# SUMMARY OF THE EU VOLUNTARY COPPER RISK ASSESSMENT

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## ABSTRACT

Within the framework of the EU Existing Substance (93/793/EEC) and REACH regulations EC/1907/2006), the copper industry initiated in 2000 a comprehensive Voluntary Risk Assessment of copper and several copper compounds. The Italian Government's Istituto Superiore di Sanità, reviewed the process and reports on behalf of the European Commission. Copper exposure levels to man and the environment from production of copper anodes and cathodes, copper powders and copper chemicals as well as fabrication and use of semi-fabrication products and down stream user products were collected across Europe. Environmental and human health effects data were obtained from literature as well as novel research programs and used to deduct safe threshold values for man and the environment. These effects threshold values were subsequently compared to the exposure information to evaluate the probability of risk at EU local (industry emission) and regional (diffuse emission sources) level. The main conclusions from the draft report are that for the general population in the EU, there are no human health risks from exposure to copper. Copper deficiency is also considered in the report and elderly people resulted to be potentially at risk from copper deficiency. The environmental risk assessment, integrated information on copper's bioavailability and concludes that no regional environmental risks exist from copper exposures in use. Some risks for man and/or the environment, identified at a local level for some companies, need to be further addressed.

# INTRODUCTION

In the framework of the EU Existing Substances Regulation (EEC 793/93) and the initiation of REACH (EC/1907/2006), in 2000, the European Commission invited a number of industries to undertake voluntary risk assessments for some substances they produce and market in the European Union. As a response to this request and on behalf of the copper industry, the European Copper Institute agreed on the submission of a comprehensive copper risk assessment report, to be drafted by a group of scientists. The initiative was endorsed by the European Commission and the EU Member States. To ensure an outcome in line with EEC 793/93, the Istituto Superiore di Sanità, on behalf of the Italian Government, was appointed by the European Commission and EU Member States to oversee the process, provide guidance on methodologies, review the results and ensure that the risk assessment was completed in compliance with the Technical Guidance Document [1]. Additionally, panels of recognised independent experts from European research institutes and academia were appointed to technically review the environment and human health chapters of the dossier.

A comprehensive EU risk assessment report aims at assessing all anthropogenic emissions of the considered substance into the 15 Member states, that were part of the EU in 2000 (EU-15). This was done for three assessment scales (figure 1): (1) a local scenario whereby risks are characterized in and around industry production sites, (2) a regional scenario, assessing reasonable worst case exposure during industrial/professional use, consumer uses and after disposal, (3) a continental scenario, assessing baseline exposure during industrial/professional use, consumer uses and after disposal in the EU-15.

The EU copper risk assessment, assesses the emissions into the EU-15 from production, use and disposal of copper and four copper compounds (copper(I)oxide, copper(II)oxide, copper oxychloride, copper(II)sulphate pentahydrate). The draft copper risk assessment report has been submitted to the European Commission and it is currently under review and discussion at the EU Technical Committee for New and Existing Substances (TCNES). This paper provides a summary of the draft report [2] and will focus on the regional scenario and not discuss the local industry-specific scenario's.

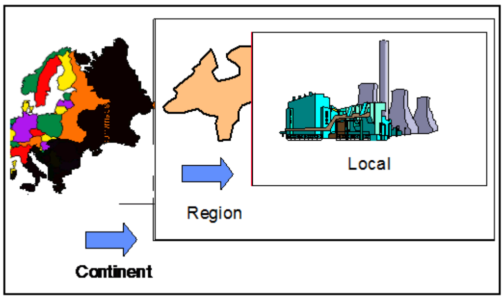


Figure 1 - Relations between the continental, regional and local scale exposure assessment

## GENERAL METHODOLOGY

The EU Regulation 793/93 requires a risk assessment to be performed according to the principles laid down in European Regulation 1488/94 and following the detailed methodology laid down in the Technical Guidance Document [1]. For the evaluation of risks, metal-specific characteristics, have not been fully considered in the EU Technical Guidance Document. These have been developed by a metals industry initiative, led by Eurometaux (the non ferrous metals' industry representative body), and supported by the European Commission and several EU Member States [3,4]. For copper, the relevant risk assessment characteristics include the following:

1. Copper is naturally occurring, with background levels varying with the local geology. These have been considered when evaluating copper exposure levels;
2. Copper is an essential nutrient for all life forms and therefore, human health and environmental limits have been based on a scientific evaluation of the potential risks with regard to both deficiency and excess;
3. Copper ions entering the environment through natural or anthropogenic (man-made) processes, are naturally detoxified in the mineral cycle. Indeed, the binding of copper ions to natural, dissolved and particulate organic matter in water, sediment and soils reduces their bioavailability. This paper assesses bioavailable copper exposure levels.

The copper risk assessment applies a tiered approach, including: (1) screening of the available published information in accordance to pre-set quality criteria; (2) data compilation and initial assessment of the effects and exposure levels and identification of uncertainties and data gaps; (3) research to fill the data gaps and (4) refined analysis of the exposures and effects and (5) risk characterization.

## RESULTS AND DISCUSSION

### Human Health Risk Assessment

Under the EU risk assessment framework, risks to the general population are assessed by comparing typical and reasonable worst case (RWC) exposure values to the safe threshold value. As the framework is driven by anthropogenic substances, only risks for excess are assessed. Copper is however an essential element and in the Cu-VRA, an additional assessment was made of risks for deficiency for the general population.

Exposure Assessment

Humans may be exposed to copper in the workplace (occupational exposure), from use of consumer products (consumer exposure) and indirectly via the environment. Indirect exposure of humans via the environment may occur by consumption of food, drinking water, inhalation of air and ingestion of soil. Because there is a substantial amount of literature reporting exposure to copper, typical and reasonable worst case (RWC) exposure values for the general population are derived using monitoring data and are defined as the 50th-percentile and 90th percentile (90P-RWC) respectively. For the assessment of risks for deficiency, the 10th percentile (10P-RWC) was used as the RWC.

The literature covering dietary exposure is extensive. Studies were screened for quality and relevancy. Two types of studies were considered in the assessment of exposure to copper in food: duplicate diet studies and market basket studies. Seventeen studies published between 1989 and 2004 covering ten member states were retained for the regional exposure assessment. These studies allowed assessing exposure for different age categories and genders. Most data are available for adults and these are highly consistent independent of study design or location. Median daily intake for adults is 1.2 mg Cu/day, the 10P-RWC is 0.6 mg Cu/day and 90P-RWC is 2 mg Cu/day. The elderly may have slightly lower intakes than younger adults. Intake by children is typical less than 0.70 mg Cu/day. A summary of exposure data is shown in Figure 1.

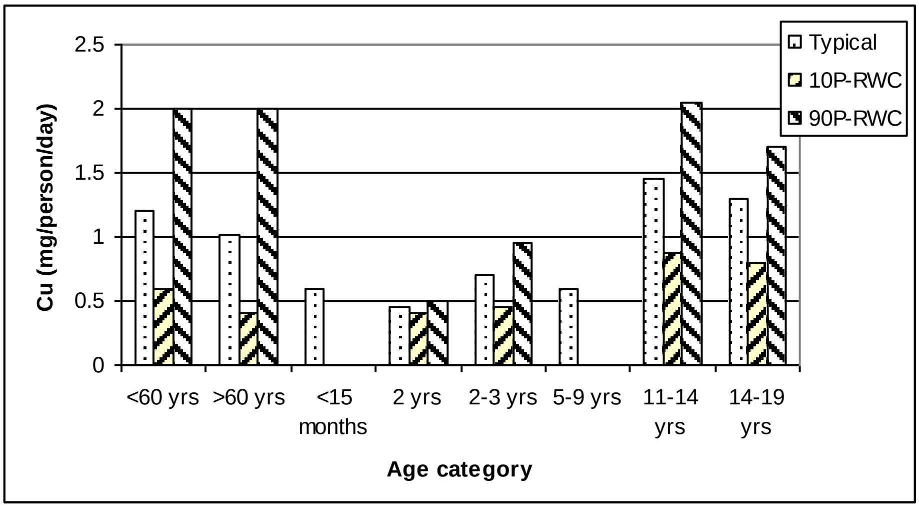


Fig 1 - Summary of typical and RWC dietary exposure data (mg Cu/person/day)

A separate analysis was made of exposure via alcoholic beverages as Cu-based fungicides are commonly used in European vineyards. The daily contribution is however low and typical less than 0.05 mg Cu/day.

Copper pipes are widely used in residential and commercial water distribution systems. A separate analysis of exposure through drinking water was made as it has been suggested that copper in drinking water may constitute a significant component of total intake in the case of corrosive water (IPCS [5]). Both acute and chronic exposures were assessed.

Acute exposure was estimated based on data for *first draw* (unflushed) water taken from five studies relevant for the EU. Typical copper concentrations in standing water range from 0.01-0.19 mg Cu/litre across a range of cities with a wide geographical spread and also from diverse locations within a single country (Germany). Similarly, estimates of RWC copper concentrations range mostly from 0.06-0.93 mg Cu/litre. Higher exposures from corrosive waters are found in specific locations, e.g. for domestic dwellings at some locations in Sweden [6]. A median copper content of 0.72 mg Cu/litre and a 90P-RWC of 2.11 mg Cu/litre were derived.

Few suitable published studies in which representative composite sampling, representative for daily intake levels (chronic exposure), were undertaken are available for the EU. From these studies, the additional daily contribution from drinking water was assessed as highly marginal. Typically, copper levels in drinking water are very low. Assuming a default consumption of 2 litre/day, the estimated median intake is 0.11 mg Cu/day, the 90P-RWC is 0.13 mg Cu/day, and the intake is less where bottled water is consumed. In areas where moderately corrosive or corrosive water is present, RWC intakes may be considerable and very variable, increasing up to levels of 3 mg Cu/day. Median copper intake from consumption of “moderately corrosive” water is estimated at 0.75 mg Cu/day with a 90P-RWC of 2.2 mg Cu/day. The available data suggest that such exposures are incurred only by isolated geographical subsets of the EU population, but the actual frequency of these events is unknown. Data are summarised in Table 1.

Young children also incur exposure through ingestion of house and garden dust by hand to mouth contact. Exposure estimates were calculated using the IEUBK model and data on copper in household dust. Daily exposure values are minor and are less than 0.1 mg Cu/day.

Inhalation exposure to copper is insignificant and less than 0.1 mg Cu/day.

Table 1 - Estimate of copper exposure for adults applicable for chronic effects (mg Cu/person/day)

| **Adults (<60 yrs)** | **Typical** | **10P-RWC** | **90P-RWC** |
|---|---|---|---|
| Food | 1.2 | 0.6 | 2 |
| Air | <0.01 | <0.01 | <0.01 |
| Drinking water -Bottled water | 0.01 | 0.01 | 0.03 |

| | | | |
|---|---|---|---|
| Drinking water -Tap water - Non corrosive | 0.11 | / | 0.13 |
| Drinking water -Tap water - Moderately corrosive | 0.75 | / | 2.2 |
| Drinking water -Tap water -Corrosive | 1.2 | / | 3.1 |
| Face cream & Haircare products | 0.24 | 0 | 1.44 |
| IUD | 0 | 0 | 0.03 |
| Paint | 0 | 0 | 4.03 |
| Cigarette smoking | 0 | 0 | $5.10^{-4}$ |
| Handling of coins | 0.14 | 0 | 0.28 |
| Copper jewellery | 0 | 0 | 0.41 |
| Food supplements | 0 | 0 | 2 |

Consumer exposure to copper may occur through inhalation of cigarette smoke, via the dermal route through the use of toiletries, cosmetics and contact with coins or jewellery and use of IUDs. Oral exposure (other than from food and water) occurs mainly by ingestion of dietary supplements containing copper. Supplements that do contain copper, contain generally 2 mg Cu/tablet. Only a very small proportion of consumers take dietary supplements containing copper.

A summary of all exposure sources for adults is shown in Table 1. It is clear that, in the absence of dietary supplements, food and corrosive drinking water are the most important exposure sources of copper.

Effects assessment

Toxicity and toxicokinetics data are extracted from scientific publications, confidential studies carried out for EU biocidal and pesticides dossiers, and from original research. Only relevant data of high quality is retained. Oral toxicity and toxicokinetics data in animals and humans are based largely on copper sulphate. No data are available for copper or the other copper compounds covered in the Cu-VRA. In absence of data, read-across was applied from copper sulphate to copper and the other copper compounds covered in the Cu-VRA, on the basis that this is both the most soluble and bioavailable substance covered, and the most well-characterised with respect to toxicokinetics and repeated dose toxicity.

Several studies are available reporting acute effects of copper to humans. The most reliable studies for the determination of a No Observed Adverse Effect Level (NOAEL) for adults are three well-controlled human volunteer studies in which copper (as copper sulphate) was administered as a bolus dose in drinking water [7-9]. All three studies reported a dose-related increase in gastrointestinal symptoms associated with single oral exposure to copper in drinking water, the earliest and most frequently reported symptom being nausea. From the studies of Araya [8-9], which appear to be the most relevant as the study populations were international and included subjects from the EU, the NOAEL for copper in drinking water was derived for nausea symptoms in adults as 4 mg Cu/litre. This threshold is applicable for both female and male. No assessment factor is applied on the NOAEL as it is based on an extensive epidemiological study using fasted subjects, including women- the most sensitive sub-population.

Several animal studies are available which investigate the effect of repeated ingestion of copper sulphate, administered either in the diet, drinking water or by gavage. Many of these studies focus on the liver which is the target organ for copper-related toxicity. The most reliable oral-dosing data come from a 13-week dietary study conducted in rats and mice under the US National Toxicology Programme (Hébert [10-11]). In rats, the more sensitive of the two species, repeated administration of copper sulphate added to feed for 13 weeks produced effects in the forestomach, liver and kidney. The rat NOAEL for these effects was 16.3 mg Cu/kgBW/day added to feed. The NOAEL is supported by the results of a two-generation study with rats (Mylchreest [8]). An assessment factor of 100 is applied on the animal based NOAEL to account for inter-species variability, intra-species variability and to derive a chronic threshold value, safe for humans. This final human threshold value of 11.4 mg Cu/person/day (adult of 70 kg) is supported by the findings of two less robust, human volunteer studies [13-14] which report a NOAEL of 10 mg/person/day.

A review of the evidence for deficiency and copper balance studies indicates that intakes below 1 mg Cu/day may be insufficient to maintain copper status. Some evidence suggests that vulnerable individuals such as pregnant women, lactating women, adolescents, peri-menopausal women, and the elderly people may require higher intakes.

The potential mutagenicity of copper sulphate is reported in a number of *in vitro* assays in bacterial and mammalian cells, and in several *in vivo* assays. The overwhelming weight of evidence indicates that copper sulphate is negative *in vitro* in bacterial cell reverse mutation assays, and in several other bacterial cell assays up to and including cytotoxic doses (1000-~3000 μg/plate). Results from *in vitro* mammalian cell tests show that copper sulphate is genotoxic only at high, cytotoxic concentrations (up to 250 mg/l). These concentrations are irrelevant under normal *in vivo* conditions, where copper is generally bound to amino acid or protein ligands. The most reliable *in vivo* data for copper sulphate come from two well-conducted, oral-dosing studies. In both of these studies copper sulphate was clearly negative. Based on the results of *in vitro* and *in vivo* tests, copper and copper compounds are considered not to be mutagenic.

There are a number of epidemiology studies that have examined carcinogenicity rates among workers in the copper mining and smelting industry. Where increased risk of lung and other cancers were found, workers were exposed to other substances which are known or suspected carcinogens, but no causal link was found with copper. Also animal data do not support a causal link between copper substances and cancer. It is concluded there is no evidence that copper and copper compounds are carcinogenic.

Results of a high quality two-generation reproduction toxicity test in rats [12] show no treatment-related effects on reproductive parameters in either the parental generation or offspring up to the highest tested concentration of copper sulphate in the diet (1500 ppm dietary copper sulphate pentahydrate). The most reliable data for developmental toxicity indicate developmental effects only in the presence of maternal toxicity. It is concluded there is no evidence of a specific effect of copper on reproduction.

As the thresholds for deficiency and excess are based on systemic effects and humans are exposed via the dermal, oral and inhalation route, both the thresholds and the exposure values have to be converted into systemic values for the risk characterisation. Systemic values are derived by application of the relevant absorption factors. Dermal absorption factors were derived from two in-vitro studies performed according to OECD test guidelines. Absorption ranges from 0.3% for wet applications to 0.03% for dry applications.
The most reliable data for oral absorption come from 2 human studies, in which true absorption factors are derived using stable isotopes [15-16]. Exposure-specific absorption factors for gastro-intestinal absorption are calculated taking the average of the results of the functions 1a and 1b:

$$\% \text{ absorption} = 15.0\ln(x)+63.2 \quad (1a)$$

$$\% \text{ absorption} = 72.9e^{-0.1167x} \quad (1b)$$

x= copper intake (mg Cu/day)

As an example, an oral intake of 1 mg Cu/day results in systemic absorption of 64%, an intake of 2 mg Cu/day results in systemic absorption of 55%, an intake of 8 mg Cu/day results in systemic absorption of 30%. No reliable data are available on inhalation absorption. A default value of 100% is applied on the respirable fraction. The non-respirable fraction is translocated to the gut where it is assumed to be subject to intake-dependent absorption along with dietary copper.

To conclude, based on an extensive literature review, copper and copper compounds evaluated in the Cu-VRA are considered not to be carcinogenic, mutagenic and not to have effects on reproduction. Repeated exposure may effect the liver and a safe threshold of 11.4 mg Cu/person/day equivalent to a systemic level of 2.85 mg Cu/person/day (applying an oral absorption factor of 23%) is derived. Copper levels below 1 mg Cu/person/day may be insufficient.

Risk characterisation

*Acute toxicity*

The RWC value of 2.11 mg Cu/litre for acute drinking water intake is below the threshold of 4 mg Cu/litre and suggests no risks of acute toxicity.

*Repeated dose toxicity*

The data for dietary and drinking water intakes and consumer exposure suggest no risks of copper toxicity to the general population even when combining RWC scenarios. Data are summarised in Table 2. The data for dietary intakes suggest a risk of marginal copper deficiency in a minority of the general population. The elderly are the group most likely to have sub-optimal intakes of copper. Although the extent and magnitude of marginal copper status is difficult to predict from the available data, the conclusions of the Cu-VRA support the conclusion of the International Program on Chemical Safety that “there is greater risk of health effects from deficiency of copper intake than from excess copper intake” (IPCS, 1998).

Table 2 - Risk characterisation for adults for repeated dose toxicity and deficiency effects

| Adults (<60) | | Oral mg Cu/person/day | Dermal | Inhalation | Total | Threshold | Risk Ratio |
|---|---|---|---|---|---|---|---|
| Typical | External | 1.2 | 0.38 | <0.01 | | | |
| | Systemic | 0.7 | <0.01 | <0.01 | 0.71 | 2.85 or 0.6 | No Risk for Excess or Deficiency |
| 10P-RWC | External | 0.6 | 0 | <0.01 | | | |
| | Systemic | 0.4 | | <0.01 | 0.41 | 0.6 | Risk for Deficiency |
| 90P-RWC | External | 6.2 | 6.19 | <0.01 | | | |
| | Systemic | 2.2 | 0.02 | <0.01 | 2.22 | 2.85 | No Risk for Excess |

**Environmental Risk Characterisation**

The first step of an environmental EU regional risk assessment is the exposure assessment. The exposure assessment quantifies copper releases throughout the life cycle and calculates the resulting Predicted Environmental Concentrations (PEC) in a pre-defined EU region.  These modelled copper concentrations are compared to actual measured copper concentration in water, sediments and soils. The second step is the effects assessment, whereby safe threshold values (Predicted No Effect Concentrations-PNEC) are determined for water, sediments and soils.  Finally, comparison of the exposure and effects levels forms the basis of the risk characterisation.

<u>Copper releases and Predicted Environmental Concentrations</u>

In accordance to the EU TGD [1], regional emissions have been quantified for two EU reasonable worst case scenario’s.  For the first regional scenario, total copper emissions into The Netherlands were estimated.  The Netherlands is used as reasonable worst case EU region because of its high population density, intensive habitational infrastructure and intensive farming activities.  The available Dutch emission inventory is used as the basis for the assessment with refinements for reliable source-specific information on emission factors (eg mg Cu/m$^2$ roof), activity data (e.g., m$^2$ roofs in the region) and distribution factors (% emitted to air, water soil), as obtained from an extensive literature search. For the second regional scenario, total regional emissions are calculated for “a hypothetical EU generic region” of 200 km$^2$ whereby one tenth of the total EU-15 copper emissions are released into this hypothetical region.

From the in-depth analysis of all sources (including releases during professional uses, consumer uses and after disposal), a total regional release of respectively 606 Ton Cu/year is calculated for the Dutch regional scenario and 891 Ton Cu/year for the EU-generic scenario. Allocation of these releases to the environmental compartments show the following partitioning: 75% direct emissions to soil, 10% direct emissions to water and 15% direct emission to air. The detailed analysis of the emission sources demonstrated that major copper emissions are related to diffuse emissions from copper compounds used as feed additives and soil fertilizers (39% of the total EU emissions) and from copper powders used in automobile brake pads (31% of the total copper EU emission). Figure 2 illustrates that only a few “massive” copper markets have measurable emissions during professional/consumer use. Among these, wear of overhead wires, corrosion of copper tubes, fittings and taps and external building applications (roofs, gutters, down pipes, facades) contribute respectively to 9, 5 and 1% of the total anthropogenic EU emissions. Interestingly, the relative contribution from waste incineration pants and landfill facilities is minor (0.4%). Other minor copper releases, that have been considered include, among others, industry releases, domestic and industrial heating, fireworks and domestic wastewaters (excl. corrosion).

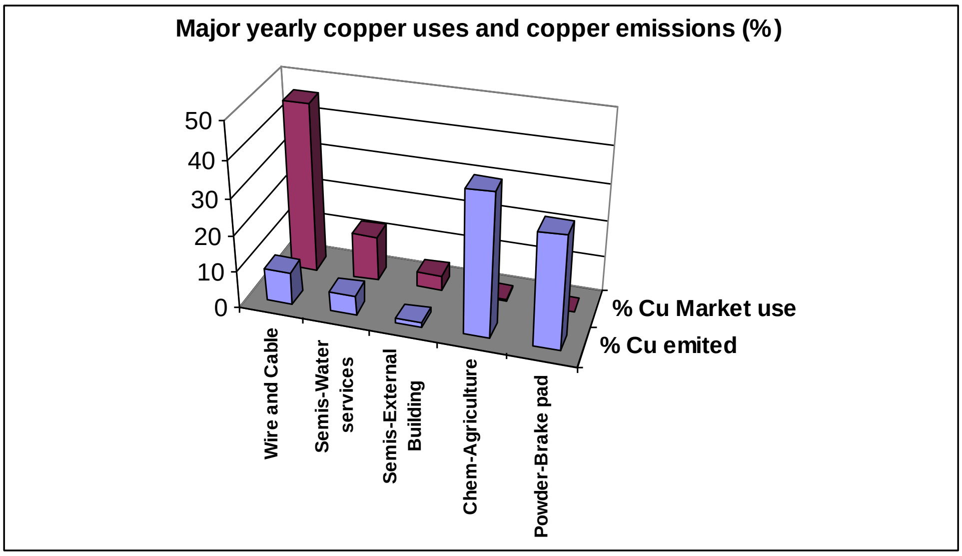


Figure 2 - Comparison of copper emissions (% of total copper emissions) with the relative importance of the copper market (% of the total copper used).

These yearly regional copper releases, are used as input into the EUSES 2.0 program [17] to derive the regional PEC, for a time scale of 100 years accumulation of Cu releases to the environmental compartments. The resulting regional anthropogenic concentrations are added to regional copper background levels to derive the final $PEC_{regional}$ for water, sediment and agricultural soil (table 1). Data on natural background values are obtained from existing monitoring data. Somewhat lower values for the Dutch RWC scenario are observed as compared to the EU generic scenario. (Table 1)

Table 1 – Modelled and measured regional copper exposure and background values

| | **Modelled $PEC_{regional*}$** ***Dutch scenario*** | **Modelled $PEC_{regional*}$** ***Generic scenario*** | **Measured $PEC_{region}$** ***Median (Min- Max)*** | **Investigated countries** for the measured $PEC_{region}$** | **Natural background levels** ***Median (Min-Max)*** |
|---|---|---|---|---|---|
| PECwater (µg/l) | 1.87 | 3.2 | 2.7<br>(0.5 – 4.7) | B, Dk, Fi, D Ir, P, Nl, Sw, UK, Sp | 0.8<br>(0.2-3.3) |
| PECsediment (mg/kg dw) | 38.0 | 69.2 | 67.2<br>(45.8-88.3) | B, Fr, Sw, Nl, Sp | 20<br>(16-32) |
| PECagr. Soil (mg/kg dw) | 29.6 | 31.4 | 31.0<br>(16.5-57.4) | Au, B, Fi, Fr D, Ir, It, Nl, No, Sw, Sp | 12<br>(3-33) |

* including the EU median background concentrations; ** may include different regions within a country

In addition to the modelled $PEC_{regional}$, actual measured copper levels in the different environmental compartments are assessed for several EU regions/countries. The frequency distributions of ambient copper exposure concentrations in the EU surface waters, sediment and soils are determined for different EU regions/countries and the predicted environmental concentrations ($PEC_{region}$) are calculated as $90^{th}$ percentiles (Table 1). The modelled $PEC_{regional}$ are very similar to the measured $PEC_{region}$ (Table 1). Differences can be related to historical contamination levels (higher emissions in the past), incomplete emission inventory (missing some sources) or uncertainties in the EUSES model applications for metals. Considering the availability of large monitoring data-sets on copper across Europe, the measured data, as opposed to modeled data, have been retained for the final risk characterisations.

Environmental Effects and Risk Characterisation

Chronic No Observed Effects Concentrations (NOEC) values extracted from literature are complemented by novel research activities and thoroughly screened against quality criteria to obtain a 'high quality' ecotoxicity datasets for water, sediments and soils. The number and coverage of the copper NOEC data allowed for the derivation of Predicted No effects Concentrations (PNECs), using statistical extrapolation methods.

The retained database revealed large intra-species variabilities related to the influence of test media characteristics (e.g., pH, dissolved organic carbon, cationic exchange capacity) on the bioavailability and thus toxicity of copper. Novel research allowed to quantify the bioavailability relationships in the different environmental compartments. In the aquatic compartment, the developed and validated chronic Biotic Ligand Models (BLM) are able to predict aquatic NOEC values in EU surface waters with different chemical characteristics. For the sediments, an organic carbon (OC) normalization approach was developed. For soils, regression models are developed and validated to correct for differences in bioavailability between soils. In addition, an aging factor is derived to account for the difference in bioavailability between freshly spiked laboratory studies and aged soils in the field. The above mentioned developed/validated models, are used to normalize each of the individual NOEC values from the Cu ecotoxicity databases to site-specific environmental conditions. Application of the bioavailability models drastically reduces the intra-species variability in chronic NOEC values for all compartments and thus allows for the calculation of site-specific and species-specific NOEC values as well as the derivation of ecological robust PNEC values for water, sediment and soils. In order to derive PNECs, applicable to an EU-15 risk characterization, RWC and typical EU-15 bioavailability conditions were determined from EU-wide bioavailability parameters (e.g., pH, dissolved organic carbon, cationic exchange capacity). Reasonable worst case conditions, maximizing bioavailability, aim at protecting at least 90% of the environments occurring in the EU-15. No additional assessment factor (AF) is applied to the PNECs as they are based on high quality chronic NOEC data, covering a wide range of taxonomic groups and ecological niches. The protective capacity of the threshold values were further confirmed by comparison to available mesocosm and field data for the aquatic compartment.

For terrestrial and sediment compartments, an AF=1 seems also to be appropriate although its adoption is under final review. The threshold values for the different EU scenario's are therefore carried forward to the risk characterization. (Table 3)

Table 3 - PNEC values derived for different environmental compartments. PNEC values were derived from a statistical extrapolation method applied on the species sensitivity distribution, using the best fit model

| PNEC derivation<br>(reliable data richness) | PNEC | Bioavailability correction of the PNEC values |
|---|---|---|
| $PNEC_{water}$<br>µg total dissolved Cu/ L<br>(149 NOECs for 27 species) | 8-27 | Bioavailability correction of the NOEC data towards reasonable worst case and typical EU bioavailability conditions |
| $PNEC_{sediment}$ bioavailable<br>mg Cu/kg dry weight<br>(62 benthic NOECs for 6 species) | 98 | OC based normalisation (TGD default 5% OC) of the NOEC. The derived PNEC is an aerobic PNEC, the inclusion of a sulphide binding factor is still under discussion |
| $PNEC_{soil}$ worst case<br>(251 NOECs from 19 species+ 9 micro-organism endpoints) | 79 -110 | Correction of the NOEC data, for bioavailability and ageing, reasonable worst case and typical EU bioavailability conditions |

The regional PECs (Table 1) are compared with the respective PNECs (Table 2) to derive the Risk Characterisation Ratio's (RCR =PEC/PNEC) (Table 4). The results show that all RCRs are below 1 in all compartments and thus, no EU-wide risks are expected for the regional environment. These conclusions are valid for both the reasonable worst case and typical cases of bioavailability conditions. For sediments, the maximum risk ratio is close to 1. The classic RCR (Table 4) assumes fully aerated sediments and thus ignores reductions in bioavailability due to sulphide binding under anaerobic conditions. Therefore, a probabilistic risks characterisation is carried out for a Flanders' sediment database, consisting of 200 sediment samples and containing information on the copper fraction bound to sulphides. The analysis demonstrates that, in 98% of the Flanders sediments all copper is bound to sulphides and therefore non-available for uptake by sediment dwelling organisms. This probabilistic analysis provides additional evidence for a no-risk conclusion for sediments at the $90^{th}$ percentile protection level.

Table 4 - Risk Characterisation Ratios (RCR) for the regional environment.

| Compartments | Regional PECs *Median (min-max)* | PNECs *RWC - Typical* | RCR |
|---|---|---|---|
| Surface water-µgCu/L | 2.7 (0.5-4.7) | 8-27 | 0.02-0. (No Regional risk) |
| Sediment -mg Cu /kg dw | 67.2 (45.8-88.3) | 98 | 0.5-0.9 (No Regional risk) |
| Agri- soils -mg Cu /kg dw | 31.1 (16-57) | 79 - 110 | 0.1-0.7 (No Regional risk) |

**RWC: reasonable worst case**

## FURTHER RECOMMENDATIONS AND CONCLUSIONS AND

The draft environmental risk assessment report integrates recent information on exposure, effects and copper's bioavailability and points the way towards confirmation that the production and use of copper products is generally safe for Europe's environment. Some further refinements of the draft report have been recommended by EU member states, which includes further demonstration that the bioavailability models are applicable to all aquatic species. In its final approved form, it is expected that the dossier will provide a sound scientific platform for broad regulatory decision making in Europe.

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