

Methodology in deriving health-based OELs

Dutch Expert Committee on Occupational Safety (DECOS)

May 12, 2021

Institutetreffen

Dr. Jolanda Rijnkels, scientific secretary

Health Council of the Netherlands



The DECOS



The Health Council of the Netherlands

Independent scientific advisory board
Advises the Dutch ministers and Parliament
Public health, health & health care

The DECOS

Multidisciplinary expert committee
Evaluation toxicity chemical substances
Recommending health-based OELs
Recommending skin notations



Occupational standards in perspective (1)



Base	Public domain	Private domain
Substances with an OEL		
Health-based	Legally binding OELs, IOELV, BLV, TRGS-list (AGW, BGW), PEL, REL	Private OELs DN(M)EL*, TLV
Alternatives for substances without an OEL		
Danger categories H(azard)-sentences	-	Kick-off values (Hazard) control banding
Feasibility	-	ALARA/ALARP

* REACH: in case the production is ≥ 10 tonnes/year than the private owner has the obligation to derive a DN(M)EL, even if there is insufficient toxicological data available (by use of an assessment factor 'quality of database').

Occupational standards in perspective (2)



The Netherlands

❖ DECOS (indep. adv. board)	Recommendation	HBR-OEL	Health-based recommended OEL
❖ 'BMAS' (ministerium)	Legally binding	OEL	Public OEL*

Germany

❖ DFG (private research inst.)	Recommendation	MAK	Maximale Arbeitsplatz-Konzentration*
❖ AGS (BAuA, federal inst.)	Recommendation	TRK	Technische Richtkonzentration (carcinogens)
❖ BMAS (ministerium)	Legally binding	AGW	TRGS 900 Arbeitsplatzgrenzwerte

European union

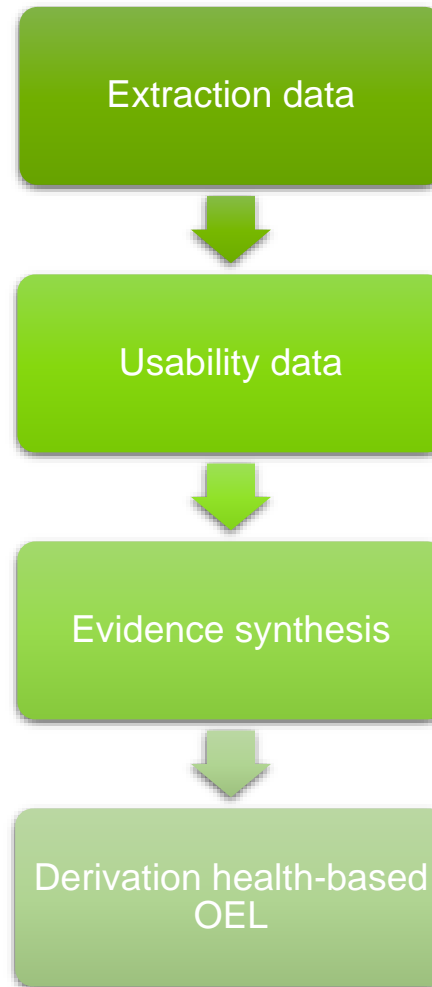
❖ RAC (ECHA, EU)	Recommendation	OEL	Opinion OEL
❖ European Commission	Non-binding	IOELV	Indicative Occupational Exposure Limit Value*
❖ European Parliament	Legally binding	BLV	Binding Limit Value*

USA

❖ ACGIH (private)	Recommendation	TLV	Threshold Limit Value
❖ NIOSH (federal inst.)	Recommendation	REL	Recommended Exposure Limit
❖ OSHA (federal govt.)	Legally binding	PEL	Permissible Exposure Limit*

* Other considerations than just health-based considerations can have been taken into account, such as exposure patterns, availability reliable measurement techniques, social-economical and/or political reasons.

The DECOS: towards a health-based OEL



Extraction data



Complete toxicological profile

Publicly available	Primary sources	Secondary sources
All types of toxicological studies	Original individual scientific studies	Reviews, risk and hazard assessment reports, toxicological evaluations, summaries

DECOS

No empirical research by the Health Council
Preference for no co-exposure studies

Usability data



To prevent poor or poorly relevant studies from disproportionately contributing to the weight of evidence exposure-response relationship

Relevance

Types of studies
Effect endpoints
Exposure data

Reliability

No study is perfect: the more complex the study, the greater the likelihood that uncontrolled variables may affect the results

Validity

Are the correct study designs and measurement methods used to determine to what extent the results can be translated into reality?

DECOS

Current scientific criteria or views
Developed frameworks and tools are not guiding but supportive
Expert judgement

No studies excluded on beforehand
Outcome: studies given more, less or no weight in evidence synthesis

Evidence synthesis



Broad approach to assess weight of evidence exposure-response relationship

Integration	Usability	Value
Inclusion data of various sources (types of studies)	Judgement on relevance, reliability and validity	Key studies Supportive studies

DECOS

Current scientific criteria or views

Developed frameworks and tools are not guiding but supportive

Expert judgement

Higher weight of evidence when multiple studies with different exposure groups show comparable outcomes, and exposure-response relationships, preferentially at exposure levels and conditions that meet the working conditions in practice; supportive studies could mechanistically explain the causality

Derivation of a health-based OEL



Point of departure (PoD) and derivation method

Choice key study/studies	Approach	Derivation method
Preferences Epidemiological data (Sub)chronic exposure Short- and long-term adverse health effects	Threshold-based OEL Risk-based OEL	Benchmark dose method (BMD) Survival analysis NOAEL/LOAEL

DECOS

PoD: Individual study versus combination of studies
Threshold- or risk-based OEL: knowledge of mode of action

Derivation of a health-based OEL (1)

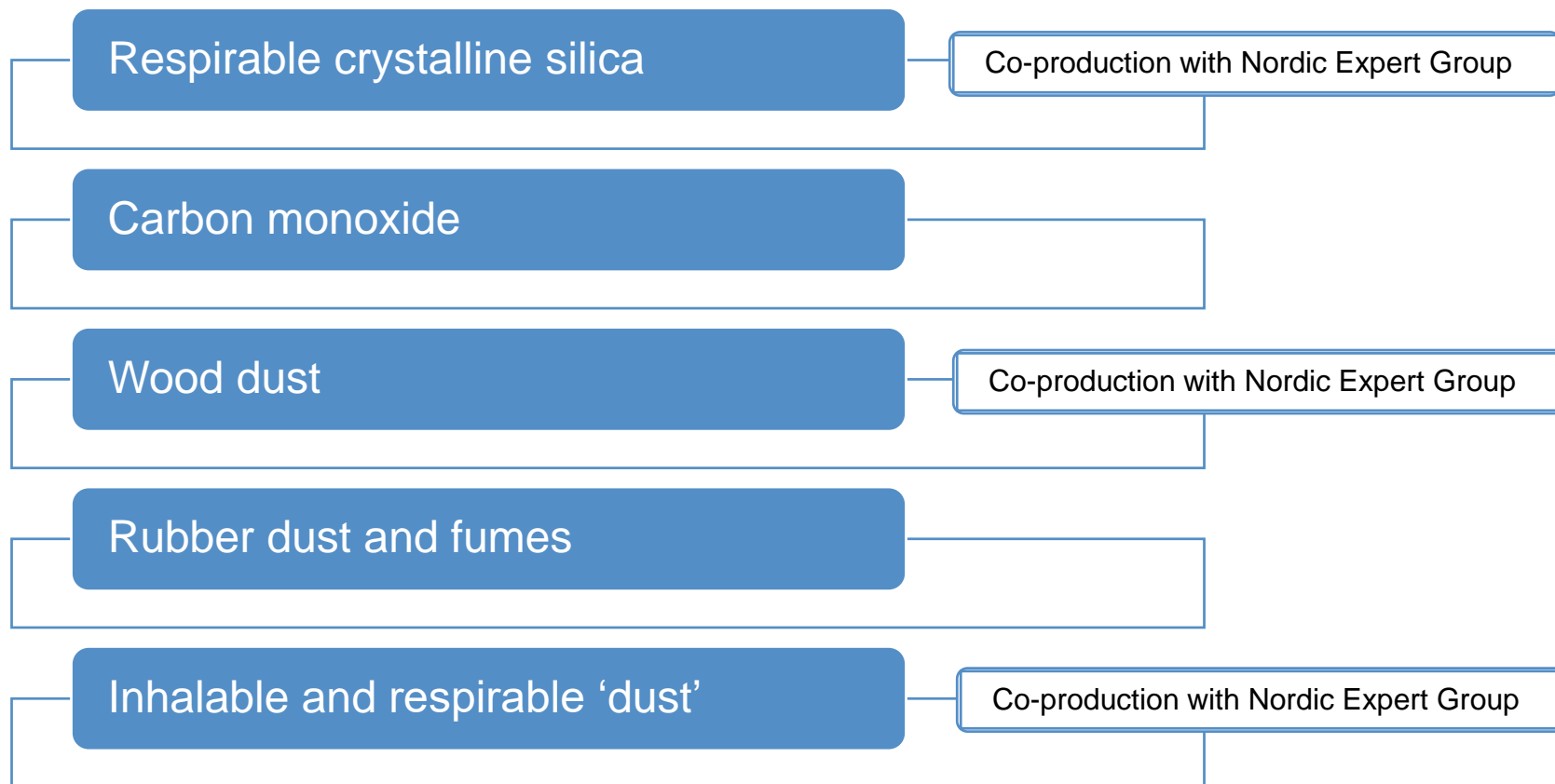
	Threshold-based	Risk-based
Exposure-response relationship	A clear cut-off point (threshold), below which no significant adverse health effects are observed during and after working life period and in progeny	No (clear) cut-off point: exposure always poses a certain health risk
Chemicals	All substances, unless otherwise indicated	<p>Direct acting genotoxic carcinogens</p> <p>Allergens which do not show a cut-off point at the lowest exposure range</p>
Starting point in deriving an OEL	Cut-off point	<p>Predefined risk levels</p> <p><i>Carcinogens</i> 4 additional cancer cases due to occupational exposure per 100,000 (target risk level) and 1,000 (prohibition risk level) general deaths</p> <p><i>Allergens</i> Additional risk of 1% due to occupational exposure compared to general population</p>

Derivation of a health-based OEL (2)



	Epidemiological data	Animal data
Threshold-based OEL	BMDL (NOAEL/LOAEL)	BMDL (NOAEL/LOAEL)
Risk-based OEL	<p><i>Carcinogens</i> Survival analysis (epidemiological data) BMD (LOAEL)</p> <p><i>Allergens</i> BMDL (LOAEL)</p>	BMD (LOAEL)
Defaults	Average healthy worker with light working activities (70 kg; inhalation 10 m ³ ; 8-hours/day, 5 days/week, 40 years)	Species-specific allometric relationships (body size and surface, inhalation volume, water and food consumption)
Uncertainty factors	Inter-individual differences Exposure conditions	Interspecies differences Exposure conditions

Work Programme



www.healthcouncil.nl



Gezondheidsraad
Health Council of the Netherlands