IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung

Beryllium: Regulatory Approaches in Germany and Europe

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Lecture Outline

- Regulating Carcinogenicity
  - General Remarks
  - The German “Traffic Light Model”
  - European Derived Minimal Effect Levels (DMEL)
  - The European SHEcan Project

- Beryllium Sensitization and Chronic Beryllium Disease
  - German Evidence-based Medical Guideline

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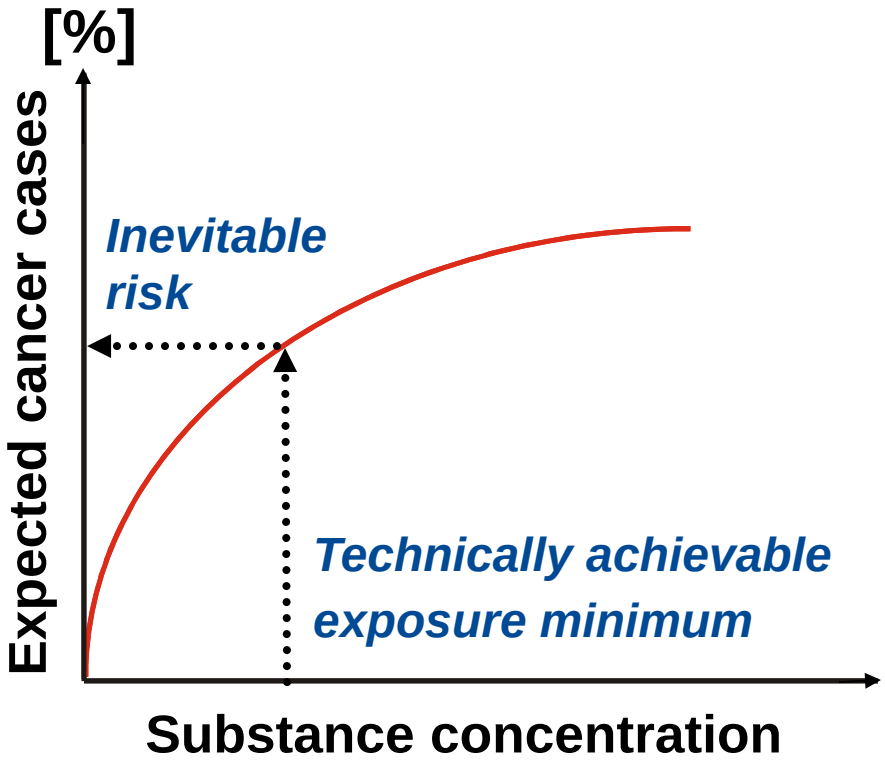
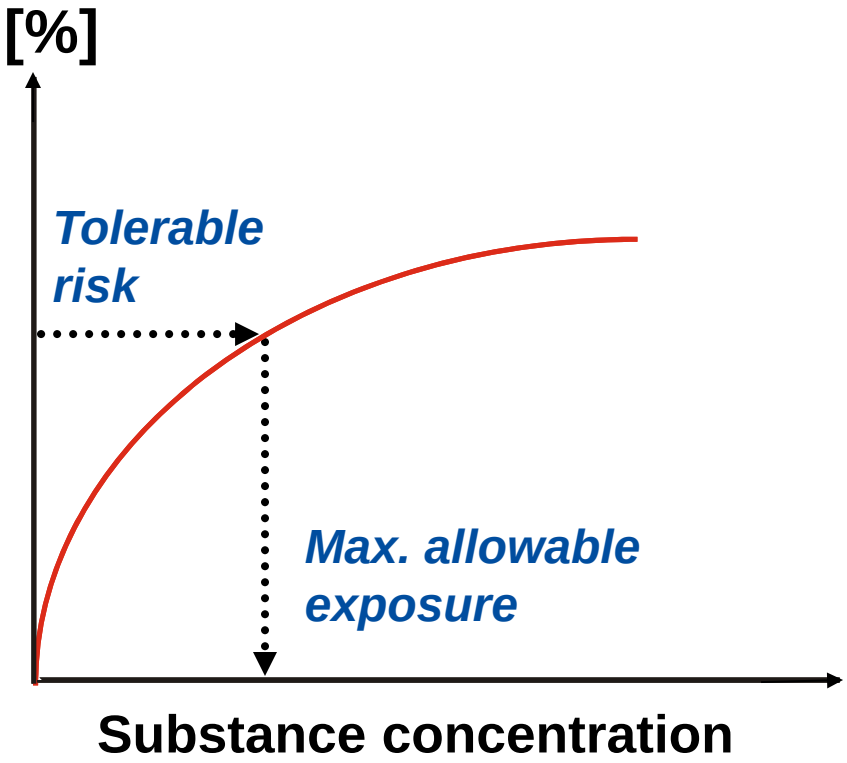
Risk policy approaches (non-threshold carcinogens)





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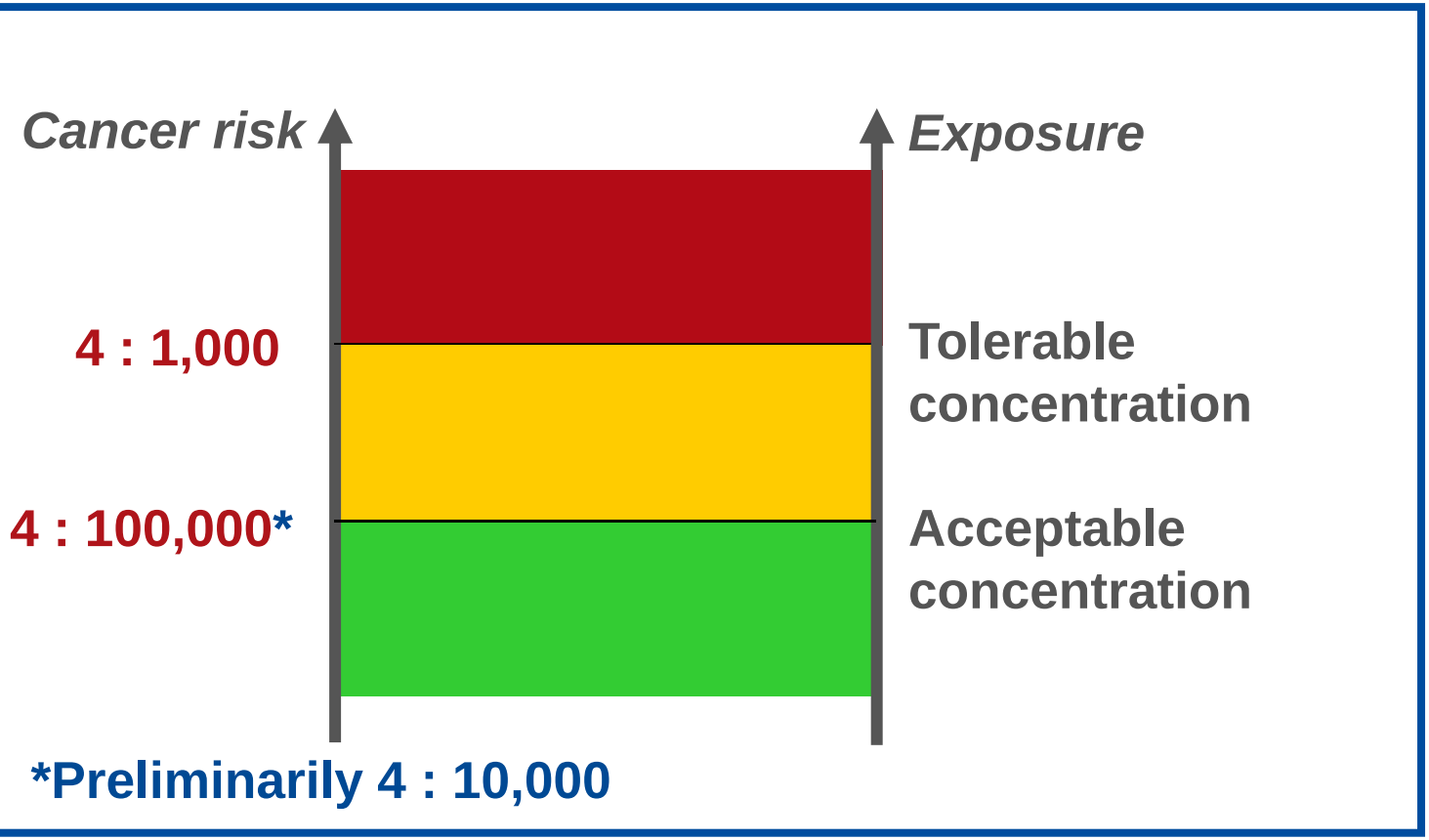
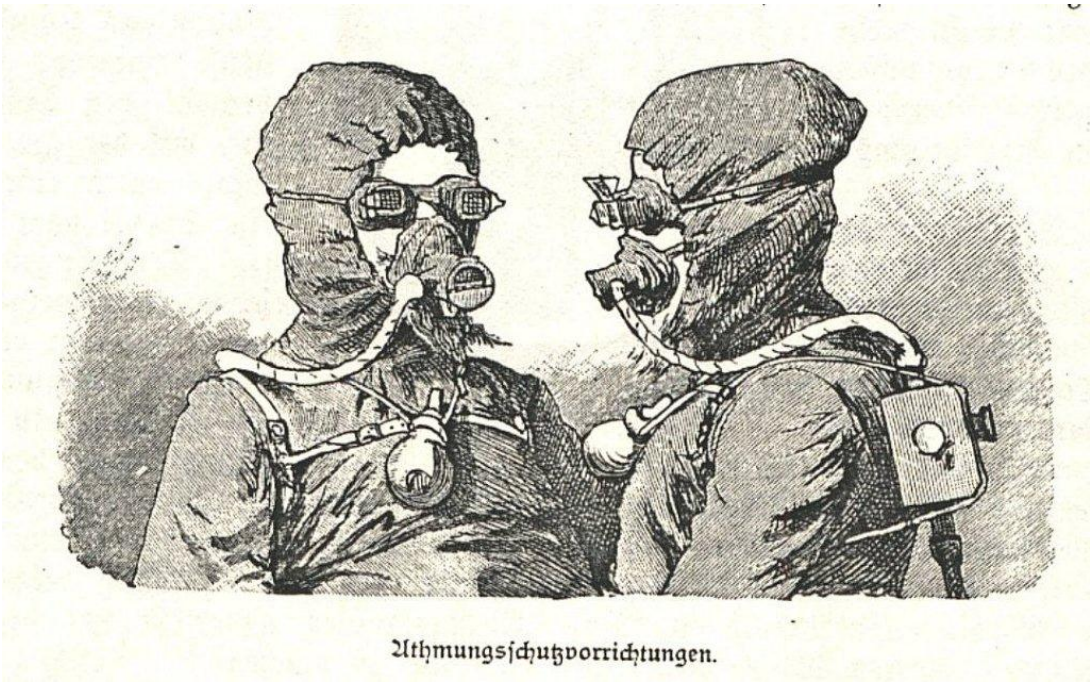
German “Traffic Light Model”



Measures according to “Announcement 910” (GER)

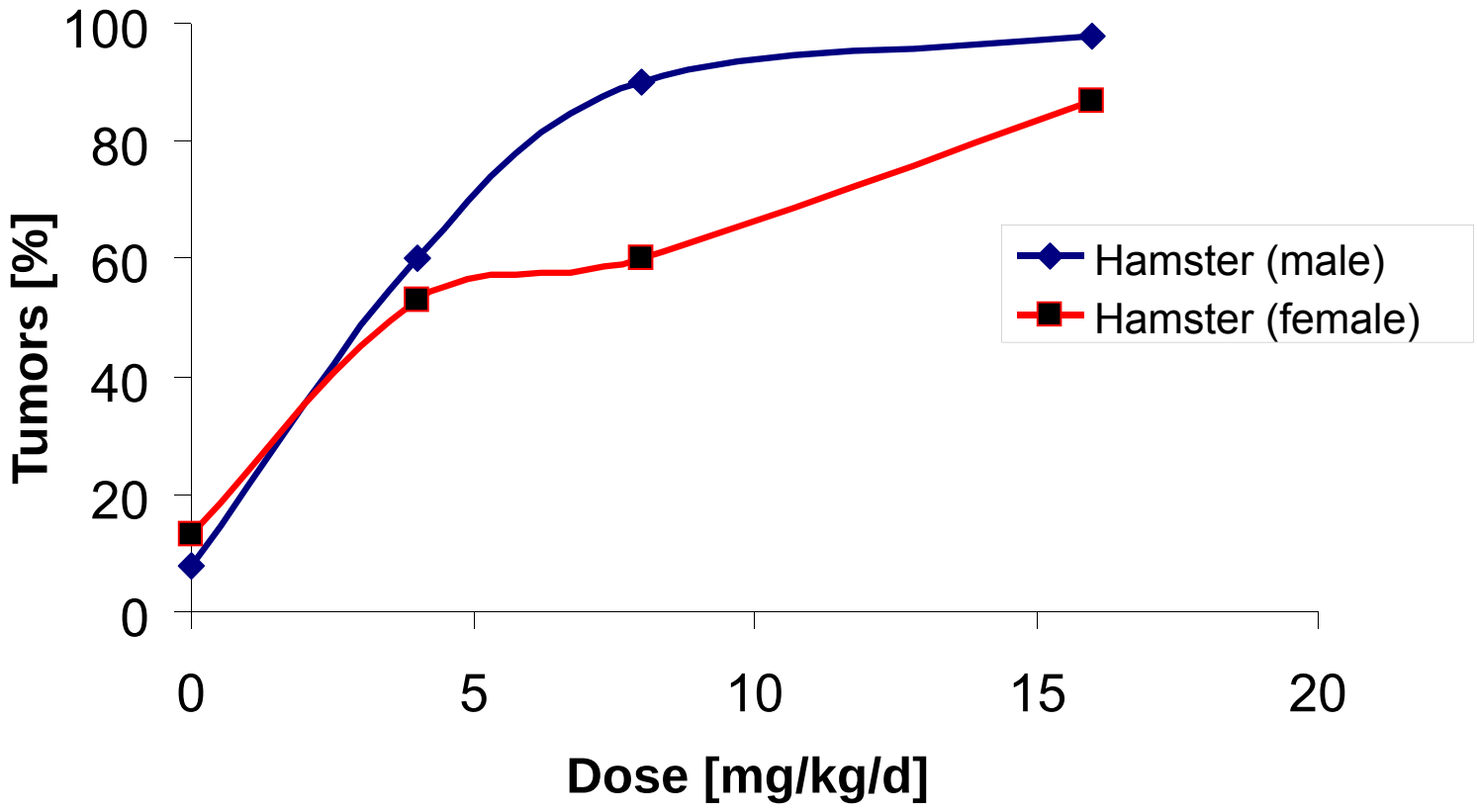
- The “Traffic Light Model” is linked to a concept of tiered control measures for minimal, medium or high risks.

  These measures include:
  - administration
  - technology
  - organization
  - occupational medicine
  - substitution

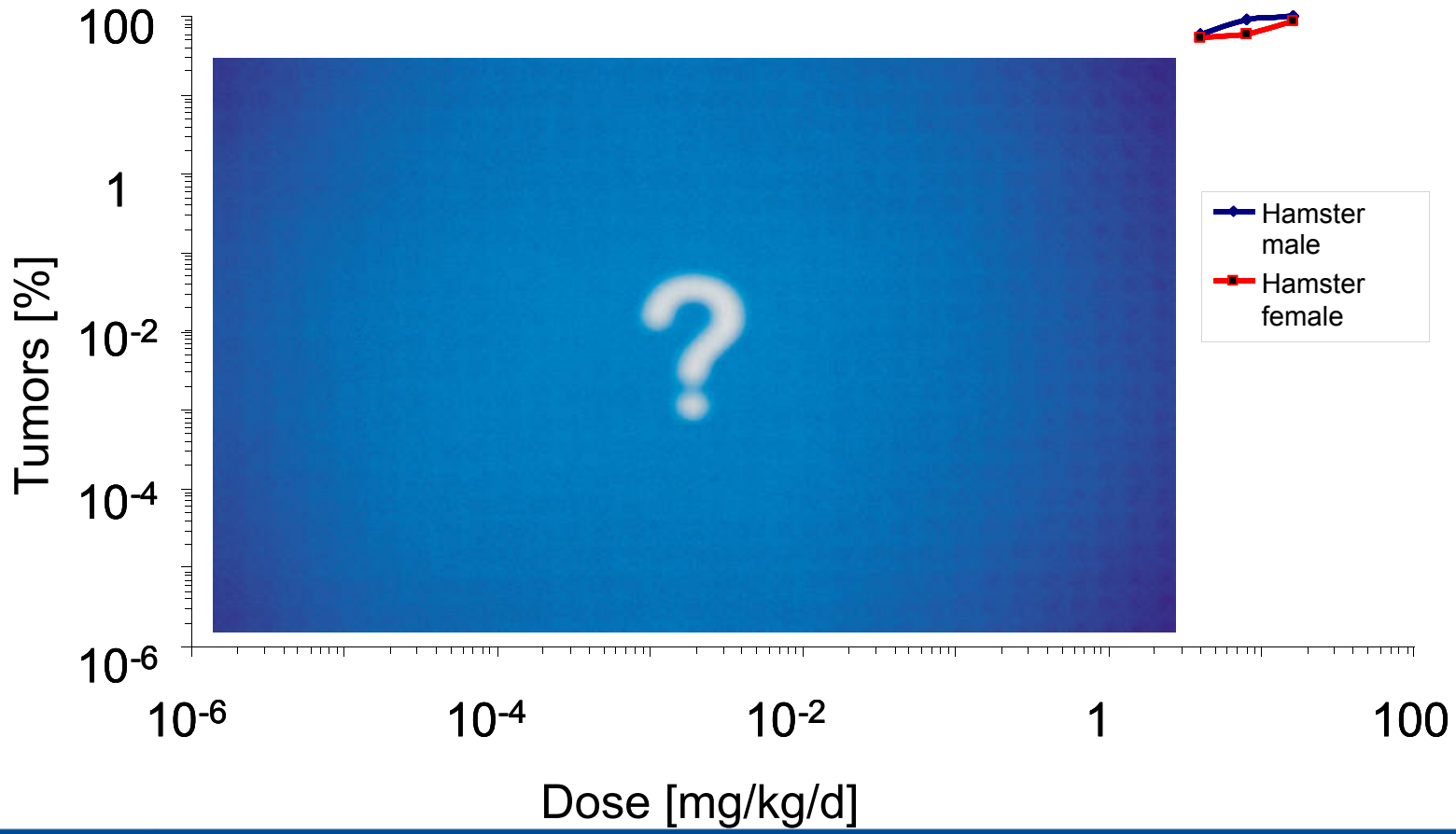


http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-910.html

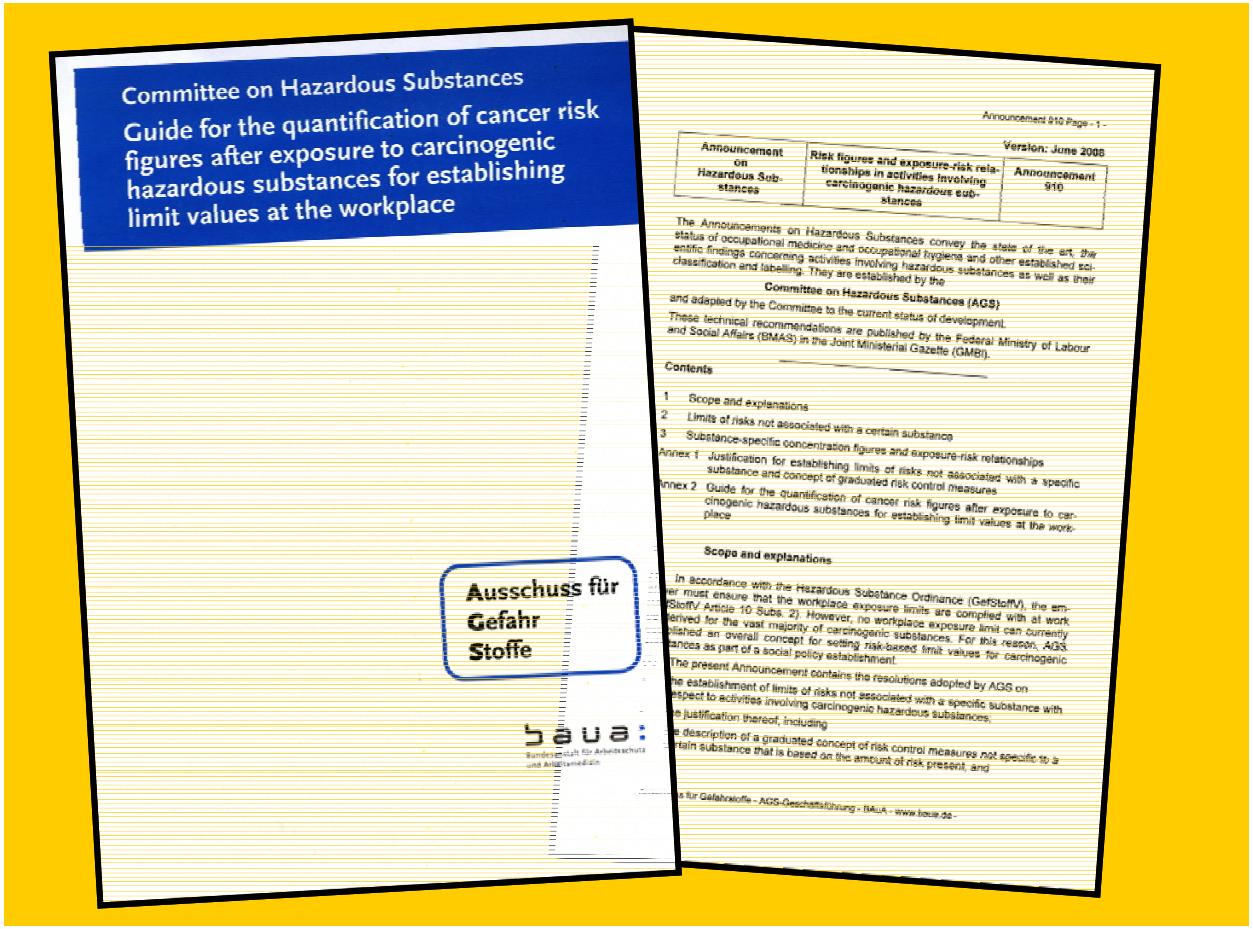
Hexachlorobenzene: dose-effect diagram



Risk extrapolation to low-dose region



Guide for the quantification of cancer risk figures


Committee on Hazardous Substances

Guide for the quantification of cancer risk figures after exposure to carcinogenic hazardous substances for establishing limit values at the workplace

Ausschuss für Gefahr Stoffe

baua:

Announcement 910 Page - 1 -

Version: June 2008

Announcement on Hazardous Substances	Risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances	Announcement 910

The Announcements on Hazardous Substances convey the state of the art, the status of occupational medicine and occupational hygiene and other established scientific findings concerning activities involving hazardous substances as well as their classification and labelling. They are established by the

Committee on Hazardous Substances (AGS)

and adapted by the Committee to the current status of development.

These technical recommendations are published by the Federal Ministry of Labour and Social Affairs (BMAS) in the Joint Ministerial Gazette (GMBl).

Contents

1 Scope and explanations

2 Limits of risks not associated with a certain substance

3 Substance-specific concentration figures and exposure-risk relationships

Annex 1 Justification for establishing limits of risks not associated with a specific substance and concept of graduated risk control measures

Annex 2 Guide for the quantification of cancer risk figures after exposure to carcinogenic hazardous substances for establishing limit values at the workplace

Scope and explanations

In accordance with the Hazardous Substance Ordinance (GefStoffV), the em-
er must ensure that the workplace exposure limits are complied with at work
/StoffV Article 10 Subs. 2). However, no workplace exposure limit can currently
erived for the vast majority of carcinogenic substances. For this reason, AGS
blished an overall concept for setting risk-based limit values for carcinogenic
ances as part of a social policy establishment.

The present Announcement contains the resolutions adopted by AGS on
he establishment of limits of risks not associated with a specific substance with
espect to activities involving carcinogenic hazardous substances;
e justification thereof, including
e description of a graduated concept of risk control measures not specific to a
rtain substance that is based on the amount of risk present, and

s für Gefahrstoffe - AGS-Geschäftsführung - BAuA - www.baua.de -

http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-910.html

Published risk-based limit values in Germany

Substance	Acceptable Level (prelimin. 4 : 10,000)	Tolerable Level (4 : 1,000)
Asbestos, Al silicate fibers	10,000 fibers/m³	100,000 fibers/m³
Acrylnitrile	0.12 ppm	1.2 ppm
1,3-butadiene	0.2 ppm	2 ppm
Trichlorethylene	6 ppm	11 ppm
4,4'-methylendianiline	0.07 mg/m³ *	0.7 mg/m³
Acrylamide	0.07 mg/m³ *	**
Ethylenoxide	0.1 ppm	1 ppm
B[a]P (specified mixtures)	70 ng/m³	700 ng/m³
Benzene	0.06 ppm	0.6 ppm
Epichlorohydrine	0.6 ppm	6 ppm

* Concentration limit can be observed by reasonable technical measures.

** 0.15 mg/m³ is the toxicological threshold for non-carcinogenic health effects.

Proposed risk-based limit values for metals/metalloids

Substance	Acceptable Level (prelimin. 4 : 10,000)	Tolerable Level (4 : 1,000)
Arsenic*	0.8 µg/m³	8.3 µg/m³
Cadmium*	0.16 µg/m³	1.6 µg/m³
Beryllium	*???*	*???*

* not published yet

Risk-based OELs for beryllium in Germany

Still under discussion

Preliminary trends:

- Lung cancer risk from epidemiological studies as a basis
- Data do not permit differentiation between Be and Be compounds
- It is not possible to derive a threshold for carcinogenicity
- Threshold for induction of CBD – though diffuse – should not be exceeded
- Below this “cut-off point” a cancer and sensitization risk is expected, but cannot be quantified

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New European chemicals legislation (REACH): DMEL

"[F]or non-threshold carcinogens/mutagens […] the registrant should develop a **DMEL** (derived minimal effect level), a reference risk level which is considered to be of very low concern. DMEL […] should be seen as a tolerable level of effects and it should be noted that it is not a level where no potential effects can be foreseen."

Guidance in information requirements and chemical safety assessment, chapter R.8

ECHA
EUROPEAN CHEMICALS AGENCY

Advanced search »

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ECHA > Information on Chemicals > Registered substances

- About Us
- Regulations
- Addressing Chemicals of Concern
- Information on Chemicals
  - Pre-registered substances
  - Registered substances
    - Identified substances for registration in 2010
    - Substances identified by industry to be registered by 31 2013
  - Classification & Lab Inventory
  - Testing proposals
  - Transitional Measures
  - Community Rolling Action

Registered substances

Chemical Substance Search

Last updated 19th of July. Database c ubstances and contains information from 30 375 dossiers.

Beryllium

Enter search st , EC No, Cas No, etc. Leave blank and press tabase.

I have read and I accept the disclaimer.

Search

Upper limit(tonnes):

search results by entering a total tonnage band (per annum)

esults

Records per page 25

EC Number	CAS Number	Name	Total Tonnage Band	
215-133-1	1304-56-9	beryllium oxide	1 - 10 tonnes per annum	View
231-150-7	7440-41-7	beryllium	10 - 100 tonnes per annum	View

Chemical Property Search (via eChemPortal)

No DMEL found for Be/BeO

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    (Socioeconomic, Health and Environmental impact of possible amendments to the EU CArciNogens and Mutagens Directive)

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SHEcan: characteristics

- Sponsor:
  European Commission (DG Employment)
- Duration:
  2009-2010 (officially); Summary Report: May, 2011
- Task:
  Estimation of socio-economic impact caused by
  - lowering of existing EU binding limit values (BOELVs) for carcinogens,
  - introduction of BOELVs for additional carcinogens,

  for the time period until 2070 and with allowance for stable trends.
- Methods:
  Cost-benefit analyses for
  - “tangible” items (exposure reduction measures, medical treatment, absence from work, etc.),
  - “intangible” items (functional limitations, disfigurement, pain & fear, etc.),
  - environmental impacts (e.g. due to emission).

SHEcan: substances

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- Hard wood dust, vinyl chloride
- Acrylamide, benzo[*a*]pyrene, beryllium & compounds, bromoethylene, 1,3-butadiene, 1-chloro-2,3-epoxypropane, chrome(VI), 1,2-dichloroethane, 1,2-dibromoethane, diesel engine exhaust emissions, 1,2-epoxypropane, ethylene oxide, hexachlorobenzene, hydrazine, refractory ceramic fibers, 4,4'-methylenedianiline, 4,4'-methylene bis, 2-chloroaniline, mineral oils in the form of used engine oil, 2-nitropropane, rubber process fumes & dust, respirable crystalline silica, o-toluidine, trichloroethylene

SHEcan: work packages

(1) Estimate the number of people exposed
(2) Estimate the exposure level
(3) Assess the risk associated with exposure
(4) Socioeconomic assessment
(5) Environmental impact
(6) Review advantages & disadvantages of introducing an OEL setting system
(7) Review requirements in Carcinogens Directive for prevtn. & expo. reduction
(8) Assess impact of adding 4 additional substances to Annex I list
(9) Assess impact of reducing the OELs for hardwood dust and VC monomer
(10) Assess impact of introducing OELs for 20 substances
(11) Consult with key stakeholders

SHEcan: results

- Determination of exposure/number of exposed individuals difficult
- Only one case in which cost-benefit ratio <1:
  Respirable cryst. silica, if an OEL ≥0.05 mg/m³ is implemented
- "Strongest cases for introducing an OEL":
  Silica, chrome(VI) (0.025-0.1 mg/m³), hard wood dust (1-3 mg/m³)
- "Evidence may support the introduction of an OEL":
  Diesel engine emissions, rubber process fume & dust, B[a]P, TRI, hydrazine, epichlorohydrine, o-toluidine, mineral oils, MDA
- "Substances with little or baseline impact":
  Incl. acrylamide, beryllium, 1,3-butadiene, ethylene- & propylenoxide, RC fibers
- "Uncertainties concerning cancer hazard associated with workplace exposure":
  1,2-dichlorethane & -dibromoethane, hexachlorobenzene (banned!), 2-nitropropane
- SMEs: disproportionate financial impact to be expected: silica, hard wood dust

SHEcan evaluation of beryllium

Specified scenario: OEL = 2 µg/m³

- Approx. 65,000 workers exposed in Europe (3,000 highly exposed)
- Fewer than 10% of exposures exceed 2 µg/m³
- Without OEL: health costs of €200-300 million over the next 60 years
- With OEL: reduction from 6 to 4 cancer deaths p.a. by 2060, total health benefits of €11-30 million
- Additional control measures (6-12% of enterprises): €5-34 billion
- No significant foreseeable environmental impacts

Conclusion:
"There is little evidence of a major health impact
from current and relatively recent exposure levels in the EU.
We do not consider there to be a strong case for introducing limits."

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First reference to CBD symptoms

Über eine Apparatur zur Erzeugung niedriger Staubkonzentrationen von großer Konstanz und eine Methode zur mikrogravimetrischen Staubbestimmung. Anwendung bei der Untersuchung von Stauben aus der Berylliumgewinnung.

Von Dr. H. H. Weber und Dr. W. E. Engelhardt.

(Aus dem gewerbehygienischen Laboratorium des Reichsgesundheitsamts Berlin.)

Für die Untersuchung von Staubluftgemischen, insbesondere von solchen, die schon in verhältnismäßig geringen Konzentrationen schwere gesundheitliche Störungen hervorrufen können, wurde gegeben. Er läßt den Staub durch einen Trichter in ein rotierendes Sieb fallen, welches diesen mit Unterstützung eines Ventilators in der Staubkammer verteilt.

BES & CBD: Evidence-based Medical Guideline (GER)

Still in preparation

Preliminary trends:

- Beryllium sensitization (BES) can be diagnosed by an adequate lymphocyte proliferation test (Be-LPT)
- Sensitization status of exposed persons should be examined regularly
- Requirements for CBD recognition are beryllium exposure plus a confirmed Be-LPT plus characteristic medical symptoms/findings

Thank you for your attention