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## **Opinion of the Sectoral Social Dialogue Committee for the Extractive Industry on the Draft Recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) for occupational exposure limits on the workplace for NO<sub>2</sub> and NO**

In June 2013 the SCOEL has submitted draft recommendations for limit values for nitrogen dioxide (NO<sub>2</sub>) at the level of 0.5 ppm and for nitrogen monoxide (NO) at the level of 2.0 ppm (8-hour averages). The affected stakeholders were invited by the relevant Directorate General Employment, Social Affairs and Inclusion (EMPL) of the European Commission to respond to the following three questions until 15th January 2014:

- 1) Are there any important or critical publications that have not been taken into account?
- 2) Were scientific data misinterpreted?
- 3) Is there any other relevant information?

### **In response to 1)**

The SCOEL draft now has taken into account most of the essential, known studies. In contrast to the previous dominance of toxicological consideration transferring results of animal experiments to humans, now - corresponding to SCOEL Methodology Document (SCOEL - METH 2011) - both recommendations take into consideration the available epidemiological studies, especially the two studies conducted in the German potash and coal mining industry respectively. The study carried out for the coal industry (Morfeld (2010) et al. and Dahmann (2009) et al.) has even been recognised as the leading study.

Concentrations on a higher level will be subject to further epidemiological studies which will be conducted in 2014 and 2015. These are respectively:

- a study launched by K+S Aktiengesellschaft on exposure of NO<sub>2</sub>/NO, conducted by the Institute for Prevention and Occupational Medicine of the German Social Accident Insurance - Institute of the Ruhr-University Bochum (IPA), Prof. Thomas Brüning and Prof. Jürgen Bünger, in collaboration with the Institute for the Research on Hazardous Substances (IGF) of the Berufsgenossenschaft "Raw Materials and Chemical Industry", Dr. Dirk Dahmann. The study is expected to be launched in 2015; initial results with respect to the exposure measurements by the IGF can be expected in the first half of 2014.
- At the Institute of Occupational and Social Medicine, Aachen, University Hospital Aachen, Prof. Thomas Kraus, controlled exposure experiments on human subjects are being carried out with concentrations at levels of 0 to 1.5 ppm NO<sub>2</sub>. The contracting body is the European Association for Research on Environment and Health in the Transport Sector e. V. (EUGT). The study will be completed in spring 2014.

- The study on the employees of Polish copper mines (analysis of the results of spirometry tests) will be conducted by the Wrocław Medical University (Department and Clinic of Internal and Occupational Diseases and Hypertension) based on research conducted by the Miedziove Centrum Zdrowia S;A. (the occupational medicine unit). It will examine the effects of the NO<sub>2</sub>- and NO-concentrations on the health status of about 900 workers in the copper mining industry in Poland.
- Furthermore the United States Environment Agency (U.S. EPA) published a study in 2008 summarizing "Human clinical studies generally did not find direct effects of NO<sub>2</sub> on lung functionality in healthy adults at levels as high as 4.0 ppm."

We expect SCOEL to consider the results of the studies mentioned above when adopting final recommendations for indicative limit values at workplaces for NO<sub>2</sub> and NO.

### **In response to 2)**

The derivation of the OEL recommendation of 0.5 ppm for NO<sub>2</sub> is crucially dependent on the uncertainties to be considered. SCOEL is correct in stating that the 13-week inhalation study (BASF b 2006) up to an exposure of 2.15 ppm NO<sub>2</sub> no exposure effects on the parameters of BALF or in terms of cell proliferation or apoptosis in the lung (SCOEL/SUM53 2013, p 10) were found. The results of these studies were not taken into account adequately. The comment of SCOEL that there were problems in the analytical measurement of NO<sub>2</sub> concentrations (SCOEL/SUM53 2013, p 12) is not understandable. The exposure levels measured are trustworthy and not "overestimated" (SCOEL/SUM53, 2013, p.12). The NOAEL of more than 2 ppm found in the BASF study (No Observed Adverse Effect Level) is therefore not considered sufficiently in the overall assessment/recommendation.

It should be emphasized that the study does not include higher exposures than 2.15 ppm, so that it is not clear what the NOAEL actually could be; a LOAEL (Lowest Observed Adverse Effect Level) could not be determined. The value of 2.15 ppm thus is an estimate of the NOAEL from below without being able to exactly determine it.

The derivation of a numerical value for a Short Term Exposure Limit (STEL/15 minutes-) - as specified by the SCOEL methodological document requires sufficient data to provide a scientifically based recommendation. This is not the case for NO<sub>2</sub>.

### **In response to 3)**

The recommended limit for NO<sub>2</sub> currently cannot be monitored reliably at the workplaces in **any** underground mining operation with the measuring techniques presently available and practically usable. There are currently no devices available for use in underground mines that could ensure a reliable, state-of-the-art mobile and **permanent monitoring** of occupational exposures at the level of the SCOEL recommendation for NO<sub>2</sub>. SCOEL also admits that "in essence, with the presently available standard instrumentation the occupational exposure limit (OEL) of 0.5 ppm NO<sub>2</sub>, as recommended here, may not be adequately controlled in underground coal mines." (SCOEL/SUM53, 2013, pp. 4).

Even though multiwarn instruments (electrochemical measuring cells) may be capable to measure NO<sub>2</sub> concentrations as low as 1 ppm reliably, when it comes to permanent measurements in underground mines in general, it is impossible to comply with the CEN standard EN 482 which defines specific requirements for compliance measurements related to the extended measurement uncertainty and the minimal value the instrument must be able to measure.

Therefore, WHEN SCOEL HAS PUBLISHED ITS RECOMMENDATIONS, the Commission and the tripartite advisory committee should specifically consider the practical risk management alternatives which are feasible in different types of industry where nitrogen dioxide occurs. Limit values shall be established or revised taking into account the availability of measurement techniques" (Directive 98/24 from 7 April 1998). Also a supervised transition period for the introduction of new OEL's might be considered.