Risk assessment methodology for soil contaminants in Germany

Hermann H. Dieter

Umweltbundesamt/Federal Environment Agency of Germany,
Department Toxicology of drinking water and swimming pool water,
Wörlitzer Platz 1, D-06844 Dessau, e-mail: hermann-h.dieter@uba.de

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Which concentration of a soil contaminant

might pose a threat to public health

- in a *children's play* area,
- in a *residential* ar-ea,
- in a *park* or a *recreational* facility
- in the unsealed parts of *industrial* and
- *commercial* properties

in accordance with actual German Soil Legislation?

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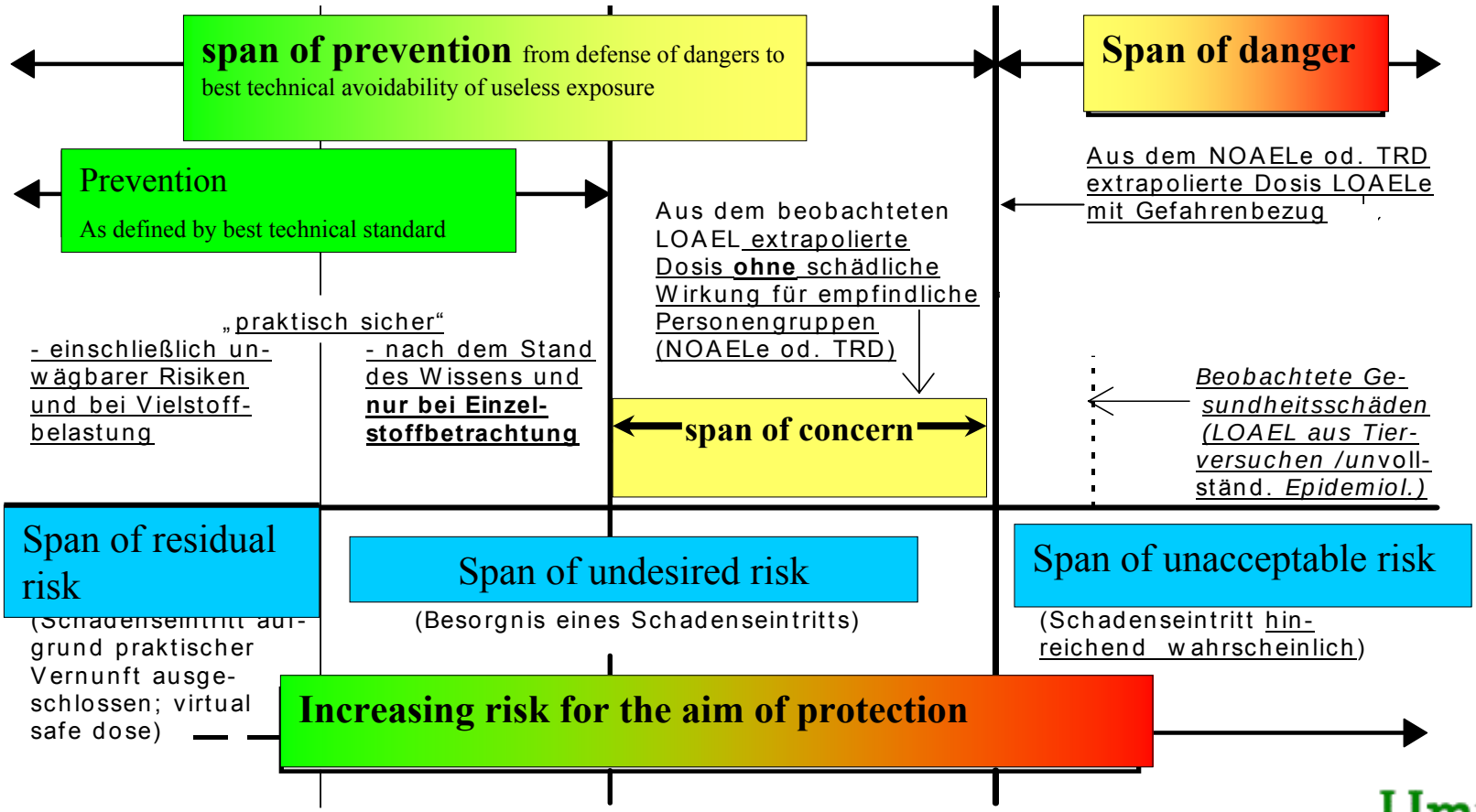
Schematic representation of risk spans for adverse effects with a threshold



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Key issues when deriving risk based and substance specific soil levels:

1. Defining a health based *body dose*, either tolerable (threshold) or acceptable (risk calculation)
2. Consider substance- and soil specific (pharmacokinetic/chemical) aspects of exposure,
3. Quantify health hazards associated with different exposure levels at a given site,
4. Assess total environmental exposure and its health hazard.

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How generic soil levels relating to the pathway "direct contact between soil and humans" are currently derived in Germany?

Our derivation of health based and *safe* or *acceptable* reference exposure levels (TRD-values) uses the “Toxicological data basis for environmental contaminants” as supported by our Agency (more than 100 substances)

See:
http://www.umweltbundesamt.de/altlast/web1/deutsch/pruefwerte_uba.pdf

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Basic Definitions of Tolerable Exposure (regulatory concept of „effect threshold“)

- A **TRD** is the path specific (oral, inhalative, dermal) *Tolerable* ***R****esorbed* ***D****ose* of a potentially harmful substance.
- The ***oral*** **TRD** is a specified fraction of the
  Tolerable or
  Acceptable
  Daily Intake *(TDI)* over a 70 years lifespan

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In the following only one path of exposure and hence only the term „TDI“ will be used

- A TDI is derived from an experimental or epidemiological **Point of Departure = PoD** by means of up to four Extrapolation Factors $EF_{a\text{-}d}$ from animals to humans

Basic Definitions of Risk per Unit of Exposure (Regulatory concept of „no-threshold-effect“)

Risk per Unit of exposure (concentr.) → Total Exposure per exposed unit (person)

- **Inhalation:** Risk for a person to contract cancer as the result of lifelong inhaling a genotoxic carcinogen at a level of RU = 1 µg per m^3 of air (→20 µg/70 kgBM and day).
- **Oral uptake:** Risk for a person to contract cancer as the result of lifelong ingestion of RU = 1 mg per kilogram of body mass and day (→70 mg/70 kgBM and day).

  70y-Risk = RU(inh) • [Mean 70y-concentration] or

  70y-Risk = RU(oral) • [Mean 70y-ingestion]
- **A 70y-Risk of higher than 10^{-5} from a sanitized waste site would not be acceptable**

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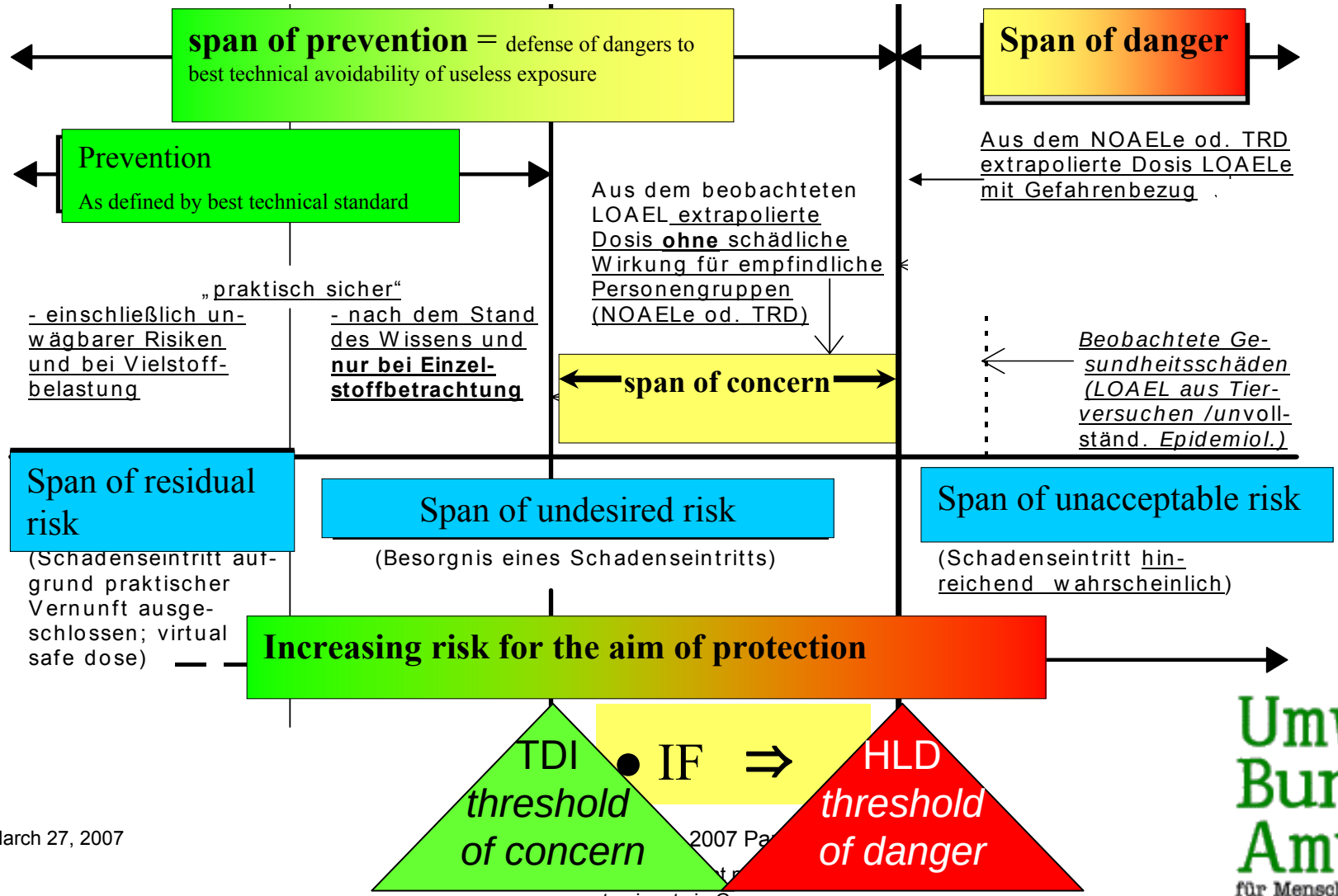
The first task was to define a link between the legal definition of a health hazard and its toxicological definition for "threshold substances".

The corresponding dose was called by us *"Hazard-Linked Dose" (HLD).*

The HLD had to be fixed in a way that it was "in all likelihood" already "*dangerous" for susceptible persons but not yet for normal ones.*

Hence, this HLD had to be virtually or actually *identical with the* $LOAEL_s$ for **susceptible** persons (s).

Schematic representation of risk spans for adverse effects with a threshold



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The interpolation factor = IF, required to multiply the TDI to get the HLD ≡ $LOAEL_s$ is the square root from the product of all (one to three) **human-relevant extrapolation factors EF_{th} between the PoD and the TDI.**

$$IF = \sqrt{EF_{th}}$$

The product **TDI • IF = HLD** is positioned half-way between the "normal" LOAEL and the TDI.

$LOAEL_{AE}$ (lowest subchronically [or EF_a ⇨ chronically] still effective dose)

EF_b ↓

$NOAEL_{AE} = LOAEL_S$ toxicological-scientific effect threshold (highest, but very probably **not yet effective *experimental* dose, e. g. in an Animal Experiment**)

: EF_c (1 to 10)

LAEL-s max

?

?

Calculated **$NOAEL_S$= $LOAEL_s$** = lowest, **very probably yet effective** dose in sensitive persons from the regulatory-toxicological view

Actual **$LAEL_s$** = (mostly) **unknown, yet effective dose**

HLD

: EF_d (1 to 10)

?

• IF = √EFth

LAEL-s min

span of extrapolation (safety) F_{th}

$NOAEL_s$ = regulatory-toxicological effect threshold = (highest, but very probably **not yet effective dose** in ***sensitive persons***)

TDI

This procedure to define a HLD ensures that the data gaps contained in a TDI do not fall heaviest on the target to be protected from a hazard. This is shown by this table:

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PoD = Database[1)]	*Total*[2)] Factor (TF_t) from PoD to TDI	**Total Extrapolation Factor[2)] (EF_{th}) from PoD to TDI**	**IF = Interpolation Factor to give TDI •IF = HLD (threshold effects)**	**IF in % of EF_{th}**
$LOAEL_{AE}$	300	**100**	**IF = √100 = 10**	**3.3**
$LOAEL_{AE}$	300	**300**	**IF = √300 = 17**	**6**
$NOAEL_{AE}$	100	**100**	**IF = √100 = 10**	**10**
$LOAEL_S$	30	**30**	**IF = √30 = 5.52**	**18**
$NOAEL_S$	10	**10**	**IF = √10 = 3.2**	**32**
$LOAEL_s$ or $NOAEL_s$	3 1	**1** **1**	**$IF = EF_{th}$** *IF = 3* *in absence of an EF*	**100**

1) **AE** = from Animal Experiments; **S** = epidemiologic study in a population group with **normal** susceptibility
s = epidemiologic study in a population group with **high** susceptibility

2) The EF_t, in contrast to the EF_{th}, may comprise one or two EF being not used to extrapolate experimental data to humans, but only to compensate for gaps in the data base earlier than the PoD was fixed.

The second task was to define a link between the legal definition of a health hazard and its toxicological definition for "non-threshold substances".

No EF, no TDI → No IF!

Instead:

1. Background Risk BGR = 10^{-5} if prevention has failed
2. Hazard-linked risk HLR = 5-fold BGR

Hence:

3. Hazard-linked Dose HLD corresponds to Hazard-linked Risk HLR = $5 \bullet 10^{-5}$

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Assessment of exposure

- **<u>Soil intake by free living individuals</u> cannot be scientifically defined, because there is no theory to predict or describe their behaviour**
- **If standard conventions are used as a surrogate, they must refer to maximal empirical values as far as they are close to "normal reality".**
- *We use the following standard conventions within the assessment framework of the German Soil Protection Bill:*

Ingestion of soil: 0 - 0,5 g/10 kg body mass and day on 240 days per year ("playing child scenario" ≙ 33 mg/kg·d*)).
Inhalation: Special conventions have to be applied to account for exclusive exposure of adults on (former) industrial and commercial areas.
Risk calculations: Exposure from an abandoned waste site is supposed to last not longer than 10/70 years = 8,75 parts of a normal lifespan

*)Lower exposure is assumed with regard to parks, residential or leisure areas.

Calculation of "Hazard-Linked" Trigger Values for Oral soil uptake by children on children's play areas:

- Substances ***with*** **effect threshold (t)**:

  Trigger Value **TV_t**

  TV_t [mg/kg] = TDI [ng/kg·d]●(IF - 0,8) / soil uptake rate [mg/kg·d]

- Substances ***without*** **effect threshold (c)**:

  Trigger value **TV_c**

  TV_c [mg/kg] = (DI at Risk 10^{-5}) [ng/kg·d]●5●8,75 / soil uptake rate [mg/kg·d]

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Some calculated (cTV) and practical (pCT) Soil Trigger Values for Playgrounds

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Parameter → *Substance* ↓	TDI µg/kg · d	IF	HLD µg/kg · d	cTV (calculated) mg/kg	pTV (practical) mg/kg	Why is aTV different from cTV?
Arsenic	0,3	1,7	0,52	8,2	25	High backgrd
Cadmium	0,5	2	1,0	18	10	Ecolog. function
Chromium	5,0	10	50	1400	130	1.+inhalation 2.Cr(VI)
Cyanides	10,0	3,2	32	715	50	Acute toxicity
Mercury						**Mixture**
inorg	**0,214**	**4,5**	**0,96**	**24**	**10**	**inorganic/**
org	**0,05**	**3,9**	**0,195**	**4,7**		**organic Hg**
HCH	**0,02**	**10**	**0,20**	**5,58**	**5,0**	**no difference**

Thank You for Your Attention!

Contact:

Priv. Doz. Dr. Hermann H. Dieter
hermann.dieter@uba.de
Umweltbundesamt, working office Berlin-Dahlem
www.umweltbundesamt.de
Wörlitzer Platz 1
D-06844 Dessau

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