German Health-Based Indoor Air Guide Values

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Overview: **History of derivation of indoor air guide values in Germany**

- *Period 1994-2000*: strictly human-based (mainly ocupational epidemiology) indoor air guide values:

  assessment factors as recommended by WHO (Air Quality Guidelines 1987)

  ► First basic scheme for derivation of indoor air guide values (1996)

- *Period 2001- now*: including animal data

  in the beginning: use of assessment factors of the German Committee on Hazardous Substances (AGS)

  since 2008: assessment factors from ECHA´s Guidance Document R8 (ECHA 2008, 2010)

  ► Second basic scheme (2012) including non-genotoxic carcinogens

- *Period 2010- now*: discussing sensory vs. cytotoxic iritation and MoA Carcinogenesis

  2010 WHO Guidelines for indoor air quality: selected pollutants including some carcinogens
  2012 Communication from the EU-Commission starting the regulation of radon in indoor air

  ► Health evaluation of indoor air (genotoxic) carcinogens (2015)

Discussion on the evaluation of odour and odorants (unfinished, currently research supported by FEA / FMin)

History of derivation of indoor air guide values in Germany (2)

Since 1985 public discussion: better ventilation, health-based or building product regulations?

► 1994 Resolution of the Conference of the German States´s Health Ministers (GMK):

- to establish a temporary national working group
- to derive health-based guide values for indoor pollutants
- to ensure guide values to be enforceable in practice, e.g. in litigations between flat owners and occupants

→ Establishment of an Ad hoc Working Group,

convening toxicology and indoor experts from federal states and federal agencies e. g. UBA, BfR

History of derivation of indoor air guide values in Germany (3)

Starting point: consideration of legal perequisites

► Building Ordinance (of the federal states) § 3: buildings must be constructed and maintained without posing a health hazard to occupants.

► toxicological point of view:

health hazard if indoor air concentrations above LOAEC following life-long exposure of sensitive people:

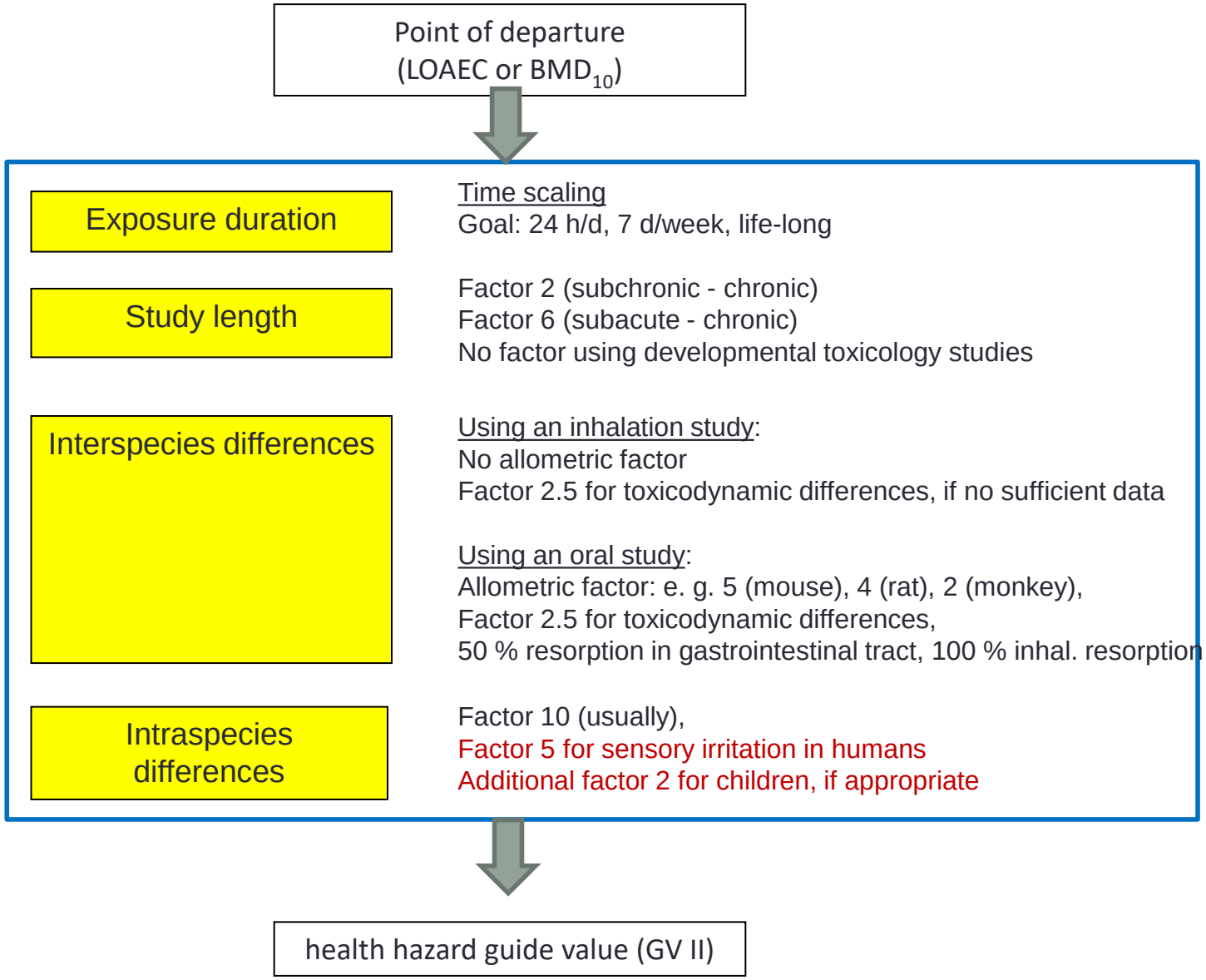
→ LOAEC as point of departure to derive two indoor air guide values:

► health hazard guide value (GV II): using chronic LOAEC + assessment factors

► precautionary guide value (GV I): GV II / 10 (or NOAEC, if available) + assessment factors

→ this approach was proven to be successful in litigations.

Derivation of indoor air guide values in Germany (4): assessment factors (following ECHA 2010)



Important genotoxic or non-genotoxic carcinogens in indoor air

Carcinogen	EU category Carcinogen.	EU category Mutagenicity
Radon	1 (WHO)	m
Benzene	1 A	1 B
Chloroethene (VC)	1 A	m
Acrylamide	1 B	1 B
Benzo(a)pyrene	1 B	1 B
Acetaldehyde	1 B *	2*
Chrysene	1 B	2
Formaldehyde	1 B	2
1,2-Dichloroethane	1 B	2*
Trichloroethene	1 B	2
Amphibole asbestos	1 A	-
Chrysotile	1 A	-
Nitrosodimethylamine	1 B	-
Butanoneoxime	1 B *	-
Dichloromethane	2	-
Furaldehyde	2	-
Naphthalene	2	-
Pentachlorophenol	2	-
Tetrachloroethene	2	-
Tris(2-chloroethyl)ph.	2	

Abbr.: m – mutagenic without EU category (mainly IARC); *ECHA-RAC

Health evaluation of indoor air carcinogens (1): **non-genotoxic carcinogens**

- If sufficient knowlegde of MoA (e.g. irritation) and a LOAEC available: derivation of indoor air guide values

Non-genotoxic carcinogen	EU category carcinogen.	GV II [mg/m³]	GV I [mg/m³]
Butanone oxime	2	0.06	0.02
Dichloromethane	2	2	0.2
Furaldehyde	2	0.1	0.01
Naphthalene + N-like	2	0.03	0.01
Pentachlorophenol	2	0.001	0.0001
Tetrachloroethene	2	1	0.1
Tris(2-chloroethyl) phosphate	2	0.05	0.005

N-like: Naphthalene-like two- and three-ring aromatic hydrocarbons

Health evaluation of indoor air carcinogens (2): **genotoxic carcinogens**

- If sufficient knowlegde of MoA and a LOAEC available: derivation of indoor air guide values

► DNA-reactive genotoxic carcinogen [ECHA-RAC+EU-SCOEL-JTF 2017]

Examples:

- **formaldehyde**: low exogenous adduct concentrations below exposure of 1 mg/m³ (rat, nasal) compared to (unavoidable) endogenous adduct(s) level; no systemic risk

WHO (2010) NOAEC for sensory irritation → IAGV I = 0.1 mg formaldehyde/m³;
no IAGV II: LOAEC not available for this endpoint

- **chloroethene** (vinyl chloride): low exogenous adduct level (rat liver) < 2 mg/m³ compared to endogenous LOAEC for hepatotoxicity available → IAGV II = 0.02 mg/m³ + IAGV I = 0.006 mg/m³ (draft 5/2018)

► non-DNA-reactive genotoxic carcinogen (e. g. aneugens) [ECHA-RAC+EU-SCOEL-JTF 2017]

Example: **benzene**: LOAEC for hematotoxicity → OEL [ECHA-RAC + EU-SCOEL 2017]

→ IAGV II = 0.03 mg/m³, → IAGV I = 0.003 mg/m³ (draft 5/2018)

acrylnitrile: LOAEC available → OEL [ECHA-RAC + EU-SCOEL 2017]

Health evaluation of indoor air carcinogens (3): **genotoxic carcinogens**

- If no suffient knowledge of MoA available (and a bad need):

  → linear extrapolation of cancer risk (or sublinear, if some data)

- But Committee on IGV acknowledges fundamental problems:

► much uncertainty e. g. regarding unknown degree of repair e. g. of adducts

→ Committee uses the term „theoretical cancer risk“ for risk communication
(in contrast to real cancer risks e.g. of radon from epidemiological studies)

► still no reference cancer risk level established by EU Commission or EU Parliament

Health evaluation of indoor air carcinogens (4): **genotoxic carcinogens**

→ „practical“ approach: comparison of theoretical cancer risk to current reference concentration (95. percentile)

► Criteria: ECHA (2010) presented an „indicative“ cancer risk level of 10^{-6} as an „example“

→ if reference concentration below theoretical cancer risk level of 10^{-6}:

Committee uses the 10^{-6}-figure as a non-binding guideline (no guide value)

Example: trichloroethene: guideline 0.02 mg/m³ (95. percentile < 0.001 mg/m³)

→ if reference concentration above theoretical cancer risk of 10^{-6}: Committee takes the current reference concentration as a starting point for risk management.

As a consequence, for some substances higher theoretical cancer risks > 10^{-6} are presently tolerated

Example: 1,2-dichloroethane: 0.001 mg/m³ (95. percentile, theoretical cancer risk ~3 x 10^{-6})
[in prep.]

Health evaluation of indoor air carcinogens (5): radon (the most important indoor air carcinogen)

- From epidemiological studies about 1900 lung cancer cases per year [BfS 2016] or even 5400 cases per year [Gredner et al. 2018] have been estimated to be attributable to indoor air radon
- German Radiation Protection Act (2017): measures below 300 Bq radon/m^3 indoor air not appropriate

	Indoor air radon concentration	**Life-long cancer risk**
Committee on Indoor GV (2014)	100 Bq/m^3 (95. percentile) 40 Bq/m^3 (median) ~ 10 Bq/m^3 (outdoor air)	6×10^{-4} 2×10^{-4} 6×10^{-5}
Radiation Protection Act (2017)	300 Bq/m^3 (~ 99. percentile)	2×10^{-3}

Results of the work of the German Committee on Indoor GV

- Currently more than 40 indoor air guide values and 10 indoor air summary guide values available,

  covering more than 130 substances in indoor air,

  each with a published explanation (free download)

- 2015 the GMK recognized „indoor air“ as a permanent task

► The temporary Ad hoc Working Group was renamed as the permanent Committee on Indoor Guide Values.

- ***Thanks to the former and present members of the Committee on Indoor Guide Values***

Period	Committee	Chair	Vice chair	Office
1994-2005	Ad-hoc Working Group	B. Seifert	N. Englert	E. Rosskamp
2006-2015	Ad-hoc Working Group	H. Sagunski	L. Müller	W. Heger
2015 - now	Committee on Indoor GV	M. Kraft	H. Fromme	M. Debiak

- ***Thanks to the many collegues from Denmark, Sverige, the Netherlands and other European countries, Health Canada, US-ATSDR, US-EPA and WHO Europe***

- More information at: http://www.umweltbundesamt.de/themen/gesundheit/kommissionen-arbeitsgruppen/ausschuss-fuer-innenraumrichtwerte-vormals-ad-hoc

Thank you for your attention!