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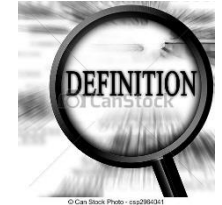
# Simple European Calculator Of DNEL (SECO-DNEL Tool 1.0)

A strategy to calculate Derived No-Effect Levels (DNEL) for dangerous substances registered under REACH

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# What are DNELs?

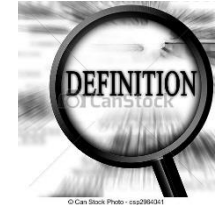


## Definition:

- Derived No-Effect Levels (DNELs) are levels of exposure above which humans should not be exposed.  
*(Annex I 1.0.1 REACH)*
- A DNEL should ensure that exposure to specific substances does not lead to adverse health effects for humans.



# What are DNELs?

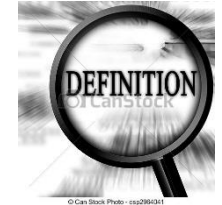


## Definition:

- DNELs shall be established based on:
  - **Population:** workers and the general population (consumers and human via the environment)
  - **Route:** oral, dermal and inhalation exposure
  - **Duration:** acute (short-term) and chronic (long-term) exposure
  - **Effect type:** systemic or local

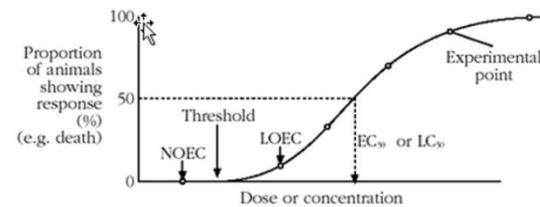


# What are DNELs?



## Definition:

- DNELs are derived for substances that exert a threshold-effect



- DNEL are derived for the leading health effect





# Why are DNELs needed?



DNELs are used for a quantitative risk characterization (RC)

- $RC = \text{Exposure} / \text{DNEL}$
- $RC > 1$ : Risk is not controlled
- $RC < 1$ : Risk is adequately controlled





# Why are DNELs needed?



- DNELs are used to establish the relevant exposure scenarios under the REACH legislation
- Exposure scenarios describe for the manufacture and all relevant identified uses of a substance under which...
  - operational conditions (e.g. process involved), and
  - risk management measures (e.g. ventilation),an adequate control of risks ( $RC < 1$ )  
...is reached.



# When do I need to derive a DNEL?

- Dangerous substances according to the CLP criteria
- Substances produced or imported in quantities  $\geq 10$  tonnes/year
- Registered under REACH as part of the Chemical Safety Assessment (CSR)





# What are the current problems faced with DNELs?

- Significant errors in calculating DNELs are made.

**Practice shows a large diversity in how DNELs are derived.**



- Different assessors may choose different leading health effects and corresponding dose descriptors based on the same dataset.
- Differences in the modification of the dose descriptor and in the individual assessment factors are applied.





# What are the current problems faced with DNELs?

**Still a «wrong» belief that DNELs are conservative.**

However, in **practice:**



- Registrants DNELs are to an equivalent percentage higher or lower than the corresponding (national) OELs
- A significant number of DNELs are even more than a factor of 10 higher than the national or European OEL
- See references at the end of the presentation



# Why should we care about DNELs?

## **1<sup>st</sup> scenario:**

In the absence of legislative Occupational Exposure Limits (OELs) worker-DNELs may become de facto OELs

## **2<sup>nd</sup> scenario:**

More importantly: Given the tens of thousands (registrants) DNELs in future, the hundreds/thousands of OELs may become redundant



# Why should we care about DNELs?

*DNELs must be listed in Section 8.1 of the Safety Data Sheet (SDS)*

## **3<sup>rd</sup> scenario:**

Employers and health practitioners may be confused to see for the same substance in the SDS an OEL and (a) different DNEL(s)

- What is the legally binding reference value?

*This question will arise whenever the OEL and the corresponding DNEL differ from each other*





# Why should we care about DNELs?



- **As a consequence**, if the DNEL derivation process is not set up properly the validity of the...
    - legislative OELs (e.g. MAKs, IOELs etc.) and
    - the DNELs themselves (!)
- ...might be questioned.



# Why should we care about DNELs?



## In practice...

- «High» DNELs will trigger protection measures that may unnecessarily increase the number of occupational diseases in a company
- «Low» DNELs will generate unnecessary costs for the companies and workers may be confronted with disproportionately high level of personal protection measures



# What needs to be done?

- Calculation errors must be reduced
- A consensus among different ways to derive DNELs has to be found
- The scientific and legislative relation of DNELs to the national or European OELs needs to be intensively discussed



**The SECO-DNEL tool offers a first step of solution to these problems...**



*SECO* **DNEL  
Tool**

**Simple European Calculator Of DNEL**



# Simple European Calculator Of DNEL (SECO-DNEL tool)

- Simple to use
- Transparent results and calculation procedure
- Consistent methodological strategy for setting DNELs
- Simple communication options (pdf)

## Tool design:

- Excel spreadsheet
- Programming language: VBA
- Language: English, German, French, Italian, ... open for more...





# The strategy of the SECO-DNEL tool

- Modular design, easy to adjust
- Each module consists of one DNEL scenario
- The DNEL scenario consists of a (derived) DNEL and a set of rules according to which the DNEL is derived
- The adoption of these rules are to be based on a broad methodological consensus and be consistent with the rules as set out by ECHA (2012)
- Only DNEL scenarios will be supported that have a wide scientific acceptance by authorities and industries

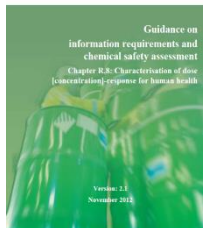


# The strategy of the SECO-DNEL tool

The methodology used in this tool follows a clear procedure

1. If possible, **substance-specific information** should be used to derive a DNEL
2. If substance-specific information is not available, a **default procedure** according to the rules as set out by **ECHA (2012)** should be applied

 ECHA  
EUROPEAN CHEMICALS AGENCY



All alterations to this procedure must be explained and justified



# Implemented DNEL scenarios in version 1.0 of the SECO-DNEL tool

- Version 1.0 of the tool supports 18 different DNEL scenarios
  - **Toxicological endpoint:**
    1. Reprotoxic effects and
    2. Other effects (i.e. all non-reprotoxic effects)
  - **Population:** workers and general population
  - **Route:** oral, dermal and inhalation
  - **Duration:** long-term
  - **Effect type:** systemic or local



# Implemented DNEL scenarios in version 1.0 of the SECO-DNEL tool

- Examples of DNEL scenarios
  - worker-DNEL long-term for inhalation route-reprotoxic effect
  - worker-DNEL long-term for dermal route-systemic-other effect
  - General population-DNEL long-term for oral route-reprotoxic effect
  - General population-DNEL long-term for dermal route-local-other effect
- For more details on the DNEL scenarios consult the User's Manual



# DNEL scenarios not (yet) included in the SECO-DNEL tool version 1.0

- Acute toxic effects
  - No straightforward methodology
  - Often only LD50-values available → high uncertainty
- Skin and respiratory sensitization
  - No straightforward methodology
  - For skin sensitizers the Local Lymph Node Assay (LLNA) may become a starting point to derive a «skin sens. DNEL» in future
- Non-threshold effects (carcinogens or mutagens)
  - Derived Minimum-Effect Levels (DMEL) not legally binding in REACH
  - (High-to-low-dose) Risk extrapolation factor
    - $10^{-3}$ ,  $10^{-4}$ ,  $10^{-5}$ ,  $10^{-6}$  risk ?



# Conclusion on DNEL scenarios

- Because of its modular set-up, the tool should be viewed as a platform for discussing and updating existing DNEL scenarios
- New scenarios will be implemented once they become accepted by authorities, industries and in the scientific community
- The tool should therefore be regularly consulted for updates



# How does the tool work?



*SECO*

**DNEL  
Tool**

**Simple European Calculator Of DNEL**



# 3-step-procedure for deriving DNELs

## General work flow for DNEL calculation - threshold effects

Step 1: Select the relevant dose descriptor for the endpoint concerned (e.g. NOAEL, LOAEL)

Step 2: Modify, when necessary, the relevant dose descriptor per endpoint to the correct starting point

Step 3: Apply, when necessary, assessment factors to the correct starting point

Results: Endpoint-specific DNEL values

**Step 1:** Select the relevant dose descriptor for the endpoint concerned (e.g. NOAEL, LOAEL)

**Step 2:** Modify, when necessary, the relevant dose descriptor per endpoint to the correct starting point

**Step 3:** Apply, when necessary, assessment factors to the correct starting point





# Starting information on substance and toxicological studies (partly mandatory)

1. Substance-specific parameters
  - For example: Vapour pressure, log Kow
2. Details on the leading health effect and the study guideline
  - For example: Study guideline, species (e.g. rat)



# Starting information on substance and toxicological studies (partly mandatory)

Starting information on the substance and toxicological studies							Delete Starting Information
Product identifier:			<i>i</i>				
Substance name	CAS-Nr.	EC-Nr.					
Please enter information on the physical-chemical properties of the substance:							<i>i</i>
Physical state	Density [kg/m3]	Pure vapour pressure [Pa]	Typical concentration [%]	Log Kow	Molar mass [g/mol]	Temperature [°C]	Pressure [hPa]
Please select:						20	1013
Please enter details on the leading health effect and the study guideline:					<i>i</i>		
Leading health effects (e.g. kidney effects)	Study guideline (e.g. OECD TG 413)	Study duration (e.g. 90 days)	Species (e.g. rat)	Number of animals per dose group			

**Mandatory for dermal-to-inhalation extrapolation in the default mode**



# Example – Starting information

Starting information on the substance and toxicological studies							Delete Starting Information	
Product identifier:			<i>i</i>					
Substance name	CAS-Nr.	EC-Nr.						
Test	XX-XX-X	XXX-XXX-X						
Please enter information on the physical-chemical properties of the substance:								<i>i</i>
Physical state	Density [kg/m <sup>3</sup> ]	Pure vapour pressure [Pa]	Typical concentration [%]	Log Kow	Molar mass [g/mol]	Temperature [°C]	Pressure [hPa]	
liquid	1000	55	99	6	550	20	1013	
Please enter details on the leading health effect and the study guideline:					<i>i</i>			
Leading health effects (e.g. kidney effects)	Study guideline (e.g. OECD TG 413)	Study duration (e.g. 90 days)	Species (e.g. rat)	Number of animals per dose group				
liver effects	OECD TG 407	28	rat	20				



# Before starting the 3-step-procedure

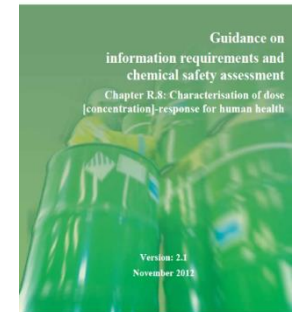
Note that there are two possibilities to use the tool:

## 1. Expert judgment

The «user» may enter manually the relevant parameters or assessment factors to derive the DNELs

## 2. Default version

The default factors refer to the [ECHA Guidance Dokument R.8](#). To use this option a button named “Set Default” has to be clicked. For example an assessment factor of 5 will be applied for the worker-intraspecies variability when the “Set Default” button is clicked



Please account for intraspecies differences in the target population:



# Step 1 – Select DNEL scenario (mandatory)



- 1. Select toxicological endpoint**
  - Reprotoxic effect
  - Other effect
- 2. Select the effect type**
  - Systemic effects
  - Local effects
- 3. Select a dose descriptor**
  - NOAEL
  - LOAEL
- 4. Select an administration route**
  - Oral, dermal or inhalation
- 5. Enter a dose descriptor value and select an appropriate unit**



# Step 1 – Select DNEL scenario (mandatory)



Step 1: Please select the relevant dose descriptor for the toxicological endpoint concerned		Step 1: Delete & Reset
Please select toxicological endpoint:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>
Please select effect type:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>
Please select a dose descriptor:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>
Please select an administration route:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>



# Step 1 – Example



**Step 1: Please select the relevant dose descriptor for the toxicological endpoint concerned** Step 1: Delete & Reset

Please select toxicological endpoint: Other effect i

Please select effect type: Systemic effects i

Please select a dose descriptor: NOAEL/C i

Please select an administration route: Oral i

Please enter a dose descriptor value for the relevant administration route and select the correct units:

Exposure route	Value	Units	
Oral	300	mg/kg bw/d	<span style="border: 1px solid black; padding: 2px;">Delete value</span>



## Step 2 – Starting point correction (mandatory)



- 1. Exposure route**
  - oral, dermal, inhalation
- 2. Relevant Population**
  - worker, consumer and human via the environment
- 3. Bioavailability / route-to-route extrapolation**
  - e.g. oral(animal)-to-inhalation(human) extrapolation
- 4. Experimental animal**
  - rat, mouse, hamster, guinea pig, rabbit, monkey, dog
- 5. Differences in experimental/human exposure conditions**
  - e.g. 7 days/week experimental exposure (animal) vs. 5 days working week





## Step 2 – Starting point correction (mandatory)



Step 2: Please modify the relevant dose descriptor per endpoint of the correct starting point		Step 2: Delete & Reset
Please select the relevant human exposure route:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>
Please select the relevant population:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>
Bioavailability		<input type="button" value="i"/>
Please account for the bioavailability of the experimental animal:	<input type="text"/> [%] <input type="button" value="Set Default"/>	
Please account for the bioavailability of the human:	<input type="text"/> [%] <input type="button" value="Set Default"/>	
Please select the experimental animal:	<input type="text" value="Please select:"/>	<input type="button" value="i"/>
Differences experimental/human exposure conditions		<input type="button" value="i"/>
Please select whether the toxic effect is 1. concentration-driven or 2. dose dependent?	<input type="text" value="Please select:"/>	



## Step 2 – Example

Step 2: Please modify the relevant dose descriptor per endpoint of the correct starting point		Step 2: Delete & Reset
Please select the relevant human exposure route:	<input type="text" value="inhalation"/>	<input type="button" value="i"/>
Please select the relevant population:	<input type="text" value="worker"/>	<input type="button" value="i"/>
Bioavailability		<input type="button" value="i"/>
Please account for the bioavailability of the experimental animal:	<input type="text" value="50"/> [%] <input type="button" value="Set Default"/>	
Please account for the bioavailability of the human:	<input type="text" value="100"/> [%] <input type="button" value="Set Default"/>	
Please select the experimental animal:	<input type="text" value="rat"/>	<input type="button" value="i"/>
Differences experimental/human exposure conditions		<input type="button" value="i"/>
Please select whether the toxic effect is 1. concentration-driven or 2. dose dependent?	<input type="text" value="dose-dependent"/>	
Experimental exposure conditions:	<input type="text" value="n.a. for oral route"/> hours/day <input type="button" value="Set Default"/>	<input type="text" value="7"/> days/week <input type="button" value="Set Default"/>



## Step 2 – Starting point correction - Results

1. Select an appropriate unit

Results		
Other effect - systemic		
Exposure route	Human NOAEC	Units
Inhalation		Please select:

Run Step 2 calculation      Delete values

2. The calculation will then be performed automatically
3. Click «Run Step 2 calculation» for recalculation of the result

Results		
Other effect - systemic		
Exposure route	Human NOAEC	Units
Inhalation	370.2631579	mg/m3

Run Step 2 calculation      Delete values



## Step 3 – Assessment factors

- **Interspecies variability:**
  - Allometric scaling
  - Remaining differences
- **Intraspecies variability:**
  - worker, consumer, human via the environment
- **Differences in duration of exposure:**
  - sub-acute-to-chronic; sub-chronic-to-chronic; sub-acute-to-sub-chronic; chronic
- **Dose-response relationship:**
  - E.g. LOAEL to NAEL
- **Quality of the whole database**
  - Compensation of potential remaining uncertainties in the quality of the whole database



# Step 3 – Assessment factors



Step 3: Please apply assessment factors to the correct starting point		Go To Step 1	Go To Step 2	Step 3: Delete & Reset
Interspecies variability		<i>i</i>		
Please account for remaining differences in interspecies variability:	<input type="text"/>	Set Default		
Intraspecies variability		<i>i</i>		
Please account for intraspecies differences in the target population:	<input type="text"/>	Set Default		
Differences in duration of exposure		<i>i</i>		
Please account for the differences in the experimental exposure duration and the duration of exposure for the population:	<input type="text"/>	Set Default		
Issues related to dose-response		<i>i</i>		
Please enter an assessment factor to account for the dose-response uncertainties:	<input type="text"/>	Set Default		
Quality of the whole database		<i>i</i>		
Please enter an assessment factor to compensate for the potential remaining uncertainties in the quality of the whole database :	<input type="text"/>	Set Default		



# Step 3 – Example

Step 3: Please apply assessment factors to the correct starting point		Go To Step 1	Go To Step 2	Step 3: Delete & Reset
Interspecies variability				<i>i</i>
Please account for remaining differences in interspecies variability:	<input type="text" value="2.5"/>	<input type="button" value="Set Default"/>		
Intraspecies variability				<i>i</i>
Please account for intraspecies differences in the target population:	<input type="text" value="5"/>	<input type="button" value="Set Default"/>		
Differences in duration of exposure				<i>i</i>
Please account for the differences in the experimental exposure duration and the duration of exposure for the population:	<input type="text" value="2"/>	<input type="button" value="Set Default"/>		
Issues related to dose-response				<i>i</i>
Please enter an assessment factor to account for the dose-response uncertainties:	<input type="text" value="1"/>	<input type="button" value="Set Default"/>		
Quality of the whole database				<i>i</i>
Please enter an assessment factor to compensate for the potential remaining uncertainties in the quality of the whole database :	<input type="text" value="1"/>	<input type="button" value="Set Default"/>		



# Explain and justify all differences from the default approach

Please explain and justify, if necessary, the deviation to the default approach (max. 1400 characters):

*i*

Delete Text



## DNEL calculation formulae

- The DNEL is calculated by dividing the starting point corrected N(L)OAEL(C) (step 2) by the overall assessment factor (AF) (step 3):
  - $\text{DNEL} = \text{Starting point corrected N(L)OAEL(C)} / \text{Overall AF}$
- The overall AF is calculated as:
  - $\text{Overall AF} = \text{AF(Interspecies)} \times \text{AF(Intraspecies)} \times \text{AF(Exposure duration)} \times \text{AF(Issues Dose-response)} \times \text{AF(Quality database)}$





## Calculate DNEL

- Press the «Run DNEL tool» button to calculate the DNEL. The calculated DNEL value will be presented in the table below (yellow cell)



# Calculate DNEL

Results: Please calculate the DNEL by clicking on the «Run DNEL Tool» button

Go To Step 1    Go To Step 2

**Run DNEL Tool**    Delete DNEL values    See DNEL Results    Add To Scenarios    *i*

Overall assessment factor

Leading health effect

liver effects

**Click here to calculate DNEL**

worker-DNEL long term				
Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				

general population-DNEL long term				
Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				



# Calculate DNEL

Results: Please calculate the DNEL by clicking on the «Run DNEL Tool» button

Go To Step 1    Go To Step 2

Run DNEL Tool    Delete DNEL values    See DNEL Results    Add To Scenarios    *i*

Overall assessment factor	
25	
Leading health effect	
liver effects	

worker-DNEL long term				
Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation	14.81052632	mg/m3		

general population-DNEL long term				
Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				



# See all important information on the calculated DNEL scenario

Results: Please calculate the DNEL by clicking on the «Run DNEL Tool» button

Go To Step 1    Go To Step 2

Run DNEL Tool    Delete DNEL value    **See DNEL Results**    Add To Scenarios    i

**Overall assessment factor**

Leading health effect

liver effects

**worker-DNEL long term**

Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				

**general population-DNEL long term**

Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				

**Click here to see the DNEL scenario**



# See all important information on the calculated DNEL scenario

Physical-chemical information		
Physical state of the substance/product	liquid	
Density	1000	kg/m <sup>3</sup>
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



# See all important information on the calculated DNEL scenario

<b>Step 2: Modify the relevant dose descriptor per endpoint of the correct starting point</b>		
<b>Starting point correction formula:</b>		
corr inh NOAEC = oral NOAEL x 1/sRVan x Diff. exp. cond. x (ABSoral,an/ABSinh,hu) x sRVhu/wRV		
Relevant human exposure 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	
<b>Corrected dose descriptor</b>		
corr inh NOAEC:	370.2631579	mg/m3
<b>Step 3: Select assessment factors</b>		
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	
<b>DNEL Results</b>		
worker-DNEL long-term for inhalation route-systemic-other effect:	14.81052632	mg/m3



# See all important information on the calculated DNEL scenario

Results: Please calculate the DNEL by clicking on the «Run DNEL Tool» button Go To Step 1 Go To Step 2

Overall assessment factor

Leading health effect

liver effects

**Click here to add this scenario to the results**

worker-DNEL long term				
Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				

general population-DNEL long term				
Exposure route	Systemic	Units	Local	Units
Oral				
Dermal				
Inhalation				



Press the «add to scenarios» button to add the DNEL scenario in the «scenarios» spreadsheet to print all added scenarios in a pdf-file

SECO-DNEL Tool 1.0 - Simple European Calculator Of DNEL Values		07.03.2015	
<b>Endpoint-specific DNEL</b>			
<b>Worker - long term</b>			
<b>Exposure Route:</b>	<b>Systemic:</b>	<b>Units:</b>	
Oral			
Dermal			
Inhalation	14.81052632	mg/m3	
<b>Worker - long term</b>			
<b>Exposure Route:</b>	<b>Local:</b>	<b>Units:</b>	
Oral			
Dermal			
Inhalation			
<b>General population - long term</b>			
<b>Exposure Route:</b>	<b>Systemic:</b>	<b>Units:</b>	
Oral			
Dermal			
Inhalation			
<b>General population - long term</b>			
<b>Exposure Route:</b>	<b>Local:</b>	<b>Units:</b>	
Oral			
Dermal			
Inhalation			

Create pdf-File

Delete Scenarios

Back

Scroll down to see all derived DNEL scenarios. They will be printed as a pdf-file.





# Where can you download the SECO-DNEL tool 1.0?

On the SECO/ABCH homepage:

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

- The tool is free of charge



# Contact

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- UBit for the technical support.



# References: DNELs compared to OELs

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**Schenk, L. and Johanson, G. (2011).** "A Quantitative Comparison of the Safety Margins in the European Indicative Occupational Exposure Limits and the Derived No-Effect Levels for Workers under REACH." Toxicological Sciences **121**(2): 408-416. 2.

**Schenk, L.; Palmen, N.; Theodori, D. (2014).** "Evaluation of worker inhalation DNELs. Part A: Quality assessment of a selection of DNELs. Part: Discussion paper on the possibilities to improve the overall quality of DN(M)ELs." RIVM Letter report 110001001/2014.

**Schenk, L.; Deng, U.; Johanson, G. (2014).** "Derived No-effect Levels (DNELs) under the European Chemicals Regulation REACH—An Analysis of Long-term Inhalation Worker-DNELs Presented by Industry." Annals of Occupational Hygiene: 1-23 (*in press*).