The SCOEL Work and Decision-Making Processes

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COMMISSION DECISION of 12 July 1995 setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents (1)

Article 2

- The task of the Committee shall be to supply the Commission with opinions at the latter's request on any matter relating to the toxicological examination of the chemicals for their effetcs on health of workers.
- The Committee shall in particular give advice on the setting of Occupational Exposure Limits (OELs) based on scientific data and where appropriate shall propose values which may include:
  - the eight-hour time weighted average (TWA)
  - short-term limits/ excursion limits (STEL)
  - biological limit values

COMMISSION DECISION of 12 July 1995 setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents (2)

The OELs may be supplemented, as appropriate, by further notations.

The Committee shall advise on any absorption of the substance in question via other routes (such as skin and/or mucous membranes) which is likely to occur.

- Any recommendation shall be supported and explained by information on the basic data, a description of the critical effects, the extrapolation techniques used, and any data on possible risks to human health. The feasibility of monitoring exposure at any proposed limit value(s) shall also be noted.

"health based" OELs

- **An OEL of this type may be established in those cases where a review of the total available scientific data base leads to the conclusion that it is possible to identify a clear threshold dose below which exposure to the substance in question is not expected to lead to adverse effects. Such OELs should meet the objective outlined above**

"Pragmatic" OELs

- **For some adverse effects (in particular genotoxicity, carcinogenicity and respiratory sensitisation) it may not be possible on present knowledge to define a threshold of activity. In such cases it must be assumed that any level of exposure, however small, might carry some finite risk and OELs for substances possessing these properties must be established pragmatically. Such OELs will be established at levels considered to carry a sufficiently low level of risk.**

Key principles agreed by SCOEL

- 8h TWA exposure limits
- Strategy to apply uncertainty factors
- Strategy for short term exposure
- Strategy for assigning a skin notation
- Interpretation of neurobehavioural studies
- Reproductive toxicity
- Assessment of sensitisers
- Biological limit values
- Role of the SCOEL in the evalutaion of chemical carcinogens

Derivation of 8 hour TWA OELs (1)

- The process of deriving a recommendation for an 8 hour TWA OEL include a review of the total available data-set on each substance in order, particularly, to determine:

1. The critical effect (or effects) that will determine the level at which the OEL will be set. This means the effect(s) most likely to occur if exposure exceeds an OEL.

Derivation of 8 hour TWA OELs (2)

2. From the key study (or studies) describing the critical effect(s), the No Observed (Adverse) Effect Level (NO(A)EL). In those cases where it is not possible to establish a NO(A)EL, a Lowest Observed (Adverse) Effect Level (LO(A)EL) may be determined.

As a general rule, SCOEL recommendations for 8h TWA OELs will use, as preferred values, decimals of the integers 1,2 or 5 ppm or mg/m^3.

It is the opinion of SCOEL that further discrimination, resulting in proposals falling in-between any two of these integers, suggests a precision that, in reality, is unjustifiable, given the limitations of the databases for the vast majority of the substances considered and the uncertainties involved in toxicological extrapolations.

The SCOEL approach to "Uncertainty Factor"

- Adequate protection will be provided in the occupational situation by the use of Ufs lower than those which would be required for the general population. This procedure will only be used where the adverse effects of concern can be shown to follow a conventional (Threshold) toxicological model (e.g. it will not be used for genotoxic carcinogens).

- Ufs must be established on a case-by-case basis and cannot be forecast or established in advance.

Uncertainty factors selected by SEG
Critical effects/information taken into account in proposing OELS

A. Critical effect is IRRITATION; key studies are on HUMAN data

HUMAN DATA acute irritative effect		ethyl-acetate	penthyl acetates	5methyl-heptan3one	phosphoric acid	diethyl-ether	cyclo-hexanone	toluene	xilene
URT/conjunctiva	NOAEL			5 ppm		100 ppm	25 ppm	40 ppm	
	LOAEL	400 ppm	185 ppm	25 ppm	400 mg/m³		75 ppm		100 ppm
lower resp tract	NOAEL								
	LOAEL								
systemic effects									
short term exposure	NOAEL							[40 ppm]	
	LOAEL								[100 ppm]
long term exposure	NOAEL								
	LOAEL							100 ppm	
8-h TWA		200 ppm	50 ppm	10 ppm	1 mg/m³	100	10	20	50
Factor cited (implied)		(2)	(c3)	(<1)	NA	(1)	2	2	2

* In absence of data on phosphoric acid, OEL derived from data on P_2O_5
[ ] significance of effect doubtful
( ) uncertainty factor implied but not cited in SUM/document

Uncertainty factors selected by SEG
Critical effects/information taken into account in proposing OELS

B. Critical effect is SYSTEMIC; key studies are on HUMAN data

HUMAN DATA acute irritative effect		4-methyl-pentan-2-one	1,1,1-trichoro-ethane	sodium azide	n-hexane	F_2, F and HF	carbon monoxide
URT/conjunctiva	NOAEL						
	LOAEL						
lower resp tract	NOAEL						
	LOAEL						
systemic effects							
short term exposure	NOAEL			0,07 mg/kg/d	70 ppm		
	LOAEL		175 ppm	0,09 mg/kg/d			
long term exposure	NOAEL					8 mg/l in urine	4 % HbCO (c. 30 ppm)
	LOAEL	50-105 ppm			50-100 ppm		
8-h TWA		20 ppm	100 ppm	0,1 mg/m³	20 ppm	8 mg/l	20 ppm
Factor cited (implied)		(2)	2	5	2	(1)	(1)

Uncertainty factors selected by SCOEL

Critical effects/information taken into account in proposing OELs

c. *Critical effect is* ***Irritation****; key studies are on* ***Animal*** *data*

HUMAN DATA acute irritative effect		phosgene	dimethyl-amine	THF	ethyl-amine	dimethyl-acetamide	PMGEA	n-butyl acrylate	methyl acrylate
URT/conjunctiva	NOAEL								
	LOAEL								
lower resp tract	NOAEL								
	LOAEL								
systemic effects									
short term exposure	NOAEL								
	LOAEL								
long term exposure	NOAEL								
	LOAEL								
ANIMAL DATA irritative effect *acute exposure*									
URT	NOAEL								
	LOAEL		10 ppm	100 ppm			300 ppm		
lower resp tract	NOAEL	0.125 ppm							
	LOAEL	0.25 ppm			48 ppm				
long term exposure									
URT	NOAEL								
	LOAEL					40 ppm		15 ppm	15 ppm
lower resp tract	NOAEL								
	LOAEL								
systemic effects									
acute exposure	NOAEL								
	LOAEL								
up to 3 m exposure	NOAEL								
	LOAEL								
long term exposure	NOAEL								
	LOAEL								
8-hTWA		0.02 ppm	2 ppm	50 ppm	5 ppm	10 ppm	50 ppm	2 ppm	5 ppm
Factor cited (implied)		5	5	2	10	5	5	5	2

d. Critical effect is ***Systemic****; key studies are on* ***Animal*** *data*

The SCOEL approach to STEL setting

- The SCOEL will consider whether there are health effects that may arise from short term exposures that would not be adequately controlled by an 8 hour TWA limit, taking into account inherent variations in exposure even when there is compliance with the 8 hour limit.

  Particular account will be taken of health effects which are not of the same type as those which would determine the level of an 8 hour TWA limit.

Skin notation

- The SCOEL has agreed that there is a need to assign a skin notation if dermal absorption could contribute substantially to the total body burden and consequently to concern regarding possible health effects. "Substantial contribution" to total body burden will be established on a case-by-case basis but may in general be of the order of 10% or more of the uptake from respiratory exposure at the 8 hour TWA.

Substances which have been shown to affect fertility

- The 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

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), the 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, the SCOEL may decide to adopt a larger Uncertainty Factor in recommending an OEL

ASSESSMENT OF SENSITISERS

- For those substances for which the data are sufficient to indicate that there is an apparent threshold for the induction of sensitisation, a health based OEL may be recommended by the SCOEL.

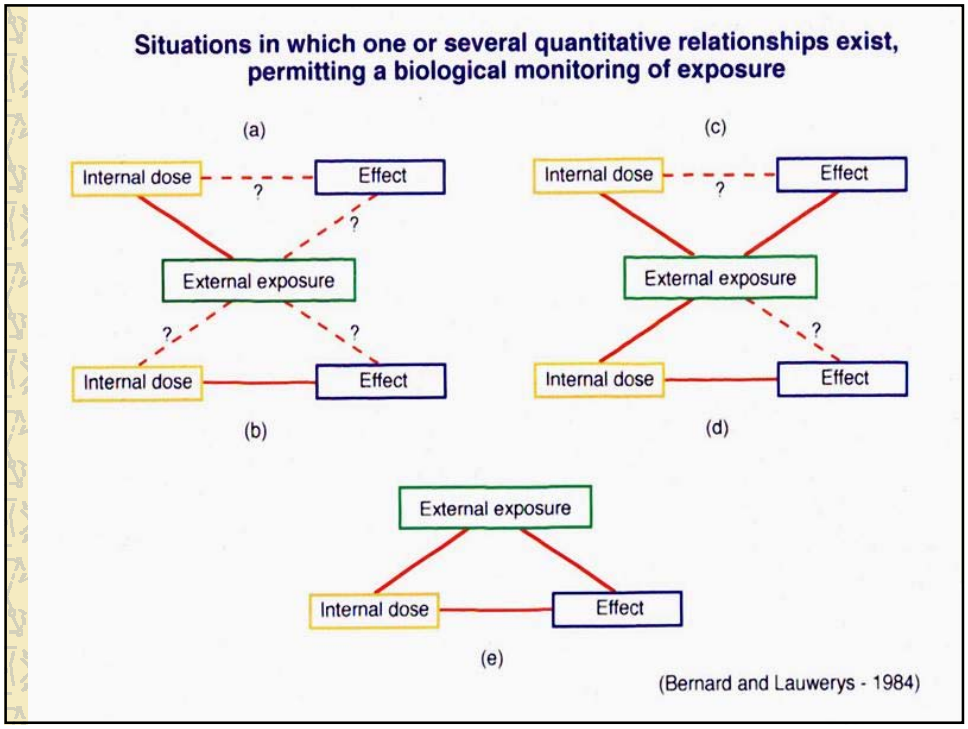
  Where such a threshold cannot be defined with some confidence, it is the opinion of the SCOEL that health based OELs cannot be established and the role of the SCOEL in these situations will be limited to offering advice to the Commission on the risk of respiratory sensitisation at particular exposure levels

Evaluation of neurobehavioural studies

- The appropriate use of neurobehavioural methods in human studies requires attention to a numbere of factors relating to:
  - The selection of the study design
  - Details of methodology
  - Selection of measures
  - Analysis of data and interpretation of results

Approaches to Biological Monitoring

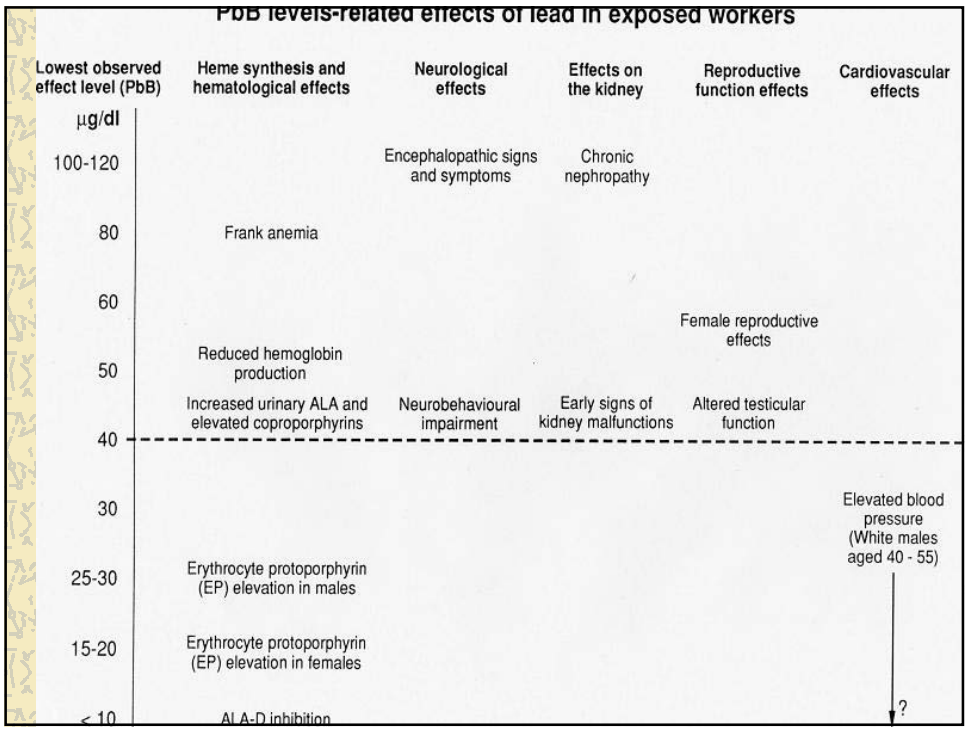
- *Determination of a substance or its metabolite in a biological medium (biological exposure monitoring)*
- *Measurement of reversible, non-adverse biological effects (biological effects monitoring)*
- *Measurement of the amount of substance interacting with a target (biological monitoring of effective dose)*



The SCOEL approach to BLVs

BLVs may be derived in one of three ways:

- *From studies providing a direct relationship between the concentration of a chemical its metabolite or adduct in a biological medium and adverse health effects (**ex.: Carboxyhaemoglobin fixed at 4% as BLV**)*
- *Where there is a health based OEL, from studies providing a direct relationship between the concentration of a chemical, its metabolite or adduct in a biological medium and airborne concentrations (**ex.: Fluorine in urine**)*
- *Studies in humans linking measurable non-adverse biological effects and adverse effects on health*



Stages leading to the establishment of OELs

- Stage 1 — Preparation of a scientific dossier for review
- Stage 2 — Evaluation of scientific dossier
- Stage 3 — Development of recommendation from the SCOEL to the Commission services for a scientifically based OEL
- Stage 4 — Development of proposal for an OEL by the Commission services
- Stage 5 — Consultation of the Advisory Committee for Safety, Hygiene and Health protection at Work
- Stage 6 — Adoption of the implementing Directive