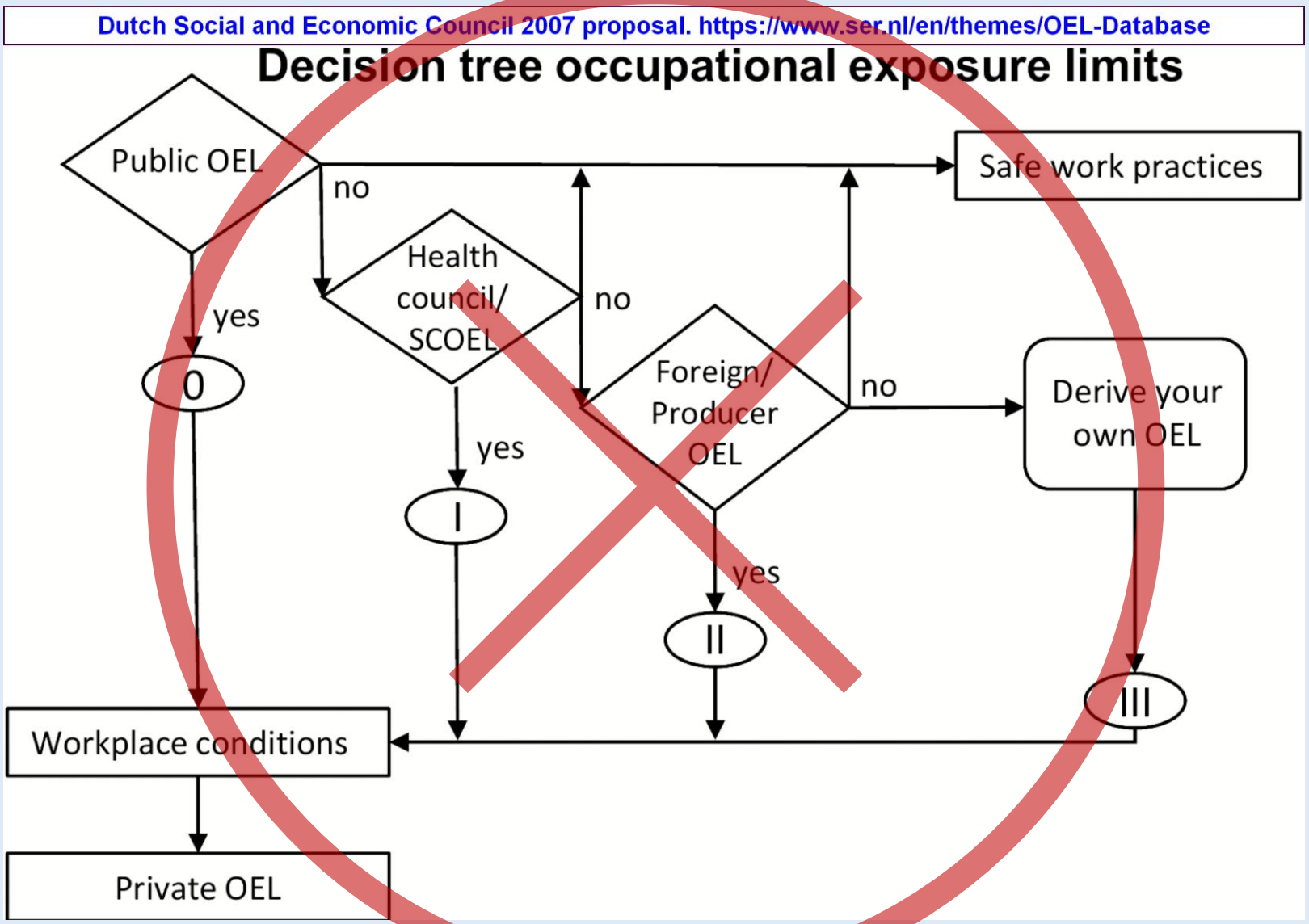
(NVvA/SER) Richtlijn Grenswaarden

Hulp bij het vinden èn afleiden van private waarden

Theo Scheffers

250409 sessie-K 14:05 uur

SER afloopschema 2007



Landschap werkplek grenswaarden

Grenswaarden voor:

- Naleving NL/EU Arbo regels 

- Gezondheidsbewaking/Letselschade, beroepsziekte

- Productveiligheid in de commerciële keten: sinds 2008 REACH DN/MEL

Naleving ≠ gezondheidskundig

- Tin verbindingen
- Isocyanaten
- PAK's van koolteer
- Koolwaterstofmengsels
- Olienevel
  - Wettelijk : 5 mg/m^3 (StC 2022, nr. 32933)
  - SCOEL 2011 : 5 mg/m^3
  - Gr 2011 : 1.6 mg/m^3
  - Gr 2011 : 0.1 mg/m^3 In metaalbewerkingsvloeistoffen
- Soja
- Kwarts
- Ethanol

Peiling (groen ja, rood nee)

Een NVvA grenswaarden leidraad adviseert de blootstellingsbeoordelaar (EN689) zich te richten op:

1. de naleving
2. de gezondheid
3. Beide,
   En bij verschillen:
   - Kiezen voor de laagste
   - de werkgever de verschillen duiden
   - Anders nl…….

Freeware voor Arbo-naleving

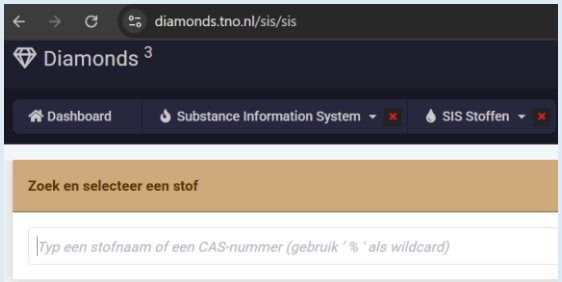
https://wetten.overheid.nl/BWBR0008587/2025-02-01#BijlageXIII

Bijlage XIII behorend bij de artikelen 4.19, eerste lid, en 4.20, eerste lid

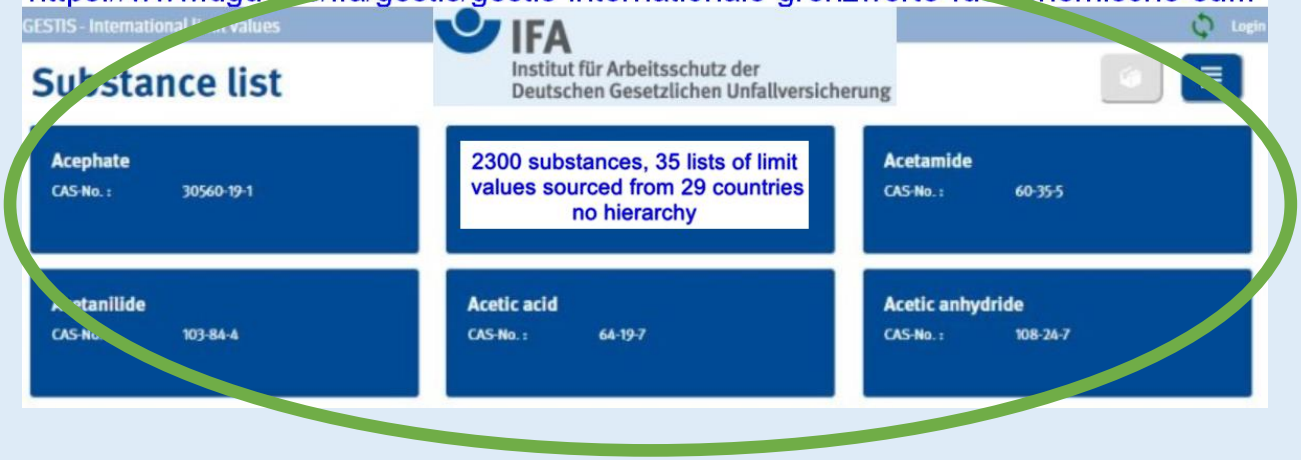
Lijst wettelijke grenswaarden

TRGS 900

Risikobezogenes Maßnahmenkonzept für Tätigkeiten mit krebserzeugenden Gefahrstoffen	TRGS 910



https://www.dguv.de/ifa/gestis/gestis-internationale-grenzwerte-fuer-chemische-su...



Peiling: bron voor de naleving

- Wie gebruikt de SER?
- Wie gebruikt Gestis ?

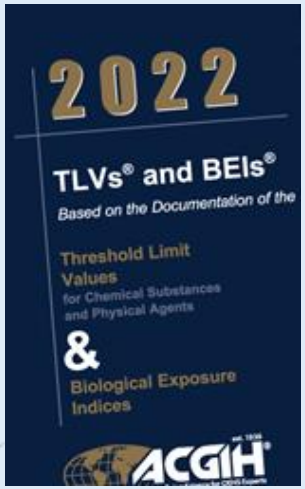
Groen is Ja

Gezondheidskundige bronnen

ECHA RAC
EUROPEAN CHEMICALS AGENCY
Committee for Risk Assessment

NEG THE NORDIC EXPERT GROUP

inrs



National Institute for Occupational Safety and Health
NIOSH

OARS WEEL

Peiling

- Wie raadpleegt de gezondheidskundige bronnen?

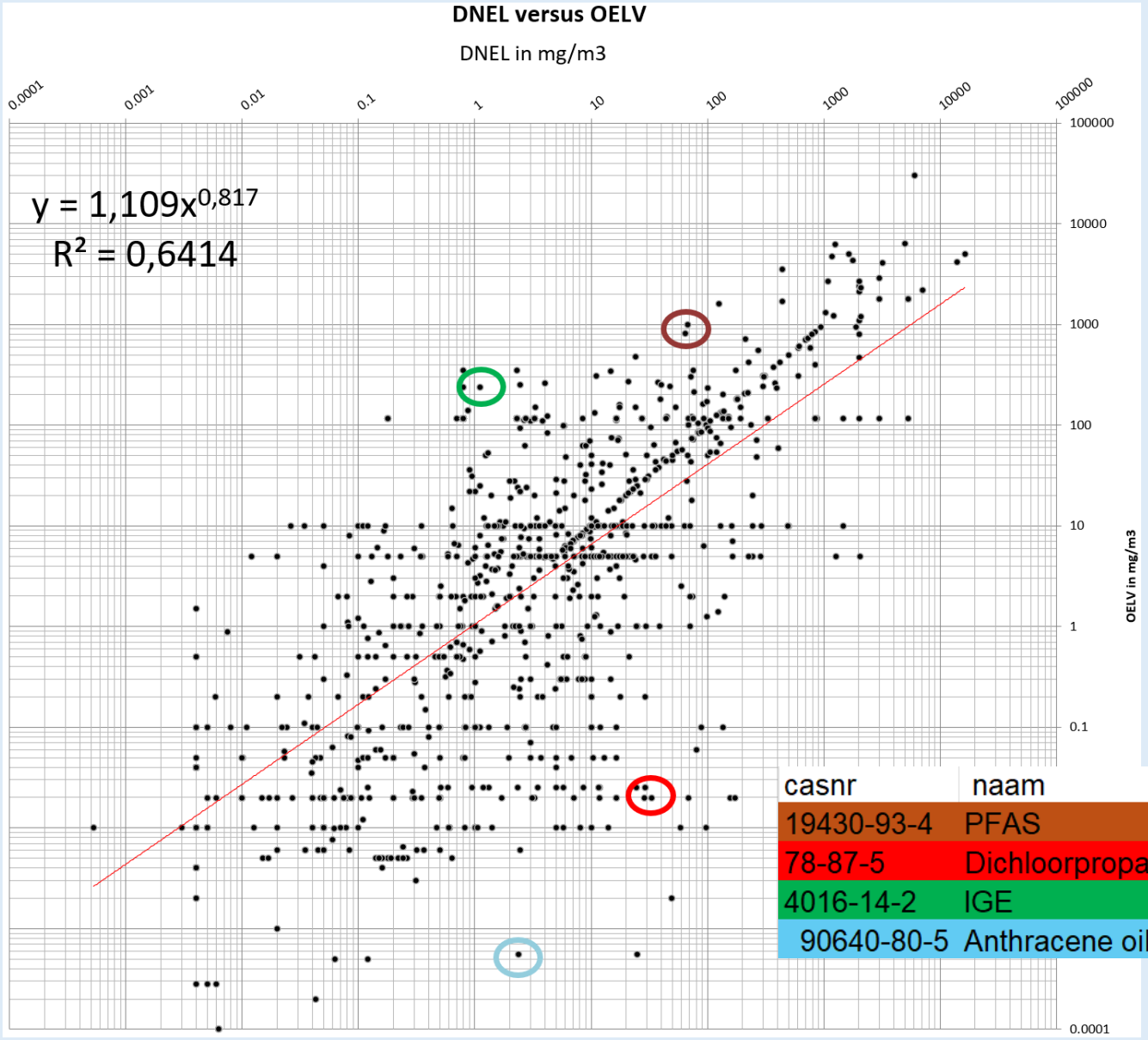
Groen is Ja

Peiling DNEL gebruik in Arbo

- Nooit
- Alleen bij het ontbreken van de OELV (~4500)
- Indien de DNEL lager is dan de OELV
- Altijd de DNEL ook als ie hoger is

Groen is Ja

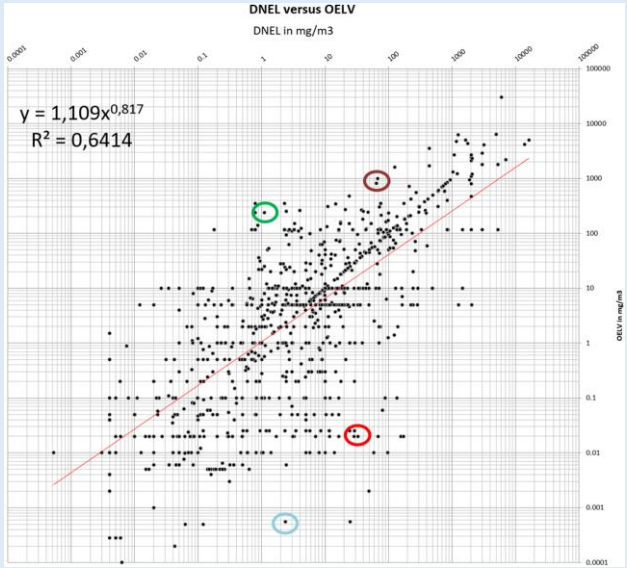
Hoogst hiërarchische OELV & Laagst numerieke DNEL



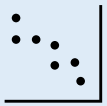
casnr	naam	DNEL	OELV	bron_OELV
19430-93-4	PFAS	67.4	1000	ACGIH
78-87-5	Dichloorpropaan	28.88	0.028	ECHA-RAC
4016-14-2	IGE	1.1	240	ACGIH
90640-80-5	Anthracene oil	2.39	0.00055	nl-wet

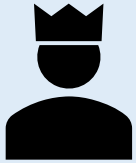
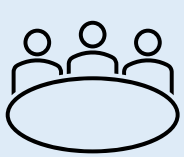
OELV(Arbo) ≠ Productveiligheid (REACH)

- Lage OELV<< lage DNELs
- DNEL poeders ≠ max 10 mg/m^3
- Chromaten (OELV als Cr, DNEL hele molecuul)
- Sensibilisatie via de ademlucht
  vaak niet in de DNEL
- Zo'n 10% DNEL=OELV (~DFG)



Hierarchie opties

- Naleving
  - Status
  - Buitenland
    - laag→ hoog  , hoog → laag 
    - Nabijheid
- Gezondheidkundig
  - Kwaliteit
  - Leeftijd



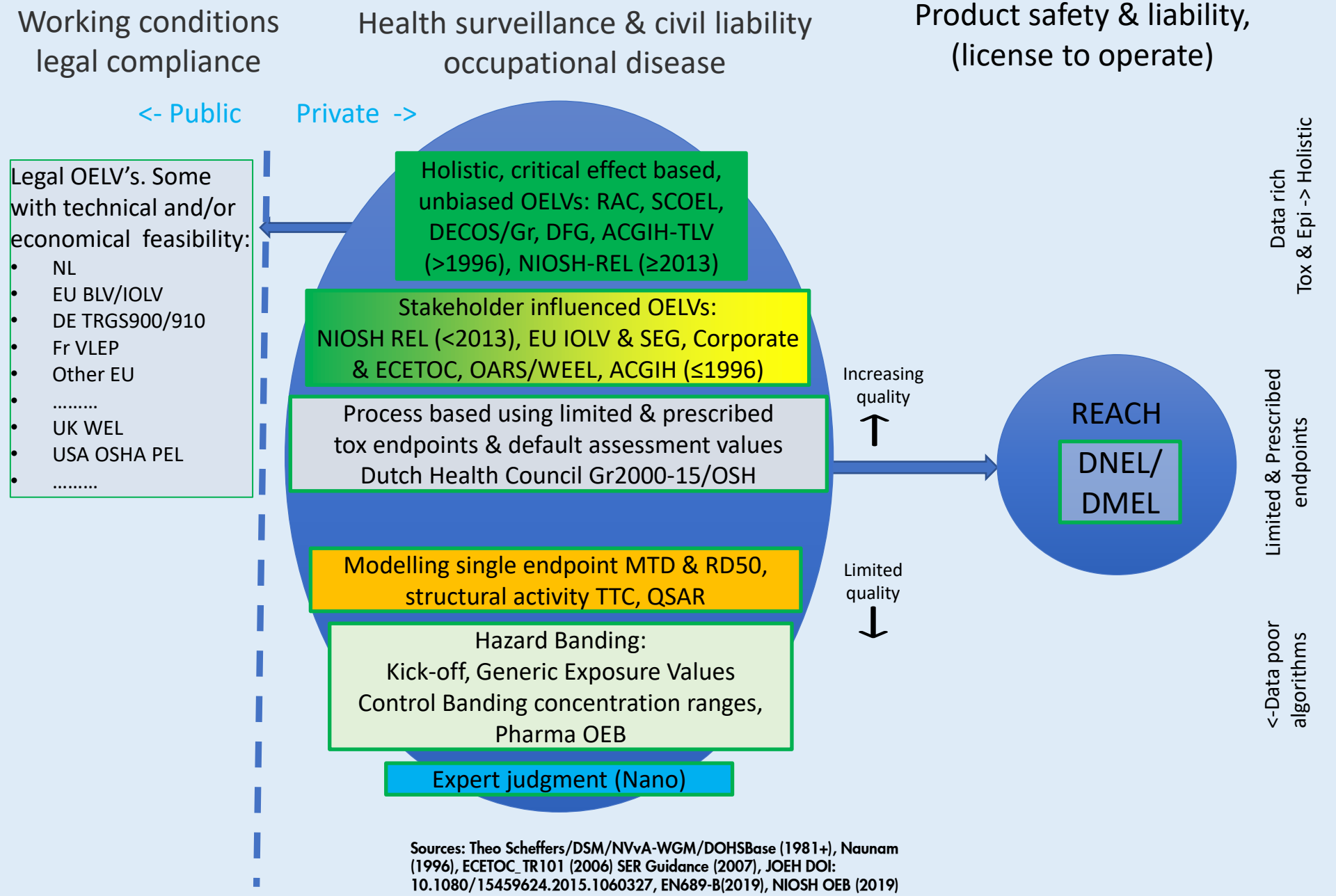

holistisch, Gr, RAC

Tox +AF fragmentic, DNEL

data poor Kickoff

vóór of ná 1996

Occupational/Workplace Exposure Limit Value landscape



Sources: Theo Scheffers/DSM/NVvA-WGM/DOHSBase (1981+), Naunam (1996), ECETOC_TR101 (2006) SER Guidance (2007), JOEH DOI: 10.1080/15459624.2015.1060327, EN689-B(2019), NIOSH OEB (2019)

Stoffen op EU werkplekken

stoffen	kenmerk	aantal	opmerking
casnr	wereldwijd	~270 miljoen	+15000/uur
EU gefabriceerd/ geimporteerd	classificaties	205000	
REACH uitgezonderd/ natuurlijke stoffen	in DOHSBase	1000	

Uitpakken/Degrouping

Minerale olien/Olienevel

- StC 2022, nr. 32933: 5 mg/m^3
- SCOEL 2011 : 5 mg/m^3
- Gr 2011 : 1.6 mg/m^3
- 39 metaalbewerkingsvloeistoffen: 0.1 mg/m^3

Metalen als groepsgrenswaarde

- 892 Chroom VI
- 94 Hg verbindingen: SCOEL BM Hg urine/blood
- 957 Nikkelverbindingen

Isocyanaten

- 3871 als NCO (UK)
- 1561 di/tri-isocyanaten
- 30 RAC di-isocyanaten
- 336 OPS geassicieerde C_{6-12} koolwaterstoffen/mengsels

900 Formaldehyde uitscheiders (polymeren)

90 Fluoride-verbindingen: EU/BLV BM F^- urine

private OELV's in numbers

Health Based (HB)	~1000
Stakeholder influenced HB	~ 2000
unfold group HB to EC#/(pseudo)CAS#	~11000
Read-across on HB OELV	~350
DN/MEL L-t/S-t (~1100 existing OELV)	~4500
modelling substitutes of HB OELV	0
GEV, OEB & H3## Kick-off	80000+
No-data expert judgement	nano

~100,000 substances with a limit value

Data rich (Tox & Epidemiology) -> Holistic

Selected data-> administrative

<-Data poor algorithms

Version 221105

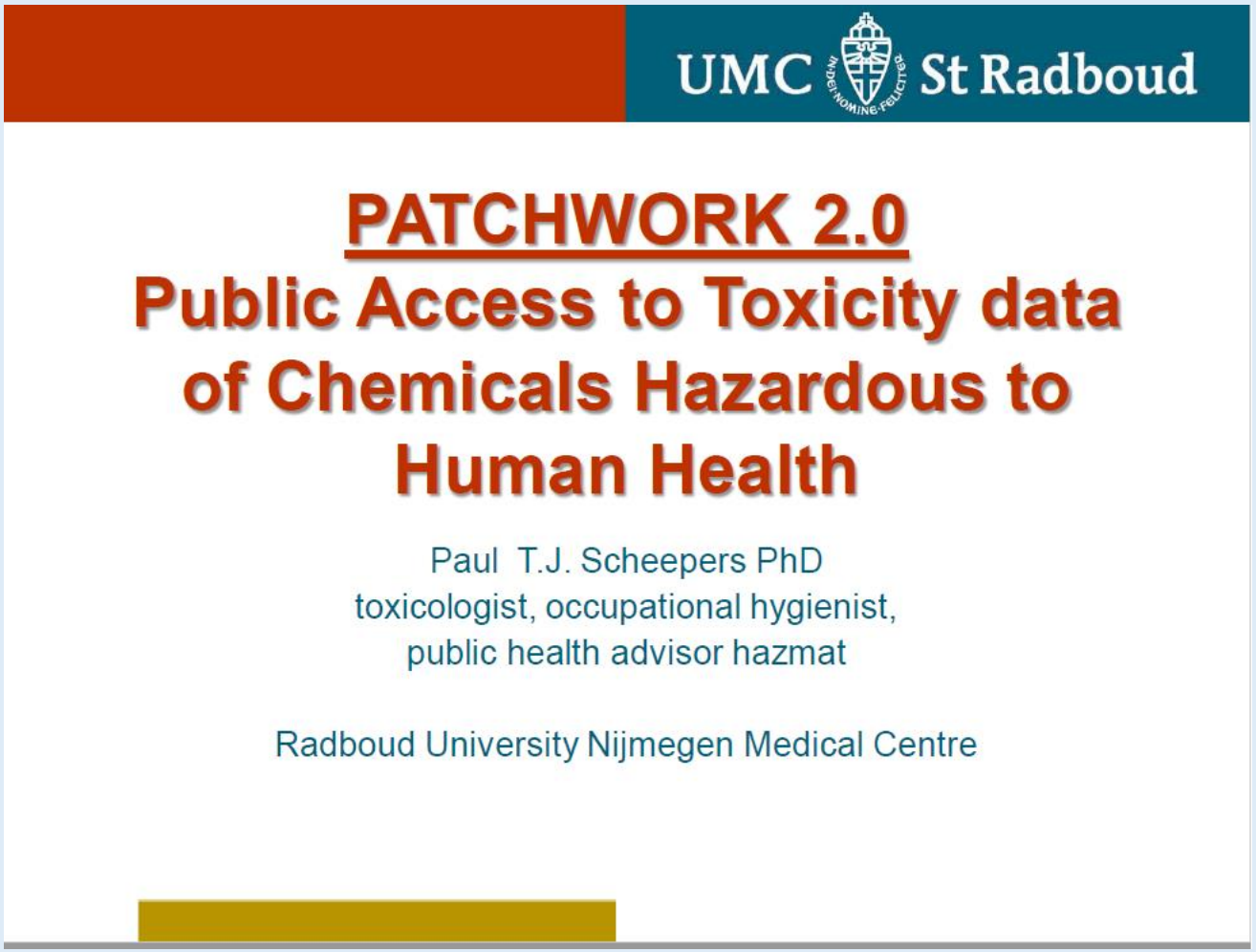
Peiling: Een NVvA leidraad grenswaarden vinden

- Moet kunnen en heeft toegevoegde waarde
- Zelfstandig als NVvA als kwaliteitsvereniging

Zelf grenswaarde afleiden?

- ~115.000 EU stoffen zonder grenswaarden
- Laagdrempelige richtlijn
  - Wat bestaat er al?

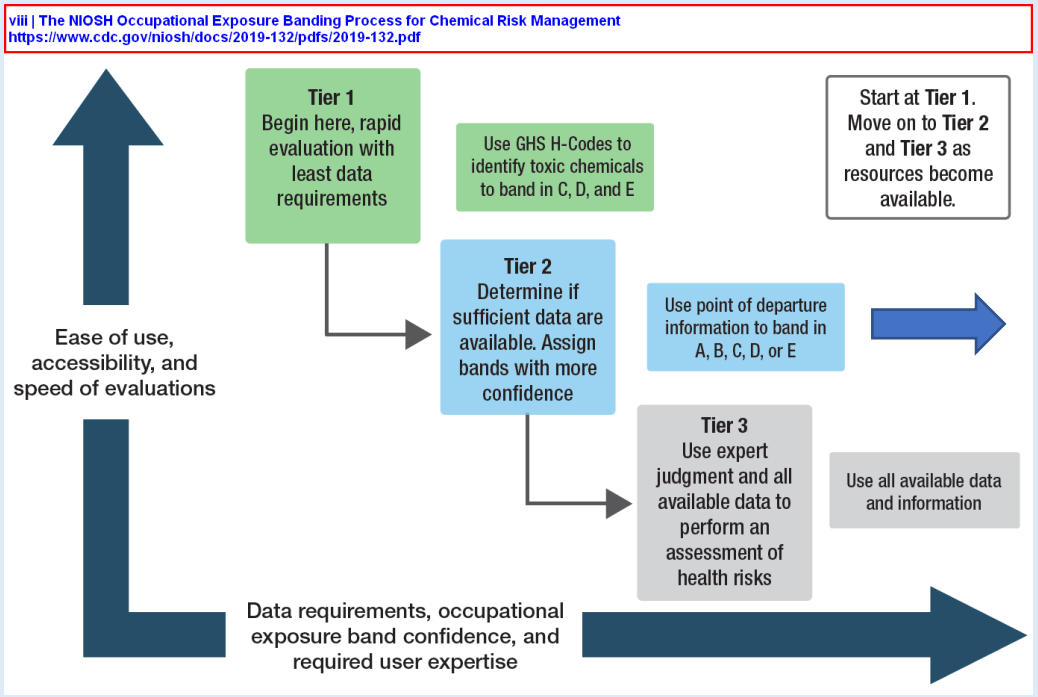
Expert aanpak



Laagdrempelige aanpak

NIOSH OEB (TR 2019-132)

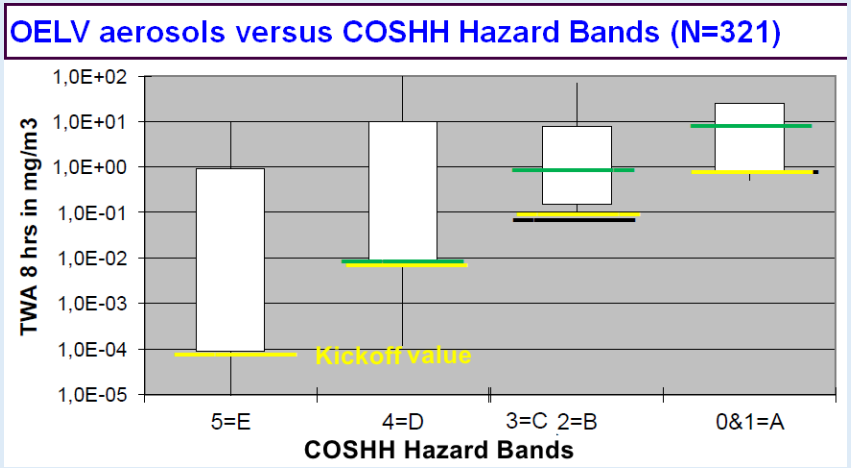
- Tier 1: Hazard Banding, data poor
- Tier 2: HB + Toxicology (DNEL-like)
- Tier 3 : Holistic, data rich

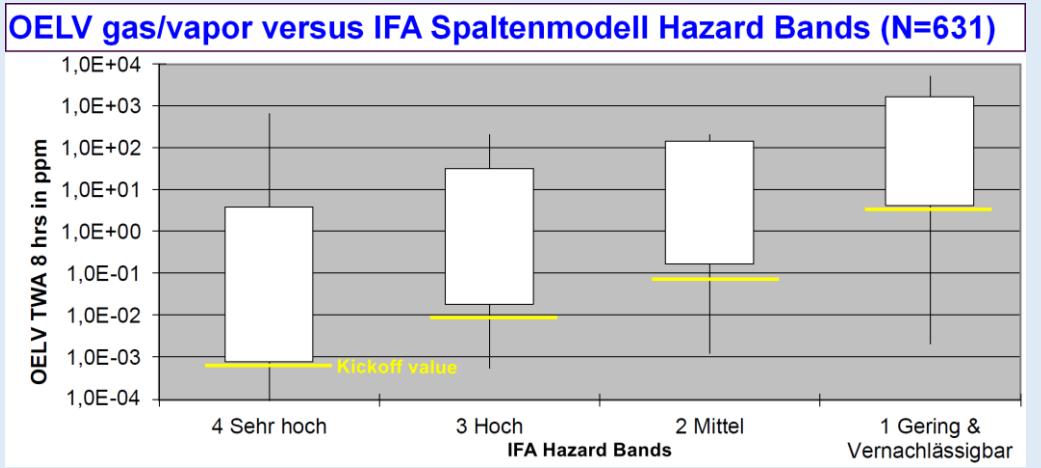


(1) carcinogenicity; (2) reproductive toxicity; (3) specific target organ toxicity; (4) genotoxicity; (5) respiratory sensitization; (6) skin sensitization; (7) acute toxicity; (8) skin corrosion and irritation; and (9) eye damage/irritation

Deduce private limit values

Tier 1: GHS H-3## based Kickoff DOHSBase (2014)





Kick-off values for dust/aerosols
(base: COSHH Essentials)

Hazard Band	5=E	4=D	3=C 2=B*	0&1=A
H-statements	H334, H340, H341, H350, H350i	H300, H310, H330, H351, H360 (F/D/FD/Fd/Df), H361 (f/d/fd), H362, H372	H301, H302, H311, H312, H314, H317, H318, H331, H332, H335, H370, H371, H373, EUH071	H303, H304, H305, H313, H315, H316, H319, H320, H333, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Dusts (mg/m^3)	**0,0001**	**0,01**	**0,1**	**1**

*: COSHH Essential Groups B+C combined

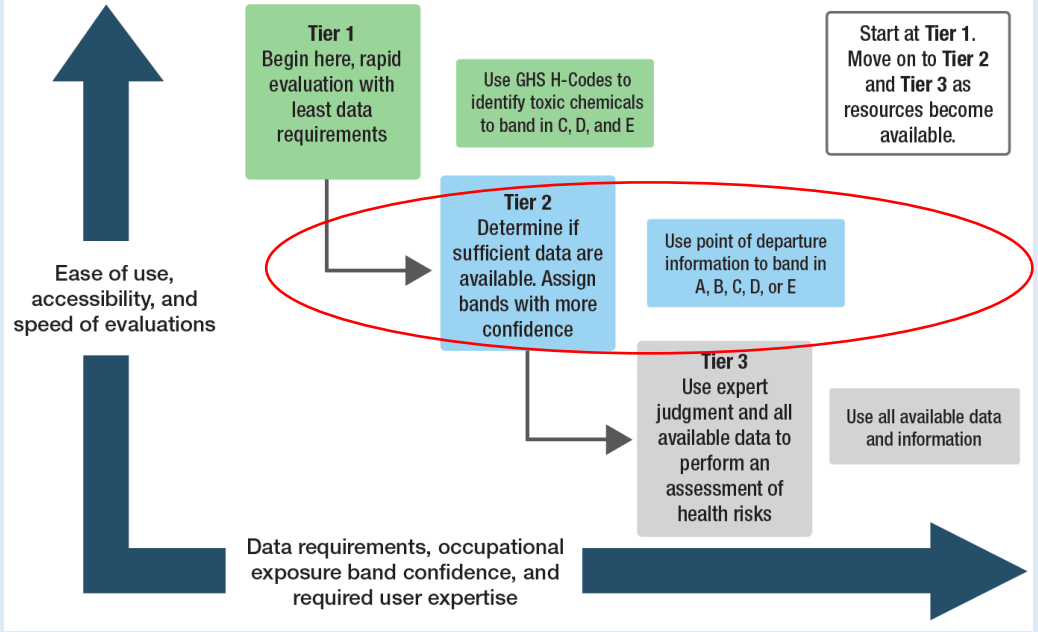
Kick-off values for gases/vapors
(base: DGUV IFA Spaltenmodell)

Hazard Band	4	3	2	1
H-statements	H300, H310, H330, H340, H350, H350i, EUH032	H301, H311, H317, H318, H331, H334, H341, H351, H360 (F/D/FD/Fd/Df), H370, H372, EUH029, EUH031, EUH070	H302, H312, H314, H332, H361 (f/d/fd), H362, H371, H373, EUH071	H304, H315, H319, H335, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Gases/vapors (ppm)	**0,001**	**0,01**	**0,1**	**5**

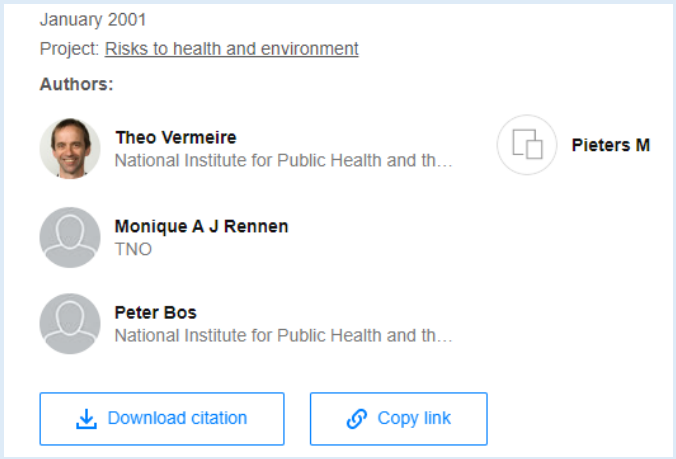
DNEL-like OELV

- Tier 1: Kickoff DOHSBase (2005/2014)
- Tier 2: Tox+Assessment-Factors
- Tier 3: Holistic

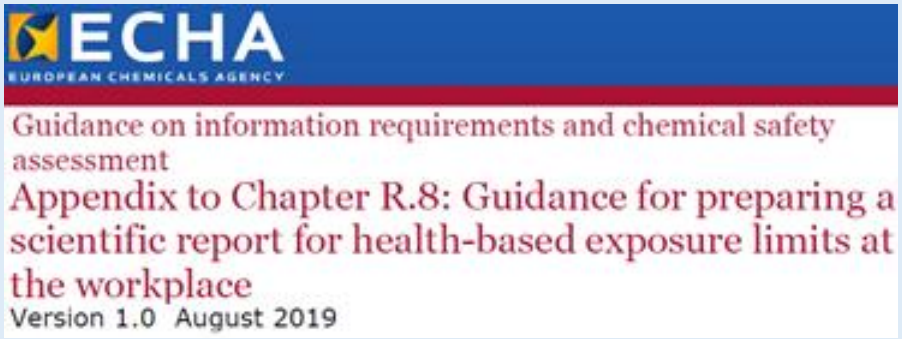
viii | The NIOSH Occupational Exposure Banding Process for Chemical Risk Management
https://www.cdc.gov/niosh/docs/2019-132/pdfs/2019-132.pdf



Assessment factors based OELV

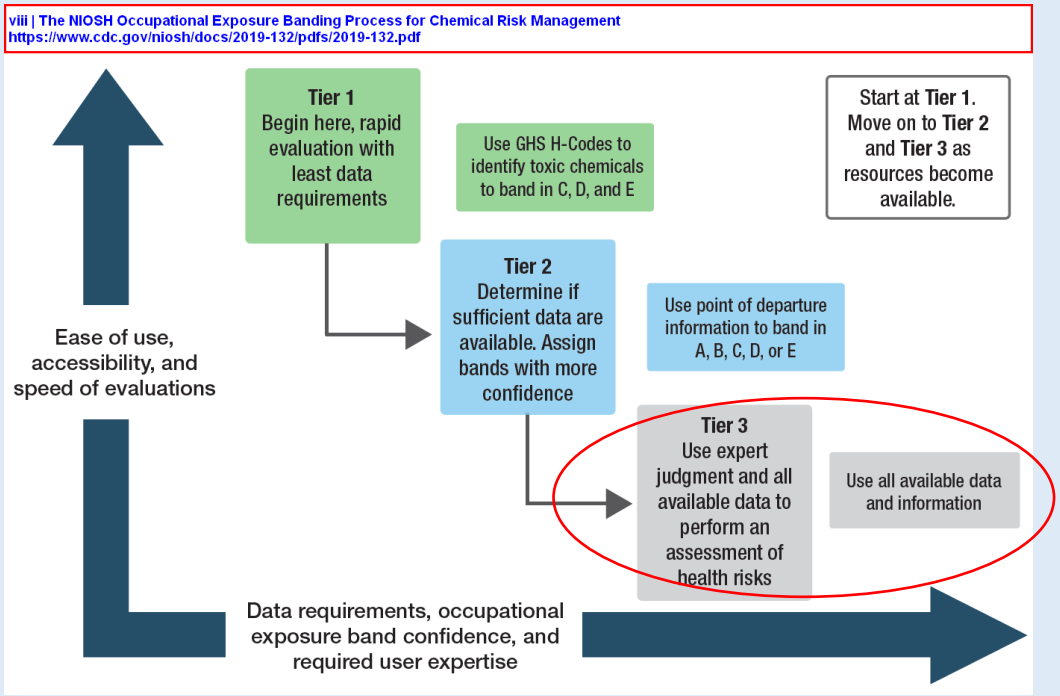


$$OELV_A = N(L)OAEL/C_{corr} / AF_1 \times AF_2 \times \ldots \times AF_n$$



Guidance deducing private OELV

- Tier 1: “Kickoff”, data poor
- Tier 2: Tox + AF, DNEL-like
- Tier 3 : “Holistic”, data rich



Holistic

Including Occupational Epidemiology/Health surveillance etc.

https://www.healthcouncil.nl/documents/other/2021/12/21/guidance-for-recommending-classifications-and-health-based-occupational-exposure-limits

Afleiden private grenswaarde NL

Richtlijn

Tier 3. Holistisch

Tier 2. Tox +AF

Tier 1. Hazard Banding

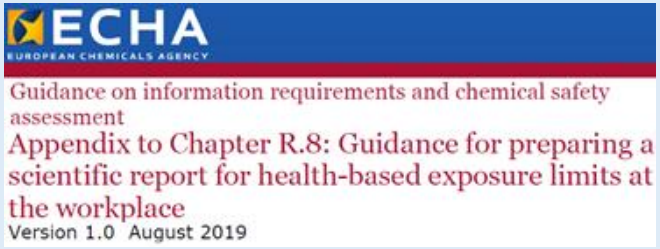
Geen (passende) grenswaarde

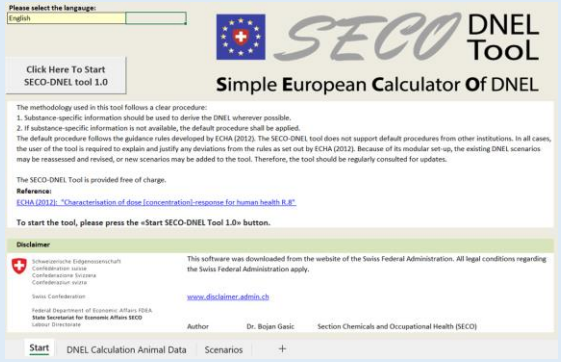
Doc

Doc

Instrument

Instrument





Kick-off values for gases/vapors
(base: DGUV IFA Spaltenmodell)

Hazard Band	4	3	2	1
H-statements	H300, H310, H330, H340, H350, H350i, EUH032	H301, H311, H317, H318, H331, H334, H341, H351, H360 (F/D/FD/Fd/Df), H370, H372, EUH029, EUH031, EUH070	H302, H312, H314, H332, H361 (f/d/fd), H362, H371, H373, EUH071	H304, H315, H319, H335, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Gases/vapors (ppm)	0,001	0,01	0,1	5

Peilig Een NVvA leidraad grenswaarden afleiden a la NIOSH

- Moet kunnen en heeft toegevoegde waarde
- Zelfstandig als NVvA als kwaliteitsvereniging
- In (betaald) project met de SER
- Anders ….

Flowchart Finding & deducing private OELV

EU Working conditions compliance

Legal limits with possible technical (and/or economical) feasibility:

- EU BLV
- NL legal OELV
- DE TRGS900
- Fr VLEP
- others
- ……..

100 - 1000

2. UK WEL
3. USA OSHA PEL
3. ……

Version 220106

Finding

Health Based

HB & stakeholders

DN/MEL L-t/S-t

Kick-off

Tox Models

Expert Judgement (nano)

deducing

Guidance

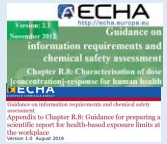
Tier 4 haalbaarheid

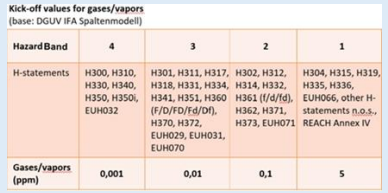
Tier 3. Holistisch

Tier 2. Tox +AF

Tier 1. Hazard Banding

SER/ AGS/IOLV/BLV




Kick-off values for gases/vapors
(base: DGUV IFA Spaltenmodell)

Hazard Band	4	3	2	1
H-statements	H300, H310, H330, H340, H350, H350i, EUH032	H301, H311, H317, H318, H331, H334, H341, H351, H360 (F/D/FD/Fd/Df), H370, H372, EUH029, EUH031, EUH070	H302, H312, H314, H332, H361 (f/d/fd), H362, H371, H373, EUH071	H304, H315, H319, H335, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Gases/vapors (ppm)	0,001	0,01	0,1	5

No (acceptable) limit found

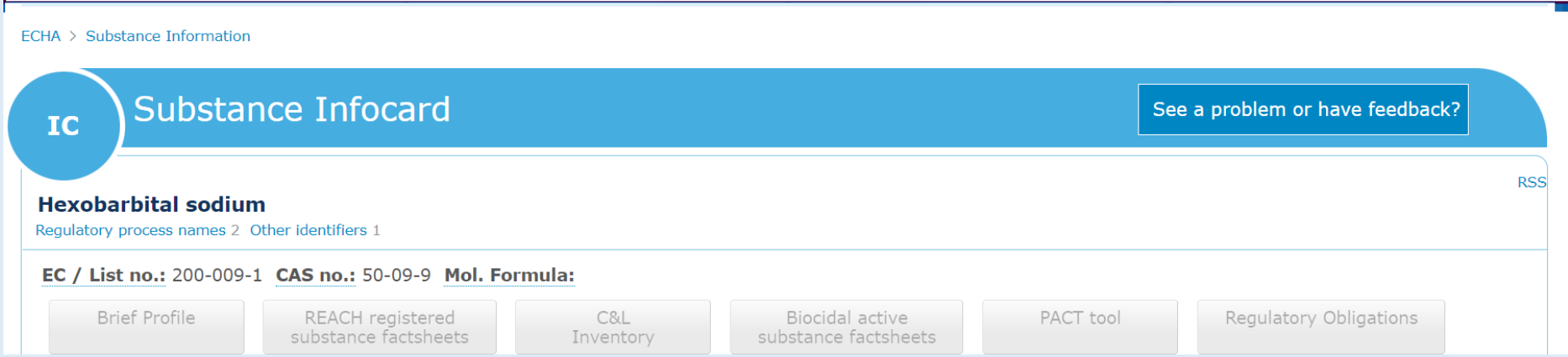
Tools & Guidelines

- 1: GHS/CLP H-code based Kickoff DOHSBase (2014)
- 2: Tox+Assessment-Factors SECO-DNEL.xlsm (2016)
- 3: Holistic Health Council Netherlands (2021)

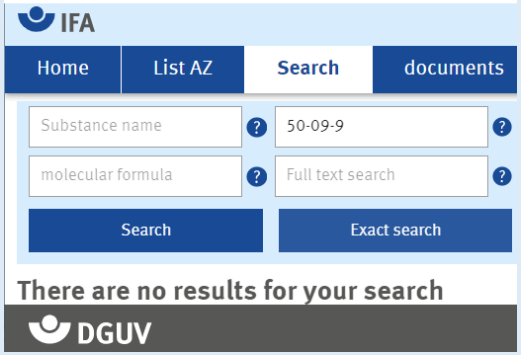
Voorbeeld

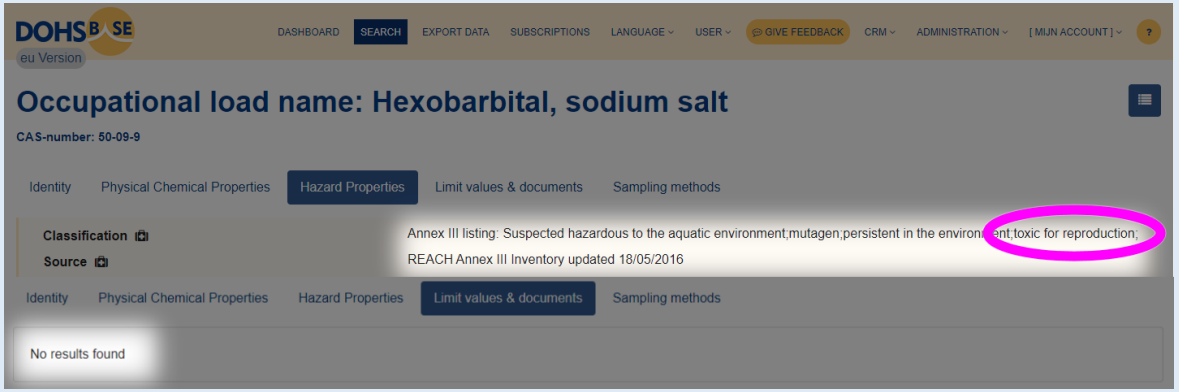
Example Na-HexoBarbiturate 50-09-9

https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.000.009



https://gestis-database.dguv.de/search





http://pubchem.ncbi.nlm.nih.gov/

LD50 rat 1 g/kg -> GHS H302 ->
Kick-off 0.1 mg/m^3 for dust
(COSHH hazard band engine)

https://pubchem.ncbi.nlm.nih.gov/compound/Hexobarbital-sodium#section=Acute-Effects...

PUBCHEM > HEXOBARBITAL SODIUM > ACUTE EFFECTS

CID 23664950

Hexobarbital sodium

Acute Effects

#	Organism	Test Type	Route	Dose	Reference
1	rat	LD50	oral	1 gm/kg	Archives of Toxicology., 54(275), 1983 [PMID:6667118]

ChemIDplus

https://www.dohsbase.nl/kick-off-waarden-een-introd...

Kick-off values for dust/aerosols
(base: COSHH Essentials)

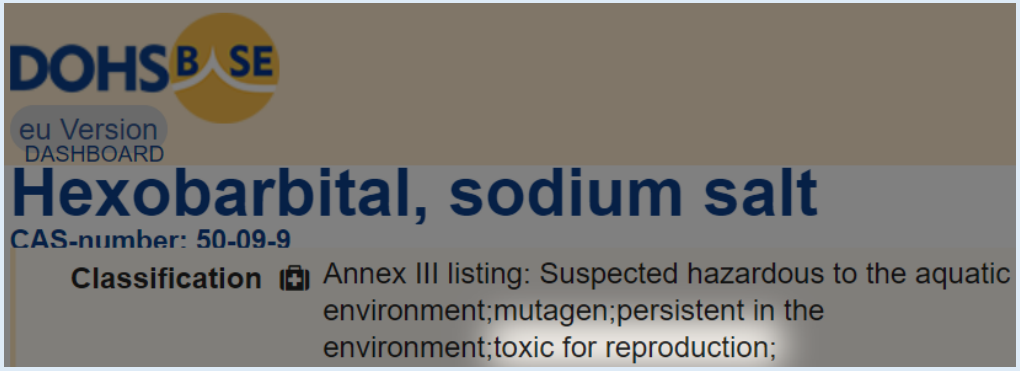
Hazard Group	4	3	2 *	1
H-statements	H334, H340, H341, H350, H350i	H300, H310, H330, H351, H360 (F/D/FD/ Fd/Df), H361 (f/d/fd), H362, H372	H301, H302, H311, H312, H314, H317, H318, H331, H332, H335, H370, H371, H373, EUH071	H303, H304, H305, H313, H315, H316, H319, H320, H333, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Dusts (mg/m^3)	**0,0001**	**0,01**	**0,1**	

dicators (HHI) R-
S

EU DSD[17,18], CLP [20] and REACH[19] non-dangerous

level (& duration)		signal word	Health hazard Pictogram	CLP Health hazard class and category code	CLP H-Statement
Quantity	Units				
5	mg/kg	D	GHS06	Acute Tox 1	300
5-25	mg/kg	D	GHS06	Acute Tox 2	300
25-50	mg/kg	D	GHS06	Acute Tox 2	300
50-200	mg/kg	D	GHS06	Acute Tox 3	301
200-300	mg/kg	D	GHS06	Acute Tox 3	301
300-2000	mg/kg	W	GHS07		302
				No REACH registration Exposure Scenario	
5000	mg/kg			Considered to cause minimum risk REACH	

Suspected toxic for reproduction



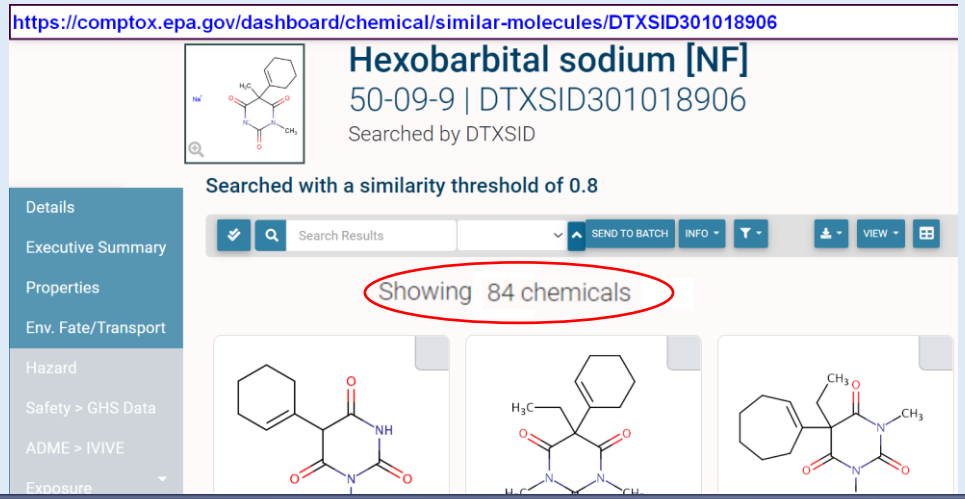
A study of the teratogenic and fetotoxic effects of large doses of barbital, hexobarbital and butobarbital used for suicide attempts by pregnant women

G Timmermann[1,2], AE Czeizel[1], F Bánhidy[2] and N Ács[2]

Toxicology and Industrial Health 2008; **24**: 109–119
http://tih.sagepub.com

- https://en.wikipedia.org/wiki/Hexobarbital#References
- https://journals.sagepub.com/doi/pdf/10.1177/0748233708089004
- https://ur.booksc.me/book/42015555/78ed83

CompTox similar Barbitals



Read-across using CompTox

DOHSBase CompareEU 22-02

File Mode Language Help

Compare; file Hexobarbital_similarities_with_0.8_threshold

Change mode

Select | Compare

TOX: COSHH OELV: TWA 8 hr in mg/m3

List of substances sorted on Risk Assessment Score (RAS)

Name	CAS-number	Physical state	H/EUH-code(s)	TOX	C_sat	OELV	TIX	RAS
pentobarbital	76-74-4	Solid	>=1 EU-CLP notified H361 H301 # 311 # 331	3	3,7 E-06	0,0100000	0,0	0,0

List of substances with no RAS-value

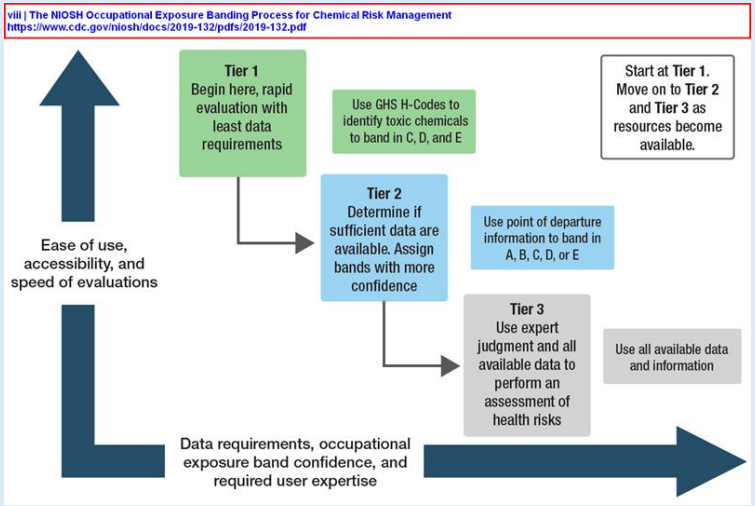
Name	CAS-number	Physical state	H/EUH-code(s)	TOX	C_sat	OELV
barbital sodium	144-02-5	Solid-like, vp<=1 ppb	>=1 EU-CLP notified H361	3	0 E+00	0,0100000
pentobarbital sodium	57-33-0	Solid	>=1 EU-CLP notified H361 H301 # 311 # 331	3	0 E+00	0,0100000
secobarbital sodium	309-43-3	Solid-like, vp<=1 ppb	>=1 EU-CLP notified H361 H301 # 311 # 331	3	0 E+00	0,0100000
5-allyl-5-(2-cyclopenten-1-yl)barbituric acid	76-68-6	Solid	>=1 EU-CLP notified H301 # 311 # 331	2	0 E+00	0,1000000
amobarbital sodium	64-43-7	Solid-like, vp<=1 ppb	>=1 EU-CLP notified H301 # 311 # 331	2	0 E+00	0,1000000

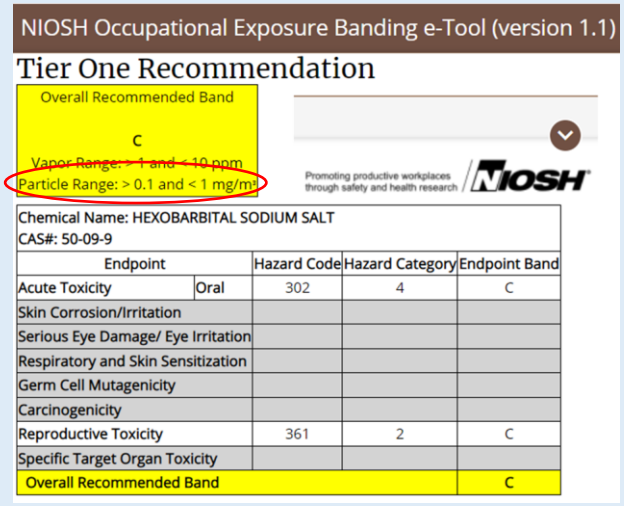
Size database Compare:: 97375 ; Selected: 21 | 1.635 MB | 04-07-2022 23:40:44

Tier 1 Kickoff Na-hexobarbiturate

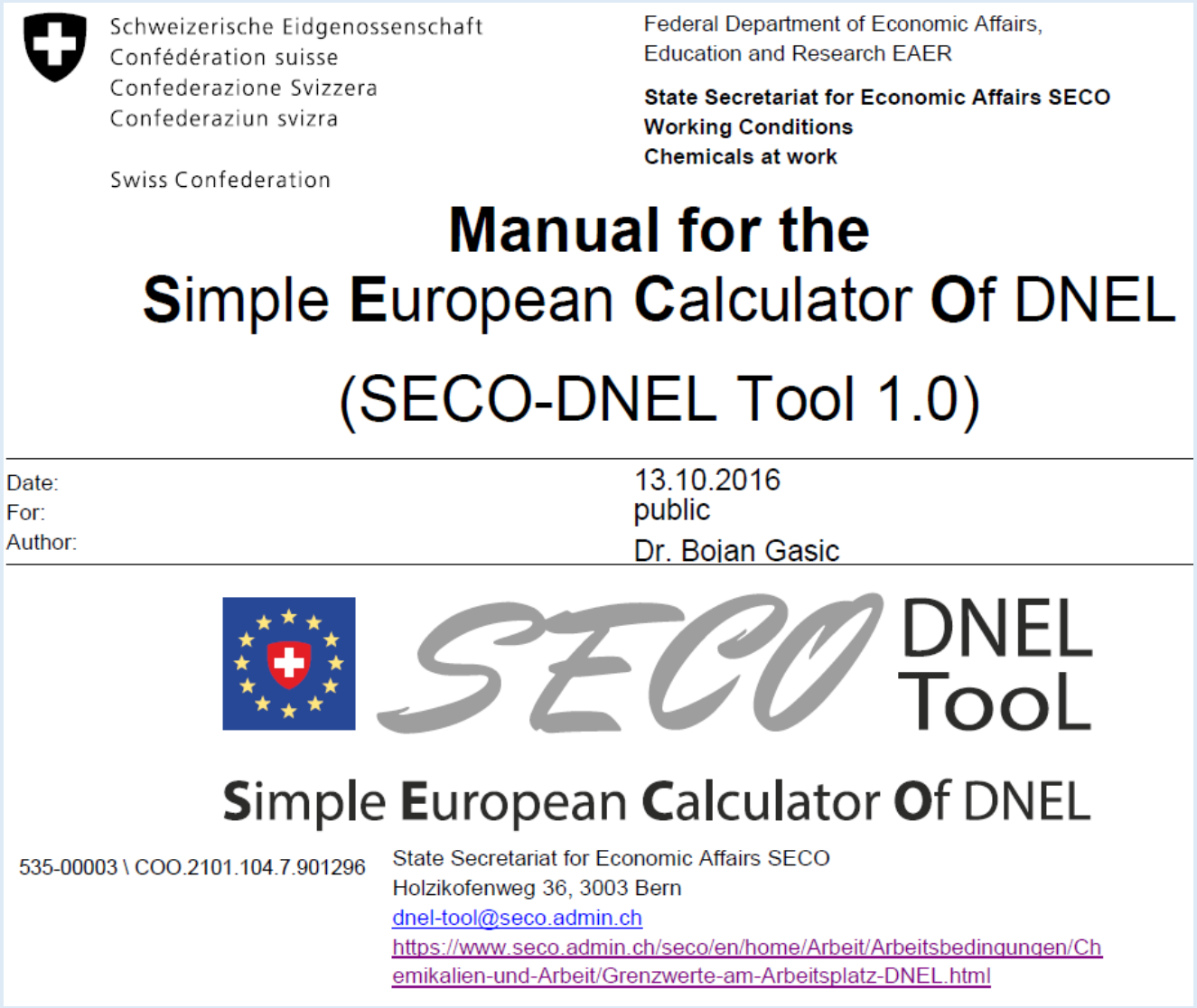
Data-poor

- Patchwork: only a LD50=> H302=> 0.1 mg/m^3
- CompTox: read-across=> H361=> 0.01 mg/m^3





Swiss DNEL calculator



Schweizerische Eidgenossenschaft
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Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO
Working Conditions
Chemicals at work

Manual for the
Simple European Calculator Of DNEL

(SECO-DNEL Tool 1.0)

Date:	13.10.2016
For:	public
Author:	Dr. Bojan Gasic

SECO DNEL Tool

Simple European Calculator Of DNEL

535-00003 \ COO.2101.104.7.901296

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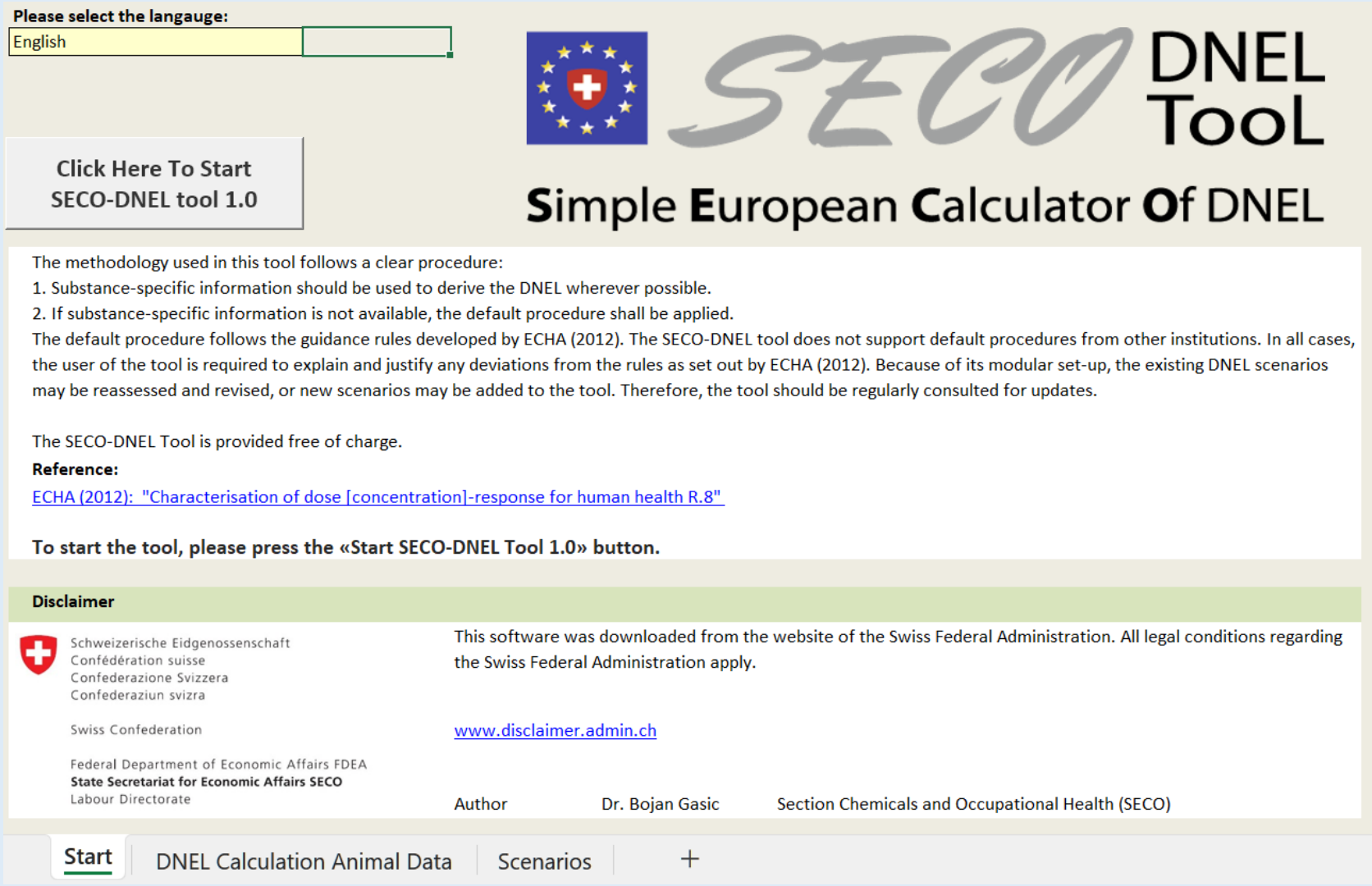
https://www.seco.admin.ch/seco/en/home/Arbeit/Arbeitsbedingungen/Chemikalien-und-Arbeit/Grenzwerte-am-Arbeitsplatz-DNEL.html

$OELV_A = N(L)OAEL/C_{corr} / AF_1 \times AF_2 \times \ldots \times AF_n$



9 end points

Excel Application, also for non-REACH substances

SECO Physchem + N(L)OAEL

Physical-chemical information		
Physical state of the substance/product	liquid	
Density	1000	kg/m3
Pure vapour pressure	55	Pa
Molar fraction	99	
Molar mass	550	mg/mol
Log Kow	6	
Study information		
Leading health effect	liver effects	
Study guideline	OECD TG 407	
Study duration	28	days
Species	rat	
Number of animals in the study	20	
Administration route	Oral	
Step 1: Select the relevant dose descriptor for the toxicological endpoint concerned		
Toxicological endpoint:	Other effect - systemic	
NOAEL - oral route:	300	mg/kg bw/d

SECO C_{corr}, $AF_{1...n}$ & OELV/DNEL

Step 2: Modify the relevant dose descriptor per endpoint of the correct starting point		
Starting point correction formula:		
corr inh NOAEC = oral NOAEL x 1/sRVan x Diff. exp. cond. x (ABSoral,an/ABSinh,hu) x sRVhu/wRV		
Relevant human expsoure route:	inhalation	
ABSoral,an/ABSinh,hu	0.5	
Experimental animal:	rat	
Standard respiratory volume, animal (sRVan)	0.38	m3/kg bw/8 h
Standard respiratory volume, human (sRVhu)	6.7	m3 / person
Worker respiratory volume (wRV)	10	m3 / person
Differences experimental/human exposure conditions	1.4	
Corrected dose descriptor		
corr inh NOAEC:	370.2631579	mg/m3
Step 3: Select assessment factors		
Interspecies, AS	1	
Interspecies, remaining differences	2.5	
AF1: Interspecies, total	2.5	
AF2: Intraspecies	5	
AF3: Exposure duration	2	
AF4: Dose response-relationship	1	
AF5: Quality of the whole data base	1	
Overall AF (= AF1xAF2xAF3xAF4xAF5)	25	
DNEL Results		
worker-DNEL long-term for inhalation route-systemic-other effect:	14.81052632	mg/m3

Afleiden private BM grenswaarde (BLV)

OBL

POBL

Geen (passende) grenswaarde

Data rich (Tox & Epidemiology) -> Holistic

<-Data poor

Schiet maar lek/ complimenten/ aanvullingen?

Wie wil meedenken?
Wie wil meeschrijven?
BM deel ?
Tegenlezers

Laat je email achter