# The EU Scientific Committee on Occupational Exposure Limits (SCOEL) – Role in prevention of ill health from chemical exposures

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Employment, Social Affairs and Inclusion

# 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 (until now) – selected by DG EMPL**

## Observers from EFTA[1] countries

## Meetings

**4 meetings/year, each of 2 days**

[1] Switzerland, Norway, Iceland, Liechtenstein

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# Key steps in the SCOEL involvement in OEL setting

1. SCOEL evaluates each substance using the best available scientific data (all acute and chronic effects).

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 (not compliance or socioeconomic issues)

4. SCOEL considers all comments and new data, amends the draft if necessary and adopts a recommendation

5. DG EMPL accepts SCOELs final recommendation and publishes it

6. DG EMPL consults tripartite Advisory Committee on Safety (WPC) and Health at Work and other relevant DGs

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# The SCOEL Recommendations may include....

**Concentrations *in air* (ppm, mg/m³)**

- **8-Hour time-weighted average – for chronic effects**
- **Short-term exposure limits (15 min) – for acute effects**
- **Biological limit values (where appropriate)**
- **Carcinogenicity evaluation (where appropriate)**
- **Supplementary notations**

  **- skin, respiratory sensitisers, noise**

# The SCOEL methodology

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

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

- Each substance considered individually using a general procedure


# The SCOEL methodology - 1

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


# The SCOEL methodology - 2

- 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 (carcinogens and mutagens) mechanism?

# The SCOEL methodology - 3

- *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 available on the Web

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

Includes:

- Agendas
- Minutes
- Recommendations
- Methodology


# Legal Basis to the work of SCOEL

**In 1998, the legal framework was further developed with the adoption of Council Directive 98/24/EC (Chemical Agents Directive, CAD) on the protection of the health and safety of workers from the risks relating to chemicals agents at work.**

**This sets indicative and binding OELs and biological limit values into a wider framework of risk management in relation to occupational exposure to chemicals.**

**Under this Directive, a number of lists of IOELVs have been developed (Directives 2000/39/EC, 2006/15/EC and 2009/161/EU). Work is on-going on candidate substances for a 4th list of IOELVs.**


# Legal Basis to the work of SCOEL

**In addition, Directive 2004/37/EC (on the protection of workers from the risks related to the exposure to carcinogens or mutagens at work, CMD) refers to the procedure to set out limit values for those carcinogens and mutagens for which this is possible.**


# Mandate for the work of SCOEL

**SCOEL is requested to evaluate prioritised substances using the best available and relevant scientific data.**
**The main outcome of the SCOEL work is substance specific Recommendations to be used as the scientific basis for the setting of OELs.**

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# Key Features of IOLEV / BOELV

- When according to the judgement of SCOEL, a highest level of exposure, at which one could have confidence that there would be no adverse effects on health, can reliably be identified, the SCOEL Recommendations have been proposed to Member States by the Commission as prospective IOELVs.
- Where a "no-effect" level of exposure cannot be reliably identified, SCOEL is asked to attempt to estimate the risk of adverse health effects at specified levels of exposure; the Commission takes account of such views in developing proposals for BOELVs.


# Use of Biological Monitoring by SCOEL

- **Under certain circumstances biological monitoring offers advantages over air monitoring in assessing risk to health, e.g. for substances with a significant skin uptake. For such compounds, biological monitoring may be preferable, if suitable methods are available.**
- **SCOEL evaluates the need to recommend biological monitoring for particular substances on a case-by-case basis and recommends biological values based on the currently available scientific data.**


# Health-based biological limit values (BLVs)

- Biological limit values (BLVs) are reference values for evaluating potential health risks in the practice of occupational health.
- A BLV is a guideline for the control of such risks and should not be used for other purposes.

# Biological guidance values (BGVs)

- Where toxicological data cannot support a health-based BLV, a biological guidance value (BGV) might be established. This value represents the upper concentration of the substance or a metabolite of the substance in any appropriate biological medium corresponding to a certain percentile (generally 90 or 95 percentile) in a defined reference population.
- If background levels cannot be detected, the BGV may be equivalent to the detection limit of the biomonitoring method, which then is to be specified in the document.

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# Some Current Challenges for SCOEL

- IOELVs/BOELVs Versus DNEL/DMELs (from the REACH process) – collaborative meetings taking place
- Ensuring DG EMPL prioritise chemical substances of greatest real concern (number exposed, toxicity, etc.) – new DG EMPL research – "CAREX 2"
- Do we know that SCOEL OELs are complied with in MSs? – SLIC remit

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# Some SCOEL Past & Current Activities

- **SCOEL has completed or is working on or completed 196 substances**
**(ec.europa.eu/social/BlobServlet?docId=3803&langId=en)**

- **Published table of 22 BLVs and BGVs**

- **New topics include:**

**- isocyanates, diesel exhaust and aviation fuels**

**- poor solubility low toxicity dusts (a possible generic approach)**

**- rubber fumes**

**- bitumen/asphalt**

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# Some Final Observations

- **SCOEL OEL recommendations are generally lower then existing MS values (reducing worker exposure in the EU)**
- **Increasingly better understanding and interactions with ECHA, DG EMPL's Advisory Committee Safety and Health (Working Party on Chemicals) and other stakeholders**
- **Better targeting on substances of greatest concern**

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