

Risk assessment methodology for soil contaminants in Germany

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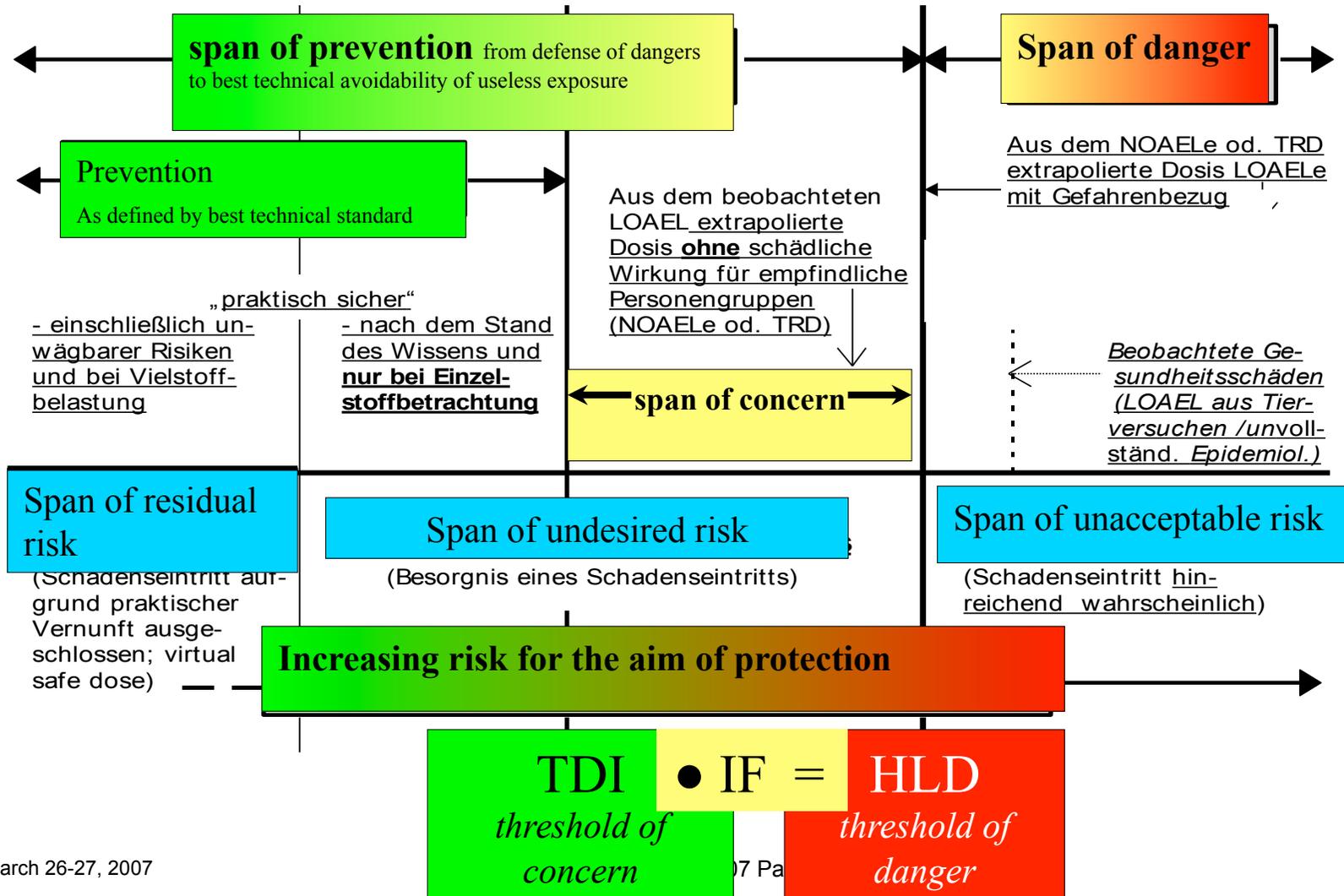
Which concentration of a soil contaminant

might pose a threat to public health

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

in accordance with actual German Soil Legislation?

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.

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

Basic Definitions of Tolerable Exposure (with effect threshold)

- A **TRD** is the path specific (oral, inhalative, dermal) *Tolerable Resorbed Dose* 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

In the following 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-d}

Basic Definitions of Risk per Unit of Exposure (without effect threshold)

Risk per unit of exposure → Total Exposure per **exposed unit**

- **By inhalation:** risk for a person to contract cancer as the result of lifelong inhaling a genotoxic carcinogen at a level of a $1 \mu\text{g per m}^3$ of air ($\rightarrow 20 \mu\text{g}/70 \text{ kgBM and day}$).
- **Oral uptake:** risk refers to the lifelong ingestion of $1 \text{ mg per kilogram of body mass and day}$ ($\rightarrow 70 \text{ mg}/70 \text{ kgBM and day}$).

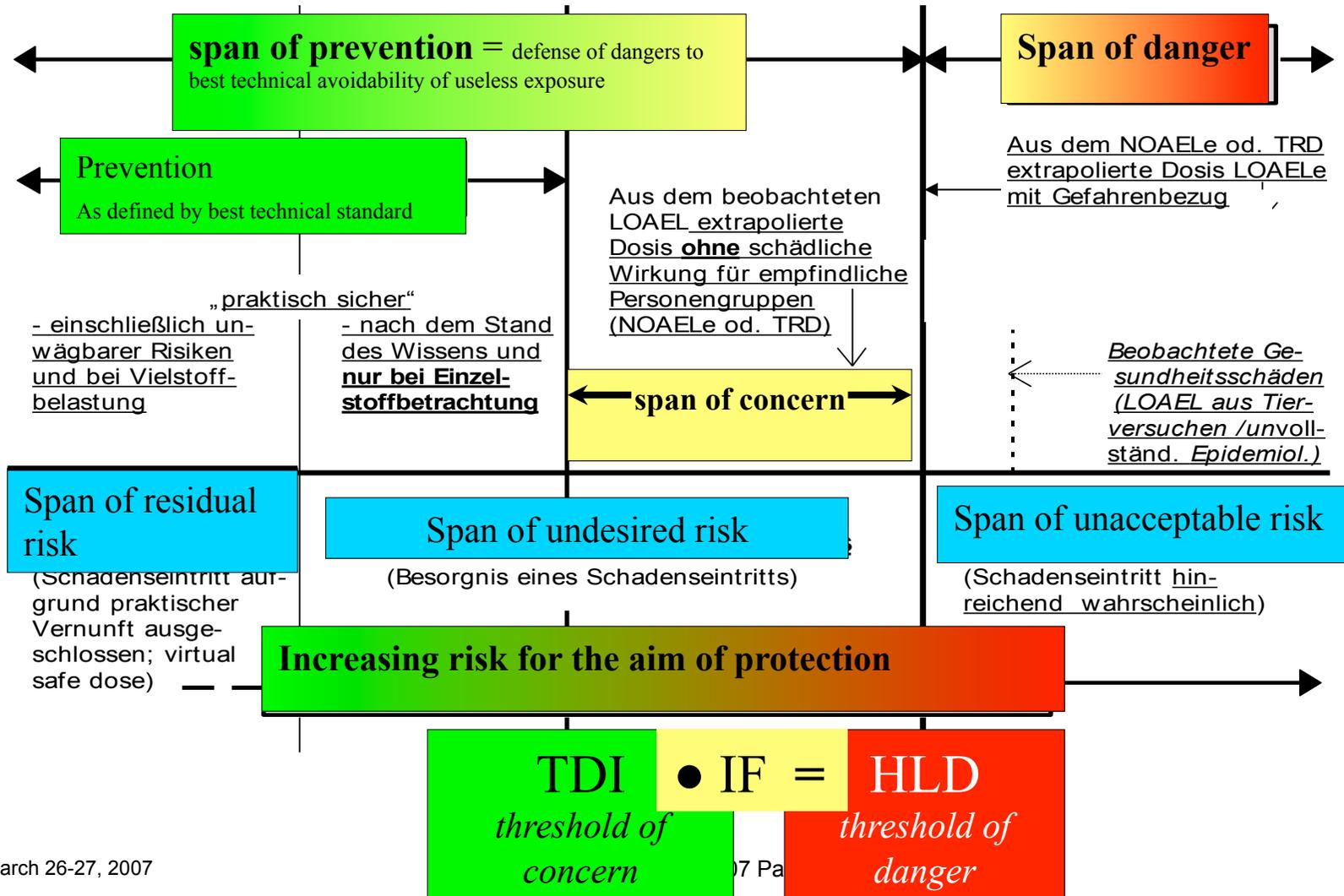
The first task was to define a link between the legal definition of a health hazard and its toxicological definition for “**threshold substances**”.

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 \equiv LOAEL_s** is the **square root** from the product of all human-relevant **extrapolation factors EF_{th}** between the PoD and the TDI.

Such a **TDI • IF = HLD** is positioned half-way between the "normal" LOAEL and the TRD.

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

$EF_b \downarrow$

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

$: EF_c (1 \text{ to } 10)$

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

$: EF_d (1 \text{ to } 10)$

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

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

HL D

• IF

TDI

span of extrapolation (safety) EF_{th}

This procedure to define a HLD ensures that the data gaps contained in a TRD do not fall heaviest on the target to be protected from a hazard.

This is shown by this table:

PoD = Database ¹⁾	Total ²⁾ Factor (TF _t) from PoD to TRD	Total Extrapolation Factor ²⁾ (EF _{th}) from PoD to TRD	IF = Interpolation Factor to give TRD • IF = HLD (threshold effects)	IF in % of EF _{th}
LOAEL _{AE}	300	100	IF = $\sqrt{100} = 10$	3.3
LOAEL _{AE}	300	300	IF = $\sqrt{300} = 17$	6
NOAEL _{AE}	100	100	IF = $\sqrt{100} = 10$	10
LOAEL _S	30	30	IF = $\sqrt{30} = 5.52$	18
NOAEL _S	10	10	IF = $\sqrt{10} = 3.2$	32
LOAEL _s or NOAEL _s	3 1	1 1	IF = EF _{th} IF = 3 <i>in absence of an EF</i>	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 a 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 = $5 \bullet 10^{-5}$

Assessment of exposure

- Soil intake by free living individuals 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" \cong 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

$$TV_t \text{ [mg/kg]} = \text{TDI [ng/kg}\cdot\text{d]} \bullet (\text{IF} - 0,8) / \text{soil uptake rate [mg/kg}\cdot\text{d]}$$

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

Trigger value TV_c

$$TV_c \text{ [mg/kg]} = (\text{DI at Risk } 10^{-5}) \text{ [ng/kg}\cdot\text{d]} \bullet 5 \bullet 8,75 / \text{soil uptake rate [mg/kg}\cdot\text{d]}$$

Some calculated (cTV) and actual (aCT) Soil Trigger Values

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