The Dutch experience

Setting risk based occupational exposure limits for non-threshold chemicals

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Social and Economic Council

- Established 1950 by law, public institution
- Advisory body to government and parliament
- Broad agenda - national and international social and economic policy
- Three groups: employers, employees & independent experts
- Financed by ‘organised business’, not government
- SER can foster (political) stability by ‘creating common ground’
- Secretariat of +/- 100

OEL Subcommittee

- Appointed by council decision (16 April 1993) and adjusted by decision of the executive board (16 February 2007)
- Task:
  - Advising the Ministry on limit values (OELs) for carcinogenic and mutagenic substances and respiratory allergens without threshold
  - Informing social partners on developments relating to OELs in the public domain
  - Preparing opinions in the policy area of harmful substances for the Commission of Working Conditions

The Dutch OEL system

Since 1 January 2007: new OEL system introduced in the Netherlands

- Public OELs, i.e. OELs set by the Minister of Social Affairs and Employment in particular for
  - substances 'without owners'
  - high-risk substances

- Private OELs, i.e., OELs which have to be identified by companies if no public OELs are set
  - legal obligation
  - numeric value private OELs non-binding

The Dutch OEL system

- All Dutch OELs are / need to be substantiated by health science (toxicology, epidemiology)

- The setting of OELs for chemicals for which no safe level of exposure can be established, the so-called non-threshold chemicals also involves feasibility considerations

Non-threshold chemicals

- no safe limit
- zero exposure only way to exclude all risk
- zero exposure not always possible
- setting OELs based on the concept of risk acceptance and feasibility considerations

The Dutch OEL system for non-threshold chemicals

- Carcinogenic and mutagenic substances
- Inhalation sensitizers

- Four-step-procedure
  1. The Ministry of Social Affairs and Employment establishes a national program of substances

  2. The Health Council (DECOS) calculates exposures at two predefined extra risk levels (guiding levels supported by employees and employers)

  3. The OEL Subcommittee of the Dutch Social and Economic Council (SER) carries out a feasibility test preferably at a low level of extra risk (target risk) and not higher than a certain level (prohibitive level) and advises the Ministry accordingly

  4. The Ministry of Social Affairs and Employment establishes legally binding OELs which eventually include feasibility considerations

The Dutch OEL system for non-threshold chemicals

- DECOS (scientific committee): threshold or non-threshold?
- If non-threshold, DECOS calculates the so-called risk numbers

Carcinogens & mutagens	target risk $1x10^{-6}$ / year*	one *extra incidence of cancer per* million exposed individuals per year
	prohibitive risk $1x10^{-4}$ / year*	one *extra incidence of cancer per* ten thousand exposed individuals per year
Inhalation sensitizers	acceptable risk $1x10^{-2}$ / year*	one *extra incidence* of sensitization per hundred exposed individuals per year

*Extra risk per working life:
$4x10^{-5}$ (target) & $4x10^{-3}$ (prohibitive) for carcinogens
and $4x10^{-1}$ for inhalation sensitizers

The Dutch OEL system for non-threshold chemicals

Risk-numbers are

- concentrations in the air of the workplace
- set at predefined extra risk levels
- extra risk levels are independent of the specific substance
- extra individual risk
- 40 working years (8 hours per day, 40 hours per week)
- starting point for calculating public OELs

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The Dutch OEL system for non-threshold chemicals

Feasibility check by the SER OEL Subcommittee

- occupational health & safety experts from industry associations and major employer and employee organizations
- six months to collect the information from the sectors
- SER concludes (no timeline obligations)

The Dutch OEL system for non-threshold chemicals

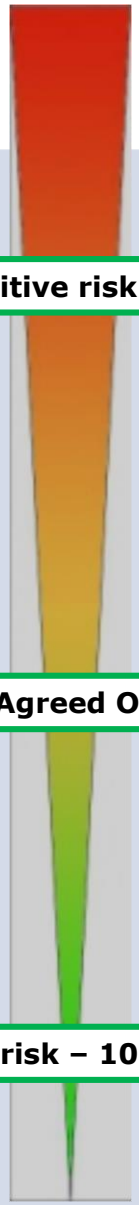
The feasibility check for carcinogens and mutagens

- to show whether 10^{-6} (target risk) is possible
- 10^{-4} (prohibitive risk) may not be exceeded
- risk levels calculated by DECOS not open for discussion
- information collected from companies, industry and workers
  - technical feasibility
  - financial consequences
- objections or comments need to be substantiated preferably with measurements and include a proposal for a feasible OEL
- if 10^{-6} is not achieved, the study needs to be repeated in 4 year

The Dutch OEL system for non-threshold chemicals

The feasibility check for carcinogens and mutagens

- no objection or reaction at all?
  - SER advises the minister to set the new legally binding OEL at the concentration corresponding to 10^{-6} (target risk)
- most often
  - legally binding OEL set between target and prohibitive risk level
- if OEL reached by companies
  - no PPE needed



concentration at the workplace

Prohibitive risk -10^{-4}/y

10^{-4}/y < Agreed OEL < 10^{-6}/y

Target risk – 10^{-6}/y

OEL not feasible at the prohibitive risk level:
- Use of the substance only allowed for exceptional applications, *or*
- Exposure to substance is inevitable, for example during maintenance or cleaning activities
- Risk management measures (RMM) mandatory at all levels so the **use of PPEs is mandatory**
- Action Plan for exposure reduction mandatory
- After 4 years new check for further OEL reduction

OEL not feasible at the target risk level:
- Feasible including RMM but,
- **PPEs NOT mandatory**, but strongly advised:
- PPEs must be available for workers
- Training for workers
- Action Plan for exposure reduction mandatory
- After 4 years new check for further reduction of the OEL

OEL at the target risk level:
- Feasible, eventually including RMMs
- **PPEs NOT mandatory**
- Activities at company level to lower the exposure advisable

The Dutch OEL system for non-threshold chemicals

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- Risk based OELs at target risk level (10^{-6}) are sometimes hard to achieve
- Sometimes difficult to measure, esp. if OEL is set at target risk level (10^{-6})
- Requires many resources
- Lengthy procedure

The Dutch OEL system for non-threshold chemicals

+
- Enforceable limits - Decreased uncertainty (for employers & employees) - Increased awareness - Lower exposures - Well-accepted by stakeholders

The Dutch OEL system for non-threshold chemicals

Two examples:

- arsenic and inorganic arsenic compounds
- 1,3-butadiene

With OELs set between the target and the prohibitive risk level

Arsenic & inorganic arsenic compounds

- Arsenic trioxide (CAS no. 1327-53-3), most relevant with regard to occupational exposure

- Uses
  - wood preservative,
  - in agriculture,
  - cotton desiccant/defoliant,
  - semiconductor applications,
  - decolouriser and fining agent in the production of bottle glass,
  - in the production of non-ferrous alloys, and
  - medication.

Arsenic & inorganic arsenic compounds

- DECOS (2012):
  - 0.28 µg/m3 target risk level (10-6)
  - 28 µg/m3 prohibitive risk level (10-4)

- SER advise to the Minister (2014):
  - 2.8 µg/m3 OEL

- Reasoning:
  - Target risk level not feasible due to exposure to fly ash at coal plants (coal contains arsenic that ends up in fly ash)

1,3-butadiene

- Cas no. 106-99-0

- Uses
  - preparation of synthetic rubber products and polymers,
  - intermediate in the production of basic petrochemicals

1,3-butadiene

- DECOS (2013):
  - 0.1 mg/m3 target risk level (10-6)
  - 10 mg/m3 prohibitive risk level (10-4)

- SER advise to the Minister (2014):
  - 2 mg/m3 OEL

- Reasoning:
  - Target risk level not feasible based on insights generated during the process of setting a BOEL for 1,3 butadiene by the European Commission

The Dutch OEL system for non-threshold chemicals

- ca. 50 OELs
- http://wetten.overheid.nl/BWBR0008587/BijlageXIII
- for single substances
- for groups of substances (e.g. arsenic compounds, PAHs)
- relatively low OELs
- supported by stakeholders
- ensures certain level of protection
- prevents abuses
- gives clarity

It works for already 20 yrs!

- Thank you!
- d.theodori@ser.nl