TIERED APPROACH FOR SITE-SPECIFIC EXPOSURE ASSESSMENT AND RISK CHARACTERISATION: REFINEMENT FOR THE ENVIRONMENTAL COMPARTMENT

I. Introduction

This is a nickel specific guidance document for performing a site-specific assessment and risk characterization for the environmental compartment at your local site. It is recommended to perform such an assessment when a site does not comply with the conditions stipulated in the safe use GES. For this assessment there are a number tools available (DU Scaling tool, SPERCs) to help estimate local exposure to the environment, developed by industry, which will be described in the guidance using practical examples provided in the relevant appendices. This guidance will not explain the relevant section of the GES as this is already provided in the DU-mmies Guidance (Eurometaux, version 1.0, 2011). For a glossary of acronyms and definitions please refer to Annex II of the DU-mmies Guidance.

II. Nickel PNECs

Exposure to the different environmental compartment of the GES is developed to satisfy all reasonable worst case (RWC) Predicted No Effect Concentrations (PNECs) for freshwater aquatic, marine aquatic , soil and exposure to microorganism in the sewage treatment plant; Table 1 below). A sediment PNEC is not yet available and is currently being finalized. The freshwater aquatic PNEC is the driver of the environmental GES, thus if the freshwater PNEC is satisfied, then this proves to demonstrate compliance for all other environmental compartments (except local air concentration for estimating exposure to Man via the Environment , which is described in a separate guidance document). The table below lists the PNECs currently in the GES since the 2011 updates. These values may change in a future update to the Ni REACH dossiers. Note that these PNECs are represented for nickel metal and all nickel substances of the Ni Consortia.

Table 1: Predicted No Effect Concentrations (Reasonable Worst Case – RWC)

Environmental Compartment	$PNEC_{RWC}$	Unit
Freshwater aquatic	3.55	µg Ni/L
Marine aquatic	8.6	µg Ni/L
Soil	29.9	mg Ni/kg dry weight
Sewage Treatment Plant	0.33	mg Ni/L
Sediment	Pending	Pending

To determine risk for the above outlined environmental compartments, the Predicted Exposure Concentration (PEC) for that compartment must be below the corresponding PNEC value. In other words, the risk characterisation ratio (RCR) must be less than 1 (RCR < 1). Please see below the following formula for calculating your RCR.

Equation 1:

RCR = PEC / PNEC

RCR: Risk Characterisation Ratio
PEC: Predicted Environmental Concentration
PNEC: Predicted No Effect Level

If RCR < 1 → NO RISK ✓

If RCR > 1 → RISK X

III. Tiered approach for doing your site-specific assessment

This section will describe all the relevant steps recommended by the Nickel Consortia in determining your compliance with the GES and scaling the GES to your site-specific conditions. As you proceed further down the tiered approach (Steps 1 – 5) more data is required at each step in order to make a site-specific assessment. Below is the recommended step-wise approachfor environmental risk characterisation.

Step 1: Calculate a site-specific PEC

Calculate the PEC_{local}-total (local contributions plus regional background) using the DU Scaling Tool (free download: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool). See Annex 1 for an example on how the tool works. For a generic calculation, it will be assumed that the ambient background concentration of nickel for the different environmental compartments can be one of the values provided in Annex 2 (Ambient background concentrations of nickel in water and soil). This represents a simplified approach because ambient background concentrations can vary considerably among different regions within Europe.

Compare the calculated PEC_{local}-total to the RWC PNEC:

> if PEC_{local}-total <RWC PNEC, NO RISK Identified (local risks are adequately controlled and no further action required);
>
> if PEC_{local}-total >RWC PNEC, RISK Identified (proceed to Step 2 Eco-region PNEC or Step 3 Site-specific PNEC)

Step 2: Calculate a site-specific $PNEC_{bioav.eco\text{-}region}$ (Eco-region approach)

Calculate a PNEC value appropriate for the regional conditions using measured or approximated site conditions. If measured data are not available for most of the abiotic factors (e.g. DOC, hardness, pH) and it is not feasible to obtain representative measured data on the lacking parameter for the local site, it is recommended to identify the ecoregion type in which best represents the site conditions in a conservative way. If measured data on all relevant abiotic parameters are available, it is recommended to proceed directly to step 3.

PNEC values have been determined for 7 different freshwater aquatic ecoregions and 6 different soil ecoregions (see Table 2 and 3) in the EU Ni Risk Assessment (2008/2009). Justification for the need of a read-across estimation has to be provided. Details showing that the ecoregion approach was applied in a precautionary manner should be provided. The conclusions made from the ecoregion approach represent probable risk situations and the risk characterisations can be further refined if needed by collecting additional site specific information (exposure data).

To apply the ecoregion concept, use Tables 2 and 3 provided below in conjunction with the EU Nickel Environmental Risk Assessment procedure (EU Ni RAR, 2008/2009). To estimate risk, compare the PNEC of the selected ecoregion to the calculated PEC_{local}-total:

> if PEC_{local}-total < PNECbioav.eco-region, NO RISK Identified (local risks are adequately controlled and no further action required);
>
> if PEC_{local}-total > PNECbioav.eco-region, RISK Identified (proceed to Step 3 4, or 5)

Two options may be considered at this stage: (a) if the risk ratio is considerably higher than one, local risks can be considered as being unacceptable and risk management measures are required (go to Step 5), or (b) if the ratio is only slightly higher than one, the relevant benefits and costs of refining the PNEC calculation further as opposed to taking further risk management measures can be considered. For further refinement of the PNEC value, then proceed to Step 3 or 4.

Table 2. Freshwater Aquatic Compartment. Summary of the physico-chemical characteristics and $PNEC_{bioav-ecoregion}$ of the different selected scenarios

Nº	Selected example repesenting ecoregion scenarios	Type	pH	Hardness (mg $CaCO_3$/L)	DOC (mgC/L)	$PNEC_{bioav-ecoregion}$ (µg Ni/L)
1	Ditch in the Netherlands	Small (ditches with flow rate of ± 1,000 m^3/d)	6.9	260	12.0	21.8
2	River Otter in the United Kingdom	Medium (rivers with flow rate of ± 200,000 m^3/d)	8.1	165	3.2	4.0
3	River Teme in the United Kingdom	Medium (rivers with flow rate of ± 200,000 m^3/d)	7.6	159	8.0	9.5
4	River Rhine in the Netherlands	Large (rivers with flow rate of ±1,000,000 m^3/d	7.8	217	2.8	5.4
5	River Ebro in Spain	Mediterranean river	8.2	273	3.7	4.4
6	Lake Monate in Italy	Oligotrophic systems	7.7	48.3	2.5	3.6
7	Neutral-Acidic lake in Sweden	Acidic system	6.7	27.8	3.8	6.1

Table 3. Terrestrial Compartment. Summary of the phys.-chem. characteristics and PNEC derived for the different selected scenarios

Nº	Selected example repesenting ecoregion scenarios	pH	OM%	Clay%	CEC Cmol/kg	PNEC (mg/kg dw)	Relative bioavailability
1	Agricultural acid sandy soil (sweden	4.8	2.8	7	2.4	4.3	High
2	Agricultural loamy soil (The Netherlands)	7.5	2.2	26	20	50	Medium
3	Agricultural peaty soil (The Netherlands)	4.7	40	24	35	94.4	Medium-low
4	Natural acid sandy soil (Germany)	3.0	9	7	6	12.6	High
5	Natural clay soil (Greece)	7.4	4.5	46	36	97.2	Low
6	Agricultural & natural soil (Denmark)	6.3	0.6	8.9	10.4	23.8	high

Step 3: Establish a site-specific $PNEC_{bioavailable}$ (when abiotic factors are available)

Collect relevant abiotic parameters from the local environment to calculate the site-specific PNEC value. For freshwater aquatic systems, the relevant parameters include DOC, pH, and hardness. For soils, the relevant parameters are pH and cation exchange capacity. There is one tool available for each compartment (freshwater/soil) for calculating a site-specific PNEC. Currently, only the PNEC calculator for soil is available free on-line (http://www.arche-consulting.be/Metal-CSA-toolbox/soil-pnec-calculator). To calculate a site-specific PNEC for the freshwater compartment, please contact the Nickel Institute where they can calculate a freshwater PNEC provided that the proper abiotic parameters listed above are available.

> if PEC_{local}-total < PNECbioavailable site specific, NO RISK Identified (local risks are adequately controlled and no further action required);

if PEC_{local}-total > PNECbioavailable site specific, , RISK Identified (proceed to Step 4)

Step 4: Clocal approach

The next step functions to discriminate between the contribution of regional background Ni concentrations versus the contribution of Ni from the local site towards the risk that has been identified. This step does not serve to remove the site from risk, but rather provide guidance on appropriate RMMs to be accounted for.

It is recommended to assess the risk characterisation ratio by using the local contributions (C_{local}) approach. By this means, the focus is placed on the site's contribution in the environment (C_{local}).

> if C_{local} < $PNEC_{bioavailable\ site\ specific}$ or $PNEC_{bioav.eco\text{-}region}$, then the local risks are not caused by the site but rather by other nickel sources in the surrounding environment;
>
> if C_{local} > $PNEC_{bioavailable\ site\ specific}$ or $PNEC_{bioav.eco\text{-}region}$, then the local risk are caused in part by the site and RMMs should be considered.

For situations where C_{local} < $PNEC_{bioavailable\ site\ specific}$ or $PNEC_{bioav.eco\text{-}region,}$ one approach would be to improve the accuracy of the $PEC_{regional}$ value that is used to derive the PEC_{local}-total value. For example, Ni concentrations within the watershed of the facility could be determined and used in lieu of $PEC_{regional}$ values obtained from regional monitoring. If more relevant $PEC_{regional}$ values are obtained, then step 4 (comparison of PEC_{local}-total < $PNEC_{bioavailable\ site\ specific}$) should be repeated. If PEC_{local}-total < $PNEC_{bioavailable\ site\ specific}$, then local risks are adequately controlled. If not, then Step 5 or 6 needs to be considered.

Step 5: Collect Monitoring Data to get $PEC_{measured}$

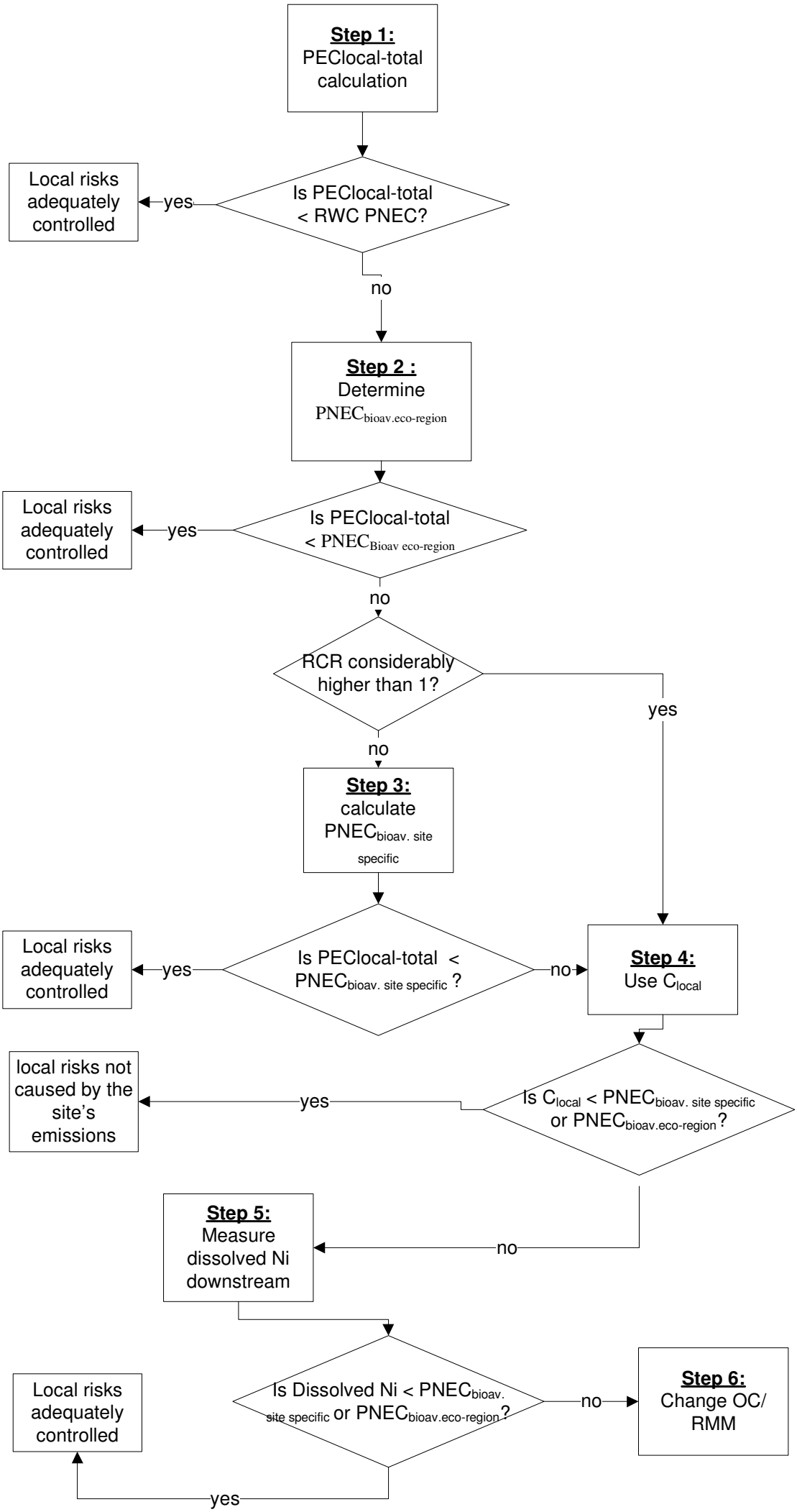
The next step involves the collection of monitoring data downstream from your sites local emissions. The dissolved nickel fraction should be measured from a statistically representative sample. The dissolved Ni measured downstream ($PEC_{measured}$) can then be compared to either the $PNEC_{RWC}$, $PNEC_{bioav.\ eco\text{-}region}$ or $PNEC_{bioavailable.}$

> If PECmeasured < $PNEC_{RWC}$, $PNEC_{bioav.\ eco\text{-}region}$ or $PNEC_{bioavailable}$ local risks are adequately controlled and no further action required).
>
> If PECmeasured > $PNEC_{RWC}$, $PNEC_{bioav.\ eco\text{-}region}$ or $PNEC_{bioavailable}$,then step 6 needs to be considered.

Step 6

If after assessing risk via steps 1-5 and the site-specific risk characterisation indicated that the PEC > $PNEC_{bioavailable\ site\ specific}$ or $PNEC_{bioav.eco\text{-}region}$, then specific Risk Management Measures (RMMs) or/and Operating Conditions (OCs) will be recommended. For instance, if the site is associated with a risk for the aquatic environment, more stringent end-of-pipe controls may be recommended in collaboration with the local licensing authorities.

Overal workflow of the Environmental tiered approach



Annex 1: Running the DU scaling tool to assess compliance with the GES

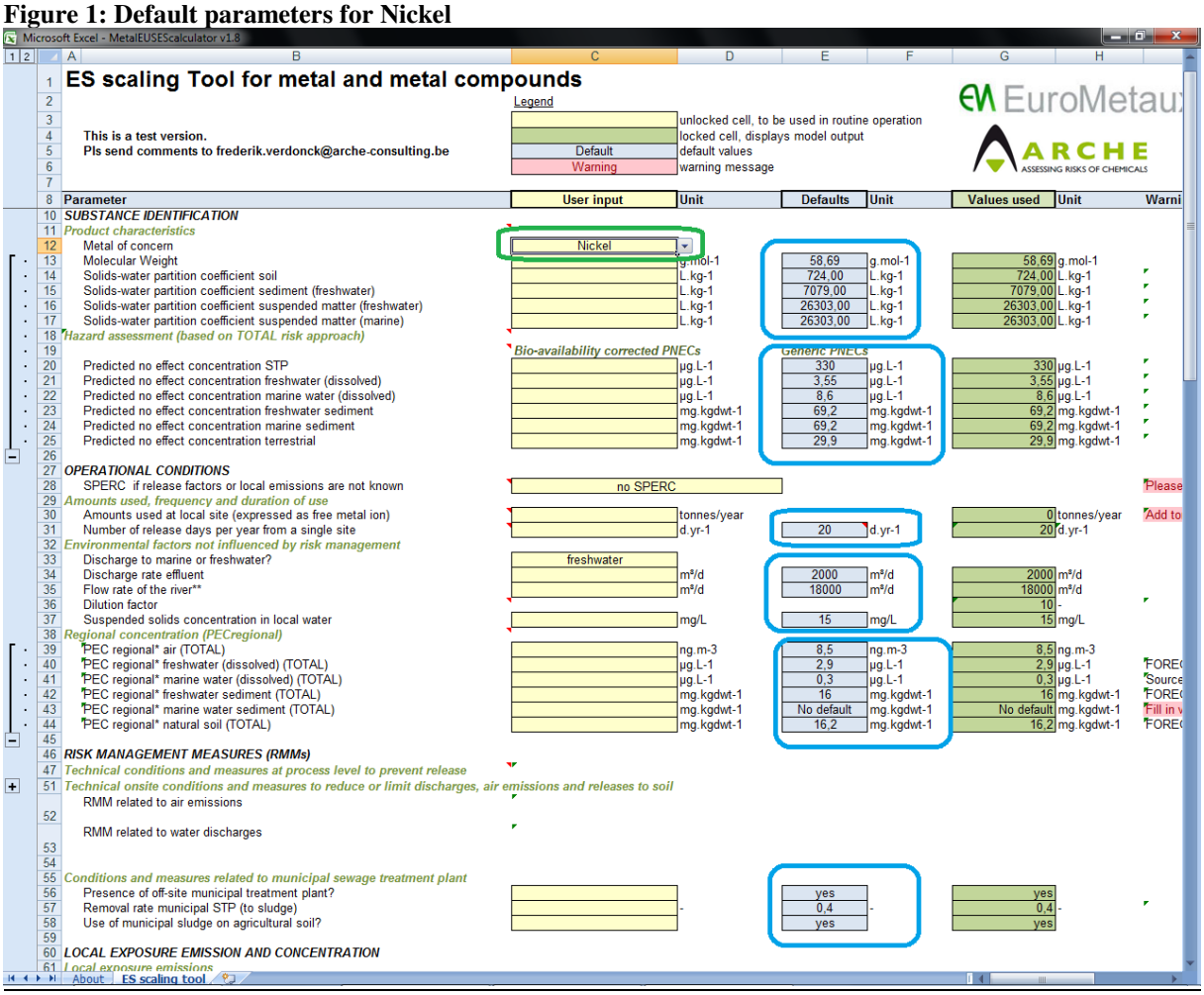
Introduction:

Under REACH the downstream user (DU) is obliged to check whether they are in compliance with the generic exposure scenario (GES) provided to them via the Extended Safety Data Sheet (eSDS). To do this, operational conditions (OC) and risk management measures (RMM) in the GES are compared to the actual conditions of the site. Where site-specific OC and RMM are not identical or deviate completely, the DU scaling tool, prepared by Eurometaux and ARCHE, can be used to scale the GES and check compliance with the environmental part of the GES. This Appendix will guide you through the DU scaling tool using Nickel as an example. The Tool is free to download from the ARCHE website:
http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool

Brief overview of the Model:

This model is meant to provide you with local predicted environmental concentrations (PEC) and to calculate your local risks. Each metal within the tool is linked to a set of default values. Below in figure 1 is an example of the excel spreadsheet with Nickel metal selected as an example to illustrate the default parameters.

Figure 1: Default parameters for Nickel



In figure 1, nickel has been selected under the tab "user input" metal of concern (circled in green). Once the metal of concern is selected, a set of default parameters will appear in the column "defaults." All the default assumptions for nickel have been circled in blue. These include the following:

- Substance identification (product characteristics and PNECs)

- Operation conditions (e.g. number of release days per from a single site, river flow rates, discharge rate of effluent, suspended solids concentration, and regional background concentrations (PECregional))
- Risk Management Measures (RMM) → Presence of municipal sewage treatment plant

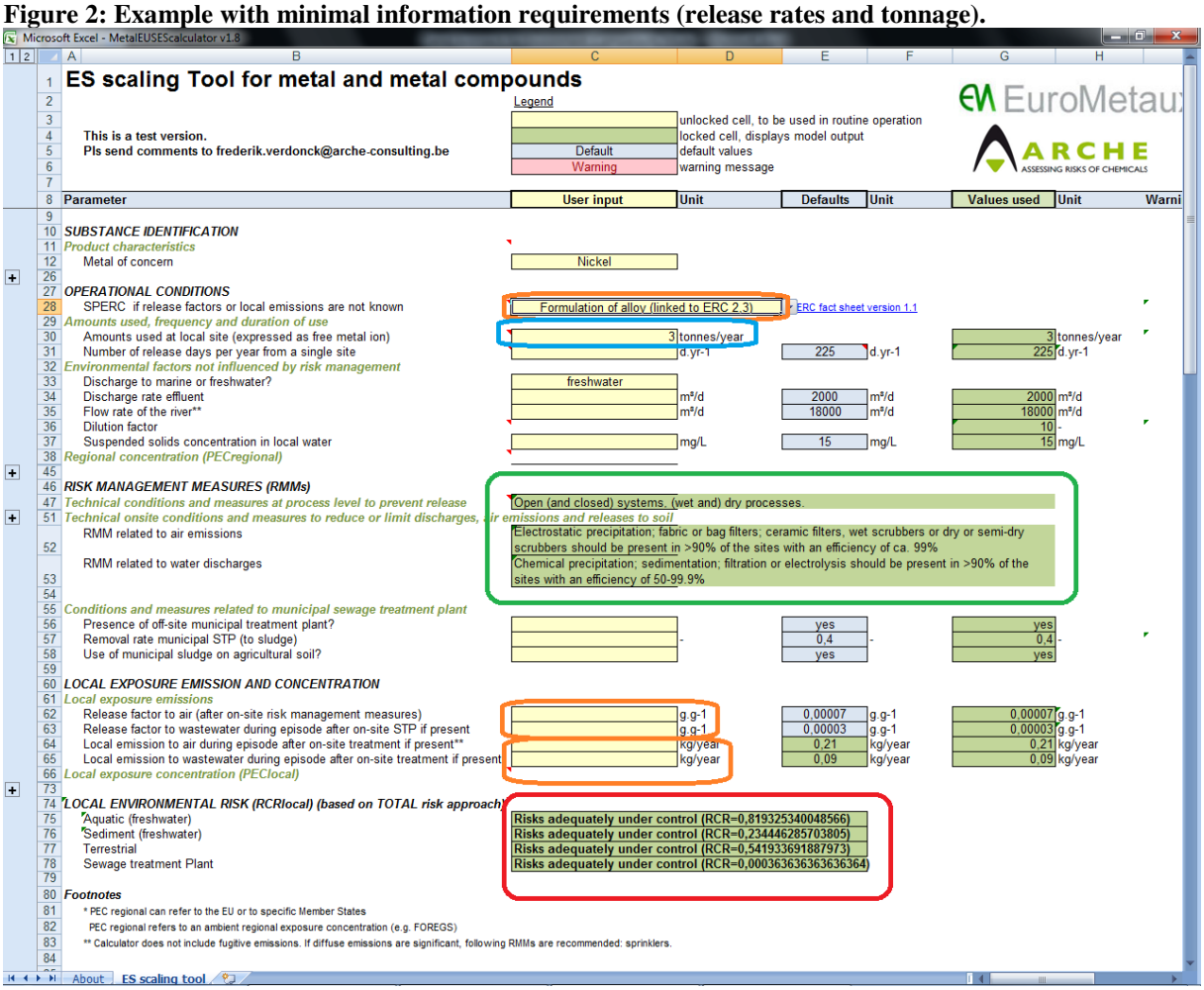
Please note that on the left hand side of the spreadsheet (column numbered 1 and 2) there are drop down spreadsheet menus indicated by a + / – signs. These are meant to hide or unhide any of the information.

Example with minimal information requirements:

Once you have selected the metal of interested, the model only requires that you fill out two additional fields to determine your sites local environmental risks. In figure 2 below, one of the 3 orange circles must be filled out along with the **tonnage** of total Ni (blue). The orange circles represent (from top to bottom) the default sector specific environmental release categories (**SPERCs**), known **release factors to air and water** or **local emissions to air and water**. The tonnage value that is input in the model needs to reflect the total tonnage of Ni either used or produced on site. For example, if you were using NiCl, NiS, NiNO3 on a same site, you would need to add the tonnages (based on Ni ion - calculated using the molecular weight of the substance) of all substances, since the assessment of environmental exposure on a same site usually does not make a distinction between the different substances or processes.

For this example (Figure 2), a SPERC for formulation of metal alloys has been selected (multiple SPERCs are available, select the one which best represents your process). Each SPERC is associated with a set of Risk Management Measures (circled in green). These RMM should be similar to the RMM you have on site. Based on the default values, the SPERC, and the tonnage entered in the spreadsheet, the local environmental risks have been calculated in the model for all relevant environmental compartments (circled in red). This is calculated as a risk characterization ratio (RCR) which must be less than 1 to be out of risk. If there are local environmental risks with the data you have entered, the RCR will appear red.

Figure 2: Example with minimal information requirements (release rates and tonnage).



Example of Scaling a GES with site specific conditions:

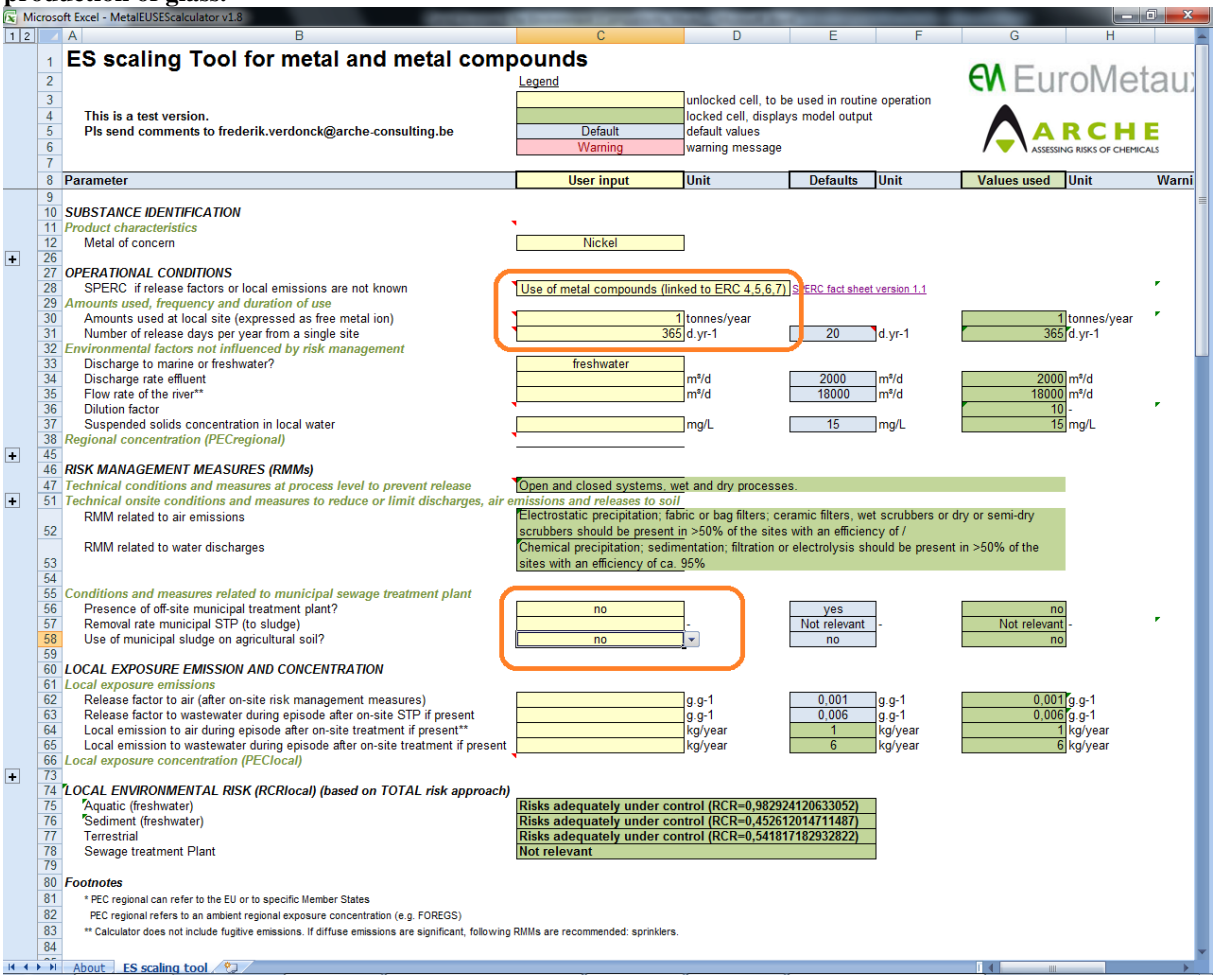
Table 1 below lists all the operational conditions and risk management measures that were input into the DU scaling tool spreadsheet to determine the local environmental risks for the GES "use of Ni oxide in glass production." The second column (GES) contains all the input parameters in the GES and is link to the modeling in figure 3 below. The third column is all input parameters from a specific site to "scale" the GES to their conditions and is linked to the modeling in figure 4 below.

Table 1: input parameters for the GES and Scaling to site specific conditions.

Operational condition or RMM	Generic Exposure Scenario (use of Ni oxide in glass production) **Figure 3**	Scaling of GES to site specific conditions **Figure 4**
SPERC	Use of metal compounds	Use of metal compounds
Tonnnage (T/year)	1	18
Number of release days/year	365	320
Discharge to marine or freshwater?	Freshwater	Freshwater
Discharge rate of effluent m^3/d	Default (2000)	1200
Flow rate of river (m3/d)	Default (18,000)	450,000
Suspended solids (mg/L)	Default (15)	Default (15)
Presence of off-site municipal sewage treatment plant (yes/no?)	No	yes
Use of Municipal sludge on agriculture	Not relevant	yes

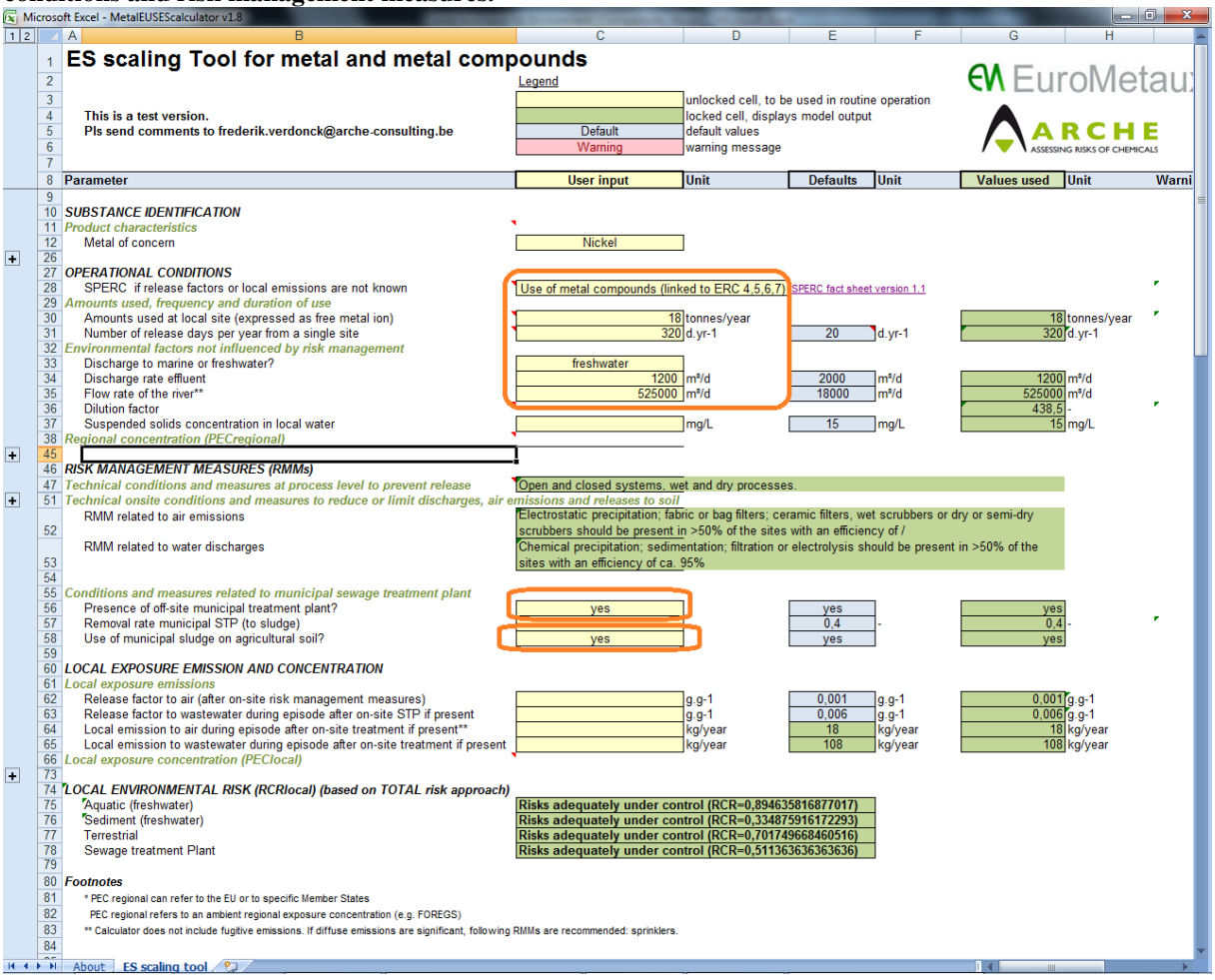
In figure 3 below, the orange circles represent additional input parameters added to the GES for this sector (in addition to the default parameters). The GES will always document a set of OC and RMM (most representative to the sector) which demonstrates a safe use for all environmental compartments (i.e. RCR<1).

Figure 3: Operational conditions and risk management measures for the GES "Use of Ni Oxide in the production of glass."



In figure 4 below, the orange circles represent site-specific input parameters for tailoring the GES to a company's own OC and RMM. By increasing the tonnage by 18 fold (compared to the GES) this company still demonstrates compliance with all environmental compartments (i.e. RCR <1). Compliance is established for the most sensitive compartment (freshwater) mainly due to an increased dilution factor as a result of the reported discharge rate of effluent and river flow rate.

Figure 4: Scaling of the GES "Use of Ni Oxide in the production of glass" for site-specific operational conditions and risk management measures.



Annex 2:

Regional Ambient Ni Concentration Levels

In order to determine PECtotal local levels; the following $PEC_{regional}$ values (modelled or measured) were selected as regional input values to add to the local environmental concentrations:

The values presented below are extracted from the Ni EU RAR (2008/2009).

Freshwater:

Country-specific measured regional PECs (µg dissolved Ni/L) for sites discharging to a freshwater environment located in the following countries:

Country	$PEC_{regional}$ (µg dissolved Ni/L)
Austria	1.4
Belgium (Walloon – ISSeP)	4.8
Denmark	1.1
France (Rhône-Mediterranean area)	4.7
Germany (Elbe)	3
The Netherlands – RWS	4.2
Sweden	1.2
UK	3.9

The median ambient regional PEC for Europe was calculated as 2.9 µg dissolved Ni/L for sites located in other EU countries. This value was carried forward in calculating the freshwater PEC in all GES.

Marine water:

Country-specific measured regional PECs (µg dissolved Ni/L) for sites discharging to a marine environment:

Marine environment	$PEC_{regional}$ (µg dissolved Ni/L)
Estuary	3.34
Baltic sea	0.79
Other seas	0.30

Sediment (freshwater):

Country-specific measured regional PECs (mg Ni/kg dw) for sites located in the following countries:

Country	$PEC_{regional}$ (mg Ni/kg dw)
Belgium - Flanders	28.0
Finland	61.2
France	31.9
The Netherlands	42.8
UK - Scotland	48.9
Spain	36.3
Sweden	25.5

median ambient regional PEC for Europe i.e. 33.5 mg Ni/kg dw (measured data) for sites located in other EU countries.

Terrestrial:

Location-specific and country-specific measured regional Ni concentrations (mg Ni/kg dw) for sites located in the following countries:

Country	$PEC_{regional}$ (mg Ni/kg dw)
Austria	20
Belgium	22.3
Denmark	2.7
Finland	5.4
France	19.8
Germany	13.0
Greece	>64
Ireland	22.6
Italy	32.2
Luxemburg	49.5
Portugal	8.5
Spain	15.6
Sweden	4.9
The Netherlands	10.1
United Kingdom	16.2

Median ambient regional PEC for Europe is 16.2 mg Ni/kg dw (measured data) for sites located in other EU countries