of refinables constituents to waste-water and air (i.e. those constituents classified as environmentally hazardous). This waste-water is assumed to be either: (ES1) treated at a municipal STP, or undergo equivalent treatment, before discharge to fresh or marine waters or (ES2) discharged directly to fresh or marine waters.

9.1.2.1. Regional background contributions

It was noted that for several of the environmental driving constituents, the regional background concentration is high and can lead to a significant probability of risk without the contribution of any local emissions. Table 1 details the RCRs calculated only on regional background concentrations, with some compartments already showing RCRs greater than 1. Where there is a recommendation to use the added risk approach to estimate sediment PEC or background sediment concentration, only the local site contribution to concentrations of the constituent in water have been used for exposure modelling of sediment concentrations via partitioning from water⁶.

9.1.3. Metal specific adjustments

As noted in the table above, some environmental marker substances have background concentrations high enough to result in RCRs greater than 1 without the contribution of local emissions. In these cases, the inclusion of the background concentrations is not always appropriate in the development of the GES or other metal specific adjustments to the GES are applied. Various metal specific adjustments have been made to the GES modelling following the approaches used in the original CSRs for each of the individual marker substances; these are detailed below.

Silver: No adjustments were made for the assessment of silver.

Nickel: No adjustments were made for the assessment of nickel.

Lead: No adjustments were made for the assessment of lead.

Zinc: Exposure assessment for zinc in sediments and soil is undertaken on the basis of the 'added risk' approach so exposure modelling for these compartments is undertaken on the basis of the local emission contributions only.

Arsenic: Exposure assessment for arsenic in soil, sediments and fresh and marine water is undertaken on the basis of the 'added risk' approach so exposure modelling for these compartments is undertaken on the basis of the local emission contributions only.

Cadmium: Exposure assessment for cadmium in freshwater and marine sediments is undertaken on the basis of the 'added risk' approach so exposure modelling for these compartments is undertaken on the basis of the local emission contributions only.

Copper: No adjustments were made for the assessment of copper.

⁶ It is considered that background water concentrations are already in equilibrium with the background sediment concentration

9.1.4. Secondary poisoning

The assessment of the bioaccumulation and secondary poisoning potential of the inorganic UVCB as such has not been considered. According to the CLP Guidance for complex substances (Annex III 3.2), it is not recommended to estimate an average or weighted BCF value but it is preferable to identify one or more representative constituents for further consideration.

Secondary poisoning is considered relevant for the following metal constituents based on their known bioaccumulation potential: Ni, Pb, As and Cd. The secondary poisoning approach is mainly driven by the hazard properties of the element.

For other metals, the bioaccumulation criterion is not applicable because they are either essential and well regulated in all living organisms or they do not magnify in aquatic and terrestrial systems. Where no hazard has been identified for substances, such as Cu, Zn, Co, etc, no secondary poisoning assessment has been conducted.

9.2. Exposure scenario 1: Manufacture, recycling and intermediate use of refinables (with discharge to freshwater and marine water via STP)

1. Title																	
ES: Manufacture, recycling and intermediate use of refinables																	
Life cycle	Manufacture, recycling and intermediate use of refinables																
Systematic title based on use descriptor	ERC: ERC 1 Manufacture of substances ERC 6A Industrial use resulting in manufacture of another substance (use of intermediates)																
2. Operational conditions and risk management measures																	
2.1 Control of environmental exposure																	
Environmental related free short title	Manufacture, recycling and intermediate use of refinables																
Systematic title based on use descriptor (environment)	ERC 1 Manufacture of substances ERC 6A Industrial use resulting in manufacture of another substance (use of intermediates)																
Processes, tasks, activities covered (environment)	Production and use of refinables: Raw material delivery and handling, production and processing, packaging, cleaning & maintenance. Industrial use of refinables as chemical intermediates for the manufacture of other substances.																
Environmental Assessment Method	Reasonable Worst Case estimates, based on the 90 th percentile tonnages and SpERC EFs, validated by refinable sector emission data, have been used to calculate the PECs.																
Product characteristics																	
Refinables as solid or aqueous solution.																	
Environmental assessment is based on the measured emission of hazardous constituents in waste-water discharge and emissions to air.																	
Amounts used																	
Maximum annual use at a site	Modelled tonnage of each environmental marker substance at a single site (based on 90 th percentiles of sector data):																
	<table border="1"> <thead> <tr> <th>Substance</th> <th>Tonnage (T/a)</th> </tr> </thead> <tbody> <tr> <td>Silver</td> <td>1811</td> </tr> <tr> <td>Nickel</td> <td>561</td> </tr> <tr> <td>Lead</td> <td>1408</td> </tr> <tr> <td>Zinc</td> <td>647</td> </tr> <tr> <td>Arsenic</td> <td>222</td> </tr> <tr> <td>Cadmium</td> <td>396</td> </tr> <tr> <td>Copper</td> <td>1296</td> </tr> </tbody> </table>	Substance	Tonnage (T/a)	Silver	1811	Nickel	561	Lead	1408	Zinc	647	Arsenic	222	Cadmium	396	Copper	1296
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Cadmium	396																
Copper	1296																
Frequency and duration of use																	
Pattern of release to the	365 days per year per site to water (sector data)																

environment	300 days per year per site to air (median from sector data)																																
Environment factors not influenced by risk management																																	
Receiving surface water flow rate	Discharge rate from WWTP to STP: 611 m ³ /d (50 th percentile) Discharge rate from STP to final receiving water: 6000 m ³ /d Flow rate of final receiving water: 594000 m ³ /d																																
Dilution factor	Due to STP: 10 (default, RWC for sector data) Due to receiving water: 100 (default, RWC for sector data) Due to marine water: 100 (EUSES default)																																
Other given operational conditions affecting environmental exposure																																	
None																																	
Technical conditions and measures at process level (source) to prevent release																																	
Appropriate process control systems shall be implemented.																																	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil																																	
<p>Waste water: On-site wastewater treatment by chemical precipitation. Efficiency 90->99% (variable for individual constituents of refinables). Emissions factors for driving constituents in wastewater based on Kd (SpERCs for metal compounds⁷):</p> <table border="1"> <thead> <tr> <th>Substance</th> <th>Release factor (g/T)</th> </tr> </thead> <tbody> <tr> <td>Silver</td> <td>20</td> </tr> <tr> <td>Nickel</td> <td>400</td> </tr> <tr> <td>Lead</td> <td>10</td> </tr> <tr> <td>Zinc</td> <td>50</td> </tr> <tr> <td>Arsenic</td> <td>135.6*</td> </tr> <tr> <td>Cadmium</td> <td>50</td> </tr> <tr> <td>Copper</td> <td>400</td> </tr> </tbody> </table> <p>* Release estimates to waste water from metal SpERCs are not applicable; release factor values are based on sector data.</p> <p>Statistical analysis of the dataset collected during 2011-13 from twelve sites processing refinables across Europe has been used to verify the use of emission factors (EFs) detailed in relevant SpERC documents for metal compounds (ARCHE 2013) to estimate emissions to water and air.</p> <p>STP removal rates:</p> <table border="1"> <thead> <tr> <th>Substance</th> <th>Fraction to water after STP</th> </tr> </thead> <tbody> <tr> <td>Silver</td> <td>0.20</td> </tr> <tr> <td>Nickel</td> <td>0.60</td> </tr> <tr> <td>Lead</td> <td>0.16</td> </tr> <tr> <td>Zinc</td> <td>0.18</td> </tr> <tr> <td>Arsenic</td> <td>0.50*</td> </tr> <tr> <td>Cadmium</td> <td>0.19</td> </tr> <tr> <td>Copper</td> <td>0.20</td> </tr> </tbody> </table>		Substance	Release factor (g/T)	Silver	20	Nickel	400	Lead	10	Zinc	50	Arsenic	135.6*	Cadmium	50	Copper	400	Substance	Fraction to water after STP	Silver	0.20	Nickel	0.60	Lead	0.16	Zinc	0.18	Arsenic	0.50*	Cadmium	0.19	Copper	0.20
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*No data available: set as worst case default

Air:

Removal of hazardous constituents from stack emissions by fabric or bag filters and wet scrubbers.
Release factor after on-site treatment: 300 g/T (SpERC for 'Manufacture of metal compounds'⁸).

Statistical analysis of the dataset collected during 2011-13 from twelve sites processing refinables across Europe has been used to verify the use of emission factors (EFs) detailed in relevant SpERC documents for metal compounds (ARCHE 2013⁹) to estimate emissions to water and air.

Organizational measures to prevent/limit release from site

Regular operator training.

Conditions and measures related to municipal sewage treatment plant (if applicable)

Municipal Sewage Treatment Plant (STP)	Yes
Discharge rate of the Municipal STP	6000 m ³ /d
Incineration of the sludge of the Municipal STP	No. Worst case default of application of sludge to agricultural soil has been assumed.

Conditions and measures related to external treatment of waste for disposal

Waste is considered not to be relevant to the life cycle of the refinables as the substances are used only as intermediates, chemically modified to become other substances, and the refinables themselves are recycled as part of the manufacturing process.

Conditions and measures related to external recovery of waste

Refinables are processed as intermediates and recycled as part of the manufacturing process.

3. Exposure and risk estimation

Environment

Silver

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.025	NA	0.0033	0.0033	0.13
Freshwater	mg/L	4.0E-05	6.1E-06	8.5E-06	1.5E-05	0.36
Freshwater sediment	mg/kg _{ww}	95	2.1	1.4	3.5	0.037
Marine water	mg/L	8.6E-04	1.9E-06	8.5E-06	1.0E-05	0.012
Marine sediment	mg/kg _{ww}	95	0.46	0.35	0.81	0.0085
Terrestrial	mg/kg _{ww}	1.24	0.075	0.0011	0.13	0.11

Nickel

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.33	NA	0.061	0.061	0.19
Freshwater	mg/L	0.0036	0.0029	4.4E-04	0.0033	0.94 [†]
Freshwater sediment	mg/kg _{ww}	NA	7.4	2.5	9.9	NA
Marine water	mg/L	0.0086	3.0E-04	5.6E-04	8.6E-04	0.10
Marine sediment	mg/kg _{ww}	NA	0.46	0.35	0.81	0.0085
Terrestrial	mg/kg _{ww}	34	14	3.4E-04	14	0.43

⁸ ARCHE (2013) Manufacture of metal compounds. SpERC code Eurometaux 1.2.v2.1. Available online at <http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/>

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‡ RCR largely attributable to regional background concentration ($RCR_{local} = 0.12$)

Lead

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.10	NA	0.0010	0.0010	0.010
Freshwater	mg/L	0.0031	6.1E-04	1.9E-06	6.1E-04	0.20
Freshwater sediment	mg/kg _{ww}	38	22	0.12	22	0.59
Marine water	mg/L	0.0035	4.6E-05	3.9E-07	4.6E-05	0.013
Marine sediment	mg/kg _{ww}	36	12	17	29	0.81
Terrestrial	mg/kg _{ww}	187	25	0.00084	25	0.13

Zinc

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.052	NA	0.0027	0.0027	0.051
Freshwater	mg/L	0.021	0.0034	1.0E-05	0.0034	0.17
Freshwater sediment	mg/kg _{ww}	26	NR	0.24	0.24	0.0094
Marine water	mg/L	0.0061	0.0030	2.4E-05	0.0030	0.49
Marine sediment	mg/kg _{ww}	12	7.5	0.032	0.032	0.0026
Terrestrial	mg/kg _{ww}	31	NR	0.00039	0.050	0.0016

Arsenic

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.061	NA	0.0070	0.0070	0.11
Freshwater	mg/L	0.013	NR	6.1E-05	6.1E-05	0.0047
Freshwater sediment	mg/kg _{ww}	28	NR	0.13	0.13	0.0047
Marine water	mg/L	9.1E-04	0.0015	6.1E-05	6.1E-05	0.067
Marine sediment	mg/kg _{ww}	2.0	0	0.13	0.13	0.067
Terrestrial	mg/kg _{ww}	0.47	NR	1.3E-04	0.029	0.062

Cadmium

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.020	NA	0.0018	0.0018	0.088
Freshwater	mg/L	1.9E-04	1.1E-04	5.9E-06	1.2E-04	0.61
Freshwater sediment	mg/kg _{ww}	0.39	NR	0.17	0.17	0.43
Marine water	mg/L	0.0011	1.5E-04	1.7E-05	1.7E-04	0.15
Marine sediment	mg/kg _{ww}	0.14	1.8	0.0023	0.0023	0.017
Terrestrial	mg/kg _{ww}	0.79	0.36	2.4E-04	0.39	0.50

Copper

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Discharge to STP	mg/L	0.23	NA	0.048	0.048	0.21
Freshwater	mg/L	0.0078	0.0029	3.3E-04	0.0032	0.41
Freshwater sediment	mg/kg _{ww}	19	15	2.2	17	0.90 [‡]
Marine water	mg/L	0.0052	0.0011	1.6E-04	0.0013	0.24
Marine sediment	mg/kg _{ww}	147	3.8	4.6	8.4	0.057
Terrestrial	mg/kg _{ww}	57	22	7.8E-04	22	0.39

‡ RCR largely attributable to regional background concentration ($RCR_{local} = 0.12$)

NA – no data available

NR – not relevant

Summary of the secondary poisoning exposure and risk characterisation for the processing

of refinables (discharge of waste water via STP)**Freshwater aquatic food chain**

Constituent	PEC _{local water} (mg/l)	PEC _{oral} (mg/kg ww)	PNEC _{oral} (mg/kg ww)	RCR
Arsenic	6.91E-04	1.87E-01	1.31	0.15
Cadmium	1.16E-04	2.70E-02	0.16	0.18
Lead	6.12E-04	9.50E-01	10.9	0.088
Nickel (aquatic bird)	3.34E-03	9.02E-01	12.3	0.076
Nickel (aquatic mammal)	3.34E-03	9.40E-01	2.3	0.41

Marine aquatic food chain

Constituent	PEC _{local seawater} (mg/l)	PEC _{oral} (mg/kg ww)	PNEC _{oral} (mg/kg ww)	RCR
Arsenic	6.10E-05	3.58E-01	1.31	0.273
Cadmium	1.67E-04	3.89E-02	0.16	0.243
Lead	4.64E-05	7.20E-02	10.9	0.007
Nickel	8.96E-04	1.45E+01	4.6	0.305

Terrestrial food chain

Constituent	PEC _{local soil} (mg/l)	PEC _{oral} (mg/kg ww)	PNEC _{oral} (mg/kg ww)	RCR
Arsenic	6.2	0.632	1.31	0.48
Cadmium	0.36	0.066	0.16	0.41
Lead	25	2.547	10.9	0.23
Nickel (terrestrial bird)	14	1.434	8.5	0.17
Nickel (terrestrial mammal)	14	0.030 (ingested dose from food)	0.12	0.25

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES**Environment**

Scaling tool: Metals EUSES IT tool (free download: <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool>)

Scaling of the release to air and water environment includes:

- Refining of the release factor to air and waste water and/or and the efficiency of the air filter and wastewater treatment facility.
- Adjustment of the flow rate for the receiving water body and subsequent dilution factor.

9.3. Exposure scenario 2: Manufacture, recycling and intermediate use of refinables (direct discharge to marine and freshwaters without STP)

1. Title													
ES: Manufacture, recycling and intermediate use of refinables													
Life cycle	Manufacture, recycling and intermediate use of refinables												
Systematic title based on use descriptor	ERC: ERC 1 Manufacture of substances ERC 6A Industrial use resulting in manufacture of another substance (use of intermediates)												
2. Operational conditions and risk management measures													
2.1 Control of environmental exposure													
Environmental related free short title	Manufacture, recycling and intermediate use of refinables												
Systematic title based on use descriptor (environment)	ERC 1 Manufacture of substances ERC 6A Industrial use resulting in manufacture of another substance (use of intermediates)												
Processes, tasks, activities covered (environment)	Production and use of refinables: Raw material delivery and handling, production and processing, packaging, cleaning & maintenance. Industrial use of refinables as chemical intermediates for the manufacture of other substances.												
Environmental Assessment Method	Reasonable Worst Case estimates, based on the 90 th percentile tonnages and the SpERC EFs, validated by refinable sector emission data, have been used to calculate the PECs. For some constituents, the maximum tonnages that can be manufactured safely without risk to the environment (Msafe tonnages) have been calculated.												
Product characteristics Refinables as solid or aqueous solution. Environmental assessment is based on the measured emission of hazardous constituents in waste-water discharge and emissions to air.													
Amounts used													
Modelled tonnages (T/a)	Modelled tonnage of each environmental marker substance at a single site (based on 90 th percentiles of sector data except where indicated. Sector data included tonnage values from sites with and without discharge to STP):												
	<table border="1"> <thead> <tr> <th>Substance</th> <th>Tonnage (T/a)</th> </tr> </thead> <tbody> <tr> <td>Silver</td> <td>1120*</td> </tr> <tr> <td>Nickel</td> <td>360*</td> </tr> <tr> <td>Lead</td> <td>1408</td> </tr> <tr> <td>Zinc</td> <td>647</td> </tr> <tr> <td>Arsenic</td> <td>40*</td> </tr> </tbody> </table>	Substance	Tonnage (T/a)	Silver	1120*	Nickel	360*	Lead	1408	Zinc	647	Arsenic	40*
	Substance	Tonnage (T/a)											
	Silver	1120*											
	Nickel	360*											
	Lead	1408											
Zinc	647												
Arsenic	40*												

	<table border="1"> <tr> <td>Cadmium</td> <td>140*</td> </tr> <tr> <td>Copper</td> <td>350*</td> </tr> </table> <p>* Msafe tonnages have been used for direct release of these constituents; this is the amount that can be processed in a year under the conditions described in this GES without posing an unacceptable risk to the environment; this is generally based on RCR = 0.8, except where regional background contributes a large proportion of the RCR, e.g. for nickel and copper.</p>	Cadmium	140*	Copper	350*
Cadmium	140*				
Copper	350*				
Frequency and duration of use					
Pattern of release to the environment	365 days per year per site to water (median) 300 days per year per site to air (median)				
Environment factors not influenced by risk management					
Receiving surface water flow rate	Discharge from onsite wwtp to final receiving water: 611 m ³ /d Flow rate of final receiving water: 600000 m ³ /d				
Dilution factor	Due to receiving water: 1000 (max)				
Other given operational conditions affecting environmental exposure					
None					
Technical conditions and measures at process level (source) to prevent release					
Appropriate process control systems shall be implemented.					
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil					
Waste water:					
Emissions factors for hazardous constituents in wastewater based on Kd (SpERCs for metal compounds ⁷):					
Substance	Release factor (g/T)				
Silver	20				
Nickel	400				
Lead	10				
Zinc	50				
Arsenic	135.6*				
Cadmium	50				
Copper	400				
* Release estimates to waste water from metal SpERCs are not applicable; release factor values are based on sector data.					
Statistical analysis of the dataset collected during 2011-13 from twelve sites processing refinables across Europe has been used to verify the use of emission factors (EFs) detailed in relevant SpERC documents for metal compounds (ARCHE 2013 ¹⁰) to estimate emissions to water and air.					
Air:					
Release factor after on-site treatment: 300 g/T (SpERC for 'Manufacture of metal compounds' ¹¹)					

¹⁰ ARCHE (2013) Manufacture of metal compounds. SpERC code Eurometaux 1.2.v2.1. Available online at <http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/>

¹¹ ARCHE (2013) Manufacture of metal compounds. SpERC code Eurometaux 1.2.v2.1. Available online at <http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/>

Statistical analysis of the dataset collected during 2011-13 from twelve sites processing refinables across Europe has been used to verify the use of emission factors (EFs) detailed in relevant SpERC documents for metal compounds (ARCHE 2013¹²) to estimate emissions to water and air.

Fugitive emissions should be reduced from material storage and handling, reactors or furnaces and from material transfer points by following hierarchical measures: process optimization and minimization of emissions, sealed reactors and furnaces, targeted fume collection.

Organizational measures to prevent/limit release from site

Regular operator training.

Conditions and measures related to municipal sewage treatment plant (if applicable)

Municipal Sewage Treatment Plant (STP) No

Conditions and measures related to external treatment of waste for disposal

Waste is considered not to be relevant to the life cycle of the refinables as the substances are used only as intermediates, chemically modified to become other substances, and the refinables themselves are recycled as part of the manufacturing process.

Conditions and measures related to external recovery of waste

Refinables are recycled as part of the manufacturing process.

3. Exposure and risk estimation

Environment

Silver

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Freshwater	mg/L	4.0E-05	6.1E-06	2.7E-05	3.3E-05	0.82
Marine water	mg/L	8.6E-04	1.9E-06	2.6E-04	2.6E-04	0.31
Freshwater sediment	mg/kg _{ww}	95	2.1	1.1	3.2	0.034
Marine sediment	mg/kg _{ww}	95	0.46	11	11	0.12
Terrestrial	mg/kg _{ww}	1.24	0.075	0.0011	0.076	0.061

Nickel

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Freshwater	mg/L	0.0036	0.0029	4.8E-04	0.0034	0.95 [‡]
Marine water	mg/L	0.0086	3.0E-04	0.0059	0.0062	0.72
Freshwater sediment	mg/kg _{ww}	NA	7.4	2.7	10.1	NA
Marine sediment	mg/kg _{ww}	NA	3.5	8.1	12	NA
Terrestrial	mg/kg _{ww}	34	14	2.2E-04	14	0.42

[‡] RCR largely attributable to regional background concentration (RCR_{local} = 0.13)

Lead

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Freshwater	mg/L	0.0031	6.1E-04	1.1E-05	6.2E-04	0.20
Marine water	mg/L	0.0035	4.6E-05	2.4E-05	7.0E-05	0.020
Freshwater sediment	mg/kg _{ww}	38	22	0.77	23	0.60
Marine sediment	mg/kg _{ww}	36	12	8.8	21	0.58
Terrestrial	mg/kg _{ww}	187	25	8.5E-04	25	0.13

Zinc

¹² ARCHE (2013) Manufacture of metal compounds. SpERC code Eurometaux 1.2.v2.1. Available online at <http://www.arche-consulting.be/metal-csa-toolbox/SPERCs-tool-for-metals/>

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Freshwater	mg/L	0.021	0.0034	5.5E-05	0.0035	0.17
Marine water	mg/L	0.0061	0.0030	1.3E-03	0.0043	0.70
Freshwater sediment	mg/kg _{ww}	26	NR	1.3	1.3	0.051
Marine sediment	mg/kg _{ww}	12	NR	1.7	1.7	0.14
Terrestrial	mg/kg _{ww}	31	NR	3.9E-04	3.9E-04	1.2E-05

Cadmium

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Freshwater	mg/L	1.9E-04	1.1E-04	1.1E-05	1.2E-04	0.64
Marine water	mg/L	0.0011	1.5E-04	3.1E-04	4.6E-04	0.41
Freshwater sediment	mg/kg _{ww}	0.39	NR	0.32	0.32	0.81
Marine sediment	mg/kg _{ww}	0.14	NR	0.043	0.043	0.31
Terrestrial	mg/kg _{ww}	0.79	0.36	8.4E-05	0.36	0.46

Copper

Compartment	Unit	PNEC	PEC _{regional}	C _{local}	PEC	RCR
Freshwater	mg/L	0.0078	0.0029	4.4E-04	0.0033	0.43
Marine water	mg/L	0.0052	0.0011	0.0021	0.0032	0.63
Freshwater sediment	mg/kg _{ww}	19	15	2.9	18	0.94 [‡]
Marine sediment	mg/kg _{ww}	147	3.8	62	65	0.45
Terrestrial	mg/kg _{ww}	57	22	2.1E-04	22	0.38

[‡] RCR largely attributable to regional background concentration (RCR_{local} = 0.15)

[‡] RCR largely attributable to regional background concentration (RCR_{local} = 0.12)

NA – no data available

NR – not relevant

Summary of the secondary poisoning exposure and risk characteriation for the processing of refinables (direct discharge of waste water)

Freshwater aquatic food chain

Constituent	PEC _{local water} (mg/l)	PEC _{oral} (mg/kg ww)	PNEC _{oral} (mg/kg ww)	RCR
Arsenic	7.01E-04	1.89E-01	1.31	0.14
Cadmium	1.21E-04	2.82E-02	0.16	0.18
Lead	6.21E-04	9.64E-01	10.9	0.089
Nickel (aquatic bird)	3.38E-03	9.13E-01	12.3	0.074
Nickel (aquatic mammal)	3.38E-03	9.40E-01	2.3	0.41

Marine aquatic food chain

Constituent	PEC _{local seawater} (mg/l)	PEC _{oral} (mg/kg ww)	PNEC _{oral} (mg/kg ww)	RCR
Arsenic	6.80E-04	3.99E+00	1.31	0.97
Cadmium	4.60E-04	1.07E-01	0.16	0.67
Lead	7.00E-05	1.09E-01	10.9	0.010
Nickel	2.62E-04	4.27E-01	4.6	0.093

Terrestrial food chain

Constituent	PEC _{local soil} (mg/l)	PEC _{oral} (mg/kg ww)	PNEC _{oral} (mg/kg ww)	RCR
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Arsenic	6.2	0.632	1.31	0.48
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