



# The EU Scientific Committee on Occupational Exposure Limits (SCOEL)

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(Vice-Chair of SCOEL)



# The task of SCOEL

Supply the Commission with Opinions on any matter relating to the toxicological evaluation of chemicals for their effects on health of workers...

...and in particular...

give advice on the setting of Occupational Exposure Limits (OELs) based on scientific data – for substances prioritised by the Commission (DG EMPL)



# The SCOEL Membership

## Composition

21 *independent* experts selected by DG EMPL based on a range of scientific expertise and experience. They are initially nominated by MSs

Observers from EFTA<sup>1</sup> countries

## Meetings

4 meetings/year, each of 2 days

<sup>1</sup> Switzerland, Norway, Iceland, Lichtenstein

## Key steps in the SCOEL involvement in OEL setting

1. SCOEL evaluates each substance using the best available scientific data
2. SCOEL prepares a draft recommendation (SCOEL/SUM) and submits to DG EMPL
3. DG EMPL initiates a 6-month external public consultation period with national contact points (ca. 40) to get comments on scientific aspects only
4. SCOEL considers all comments and new data, amends the draft if necessary and adopts a recommendation
5. DG EMPL accepts SCOEL's final recommendation and publishes it
6. DG EMPL consults tripartite Advisory Committee on Safety and Health at Work and other relevant DGs

# The SCOEL Recommendations may include....

Concentrations *in air* (ppm, mg/m<sup>3</sup>)

- 8-hour time-weighted average - chronic effects
- short-term exposure limit (15 min) - acute effects

*Biological limit values (where appropriate)*

*Carcinogenicity evaluation (where appropriate)*

*Supplementary notations*

- skin, respiratory sensitisers, noise



# The SCOEL methodology

## Case by case approach

Each substance considered individually  
using a general procedure

Key principles outlined in the methodology document  
(last update version 7 June 2013)

<http://ec.europa.eu/social/main.jsp?catId=148&langId=en&intPagelId=684>

## ***Cont.* The SCOEL methodology**

- Assemble all relevant available data on hazards of the substance (human, animal and other experimental) + background data (e.g. chemical-physical properties).
- Identify adverse effects that may arise from exposure to the substance
- Is the database adequate for recommending an OEL?

## ***Cont.* The SCOEL methodology**

- Identify the adverse effect(s) considered critical for deriving a recommendation for an OEL (e.g. by no-observed-adverse-effect-levels or lowest-observed-adverse-effect-levels).
- Review carefully the quality of the relevant human or animal studies which describe these key effects.
- Conventional (threshold) or non-threshold mechanism?

## ***Cont.* The SCOEL methodology**

*If threshold mechanism:*

Recommend a "health based" OEL (IOELV)

*If non-threshold mechanism:*

No "health based" OEL can be recommended. Different considerations will apply, leading to a pragmatically based OEL (BOELV)

## SCOEL on the web

<http://ec.europa.eu/social/main.jsp?catId=148&langId=en&intPageId=684>

Includes:

- Agendas
- Minutes
- Recommendations
- Methodology

# Reproductive toxicity

*The objective of OEL setting is to prevent adverse health effects in occupationally exposed persons and/or their progeny. Thus, the potential of each substance to produce adverse effects on various aspects of the reproductive process needs to be considered, even though the availability of relevant data in this field of toxicity is limited for quite a number of substances.*

## ***(1) Effects on male and female fertility***

*Such effects are of concern to all men and women of a fertile age exposed to chemical substances in the workplace. They include adverse effects on libido, sexual behaviour, spermatogenesis or oogenesis, any interference with hormonal activity or physiological parameters impacting the ability to fertilise, as well as adverse effects on fertilisation itself or the development of the fertilised ovum up to and including implantation.*

## ***(2) Developmental toxicity***

*In its widest sense this covers any effect interfering with normal development both before and after birth. It includes embryotoxic/foetotoxic effects (such as reduced body weight, growth and developmental retardation, organ toxicity, death, abortion), structural defects (teratogenic effects), functional defects, peri-postnatal defects and impaired postnatal mental or physical development up to and including normal pubertal development.*

## Background Considerations (1)

*In contrast to mutagens and many genotoxic carcinogens, the current state of scientific knowledge considers substances interfering with fertility or with pre/postnatal development as likely to act by threshold mechanisms, thus permitting the determination of NOAELs.*

## Background Considerations (2)

*However, it should be noted that some substances show adverse effects on reproduction at exposure levels considerably lower than those causing other forms of toxicity. Because of the relative sensitivity of the rapidly developing individual (from conception to puberty) to specific toxic effects, OELs established to protect adults cannot a priori guarantee the absence of pre- or post-natal adverse effects. Thus pregnant or lactating women may represent a special risk group in the workplace*



# The SCOEL approach

*It is of concern to SCOEL that for many occupational substances only limited data are available on this particular aspect of toxicology. However, in the light of the above described technical and legal background, ("Framework" Council Directive 89/391/EEC and Council Directive 92/85/EC on pregnant workers) SCOEL, when recommending OELs, will consider reproductive effects along with all other aspects of toxicity. The absence of relevant data will not normally be a factor in determining the size of an 'Uncertainty Factor', although it will be noted in the 'Summary and Recommendation' document.*

## **(1) Substances which have been shown to affect fertility**

*SCOEL will take the observed adverse effects on fertility into account, recommending an OEL that is considered sufficiently low to protect workers against such adverse effects.*

## (2) Substances which have been shown to cause developmental toxicity

- *Where the available data allow the definition of a NOAEL for developmental toxicity (either on the basis of human or animal experience), SCOEL will take this into account, recommending an OEL that is considered sufficiently low to protect workers against such adverse effects.*
- *Where data indicate a developmental toxicity hazard but do not allow the definition of a NOAEL with some confidence, SCOEL may decide to adopt a larger Uncertainty Factor in recommending an OEL.*