Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

DNEL OEL DNEL OEL Assessment Factors Case-by-Case Protection Level DNEL OEL Assessment Factors DNEL Species Intraspecies Duration Adjustment Data Gaps Safety Data Sheet DNEL OEL Sensitive Workers DNEL OEL DNEL Assessment Factors Case-by-Case

Purpose and scope of presentation

How to derive
DNELs and OELs?

A
Comparison
Of
Health-
Related
Aspects

Safety **D**ata **S**heet

8.1 Exposure Limits

DNEL (inhalation)
OEL (inhalation)

DNEL (dermal)
Skin Notation

Private DNELs and official OELs

Private DNELs

Thousands
of substances
> 10 t/a

Selective
quality check
by Agency

Official OELs

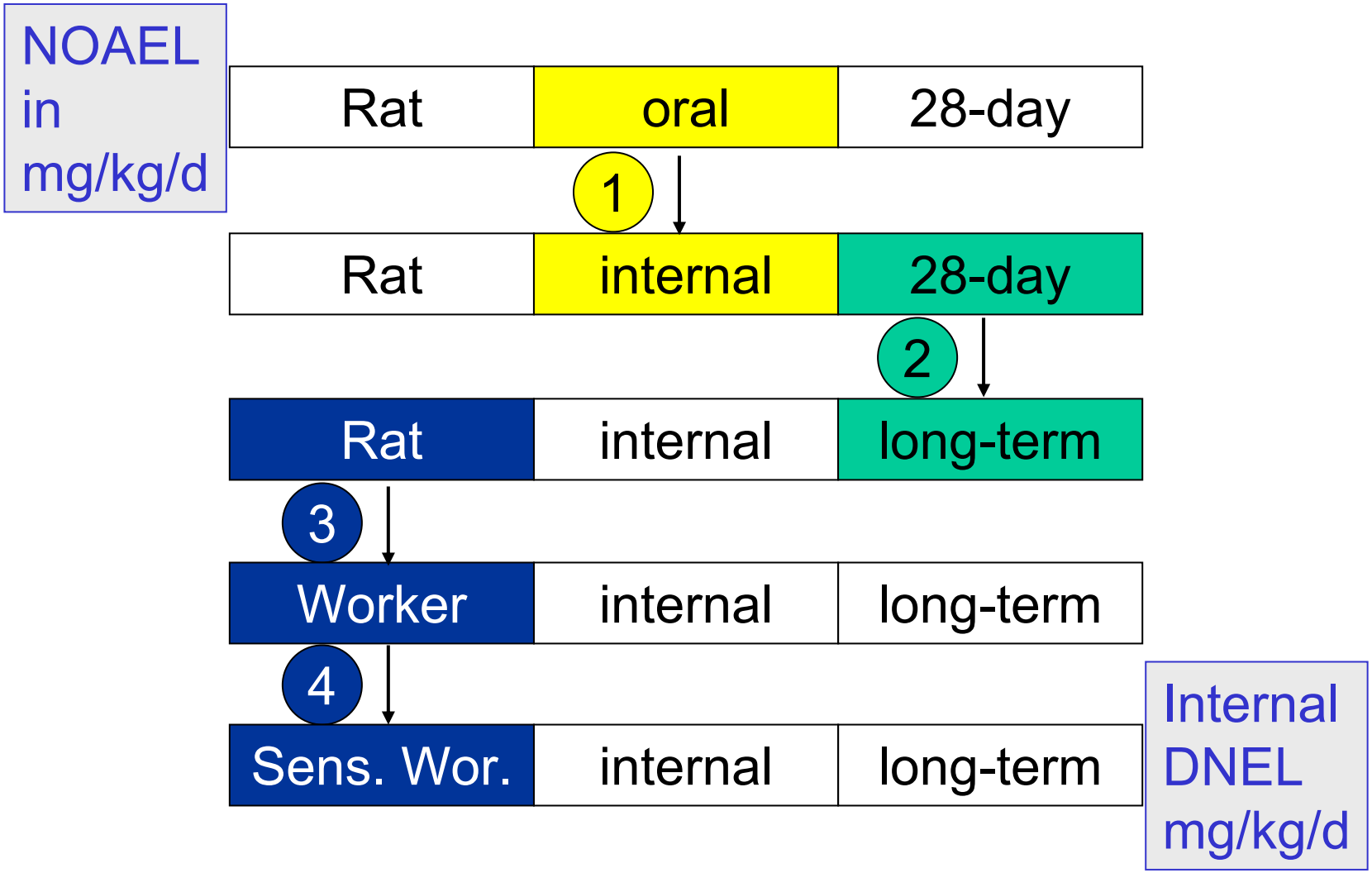
Hundreds
of economically
important
substances

Quality check
by scientific
committee(s)

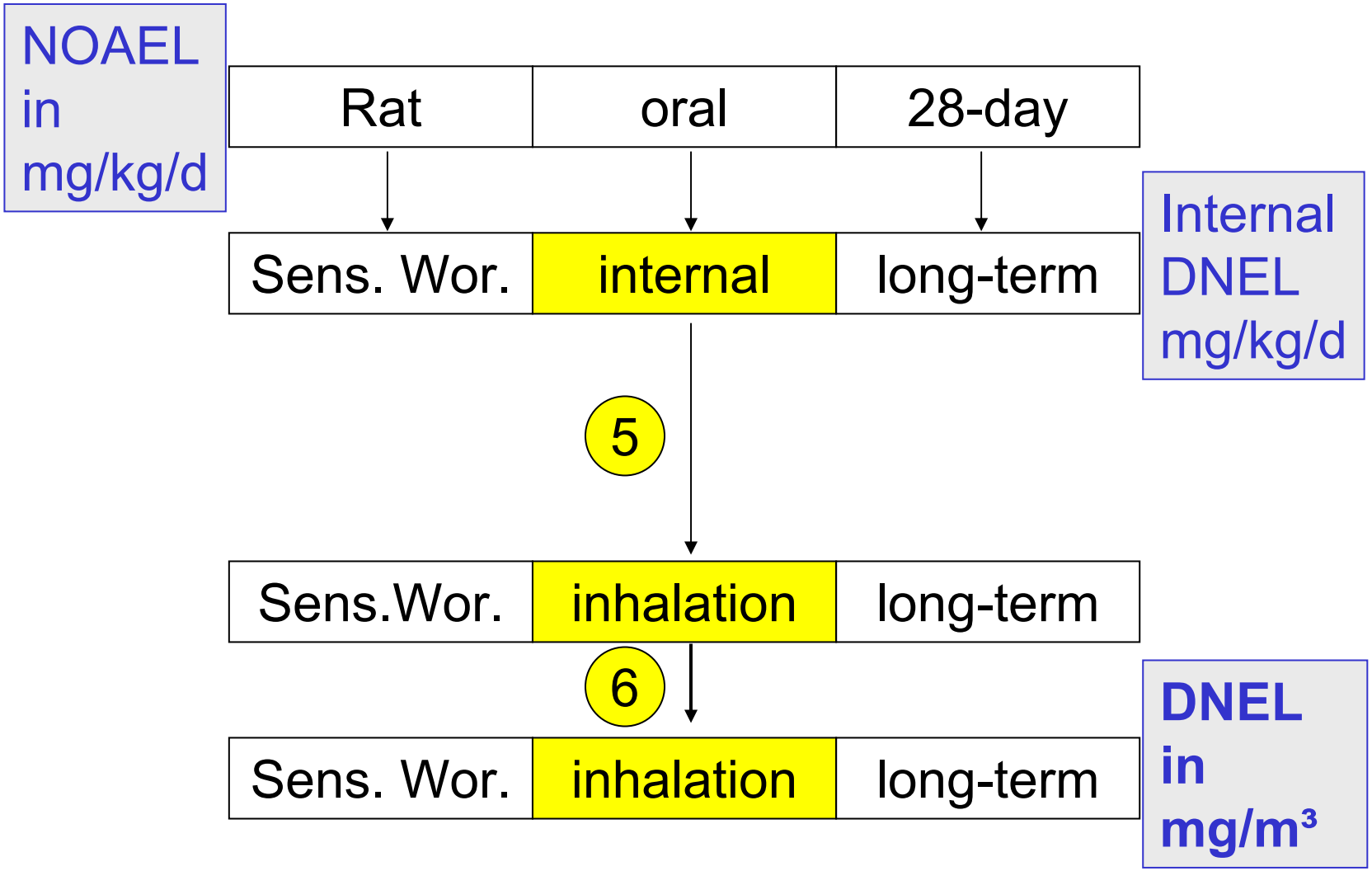
A common
health-related
objective**!**

Different values **?**

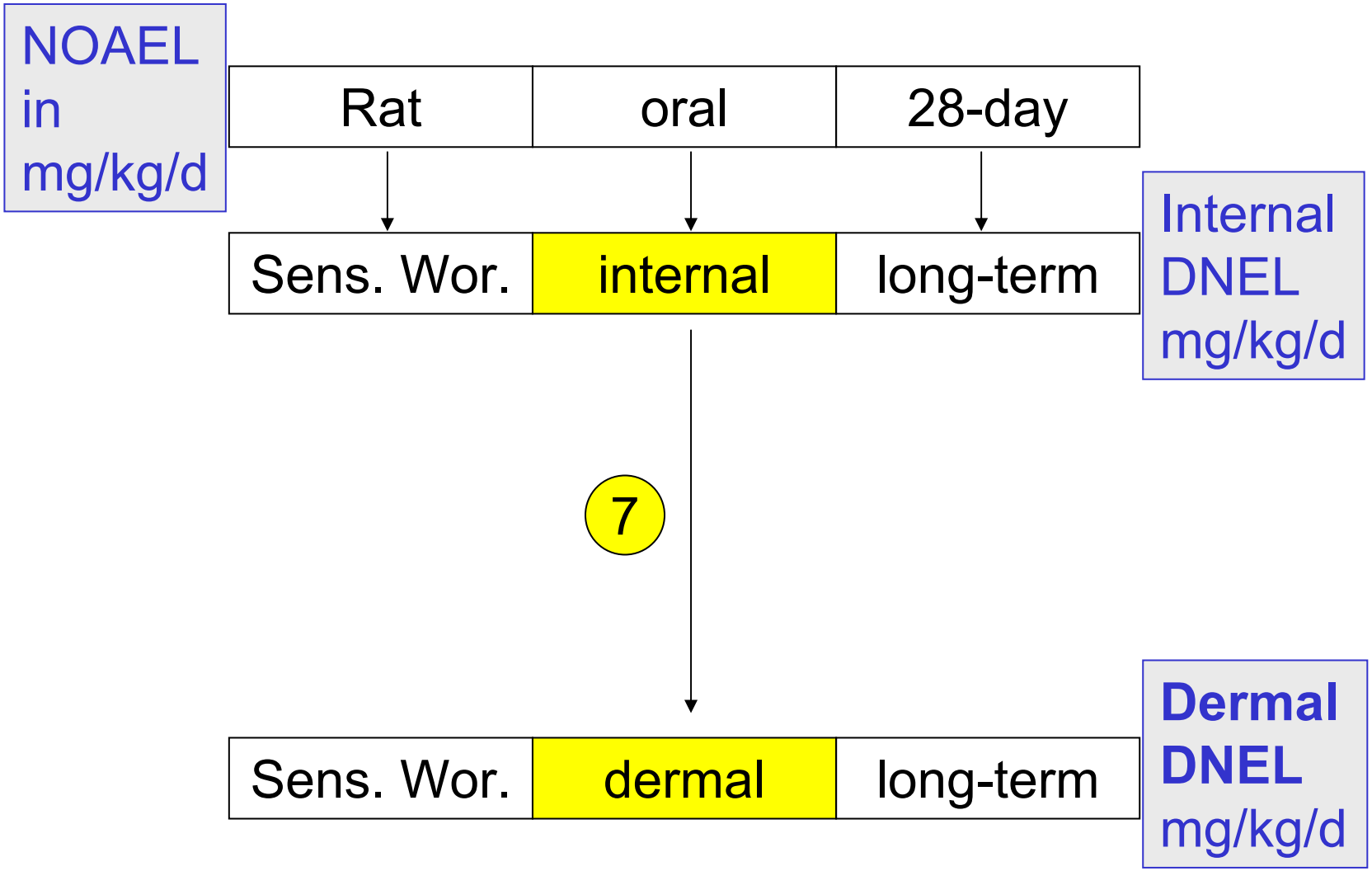
How to derive a DNEL (oral -> internal)



How to derive a DNEL (internal -> inhalation)

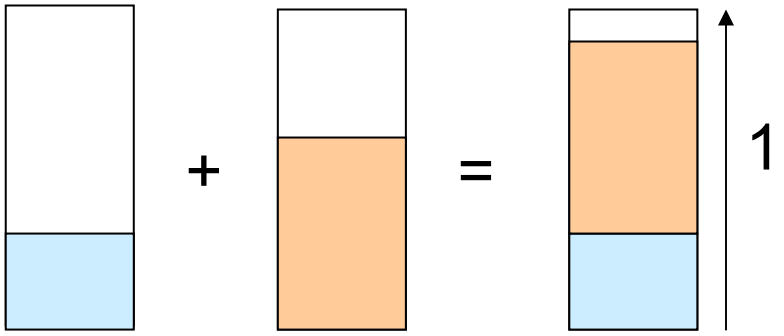


How to derive a DNEL (internal -> dermal)



DNEL-based risk characterisation

$$\frac{\text{Exposure by Inhalation}}{\text{DNEL (inhalation)}} + \frac{\text{Dermal Exposure}}{\text{DNEL (dermal)}} = \textbf{RCR} \text{ (combined exposure)}$$



Risk is adequately controlled if RCR is less than “1”

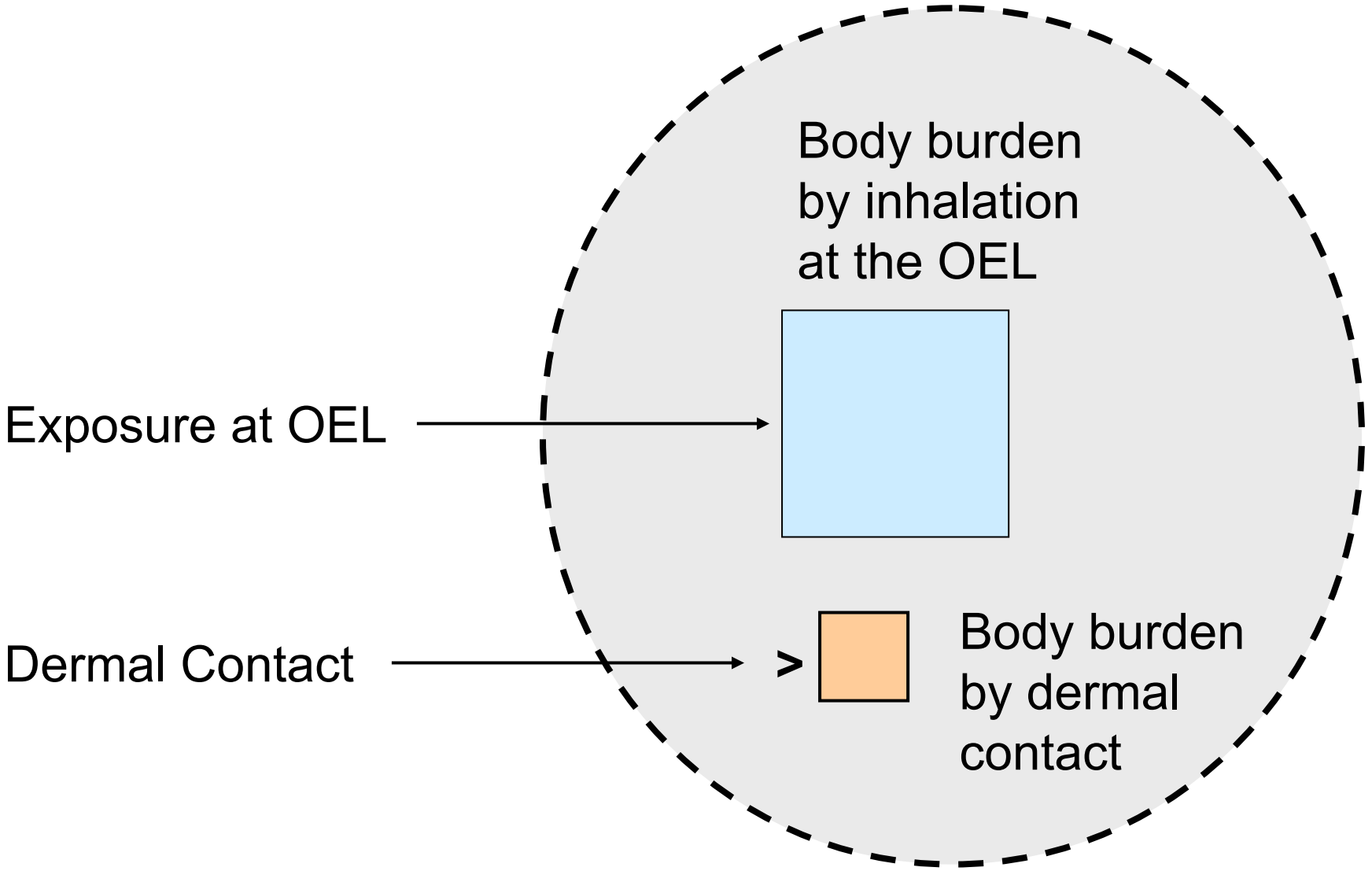
OEL methodology

..... **c**onsidering all relevant scientific aspects when translating available data to an OEL

~~Default Assessment Factors~~

Overall uncertainty factor on a case-by-case basis

Skin notation



OEL-based risk characterisation

$$\frac{\text{Exposure by Inhalation}}{\text{DNEL (inhalation)}} + \frac{\text{Dermal Exposure}}{\text{DNEL (dermal)}} = \textbf{RCR (combined exposure)}$$

Identical to DNEL

Concept of skin notation

Semi-quantitative risk characterisaton

Impact of data gaps

DNELs and OELs
for substances
with limited data
by no means
are purely
substance-specific.

That is
the chief cause
for differences!

Substance-specific
NOAEL or BMD

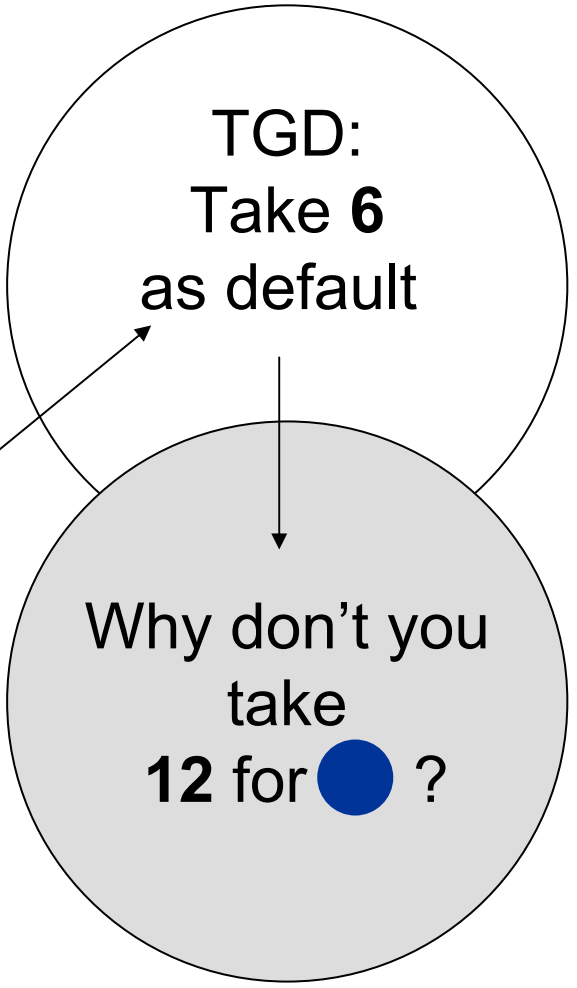
From other chemicals:
Duration factor **?**
Species extrapolation **?**
Intraspecies extrapolation **?**

How to bridge a specific data gap?

Only subacute NOAEL
No chronic data
Dose ratio subacute / chronic ?
Duration factor to be used?

Empirical distribution for many dose ratios subacute /chronic:

25%	: ~ 3
Median	: ~ 4
75%	: ~ 7
95%	: ~12



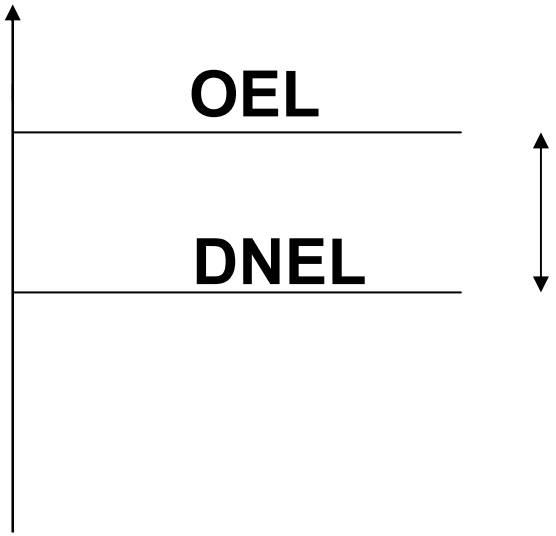
Key aspects for DNELs and OELs

The common health-related objective is to protect susceptible workers.

Data gaps may be bridged differently.

Bridging data gaps is a decision on the protection level aimed at.

Final note



We should avoid inconsistent statements .....

the end

Annex

Try to calculate the DNELs!

Rat oral subacute
NOAEL 100 mg/kg/d

1. Absorption (oral): here 80%
2. Duration Factor of 6
3. Interspecies of 4 x 2.5
4. Intraspecies Factor of 5
5. Absorption (inh): here 100%
6. Dose Unit: 70 kg, 10m³
7. Dermal absorption: here 10%

Dermal
DNEL
~ 3 mg/kg/d

DNEL
~ 2 mg/m³