



THE MANGANESE SCIENTIFIC CRITERIA DOCUMENT PROJECT

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The Global Framework

- The aim of all environmental regulations, regardless of the country, is to protect human health and the environment.
- Today all chemical products, including metals such as manganese, are subject to severe scrutiny.
- Increasingly, regulatory bodies are reversing the burden of proof. Industry is being asked to prove that their products are safe to use. Until it can do so, products are labelled “unsafe”.

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The Role of IMnI

- In order to work effectively with regulatory bodies, industry must be able to produce sound scientific data to back its claims.
- One case in point: establishing safe OELs (Occupational Exposure Limits) for Europe.



The Role of IMnI

- Many health-related research studies have been done about Mn (+600 references), but they never been collated or systematically evaluated as to their scientific validity.
- To remedy this information vacuum, the industry asked IMnI to commission a Scientific Criteria Document.
- After a call for tenders, IMnI chose 2 prestigious UK-based institutes to co-author the Document:

The Institute of Occupational Medicine in Edinburgh (IOM)

The Institute for Environment and Health in Leicester (IEH)



Criteria Document Objectives

- The CD has to be a comprehensive and critical review that can stand up to international scrutiny.
- It should be used as a basis for standard setting by ANY country, not just the EU.
- Any OEL recommendation in the CD will be health-based only, and will not take account of cost of implementation or practicability.



The Criteria Document Content

- Summarize the physico-chemical properties, occurrence, production and use data.
- Review and summarize data on occupational and environmental exposures (including techniques and biological monitoring).
- Identify and critically evaluate quantity and quality of health effects literature (toxicology and epidemiology).



The Criteria Document Content

- Document knowledge gaps, identify vulnerable groups and summarize existing OELs.
- Prepare an overall evaluation and recommendation for health-based OELs for Mn in the workplace.



Criteria Document

A Tool for Establishing OELs

- Currently each EU member State operates on its own list of exposure limits.
- The EU has agreed to establish OELs to be adopted by all member countries.
- The Commission of the European Communities (CEC) has mandated DG Employment and Social Affairs (formerly DG V) to establish IOELVs (Indicative Occupational Exposure Limit Values).



CD: A Tool for Establishing OELs

- The Scientific Committee on OELs (SCOEL), an independent body of scientists, recommends a limit value to DGV based on available information (a Criteria Document).
- SCOEL's recommendation then goes through a number of committees, where industry can also be heard, until a limit value is set by a Commission Directive, which each EU member country must adopt in its own legislation.



CD: IMnI Timetable

- Survey of Institutes Jan-Feb 2001
- Call for Tenders March 2001
 - 8 Institutes approached
 - 4 Positive replies
- SC Visits 2 short-listed Institutes June 2001
- Institutes meet OHES Comm Sept 2001
- Contract Signed & Work Begins Nov 2001



CD: Timetable

- Progress Meetings (SC & Institutes) Apr & Sept 2002
- Copy of CD for Peer-Review Nov 2002
- Delivered
- Peer-Review Finished Jan 2003
- CD Published & Presented to June 2003
- Members at 2003 Annual Conf

Total Time for Project

2 ½ Years



CD: A Sound Investment

- By commissioning the Criteria Document that will be used to set the OELs, IMnI is proving that it represents a responsible and pro-active industry.
- Our initiative will also help us determine the agenda of when Mn will come up for review.
- Beyond this, the Criteria Document will highlight information gaps that will have to be filled.
- It will also help us devise an industry standard for testing workers.