

# **Risk assessment methodology for soil contaminants in Germany**

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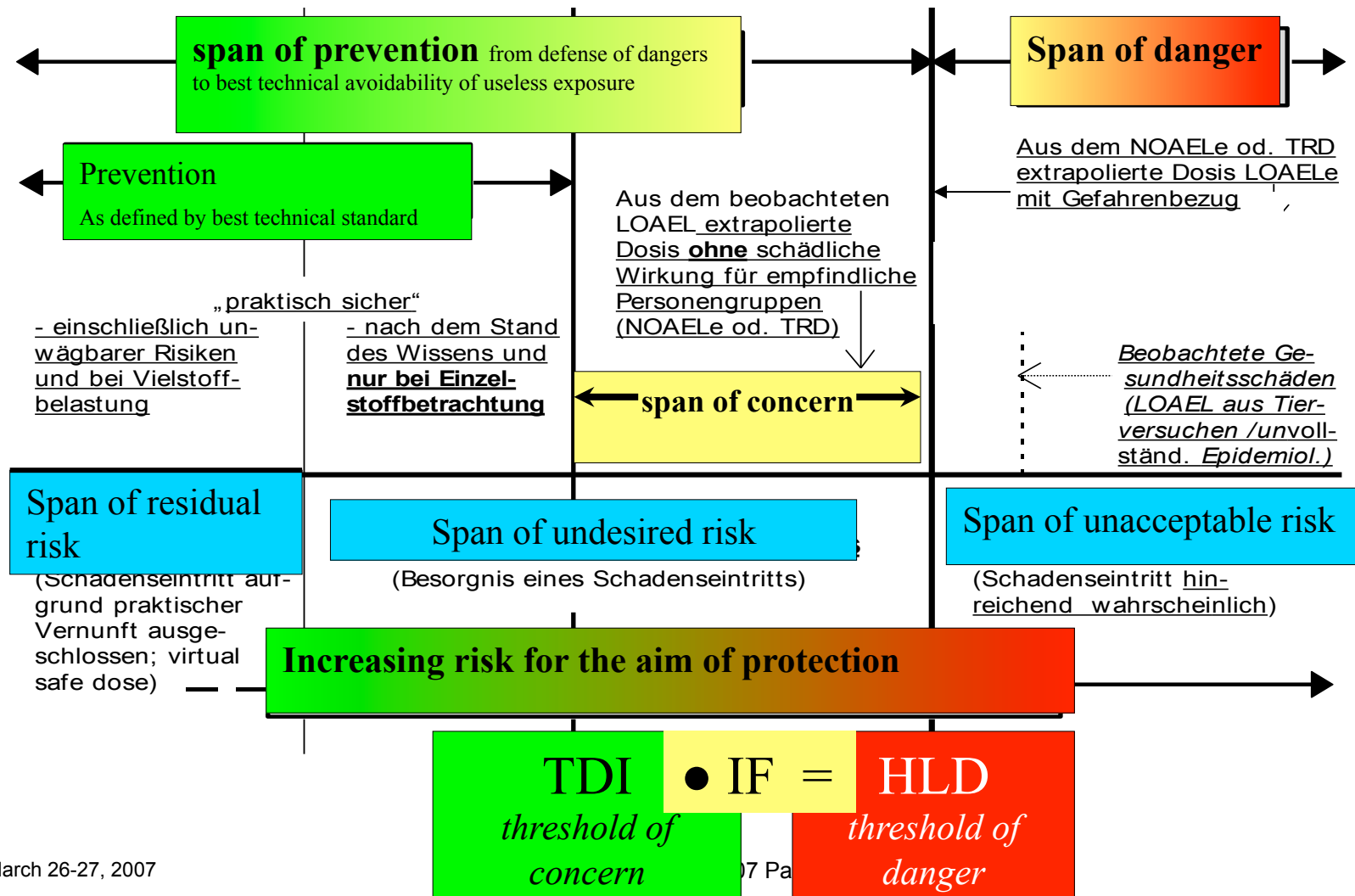
# Which concentration of a soil contaminant

might pose a threat to public health

- in a *children's play area*,
- in a *residential ar-ea*,
- 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](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 (→  $20 \mu\text{g}/70 \text{ kgBM and day}$ ).
- **Oral uptake:** risk refers to the lifelong ingestion of  $1 \text{ mg per kilogram of body mass and day}$  (→  $70 \text{ mg}/70 \text{ kgBM and day}$ ).

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

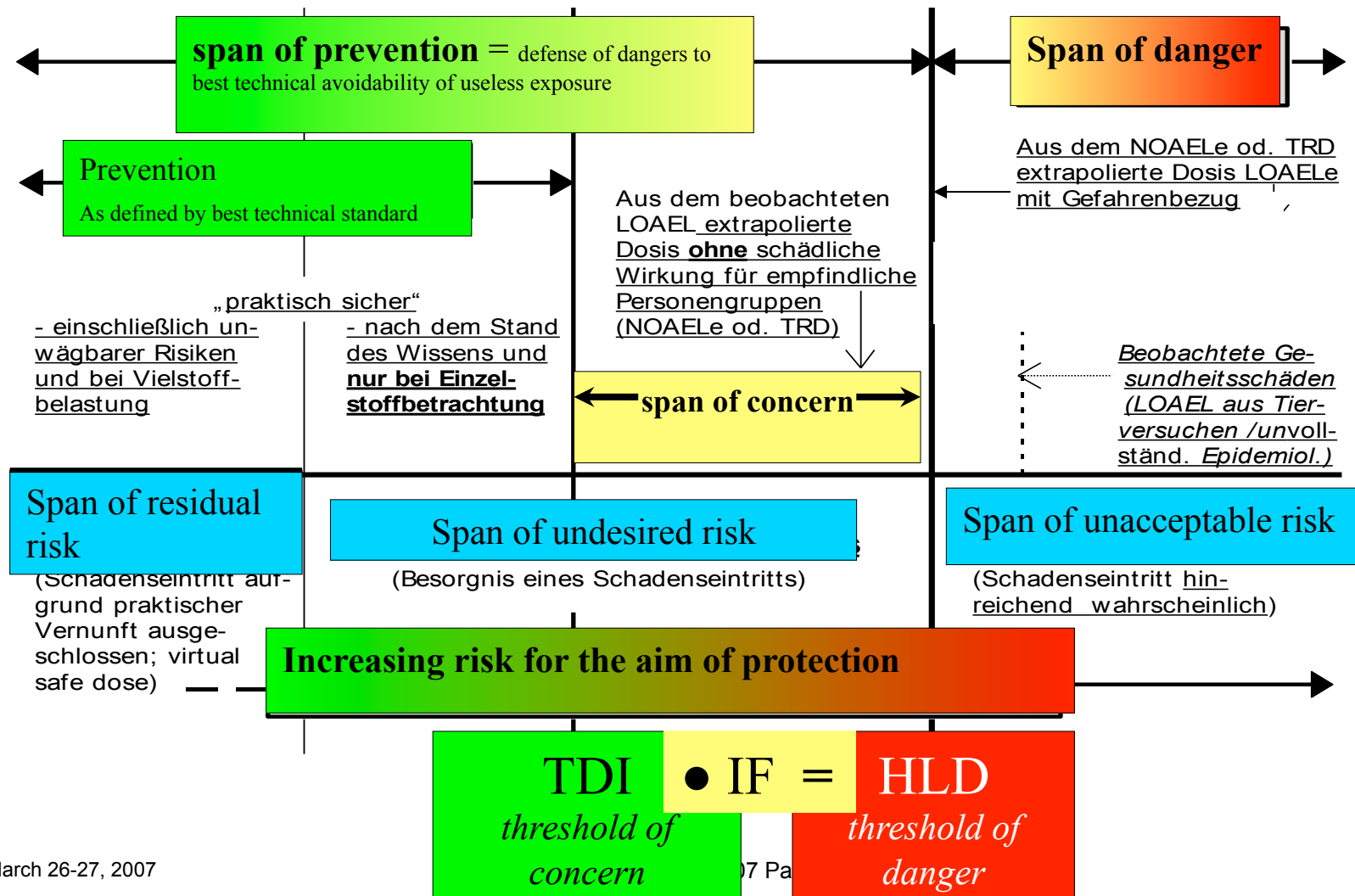
The corresponding dose was called by us “*Hazard-Linked Dose*” (HLD).

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  **$TDI \bullet IF = HLD$**  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**

HLD

• 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 <sup>1)</sup>	Total <sup>2)</sup> Factor (TF <sub>t</sub> ) from PoD to TRD	Total Extrapolation Factor <sup>2)</sup> (EF <sub>th</sub> ) from PoD to TRD	IF = Interpolation Factor to give TRD • IF = HLD (threshold effects)	IF in % of EF <sub>th</sub>
LOAEL <sub>AE</sub>	300	100	IF = $\sqrt{100} = 10$	3.3
LOAEL <sub>AE</sub>	300	300	IF = $\sqrt{300} = 17$	6
NOAEL <sub>AE</sub>	100	100	IF = $\sqrt{100} = 10$	10
LOAEL <sub>S</sub>	30	30	IF = $\sqrt{30} = 5.52$	18
NOAEL <sub>S</sub>	10	10	IF = $\sqrt{10} = 3.2$	32
LOAEL <sub>s</sub> or NOAEL <sub>s</sub>	3 1	1 1	IF = EF <sub>th</sub> 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<sub>t</sub>, in contrast to the EF<sub>th</sub>, 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"  $\hat{=}$  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**

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\*) 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