**EUROPEAN UNION RISK ASSESSMENT REPORT**

# VOLUNTARY RISK ASSESSMENT OF COPPER, COPPER II SULPHATE PENTAHYDRATE, COPPER(I)OXIDE, COPPER(II)OXIDE, DICOPPER CHLORIDE TRIHYDROXIDE

CAS No: 7440-50-8, 7758-98-7, 1317-3-1, 1317–38–0, 1332-65-6

EINECS No: 231–159–6, 231–847–6, 215-270-7, 215–269–1, 215-572-9

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## CHAPTER3 – ENVIRONMENTAL EXPOSURE

## PART 3 : MARINE EXPOSURE

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| **Date of Last Literature Search :** | **2006** |
| **Review of report by MS Technical Experts finalised:** | **April 2008** |
| **Final report:** | **June 2008** |

## Foreword

In response to a request from the European Commission to "start preparing the initial assessments for substances on the EU working list as these were considered as Community priorities in the context of the industry voluntary initiatives for high production volume chemicals" the copper industry committed to undertake a Voluntary Risk Assessment (VRA) for copper and the copper compounds on the EU working list: Cu, CuO, $Cu_2O$, $CuSO_4$ and $Cu_2Cl(OH)_3$. This initiative was endorsed by the EU CAs in 2001. Yearly summaries on progress have been presented at the CA meeting.

This comprehensive VRA dossier has taken four years to complete, with the whole process managed by the European Copper Institute. It was compiled in co-operation with expert consultants from the University of Birmingham/ICON for human health toxicity, from BR. Stern and Associates for human health deficiency, and from Euras/Ecolas for the environment. It is based on the principles of Regulation 793/93, 1488/94 and the detailed methodology laid down in the revised Technical Guidance Document on Risk Assessment for New and Existing Substances. Methodological experiences gained through other metal Risk Assessments, e.g. the incorporation of bioavailability for zinc, were incorporated as appropriate. Additional up to date scientific information was integrated into the assessment where scientifically relevant (i.e. the use of bioavailability models for water, sediment and soil, plus information on copper as an essential nutrient). A broad cross section of the European copper industry has been fully involved in the process and has submitted a significant amount of proprietary data.

To ensure the transparency and quality of the dossier, the initial draft RA reports have been refined by incorporating inputs from the Review Country (Italy – Istituto Superiori di Sanità) and independent peer review panels.

For several of the substances under consideration, targeted risk assessments are required under the Biocidal Product Directive (98/8/EC) and the Plant Protection Products Directive (91/414). These dossiers, which have been/will be provided to the competent authorities (France) by the respective end user industry groups, contain confidential information not available to ECI. However, ECI has worked closely with both of these groups in incorporating relevant information to ensure consistency to the extent possible.

A single dossier covers the assessments for copper metal and the copper compounds, with substance specific aspects provided where relevant. For the base data compilation, extensive literature searches were performed for each substance. Data gaps were filled with analogous data, where relevant, or by additional testing where possible. Where the information was either unnecessary for the copper risk assessment, or impossible to obtain, waiving for testing and/or justification to support derogation is discussed. Some remaining data gaps were identified and will be tackled as a follow-up to this report.

Since the initial submission of the dossier on 15 May 2005, comments have been received from several Member States. The current version reflects comments made by the Member States in writing and during the TCNES meetings. To ensure the transparency and quality of the dossier, the current version and the responses to Member States comments have been refined in close co-oporation with the Review Country (Italy – Istituto Superiori di Sanità).

The human health and environmental sections of the report have been agreed by TCNES (see TCNES opinions) and sent to SCHER for final review.

This Draft Risk Assessment Report is the responsibility of the European Copper Insitute (ECI). The member companies of the copper industry risk assessment consortium are the owners of the assessment. These companies are listed below.

Industries/companies wishing to use all or part of the Risk Assessment Reports, and/or their appendices, for regulatory purposes such as for EU REACH registrations, EU Biocidal Products Directive Registrations, or EU Plant Protection Product Directive Registrations, are required to contact ECI to agree terms of access.

In order to avoid possible misinterpretations or misuse of the findings in this draft, anyone wishing to cite or quote any part of this report, or its related appendices, is advised to contact ECI beforehand.

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## Ownership

The industry companies that are part of the industry consortium are listed here:

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| Atlantic Copper Barcelona | Ctra. Palaudaries, Km 0.4 | E-08185 Llica de Vall | SPAIN |
| ATLANTIC COPPER HOLDING S.A. -Huelva | Avda Francisco Montenegro, s/n | E-21001 HUELVA | SPAIN |
| B. MASON & SONS LTD. | WHARF STREET, ASTON | BIRMINGHAM B6 5SA | UK |
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| DEUTSCHE GIESSDRAHT GmbH | Kupferstraße 5 | D-46446 EMMERICH | GERMANY |
| ELMET S.L. | Barrio Arene 20 | E-48640 BERANGO (Vizcaya) | SPAIN |
| ENZESFELD-CARO METALLWERKE AG | Postfach 1, FABRIKSTRASSE 2 | A-2551 ENZESFELD/TRIESTING | AUSTRIA |
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| HALCOR METAL WORKS S.A. casting shapes | Foundry, Oinofyta (55th km) | GR | GREECE |

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| HALCOR METAL WORKS S.A. rolling mill | Rolling Mill, 252 PIRAEUS STREET | GR-17778 ATHENS | GREECE |
| HALCOR METAL WORKS S.A. tube | Copper Tube Mill, Oinofyta (57th km) | GR | GREECE |
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European Copper Institute - May 12th 2005

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| HALCOR METAL WORKS S.A. casting shapes | Foundry, Oinofyta (55th km) | GR | GREECE |
| HALCOR METAL WORKS S.A. rolling mill | Rolling Mill, 252 PIRAEUS STREET | GR-17778 ATHENS | GREECE |
| HALCOR METAL WORKS S.A. tube | Copper Tube Mill, Oinofyta (57th km) | GR | GREECE |
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| Nexans IKO Sweden AB | | S-514 81 Grimsas | SWEDEN |
| NEXANS MEHUN SUR YEVRE | | F-18500 Mehun Sur Yevre | FRANCE |
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| TREFILERIES ET LAMINOIRS DE LA MEDITERRANEE | 35 RUE LE CHATELIER | F-13015 MARSEILLE CEDEX 15 | FRANCE |
| TREFIMETAUX - Givet Plant | Rue des Vieilles Forges | F-08600 Fromelennes | FRANCE |
| TREFIMETAUX - Niederbruck | 31, Rue Joseph Vogt | F-68290 Niederbruck | FRANCE |
| TREFIMETAUX - Serifontaine | Rue M. Thorez, BP3 | F-60590 Serifontaine | FRANCE |
| TREFIMETAUX --usine de Boisthorel | | F-61270 Rai | FRANCE |
| UMICORE ITALIA SRL | nucleo industriale di Pianodardine (Avellino) | I-AVELLINO | ITALY |
| WEDNESBURY TUBE & FITTINGS - MUELLER EUROPE | OXFORD STREET | GB- BILSTON WEST MIDLANDS WV14 7DS | UK |
| WIELAND-WERKE AG Ulm Vöhringen | POSTFACH 42 40, Graf-Arco-Straße 36 | D-89070 ULM, D-89079 ULM | GERMANY |
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| WIELAND-WERKE AG, WERK VILLINGEN | POSTFACH 1780, Lantwattenstr 11 | D-78007 VILLINGEN, D-78050 VILLINGEN-SCHWENNINGEN | GERMANY |
| WILLIAM BLYTHE LIMITED | Church, Accrington | Lancashire, BB5 4PD | UK |
| WMC Copper uranium/WMC Resources Limited | IBM Tower 60 City Road | Southbank Vic 3006 | AUSTRALIA |
| Wolstenholme International | Springfield House, Lower Ecclesfield Road, Darwen | Lancashire BB3 0RP | UK |
| XSTRATA Copper | Level 9, Riverside Centre, 123 Eagle Street | Brisbane Q 4000 | AUSTRALIA |
| YORKSHIRE COPPER TUBE LTD. (KME) | East Lancashire Road, Kirby | LIVERPOOL L33 7TU | UK |
| YORKSHIRE Fittings Ltd | P.O. Box 166 | Leeds, LS10 1NA | UK |

European Copper Institute - May 12th 2005

# CHAPTER3 – ENVIRONMENTAL EXPOSURE – PART 3: MARINE EXPOSURE

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### 3.1.5.2.6. Derivation of a regional PEC for the marine aquatic environment

### 3.1.5.2.6.1 Data availability and data treatment

**a. Data treatment**

The procedures used in this study are based on the methods and concepts laid down in the TGDs (EC, 2003) for environmental risk assessment in the European Union and on the Combined Monitoring-based and Modelling-based Priority Setting procedure (COMMPS, 1999).

In general, concentrations in the environment can be affected by a large number of processes that relate to the amount released, the spatial and temporal distributions of the releases, and the results of the action of a large number of transportation and transformation processes on the substance. The likelihood and extent to which these myriad of processes will affect a particular quantity of substance in the environment is essentially random and frequency distributions of exposure concentrations in the environment will therefore most likely be distributed according to a particular model with the log-normal model being the most often observed (Klaine et al.; 1996, Solomon et al., 1996; Solomon and Chappel, 1998).

The following selection criteria for the collection of monitoring data from surface waters were applied:

- To increase the relevance of the monitoring data, only the most recent monitoring data were used for PEC derivation;
- With respect to the measurements below the detection limit (DL), it was decided to set those entries <DL to DL/2. However, detection limits that differed more than a factor of 5 with the lowest actual measured value, were also discarded from the data set. No data <DL were however reported.

Outliers were identified according to the statistical approach proposed in the TGD (EC, 2003), i.e. Log10(Xi) > log10(p.75) + K(log10(p.75) – log10(p.25)) with Xi being the concentration above which a measured concentration may be considered an outlier, $p_i$ the value of the $i^{th}$ percentile of the distribution and K a scaling factor. A scaling factor K=1.5 is applied, as this value is used in most statistical packages.

Using the statistical computer package @Risk (Palisade Decision Tools) - a computational tool hat allows to select the best parametric distribution that fits the input data - the distribution that most likely produced the monitoring data is identified. The goodness-of-fit tests that are used for screening the selected distribution are Chi-Square, Kolgomorov-Smirnov and Anderson-Darling. The latter test is mainly focussing on the goodness-of-fit in the tails of the distribution, and is therefore the most appropriate test when 90th percentiles are considered (ambient PEC). Non-parametric distributions were used when no parametric distribution could be fitted significantly ($p<0.05$) to the data points.

From the produced distributions it is possible to assign probabilities to the likelihood that a measure will exceed a certain value. This principle can also be applied to concentrations of substances in the environment, taking into account, however, that these data are usually censored by the limits of analytical detection. The ambient PECs for the different surface waters is computed as $90^{th}$ percentiles of the measured copper concentration in the sampled surface waters, which is in agreement with the procedures as described in the TGD (EC, 2003). The principle of deriving the PEC from the computed frequency distribution of exposure concentrations is illustrated in Figure 0-1. This cumulative distribution function, hereafter called CDF, can be used to estimate the likelihood that a particular concentration of the substance will be exceeded in the environment.

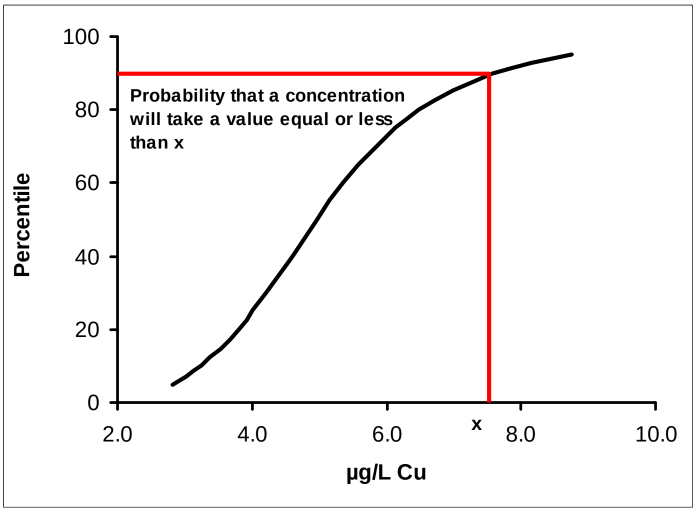


Figure 0-1: Cumulative distribution function and PEC derivation as 90th percentile

## b. Data availability

All data used in this report for the derivation of PEC for the marine environments were provided by ICES (International Council for the Exploration of the Sea), 2006. Although the ICES were retrieves in 2006, the information obtained is often rather old because most member states currently focus on biota for the marine copper monitoring activities. The ICES information was supplemented with other information from OSPAR, HELCOM and literature.

The ICES (2006) database contains individual monitored ambient Cu-concentrations for 7 different EU-countries. Reported detection limits varied between the different countries, between the sampling year and sometimes even differed between the individual sites of the same monitoring program. The ICES database was supplemented with information from the OSPAR (2001) quality status report, HELCOM (2001) report and literature.

Table 0-1 : Summary of used Cu-data included in ICES database for the derivation of ambient PECs in different European EU marine waters

| Country | Year | Detection limits (µg/l) | No. of data points |
|---|---|---|---|
| Belgium | 1990-1991 | / | 8 |
| Denmark | 1985-1987 | / | 108 |
| Germany | 1985-2005 | Range: 0.003-6.0 | 2,939 |
| The Netherlands | 1985-2005 | Range: 0.1-1.0 | 960 |
| Norway | 1985-1990 | 0.1 | 64 |
| Sweden | 1984-1985 | / | 26 |
| United Kingdom | 1983-1992 | Range: 0.4-0.8 | 620 |

### 3.1.5.2.6.2 Ambient Cu-concentrations in Belgium

In the ICES database, Cu-measurements for the Belgium continental plateau are reported in 1990 and in 1991 at four sampling stations (off shore samples). In 1990, the copper concentrations in the four samples ranged between 2.6 and 7.8 µg Cu/L, with a PEC (90$^{th}$ percentile) of 6.8 µg Cu/L. In 1991, the reported copper concentrations in the four samples (same geographic co-ordinations) ranged between 0.6 and 1.7 µg Cu/L with a PEC (90$^{th}$ percentile) of 1.5 µg Cu/L. Considering the limited data and significantly different concentrations obtained for the two sampling years, additional data were obtained for the Belgium coastal zone.

Baeyens (1998), reported for the Belgium Coastal zone (Figure 0-2), station-specific average copper levels (averages from 11 sampling campaigns) ranging between 0.5 and 1.5 µg dissolved Cu/L for the period 1981 and 1983 and ranging between 0.2 and 0.8 µg dissolved Cu/L for the period 1995-1996. The survey further showed that dissolved copper levels were related to the salinity of the samples (Figure 0-3).

For the most recent period (1995-1996), a dissolved PEC (as 90$^{th}$ percentile) of 0.8 µg Cu/L was derived for the Belgium coastal zone (Figure 0-4).

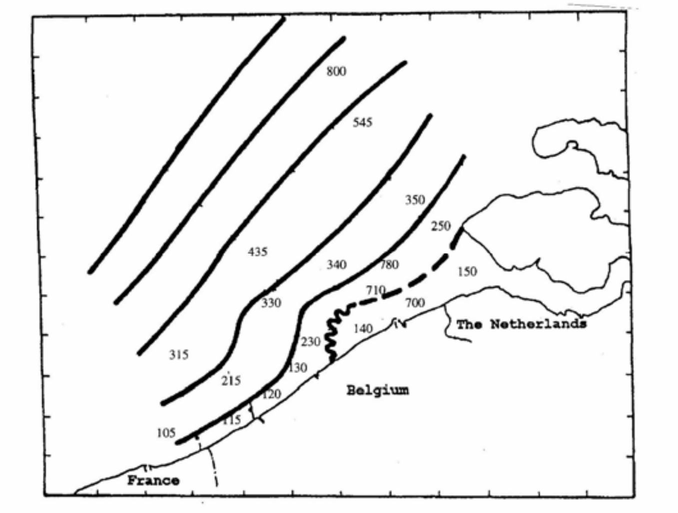


Figure 0-2 : Sampling stations for the Belgium coastal zone

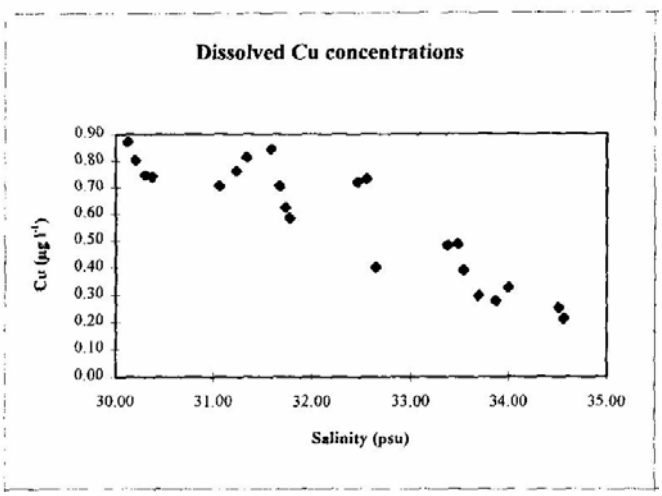


Figure 0-3: Relationship between dissolved copper concentrations and salinity in the Belgium coastal zone

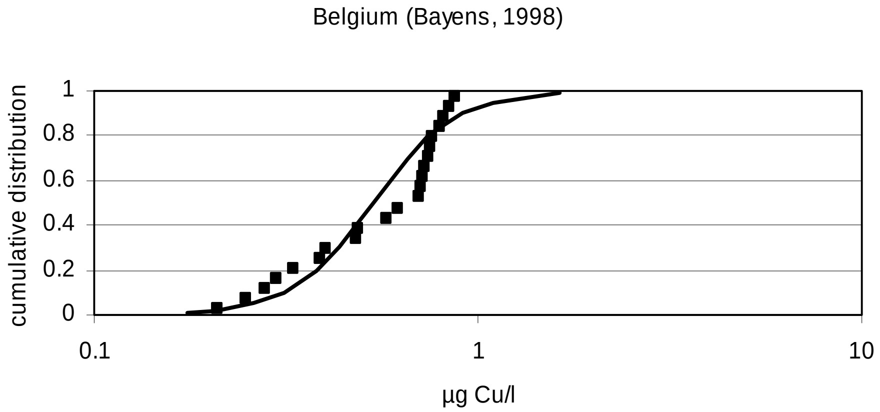


Figure 0-4: Ambient PEC of copper (in µg/L Cu) for Belgian marine waters

The dissolved copper concentrations measured by Baeyens et al., 1998 are in the range of the copper levels reported for the English channel and the North sea (Table 0-2) by other scientists, giving additional confidence to the data from Baeyens et al. (1998).

Table 0-2 : Concentrations of dissolved copper in the English Chanel and North Sea (from Baeyens et al., 1998)

| Location | Dissolved metal concentrations µg Cu/L | Reference |
|---|---|---|
| | | |
| **Dover Straight** | 0.343 | Stratham et al., 1993 |
| | | |
| **Western English Channel** | 0.14-0.36 | (OSPAR/ICES) |
| | | |
| **Central North Sea** | 0.178 | (Burton, 1993) |
| | | |
| **Northern North Sea** | 0.05-0.1 | (OSPAR/ICES) |

For the Belgium coastal zone, a reliable PEC of 0.8 µg dissolved copper/L is therefore derived from Baeyens et al, 1998.

### 3.1.5.2.6.3 Ambient Cu-concentrations in Denmark

The available Cu-measurements reported in the ICES database did allow the derivation of a country specific PEC value. Data for the sampling year 1987 were used for the PEC derivation. None of the data reported were below detection limit. No outliers were identified based on the 25$^{th}$ and 75$^{th}$ percentiles of the derived CDF. The ambient Cu concentration in the marine environment varied between 0.14 and 1.46 µg/l. The sampling campaigns included 6 sites from the N. Sea coastline (Western Coast of Denmark), 3 sites in the Kattegat and 5 sites in the Skagerrak. Two or three samples were taken at each station. The median (Min-max) copper levels in these three area's are: N Sea coast : 0.9 (0.5-1.5) µg dissolved Cu/l; Kattegat : 0.7 (0.4-0.9) µg dissolved Cu/l and Skagerrak 0.4 (0.14-0.55) µg dissolved Cu/l. From the complete database, a 90$^{th}$ percentile PEC value for Denmark of 1.14 µg/l based on the best fitting log-logistic distribution (Figure 0-5) can be derived as reliable PEC.

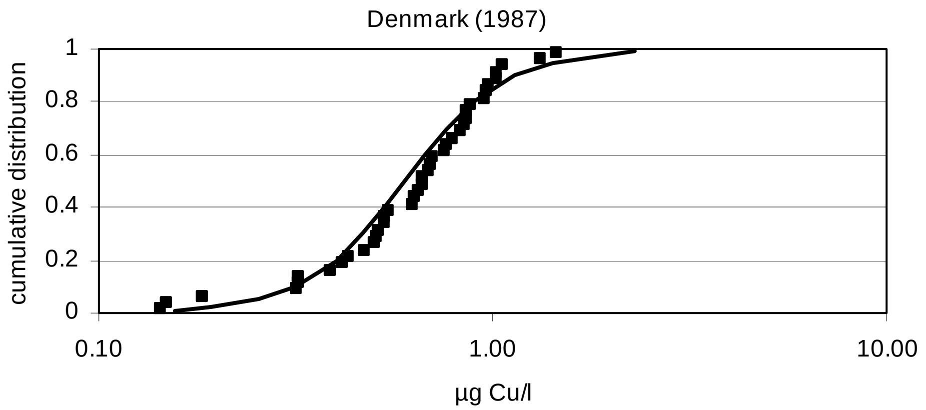


Figure 0-5 : Ambient PEC of copper (in µg/L Cu) for Danish marine waters

### 3.1.5.2.6.4 Ambient Cu-concentrations in Germany

The most recent Cu-measurements reported in the ICES database are obtained for the year 2005. All data were obtained in German coastal area of the N. Sea. 16 individual data points reported were below detection limit. No outliers were identified based on the 25th and 75th percentiles of the derived CDF. The ambient Cu concentration in the marine environment varied between 0.12 and 165.0 µg/l, giving a PEC value for Germany of 35.0 µg/l (

Figure 0-6). None of the distribution functions significantly fits the data, because the database shows two distinctive ‘exposure groups (low and high)’ with extremely high Cu concentrations in the ‘high exposure group’.

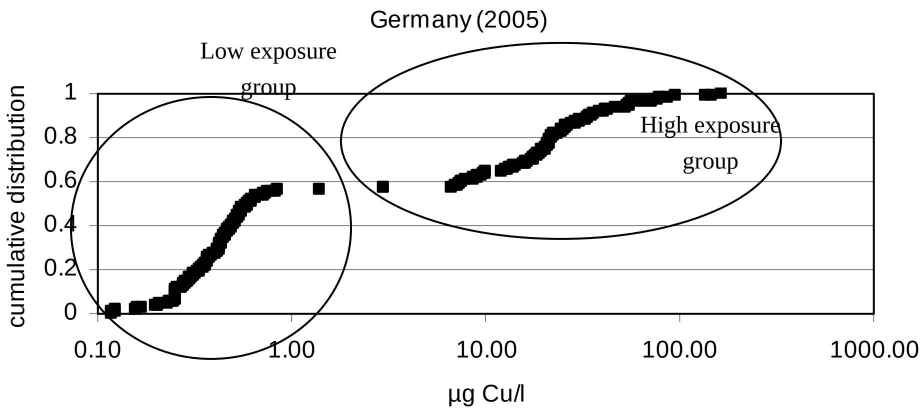


Figure 0-6: Ambient PEC of copper (in µg/L Cu) for German marine waters (2005)

Further evaluation of the German ICES 2005 data shows that the higher and lower group are corresponding to the same geographical co-ordinates and year. The 2005 data are therefore considered as unreliable and the copper levels for the period 2000-2004 were evaluated.

Table 0-3 : Extract example from the ICES Germany-2005 database

| | latitude | longitude | µg Cu/L |
|---|---|---|---|
| Germany | 53.4751 | 6.917667 | 0.5 |
| Germany | 53.4751 | 6.917667 | 18 |
| Germany | 53.476 | 8.176367 | 0.84 |
| Germany | 53.476 | 8.176367 | 9.2 |
| Germany | 53.5908 | 8.167167 | 0.5 |
| Germany | 53.5908 | 8.167167 | 7.5 |
| Germany | 53.6093 | 6.871867 | 0.5 |
| Germany | 53.6093 | 6.871867 | 9.2 |
| Germany | 53.6333 | 8.305 | 0.66 |
| Germany | 53.6333 | 8.305 | 12 |
| Germany | 53.6717 | 6.419667 | 0.37 |
| Germany | 53.6717 | 6.416867 | 0.43 |
| Germany | 53.6717 | 6.416867 | 12.9 |

Cu-measurements reported in the ICES database are also obtained for the year 2001, 2002 and 2003 (no 2004 data). The reported data show PEC values ranging between 0.7 and 2.5 µg Cu/L (Table 0-4 and Figure 0-7)

Table 0-4 : ICES - PEC values for Germany, reported in different years

| Country | Year | no of data | PEC (µg/L) |
|---|---|---|---|
| Germany | 2001 | 70 | 2.5 |
| Germany | 2002 | 210 | 0.7 |
| Germany | 2003 | 188 | 2.2 |

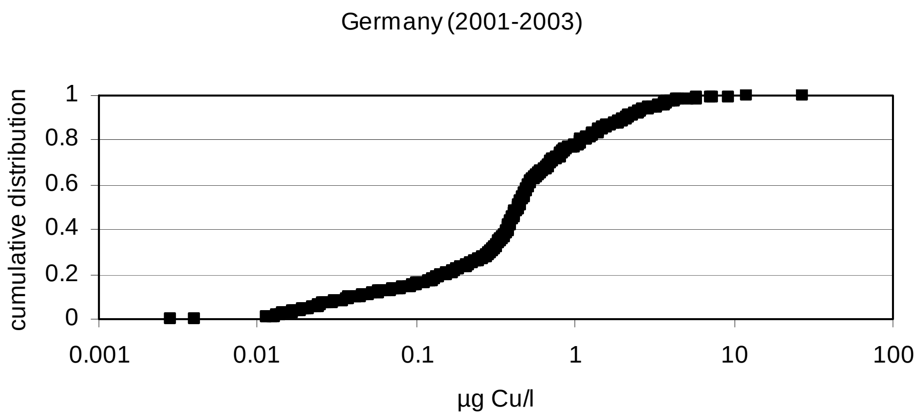

Figure 0-7: Ambient PEC of copper (in µg/L Cu) for German marine waters (2001-2003)

These data still show two distinct distributions (Figure 0-7), within the same sampling year and location and, until these data are better understood, the German marine waters, a PEC of 2.5 µg dissolved copper/L is considered as unreliable. Further discussion, with marine scientists involved in monitoring programs revealed that often dissolved and particulate phases are measured separately and therefore it is most likely the group with "higher" copper levels are particulate concentrations. Considering the uncertainty about this dataset, they were not retained for the risk characterisation

### 3.1.5.2.6.5 Ambient Cu-concentrations in The Netherlands

The available Cu-measurements reported in the ICES database did allow the derivation of a country specific PEC value. Data for the sampling years 2000 to2005 were used for the PEC derivation. In each year, the sampling campaign included three sites from the Waddensea (4 samples/site). None of the reported datapoints were below detection limit. No datapoints were identified as outliers from the 25$^{th}$ and 75$^{th}$ percentiles of the derived CDF. The ambient Cu concentration in the marine environment varied between 0.25 and 1.0 µg/l,

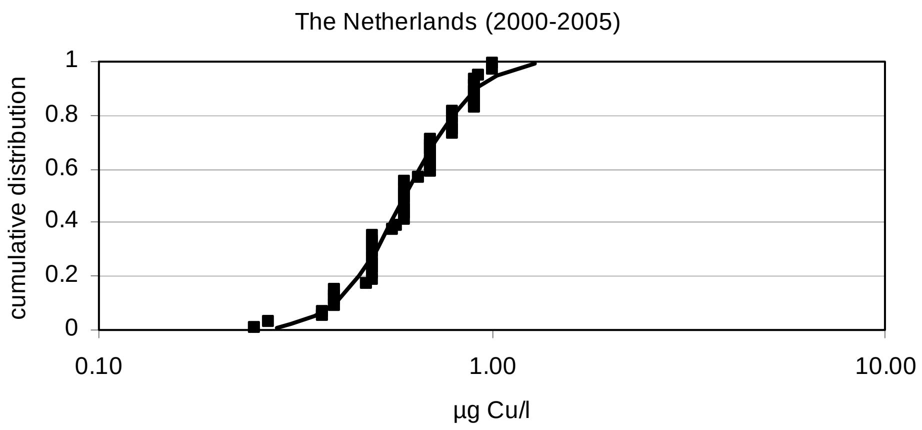


Figure 0-8 : Ambient PEC of copper (in µg/L Cu) for Dutch marine waters

Comparing the ICES copper levels in different years, shows stability in the reported copper levels in the Dutch marine waters.
The median (min-max) copper levels reported in the subsequent years for the Waddensea are :
2000 : 0.65 (0.4-1.1) µg dissolved copper/l;
2002 : 0.9 (0.6-1.3) µg dissolved copper/l;
2003 : 0.6 (0.4-1.1) µg dissolved copper/l;
2004 : 0.7 (0.5-1.3) µg dissolved copper/l;
2005 : 0.5 (0.3-0.9) µg dissolved copper/l.

Considering all samples, a PEC value for The Dutch marine waters of 1.1µg/l was calculated as the 90$^{th}$ percentile of best fitting log-normal distribution (Figure 0-8).

### 3.1.5.2.6.6 Ambient Cu-concentrations in Norway

The available Cu-measurements reported in the ICES database did allow the derivation of a country specific PEC value. Data for the sampling years 1988 to1990 were used for the PEC derivation. Eight sites were samples 2 to 5 times during this period. The sampling campaigns included four sites from the West Coast (Atlantic Ocean) and four sites from the Kattegat/Skagerrak. None of the reported datapoints were below detection limit. 5 from the 28 recent datapoints (18%, all belonging to one sampling station/year) were identified as outliers, based on the 25$^{th}$ and 75$^{th}$ percentiles of the derived CDF. The ambient Cu concentration in the marine environment varied thus between 0.24 and 1.49 µg/l. The median (Min-max) copper levels are: Atlantic coast : 0.9 (0.4-1) µg dissolved Cu/l; Kattegat/Skagerrak : 0.6 (0.4-0.6) µg dissolved Cu/l.

Considering all samples, a PEC value for a PEC value for the Norwegian marine waters of 1.1 µg/l was calculated as the 90$^{th}$ percentile of the best fitting log-normal distribution ( Figure 0-9).

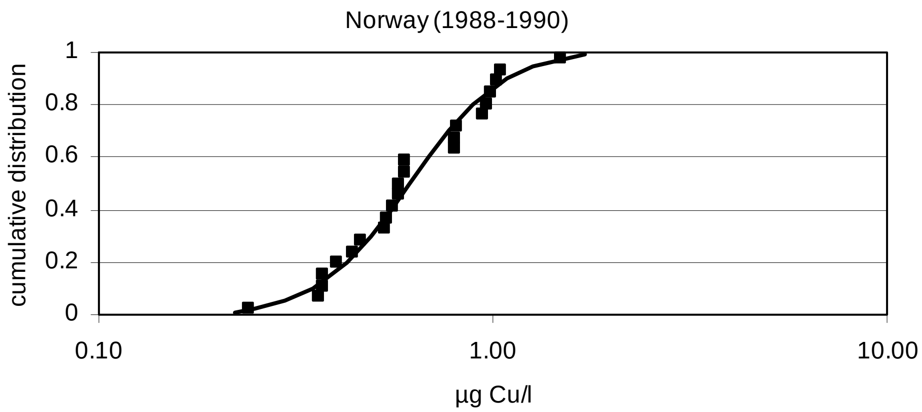


Figure 0-9 : Ambient PEC of copper (in µg/L Cu) for Norwegian marine waters

### 3.1.5.2.6.7 Ambient Cu-concentrations in Sweden

The available Cu-measurements reported in the ICES database did allow the derivation of a country specific PEC value. Data for the sampling years 1984 to1985 were used for the PEC derivation. Samples were taken at three sites of the Kattegat/Skagerrak area and each site was sampled 3 to 6 times. None of the reported datapoints were below detection limit. None of the data were identified as outliers , based on the 25$^{th}$ and 75$^{th}$ percentiles of the derived CDF. The ambient Cu concentration in the marine environment varied between 0.24 and 2.17 µg/l with a median value of 0.63 µg Cu/L

Considering all samples, a PEC value for the Swedish Kattegat/Skagerrak coastal area of 1.5 µg/l was calculated as the 90$^{th}$ percentile of the best fitting log-normal distribution (Figure 0-10). It must be realised that these data are rather old (1984-1985).

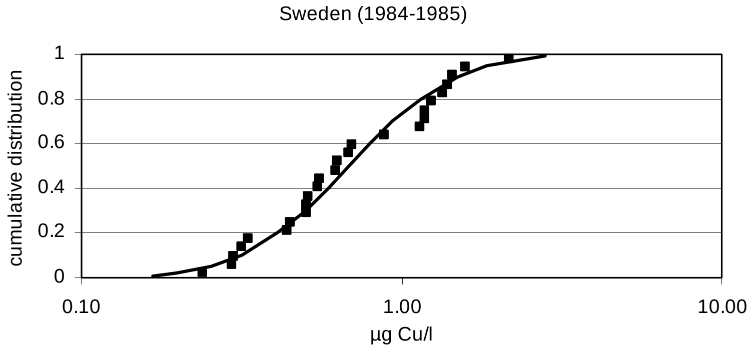


Figure 0-10 : Ambient PEC of copper (in µg/L Cu) for Swedish marine waters

### 3.1.5.2.6.8 Ambient Cu-concentrations in the United Kingdom

The available Cu-measurements reported in the ICES database did allow the derivation of a country specific PEC value. The most recent dataset available are the data for the sampling years 1991 to1992. These data, representing 38 samples from different sites in the Eastern Coastal area of the UK (N sea) were used for the PEC derivation. None of the reported datapoints were below detection limit. None of the data were identified as outliers were identified based on the 25$^{th}$ and 75$^{th}$ percentiles of the derived CDF. The ambient Cu concentration in the marine environment varied between 0.23 and 10.3 µg/l, giving a PEC value for Sweden of 2.7 µg/l based on the best fitting log-normal distribution (Figure **0-11**).
For the UK marine waters, a PEC of 2.7 µg dissolved copper/l is thus therefore derived for the period 1991-1992 from the ICES data-set.

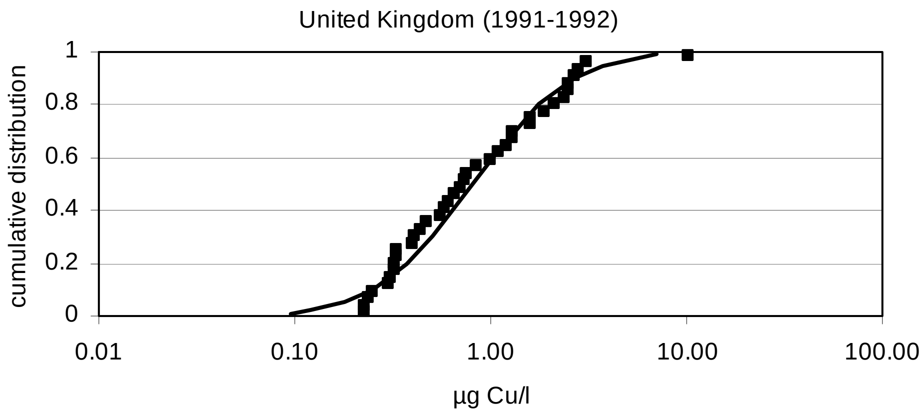


Figure 0-11 : Ambient PEC of copper (in µg/L Cu) for UK marine waters

In the framework of the copper biocidal products dossier, 306 marine samples were taken in 2002/2003 in UK marina’s (Neyland, Queen Anne’s Battery and Ocean Village) and nearby harbours and estuaries. At each site samples were taken four times (winter, spring, summer autumn), at different depths (Jones and Bolam, 2005). These data, focussing on very localized uses were generated and submitted under the BPD and are discussed in detail in the BPD copper dossiers and are not considered as relevant for the ESR regional PEC determination.

**3.1.5.2.6.9 Ambient Cu-concentrations in the Baltic**

Copper concentrations for the Baltic Sea were obtained form Kremlin and Streu (2000). These authors measured dissolved trace metals concentrations in 52 samples, collected from the Baltic in 1995 and compared these values to the measurements obtained in 1982. The reported mean dissolved copper concentrations measured in respectively the Gotland Sea /Borholm Sea and Arkona Belt Sea area are 8.4 and 8.7 nmol Cu/kg seawater, corresponding to respectively 0.54 and 0.56 µg Cu/l.

Also HECLCOM, 2002 provides information on dissolved copper levels in the Baltic Sea and between 1978 and 1996 (Figure 0-12) When only the period 1994-1998 is assessed, the data reveal that the dissolved copper concentrations remained almost constant at about 9 nmol/l (0.57 µg Cu/l).

The HECLCOM 2002 data are thus consistent with the Kremlin and Streu (2000) data and an average value of 0.56 µg Cu/L is therefore retained for the Baltic Sea.

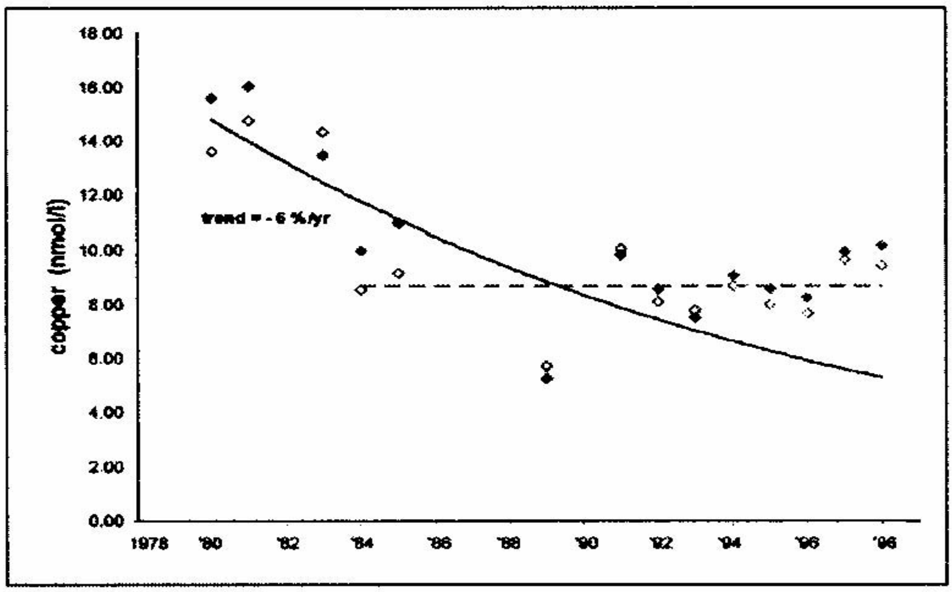


Figure 0-12 . Trends Changes in copper concentrations in the Baltic Sea between 1987 and 1996 (Helcom 2002)

**3.1.5.2.6.10 Derivation of the regional marine PEC**

From this analysis, the PEC values (90$^{th}$ percentile per region) for the coastal areas of Belgium, The Netherlands, Norway Denmark and the Baltic sampled between '88 to 2005 range between 0.8 and 1.1 µg Cu/l. Somewhat higher values were recorded in the older Swedish and UK ICES datasets. An overall median of the 90$^{th}$ percentiles of 1.1 µg Cu/l is thus derived across all data (table 0-5) and forwared to the regional and local risk characterisation.

Table 0-5 : Summary of the median and 90$^{th}$ percentiles of the marine datasets

| Country | Median<br><br>µg dissolved Cu/L | 90th percentile PEC<br><br>µg dissolved Cu/L |
|---|---|---|
| Begium '89 (Baeyens, 1998) | 0.5 | 0.8 |
| Denmark '87 (ICES, 2006) | 0.7 | 1.1 |
| The Netherlands '00-'05 (ICES,2006) | 0.7 | 1.1 |
| Norway '88-'90 (ICES,2006) | 0.6 | 1.1 |
| Sweden '84-'85 (ICES 2006) | 0.6 | 1.4 |
| UK '84-'85 (ICES 2006) | 0.7 | 2.7 |
| Baltic Sea '96 (Kremlin & Streu, 2000) | 0.6 | |
| **Median** | **0.6** | **1.1** |

3.1.5.2.6.11 Copper marine background levels

For the OSPAR regions, dissolved background copper levels, estimated from off shore samples, range between 50 and 360 ng/L (OSPAR,2001).

### 3.1.5.2.6.12 Trends in inputs and observed copper levels

Trends in direct and riverine inputs between 1990 and 1996 were evaluated in the OSPAR quality status report (2001). A decreasing trend in copper inputs as a function of time was observed (Figure 0-13). The calculated total direct and riverine input for Belgium, Denmark, Germany, The Netherlands, Norway, Sweden and UK amounted to 1500 to 1600 tons/year in 1990 and decreased to 1050 to 1160 tons/year in 1996.

OSPAR (2001) also reported a downward trend in copper levels in mussels from the Elbe, related to a decline in industrial emissions. OSPAR further reported significant decreases in copper concentrations of mussels from Denmark, Germany, The Netherlands, Norway and Spain. On the other hand, increasing copper concentrations were observed for the bay of Arcachon (related to anti-fouling paints use).

OSPAR (2001) evaluated metal levels in mammals and recognizes that copper concentrations are homeostatically controlled in marine mammals and are therefore of no concern.

Kremling and Streu (2000) concluded that copper levels in the Baltic had significantly decreased between 1982 and 1995 with an average decrease of 19% between the two periods.

HELCOM 2002 reports a 5%/year decrease in copper levels in the Baltic between 1980 and 1993. When only the period 1994-1998 is assessed, the data revealed that the dissolved copper concentrations remained almost constant.

HELCOM further assessed copper time series (> 15 years) in Biota (herring and cod fish liver and mussel) and concluded that “the copper levels has remained stable during the assessment period”. Some variations were observed and considered as inconclusive due to observed seasonal variations. These variations were related to natural homeostasis factors rather than to anthropogenic activities. The HELCOM report also concluded that copper concentrations in blue mussels from Denmark and Sweden were lower then the ones reported at the reference sites and lower than the concentrations levels regarded as “high” background levels at diffuse loading.

The OSPAR quality status report mentions that for oceanic and offshore areas, the reported metal concentrations are comparable to background levels, indicating that widespread contamination is not a problem. The report also compared copper (and other metals) levels in different areas and mentions that inevitable, river concentrations exceed background values as these are based on offshore concentrations, and in coastal/estuarine areas, the estuarine geochemistry of metals must be taken into account. Dissolved copper levels were shown to be inversely related to salinity due to dilution effects and precipitation effects. The report further recognizes that there have been improvements in analytical methods and therefore, it is not always possible to compare recent with historical data.

Considering the trends reported by OSPAR and HELCOM, the PEC values reported in table 0-5, it can be noted that most of the copper values useful for the PNEC derivation have been derived from pre-1996 samples and are therefore expected to be overestimations of the current concentrations.

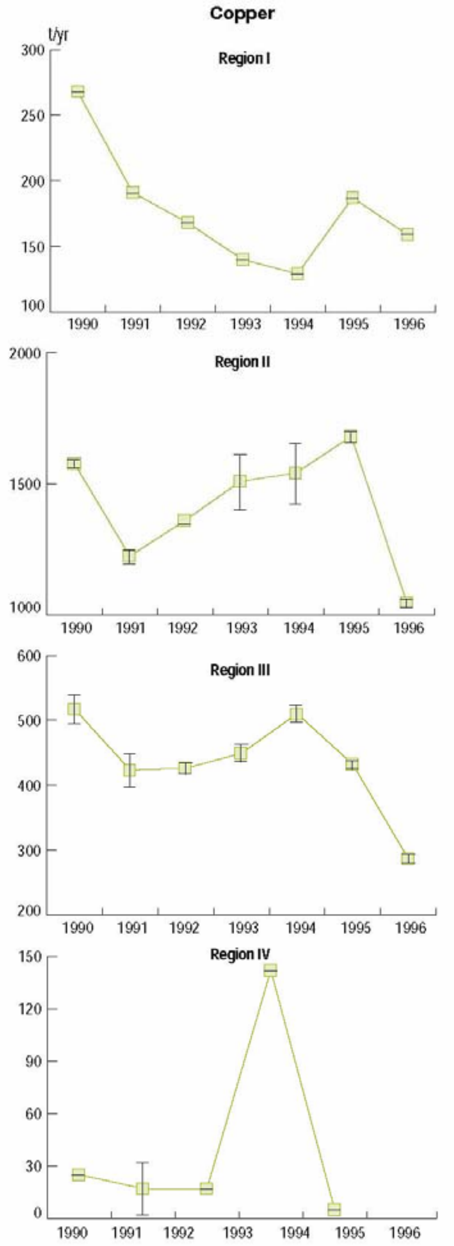


**Table 2.1 Catchment areas and river run-off.**

| | Catchment area (km² x 10³)* | River run-off (m³/s)† |
|---|---|---|
| **Region I** | | |
| Greenland‡ | 600 | 16 000 |
| Iceland | 103 | 5 400 |
| Norway > 62° N | 190 | 8 700 |
| Russia and Finland | 914 | 9 500* |
| SUB-TOTAL: | 1 807 | 39 600 |
| **Region II** | | |
| Baltic Sea | 1 650 | 14 900 |
| North Sea | 850 | 9 500 |
| SUB-TOTAL: | 2 500 | 24 400 |
| **Region III** | | |
| Ireland | 68 | 900 |
| western UK | 110 | 1 600 |
| SUB-TOTAL: | 178 | 2 500 |
| **Region IV** | | |
| France | 260 | 2 200 |
| Iberian Peninsula | 395 | 3 450 |
| SUB-TOTAL: | 655 | 5 650 |
| **Region V** | | |
| Azores | 2.3 | Low |
| SUB-TOTAL: | 2.3 | Low |
| TOTAL: Convention Area | 5 142 | 72 150 |
| **3 Siberian Rivers** | | |
| Lena | 2 486 | 16 656 |
| Ob | 2 990 | 12 857 |
| Yenisey | 2 580 | 19 866 |
| TOTAL: 3 Siberian rivers | 8 056 | 49 379 |

* approximate; † mean values for different base periods; ‡ the data for eastern Greenland are taken as being two-thirds of the totals for the whole of Greenland. The catchment area for Greenland as a whole is ~ 900 x 10³ km², and the modelled average run-off according to Janssens and Huybrechts (in press) is 23 920 m³/s (run-off from ice sheet: 8800 m³/s; basal melting from ice sheet: 320 m³/s; iceberg calving: 9800 m³/s; run-off from ice-free land: 5000 m³/s).

c

Figure 0-13: Trends in direct and riverine inputs of copper in the OSPAR regions. Data for region I cover Norwegian and Barent Sea data only (OSPAR 2001).

### 3.1.5.2.6.13 Summary of copper levels in EU marine waters

Dissolved copper levels have been obtained for different EU coastal/open ocean marine waters, from different databases. For open ocean waters, copper background levels between 50 and 360 ng Cu/L are reported by OSPAR. Due to inputs from terrestrial origin (natural and anthropogenic) and geochemical effects, copper levels are higher in coastal areas than offshore. Nevertheless, coastal area copper PEC values are typically below 1.1 µg Cu/L.

## 3.1.5.2.7.Derivation of a regional PEC for the marine sediment environment

### 3.1.5.2.7.1 Data availability and data treatment

#### a. Data treatment

The procedures used in this study are based on the methods and concepts laid down in the TGDs (EC, 2003) for environmental risk assessment in the European Union and on the Combined Monitoring-based and Modelling-based Priority Setting procedure (COMMPS, 1999).

In general, concentrations in the environment can be affected by a large number of processes that relate to the amount released, the spatial and temporal distributions of the releases, and the results of the action of a large number of transportation and transformation processes on the substance. The likelihood and extent to which these myriad of processes will affect a particular quantity of substance in the environment is essentially random and frequency distributions of exposure concentrations in the environment will therefore most likely be distributed according to a particular model with the log-normal model being the most often observed (Klaine et al.; 1996, Solomon et al., 1996; Solomon and Chappel, 1998).

All reported copper levels that are reported in the ICES data set represent actual values, i.e., no values below the detection limit are present in the ICES data set. Outliers were identified according to the statistical approach proposed in the TGD (EC, 2003), i.e. Log10(Xi) > log10(p.75) + K(log10(p.75) – log10(p.25)) with Xi being the concentration above which a measured concentration may be considered an outlier, $p_i$ the value of the $i^{th}$ percentile of the distribution and K a scaling factor. A scaling factor K=1.5 is applied, as this value is used in most statistical packages.

Using the statistical computer package @Risk (Palisade Decision Tools) - a computational tool hat allows to select the best parametric distribution that fits the input data - the distribution that most likely produced the monitoring data is identified. The goodness-of-fit tests that are used for screening the selected distribution are Chi-Square, Kolgomorov-Smirnov and Anderson-Darling. The latter test is mainly focussing on the goodness-of-fit in the tails of the distribution, and is therefore the most appropriate test when $90^{th}$ percentiles are considered (reasonable-worst-case (RWC) ambient PEC). Non-parametric distributions are used when no parametric distribution can be fitted significantly ($p<0.05$) to the data points.

From the produced distributions it is possible to assign probabilities to the likelihood that a measure will exceed a certain value. This principle can also be applied to concentrations of substances in the environment, taking into account, however, that these data are usually censored by the limits of analytical detection. The ambient PECs for marine sediments representing different countries is computed as $90^{th}$ percentiles of the measured copper concentration in the sampled sediments, which is in agreement with the procedures as described in the TGD (EC, 2003). This cumulative distribution function, hereafter called CDF, can be used to estimate the likelihood that a particular concentration of the substance will be exceeded in the environment.

#### b. Data collection

The ICES (2006) database was used for the exposure assessment of copper in European marine waters and sediments. This database contains individual monitored ambient Cu-concentrations in sediment for eight different EU-countries. An overview of available data is provided in Table 0-6. Although the ICES were retrieves in 2006, the information obtained is often rather old because most member states currently focus on biota for the marine copper monitoring activities. The ICES information was supplemented with other information from OSPAR, HELCOM and literature

Table 0-6: Summary of used Cu-data included in ICES database for the derivation of ambient PECs in different European EU marine sediments.

| Country | Years + No. of data points |
|---|---|
| Belgium | 1990: n=4 ; 1991: n=4 |
| Denmark | 2003: n=81 ; 2004: n=7 |
| Germany | 2003: n=34 |
| Ireland | 1994: n=42 ; 1995: n=25 |
| The Netherlands | 1990: n=30 |
| Norway | 1997: n=31 ; 2004: n=39 |
| Sweden | 1990: n=9 |
| United Kingdom | 2003: n=30 ; 2004: n=30 |

### 3.1.5.2.7.2 Ambient Cu-concentrations in Belgian marine sediments

A limited amount of data points are available for Belgian marine sediments, i.e., four Cu-concentrations were reported for respectively 1990 and for 1991. The samples were taken in the Belgium coastal zone at 4 sampling stations (1 sample/station,). Sediment copper concentrations were situated between 1.1 and 3.3 mg/kg, with exception of one value of 28.9 mg/kg, which is more ore less one order of magnitude higher than all other measurements. Using the methodology outlined in section 4.1, the value of 28.9 mg/kg was identified as an outlier and was not used for the derivation of a Cu-PEC for Belgian marine sediments.
With the remaining seven data points, a median value of 2.4 mg Cu/kg dry weight was calculated and a RWC-ambient (90$^{th}$ percentile) PEC of 4.2 mg/kg dry wt was derived (based on the best fitting log-normal distribution) (Figure 0-13).

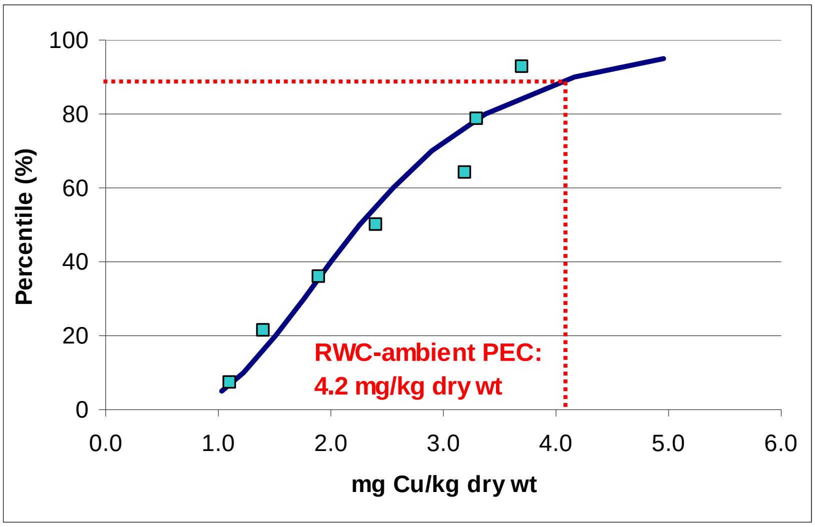


Figure 0-13: Ambient PEC of copper (in mg Cu/kg dry wt) for Belgian marine sediments.

### 3.1.5.2.7.3 Ambient Cu-concentrations in Danish marine sediments

Data for the sampling year 2003 (n=81) were used for the PEC derivation. For 2004, only 7 data points were available. No outliers were identified based on the 25$^{th}$ and 75$^{th}$ percentiles of a non-parametric distribution. In 2003, 30 sites were sampled in the Baltic (1-3 samples/site), 3 sites in the Kattegat (2 samples/site) and 12 sites in the N. Sea (1 to 2 samples/site). In 2004, 6 sites were sampled from the Baltic and 1 Open Sea North Sea site (1 sample/site). The ambient Cu concentrations in marine sediments were situated between 0.4 and 42.6 mg Cu/kg dry wt.
The 2003 Baltic samples are characterised by a median (10$^{th}$-90$^{th}$ percentile) of 18.1 (4.3-34.7) mg Cu/kg dry wt, the 2003 Kattegat samples are characterised by a median (10$^{th}$-90$^{th}$ percentile) of 13.1 (12.2-16.6) mg Cu/kg dry wt and the North Sea samples are characterised by a median (10$^{th}$-90$^{th}$ percentile) of 12.0 (3.6-26.4) mg Cu/kg.
The 2004 Baltic samples characterised by a median (10$^{th}$-90$^{th}$ percentile) of 8.9 (5.4-19.3) mg Cu/kg dry wt and the Open Sea sample had 0.4 mg Cu/kg dry wt.
The median values for the Baltic, North Sea and Kattegat are thus quite similar and somewhat higher than the open sea sample (on replica only). Combining all 2003 data, results in a RWC-PEC value for Denmark of 33.6 mg Cu/kg dry wt, based on a non-parametric distribution (Figure 0-14); with the data provided in the ICES database it was not possible to significantly fit a relevant distribution through the data points. With the limited data for 2004, a 90$^{th}$ percentile of 30.3 mg Cu/kg dry wt could be derived (data not shown). This value is similar to the RWC-ambient PEC of 33.6 mg Cu/kg dry wt that is proposed for Danish marine sediments.

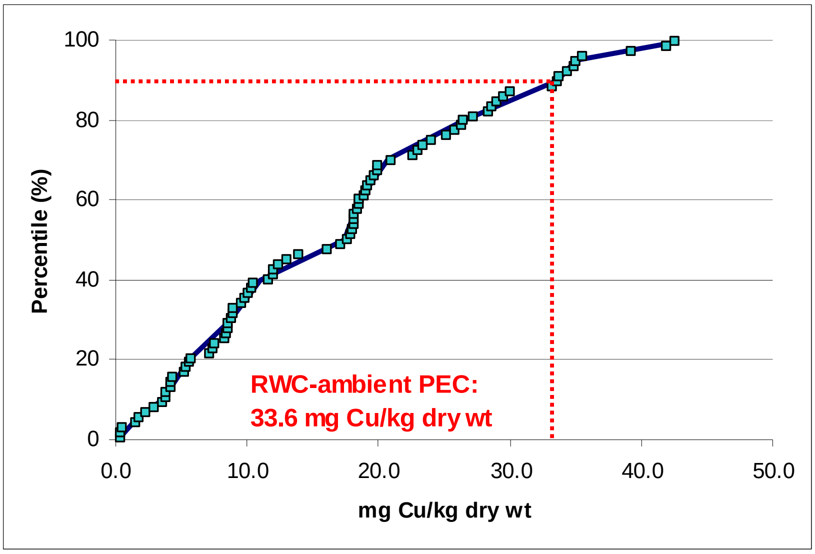


Figure 0-14: Ambient PEC of copper (in mg Cu/kg dry wt) for Danish marine sediments.

### 3.1.5.2.7.4 Ambient Cu-concentrations in German marine sediments

The available Cu-measurements reported in the ICES database (n=34) did allow the derivation of a country-specific PEC value for Germany. In 2003, 34 samples were taken at different sites of the N. sea (1 to 2 replica's /site) and used for the PEC derivation. No outliers were identified based on the 25$^{th}$ and 75$^{th}$ percentiles of a non-parametric distribution. The ambient Cu concentration in the marine sediment varied between 1.1 and 19.0 mg Cu/kg dry wt, with a median value of 6.7 mg Cu/kg dry wt and a 90$^{th}$ percentile PEC value for Germany of 18.5 mg Cu/kg dry wt, based on the best fitting log-Rayleigh distribution (Figure 0-15).

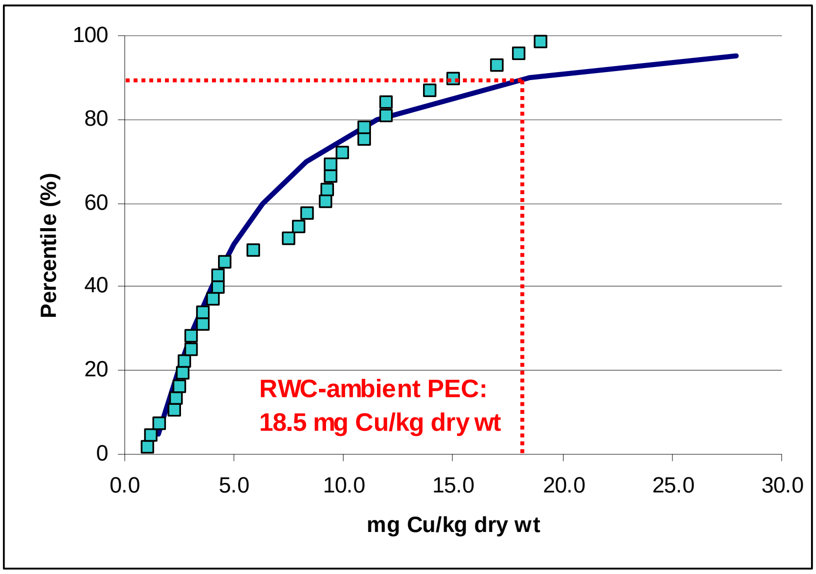


Figure 0-15: Ambient PEC of copper (in mg Cu/kg dry wt) for German marine sediments.

### 3.1.5.2.7.5 Ambient Cu-concentrations in Irish marine sediments

Sediment data for 1994 and 1995 were pooled for the derivation of an RWC-ambient PEC in Irish marine sediments. In 1994, 42 samples were taken in the Irish sea, in 1995, 22 samples were taken in the Irish Sea and 3 samples in the Atlantic coast. The median (10-90th percentiles) recorded for these waters are :

- Irish Sea, 1994 : 7.7 (3.4-14.4) mg /kg dry wt
- Irish Sea, 1995 : 2.3 (2-3.2) mg /kg dry wt
-Atlantic Ocean, 1995 : 4.9 (3.1-31.85) mg/kg dry wt

A total of 67 data points were thus available without clear difference between the samples from the Irish Sea and the Atlantic Ocean. Copper levels range between 1.8 and 64.8 mg Cu/kg dry wt. Based on the 25th and 75th percentiles of a non-parametric distribution (i.e., 3.7 and 8 mg Cu/kg dry wt, respectively), the outlier cut-off level was set at 29.7 mg Cu/kg dry wt. Five reported measurements, ranging between 33.4 and 34.8 mg Cu/kg dry wt, exceeded this threshold and were not used for PEC-derivation.

A log-Weibull distribution was fitted through the remaining 62 data points, and a RWC-ambient PEC of 11.9 mg Cu/kg dry wt was estimated from this CDF (Figure 0-16).

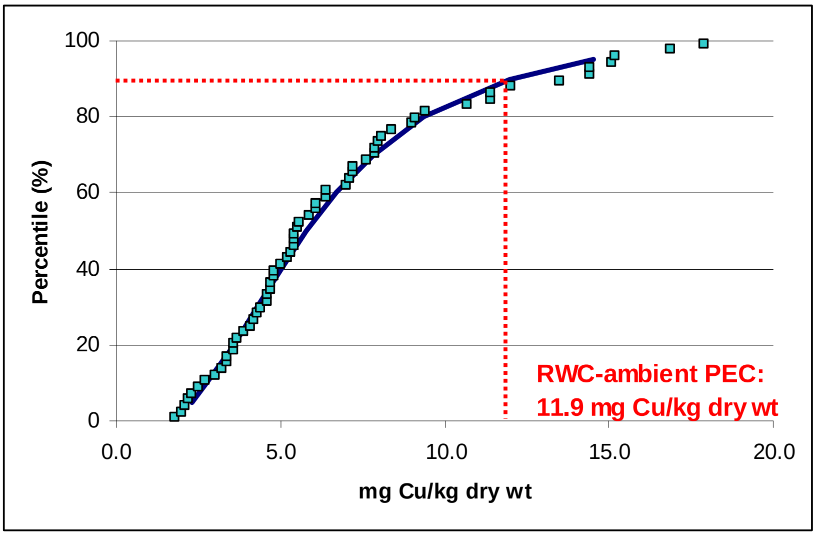


Figure 0-16: Ambient PEC of copper (in mg Cu/kg dry wt) for Irish marine sediments.

### 3.1.5.2.7.6 Ambient Cu-concentrations in Dutch marine sediments

The available Cu-measurements reported in the ICES database did allow the derivation of a country-specific PEC value for The Netherlands. Data were collected in 1990 and covered 30 samples taken in the North Sea coastline and Waddensea. Cu-levels in Dutch marine sediments ranged between 0.77 and 9.63 mg Cu/kg dry wt with a median value of 1.27 mg Cu/kg dry weight. Outlier analysis showed that none of the reported sediment copper concentrations could be considered as an outlier (based on the 25th and 75th percentiles of a non-parametric distribution). A log-Weibull distribution was fitted through the 30 data points, resulting in a RWC-ambient PEC of 6.2 mg Cu/kg dry wt for sediments in this country. The CDF for The Netherlands is presented in Figure 0-17.

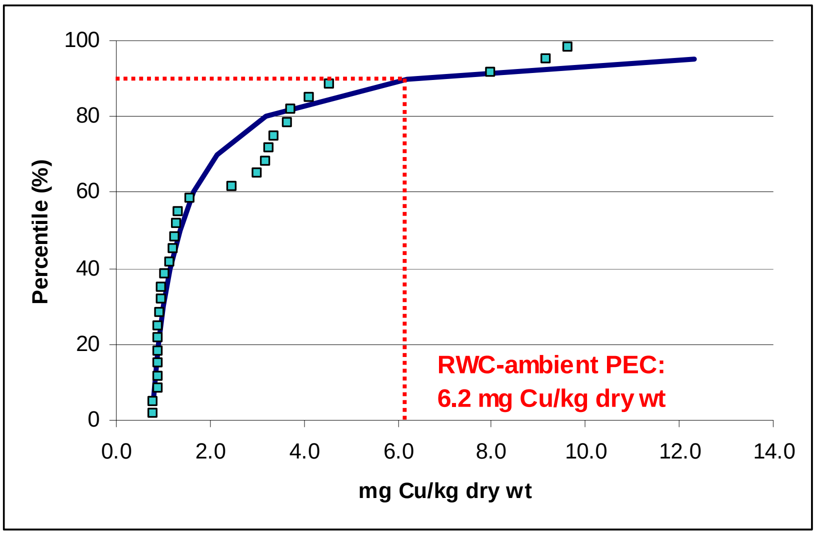


Figure 0-17: Ambient PEC of copper (in mg Cu/kg dry wt) for Dutch marine sediments.

### 3.1.5.2.7.7 Ambient Cu-concentrations in Norwegian marine sediments

Norwegian samples were obtained form the N. Sea (11 sites in 1994 and 13 sites in 2004) and from the Skagerrak (1 site sampled three times in 1994). The median (10-90$^{th}$ percentiles) recorded were :

- N. Sea, 1994 : 38.8 (16.6 – 98.8) mg Cu/kg dry wt.
- N. Sea, 2004 : 30.0 (8.8 – 186) mg Cu/kg dry wt.
- Skagerrak 1994 : 20.6 (18.4 – 21.1) mg Cu/kg dry wt

The Norwegian data set in the ICES database included sediments that were taken at locations in the proximity of industrial sites. As a result the measured copper levels in these sediment samples represent the sum of ambient copper and anthropogenic copper coming from a local point source. Such data cannot be used for the derivation of a regional reasonable worst-case ambient PEC. The data available for 1997 and 2004 were combined for the calculation of a marine Cu-RWC ambient PEC in Norwegian sediments.

After elimination of values known to be affected by point source contamination, 30 data points were retained, ranging between 7 and 79 mg Cu/kg dry wt. The most optimal CDF that was fitted through these data was a log-Weibull distribution (Figure 0-18), and the 90$^{th}$ percentile of this distribution, i.e., 55.3 mg Cu/kg dry wt is proposed as an initial RWC-ambient PEC of copper in Norwegian marine sediments.

It should be noted that some of the (higher) Cu-concentrations may be affected by currently unidentified point sources, and elimination of such data points from the data set in the near future (i.e., when identified) may alter the outcome of the analysis for this country.

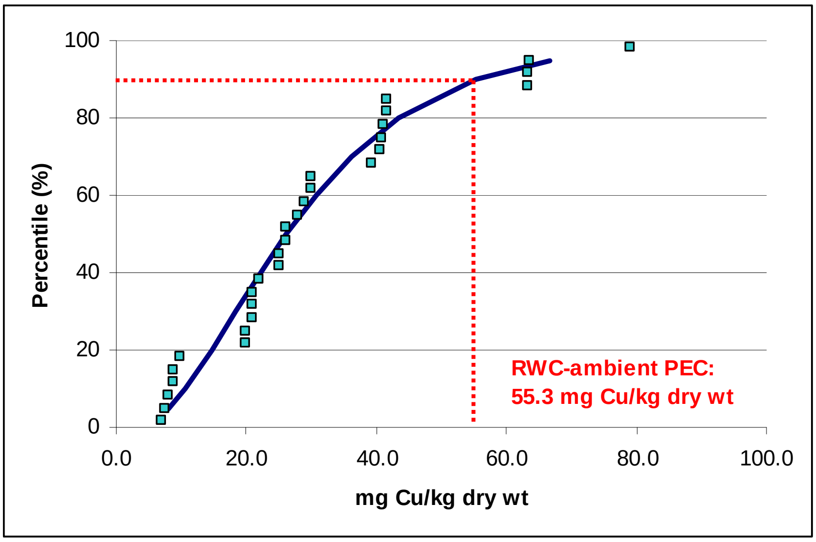


Figure 0-18: Ambient PEC of copper (in µg/L Cu) for Norwegian marine sediments.

### 3.1.5.2.7.8 Ambient Cu-concentrations in Swedish marine sediments

A limited data set (n=9) of copper levels in marine sediment, sampled in 1990, was available in the ICES dataset. Data were obtained for 6 sites from the Skagerrak, 1 site from the Baltic and 2 sites from the Kattegat. Cu-concentrations in sediment samples, all taken in 1990, ranged between 6.7 and 25.2 mg Cu/g dry wt. The median (10-90$^{th}$ percentiles) recorded were

- Skagerrak : 11.4 (7.3-26.6) mg Cu/kg dry wt
- Baltic : 20.3 mg Cu/kg dry wt
- Kattegat : 24.8 mg Cu/kg dry wt

Combining all data, none of the data were identified as outliers (based on the 25$^{th}$ and 75$^{th}$ percentiles of a non-parametric distribution). Analysis of this data set resulted in a PEC value of 27.1 mg Cu/kg dry wt for Swedish marine sediments, based on the best fitting log-normal distribution (Figure 0-19).

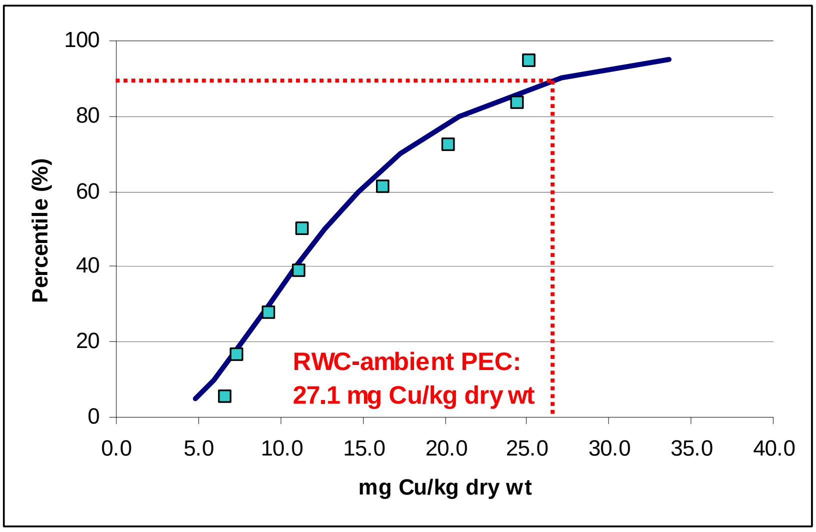


Figure 0-19: Ambient PEC of copper (in mg Cu/kg dry wt) for Swedish marine sediments.

HELCOM 2002, reports that copper has been effectively transported towards the central basin of the Baltic. The highest levels are reported in the Gotland deep, Faro deep, Western

Gotland Basin and Northern central basin with copper levels of respectively 176, 119, 71 and 73 mg Cu/kg Dwt). Moderate levels were obtained at almost all near coastal stations, such as Lubeck Bay, the Gulf of Gdansk, the Gulf of Riga, the Gulf of Finland and in the Bothnia Bay. The report further mentions that in several of the sediment cores, the trace metal concentrations decrease in the upper few cm (2 to 5 or 10 cm) thus indicating a general decrease in concentration level since the early 1980s

### 3.1.5.2.7.9 Ambient Cu-concentrations in United Kingdom sediments

The available Cu-measurements reported in the ICES database did allow the derivation of a country specific PEC value. Data for the sampling years 2003 and 2004 were available for the Hebrides (1 site, 5 samples/site.year), the Northern Channel (2 sites, 5 samples/site.year) and the N. Sea (3 sites, 5 samples/site.year). The median (10-90$^{th}$ percentiles) recorded were

- Hebriden, 2003 : 10.3 (9.9-11.9) mg Cu/kg dry wt
- Hebriden, 2004 : 7 (6.2-7.7) mg Cu/kg dry wt
- N. Sea, 2003 : 5.4 (2-6.7) mg Cu/kg dry wt
- N. Sea, 2004 : 3.2 (2.6-3.5) mg Cu/kg dry wt
- N. Channel 2003 : 8.5 (6.2-12.4) mg Cu/kg dry wt
- N. Channel 2004 : 11.6 (6.4-17.0) mg Cu/kg dry wt

Combining all data, none of the reported data points were identified as outliers based on the 25$^{th}$ and 75$^{th}$ percentiles of a non-parametric distribution. The ambient Cu concentration in marine sediments varied between 1.82 and 17.2 mg Cu/kg dry wt. With these data a PEC value of 12.8 mg Cu/kg dry wt for British sediments was calculated, using the best fitting log-Weibull distribution (Figure 0-20).

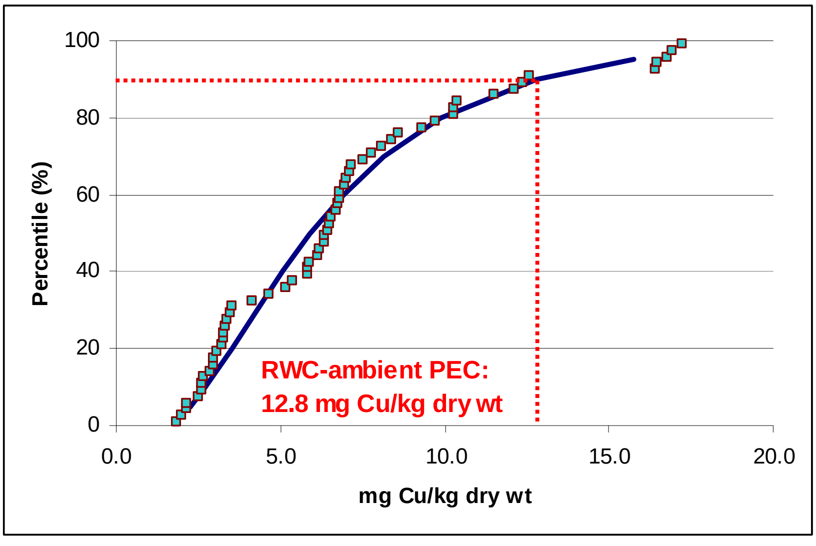


Figure 0-20: Ambient PEC of copper (in mg Cu/kg dry wt) for UK marine sediments.

### 3.1.5.2.7.10 Summary of country-specific RWC-ambient PECs of Cu in marine sediments

Table 0-7 gives an overview of the different RWC-ambient PECs that are calculated in this study. Typical country-specific Cu-concentrations (50$^{th}$ percentiles) are also shown in this table but are not further discussed.

The lowest RWC-ambient PECs were found for the lowlands (Belgium, The Netherlands) with values situated around 5 mg Cu/kg dry wt. The highest copper levels were observed in the Scandinavian countries, with RWC-ambient PECs situated between 27.1 and 55.3 for Denmark, Norway and Sweden. For the remaining countries the RWC-ambient PECs ranged between 10 and 20 mg Cu/kg dry wt.

Using these country-specific RWC-ambient PECs a typical value of 16.1 mg Cu/kg dry wt (log-Weibull distribution) is calculated for European marine sediments (Figure 0-21).

Table 0-7: Overview of country-specific RWC- and typical ambient PEC values for copper in marine sediments

| **Country** | **RWC-ambient PEC (90th percentile of the CDF)** | **Typical ambient PEC (50th percentile of the CDF)** |
|---|---|---|
| Belgium | 4.2 mg Cu/kg dry wt | 2.3 mg Cu/kg dry wt |
| Denmark | 33.6 mg Cu/kg dry wt | 17.4 mg Cu/kg dry wt |
| Germany | 18.5 mg Cu/kg dry wt | 5.0 mg Cu/kg dry wt |
| Ireland | 11.9 mg Cu/kg dry wt | 5.8 mg Cu/kg dry wt |
| The Netherlands | 6.2 mg Cu/kg dry wt | 1.4 mg Cu/kg dry wt |
| Norway | 55.3 mg Cu/kg dry wt | 26.2 mg Cu/kg dry wt |
| Sweden | 27.1 mg Cu/kg dry wt | 12.7 mg Cu/kg dry wt |
| United Kingdom | 12.8 mg Cu/kg dry wt | 5.9 mg Cu/kg dry wt |
| **Europe:** | **Median: 16.1 mg Cu/kg dry wt** | |

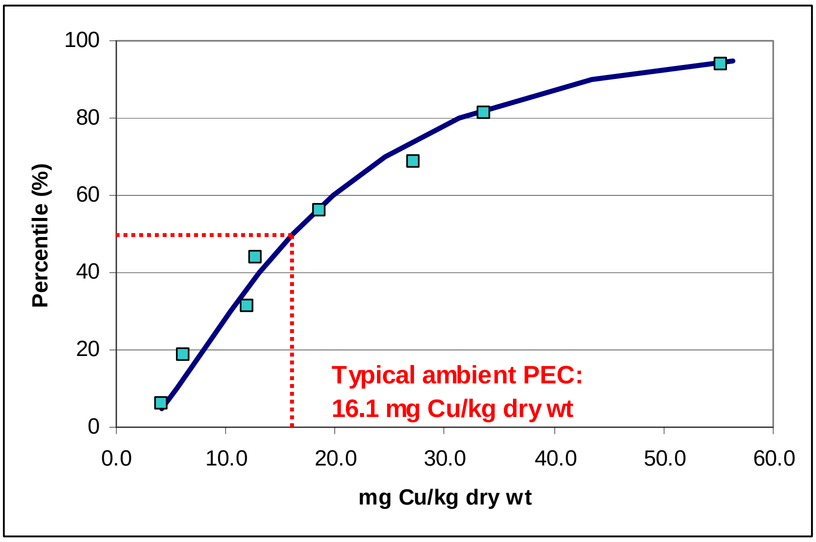


Figure 0-21: Typical ambient PEC of copper (in mg Cu/kg dry wt) for European marine sediments