# THE COPPER VOLUNTARY RISK ASSESSMENT

## A Pioneering Industry/Member State Partnership Approach to the Duty of Care

EUROPEAN COMMISSION
REVIEW BY
AND EU MEMBER STATES COMPLETED

### Executive Summary:


In 2000, the copper industry initiated a voluntary risk assessment for copper.

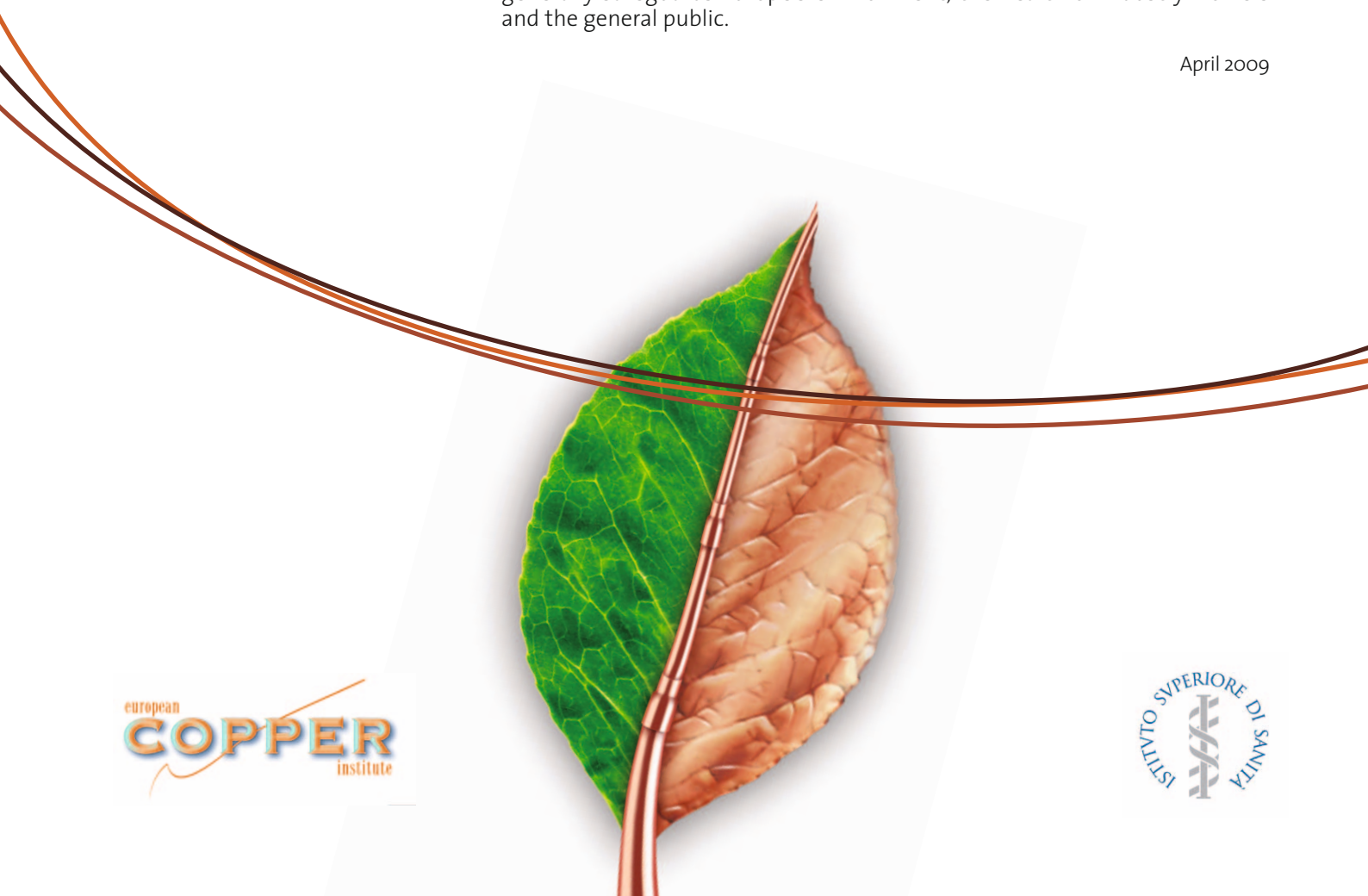
The assessment process was agreed with the Italian Government's Istituto Superiore di Sanità, acting as the review country on behalf of the European Commission and the EU Member States.

In May 2005, on behalf of the European Copper Institute, Italy submitted the draft risk assessment for review by the European Commission and EU Member States. In April 2008, after three years of detailed analysis and improvement, this review process was completed.

- The risk assessment dossier has been agreed by the European Commission's Technical Committee for New and Existing Substances.
- The European Commission's Scientific Committee on Health and Environmental Risk (SCHER) performed a final evaluation and further endorsed the conclusions on the environmental and human health risk characterisations.

This comprehensive assessment, covering the production, use and end-of life aspects of the copper value chain, shows that the existing legislative framework generally safeguards Europe's environment, the health of industry workers and the general public.


April 2009



european COPPER institute

ISTITVTO SVPERIORE DI SANITA

Anticipating REACH

## EU Policy Background:

In 2000, the copper industry initiated a voluntary risk assessment for copper.

The assessment process was agreed with the Italian Government's Istituto Superiore di Sanità, acting as the review country on behalf of the European Commission and the EU Member States.

In May 2005, on behalf of the European Copper Institute, Italy submitted the draft risk assessment for review by the European Commission and EU Member States. After three years of detailed analysis and improvement, this review process was completed.

This comprehensive assessment, covering the production, use and end-of life aspects of the copper value chain, shows that the existing legislative framework generally safeguards Europe's environment, the health of industry workers and the general public.

## The Concept of Risk Assessment:

The first step of an EU risk assessment is to quantify the emissions to the environment and the exposures to human health, from the production (local), use and disposal (regional) of a chemical.

The second step is to determine at what levels these emissions or exposures start to give rise for concern:

- Where emissions or exposures are above these levels, corrective action, usually described as risk management, is needed.
- Where emissions or exposures are below these levels, there is no need for concern or action.

Both the quantifying of these emissions and exposures, and the setting of these levels, are highly complex. The European Commission provides a Technical Guidance Document to ensure a common approach to issues such as methodologies, data collection and analysis methods.

## The Copper Industry's Commitment:

In late 2000, the copper industry agreed to proceed with a voluntary risk assessment for copper metal, copper powder and four copper compounds used to make wood preservative, plant protection and biocidal products. The industry committed to:

- Prepare for REACH, by taking responsibility for the safe production and use of its products
- Involve regulatory, industrial and scientific stakeholders in reaching agreement on the methodologies to be used, the analyses and the conclusions
- Use the latest, peer reviewed, science to carry out the assessments
- Assemble industry and literature data on actual emissions, exposures and safe levels
- Produce an objective scientific dossier as input into the Existing Substances Regulation and into upcoming Directives on water, soil, sediment and workplace quality
- Complete the project within four years

The Copper Risk Assessment, a Multi-Stakeholder Activity

In consultation with the global mining industry, the European copper industry appointed the European Copper Institute (ECI) to manage the voluntary risk assessment process.

## Ensuring Transparency throughout the Process:

The European Copper Institute has worked closely with the European Commission, the Member States and the industry to ensure objectivity, credibility, transparency and high quality throughout. All parties endorsed a common set of principles, including:

- Review Country: The European Commission and Member States agreed that Italy would act as the Review Country. The Istituto Superiore di Sanità was appointed 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. Italy presented the copper risk assessment dossier for Commission and Member State review in May 2005.
- Independent Scientific Peer Review Panels: Two panels of eight recognised independent experts from European research institutes and academia were appointed - one for the environment, the other for human health. These panels, plus experts from the Istituto Superiore di Sanità, jointly validated all protocols, analyses, results and conclusions.
- European Technical Committee: The report has been extensively evaluated by the European Commission's Technical Committee for New and Existing Substances (TCNES), involving experts from all EU Member States. All chapters were reviewed and subsequently agreed by this committee.
- Broad Industry Participation: Producers of copper metal, powders and chemicals, along with representatives of downstream users, were involved in the collection and evaluation of site specific production and market demand data. The European Copper Institute built a consortium to fund the copper risk assessment, estimated to have cost €8 million. An industry steering committee of producers and downstream users oversaw the project.
- Project Management: The European Copper Institute was the project manager. It assembled an extensive network to analyse existing data, conduct research to close knowledge gaps, communicate results, resolve stakeholder issues, and develop conclusions. Authorised stakeholders had full access to all reports, reference papers, research initiatives, meeting minutes, and comments through a dedicated website.
- Project Implementation: Consultants, experienced in risk assessment methodologies, carried out the bulk of the process. They gathered data from industry and peer reviewed literature, conducted research where data gaps were identified, developed appropriate methodologies where none existed, analysed the data, and prepared the draft reports.
- Integration with other Regulatory Directives: The four copper compounds in the scope (copper II sulphate pentahydrate, copper I oxide, copper II oxide and dicopper chloride trihydroxide) are also being evaluated, by France, under the EU's Plant Protection and Biocidal Products Directives. The European Commission asked Member States to co-ordinate the review related to the copper dossiers between the Existing Substance Regulations and Biocidal Products Directive. The European Copper Institute has been working closely with the relevant industries, the French Government and the European Commission to ensure a consistent approach.

## Results of the Copper Risk Assessment:

The European Copper Institute has worked closely with the European Commission, the Member States and the industry to ensure objectivity, credibility, transparency and high quality throughout. All parties endorsed a common set of principles, including:

The 1,800-page dossier comprehensively assesses the health and environmental effects of the target chemicals during their production, use, recycling, and disposal. Information from the producers of anodes, cathodes, copper powders and copper chemicals, as well as from many semi-fabricators, cable companies and other downstream users, was collected from over 100 sites across the EU.

■ A Common Set of Principles for All Parties

The main conclusions, accepted by the European Commission and EU Member State experts, are:

- The use of copper products is in general safe for Europe's environment and the health of its citizens.
- The threshold value for acute effects in drinking water is 4.0 mg/l of copper, with the general public typically exposed to 0.7 mg/l. This is consistent with the 2.0 mg/l guideline for copper advised by the World Health Organisation.
- For adults, the minimum daily dietary intake is 1 mg, with a maximum threshold of 11 mg. Actual intakes range between 0.6 and 2 mg, suggesting that deficiency may be of concern.
- The European-wide safe levels for copper in freshwater and marine waters are respectively 7.8 and 2.6 µg Cu/L. The safe level for copper in soil is 79 mg/kg dry weight. The safe levels for copper in freshwater, estuarine and marine sediments are respectively 87, 144, and 338 mg Cu/kg dry weight. The copper levels measured in European waters, sediments and soils are usually well below these safe threshold levels.
- Environmental risks are possible at 14% of industrial sites - where there is insufficient on-site water treatment, or where the effluent goes into a water body with low dilution.
- Occupational health risks are possible at some industrial sites, specifically for workers involved in the production of copper chemicals and powders.
- Copper is not a CMR (carcinogenic, mutagenic, reprotox) or a PBT (persistent, bio-accumulative, toxic) material.

## Linking the Voluntary Risk Assessment to REACH:

ECI is now acting as the manager of the REACH Copper Consortium and is preparing a copper registration dossier fully harmonised with the Voluntary Risk Assessment. For example, ECI is using the effects and exposure sections as the bases for the Chemical Safety Report. Further refinements and remaining specific site/sector issues will be handled under REACH, with Risk Reduction Measures introduced where needed. The evaluation of exposures from these sites will be done in cooperation between ECI and the Istituto Superiore di Sanità.

In December 2008, the European Chemicals Agency agreed with this approach and is now investigating the way in which the voluntary risk assessment can be made available through its website.

## Conclusions:

With this risk assessment, the copper industry is meeting its duty of care to all stakeholders by demonstrating the safe use of its products for the environment and for human health. It also identifies specific local situations where risk management actions may be required.

The copper risk assessment has been completed in close cooperation with the Italian Government and extensively reviewed by the European Commission and EU Member States.

The European Copper Institute has ensured alignment with the EU's Biocidal Products Directive.

The European Copper Institute and Italy have agreed to co-operate in preparing a risk reduction measurement plan in areas where potential risks are observed.

The voluntary risk assessment provides the copper industry with the solid scientific platform needed to address the requirements of REACH.

European Copper Institute (ECI)
Av. de Tervueren 168 - Bte 10 - 1150 Bruxelles
Tel +32 (2) 777 70 70 / Fax +32 (2) 777 70 79
eci@eurocopper.org / www.eurocopper.org

Istituto Superiore di Sanità (ISS)
Viale Regina Elena 299 - 00161 Roma
Tel +39 06 49 901 / Fax +39 06 49 38 71 18
web@iss.it / www.iss.it