Welcome to the ACGIH® Derived No Effect Levels (DNELs): What Are They and How Will They Change the Occupational Health OEL Landscape? Webinar

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Presenters

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  Experien Health Sciences

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Experien Health Sciences

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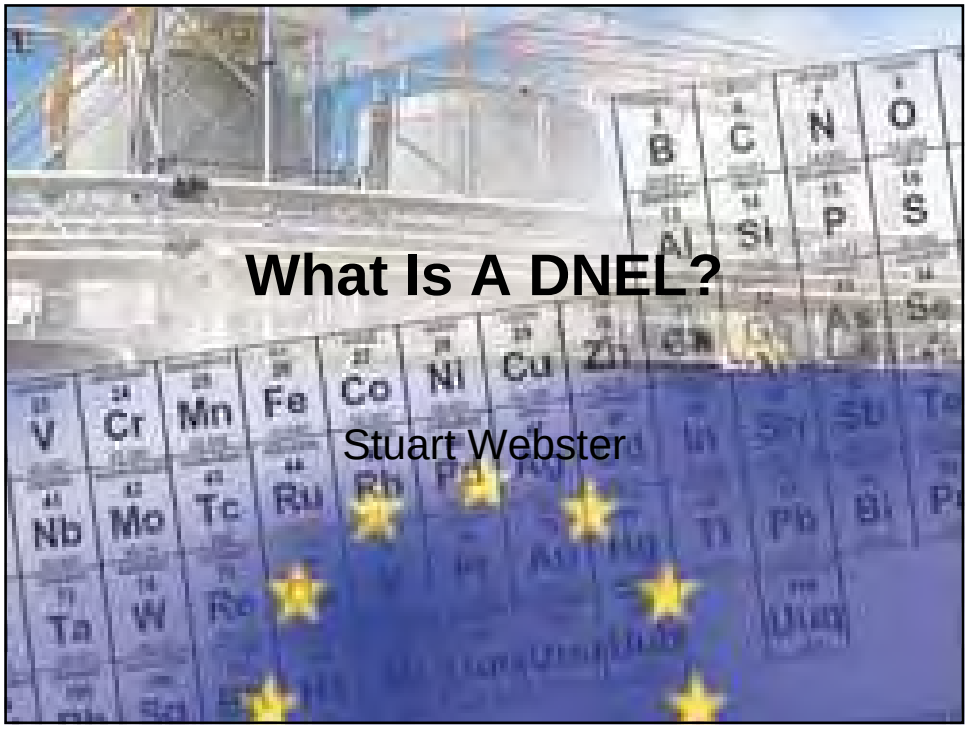


How Did We Get Here?

To set the stage for the remainder of the presentation, it is necessary to briefly review some history.

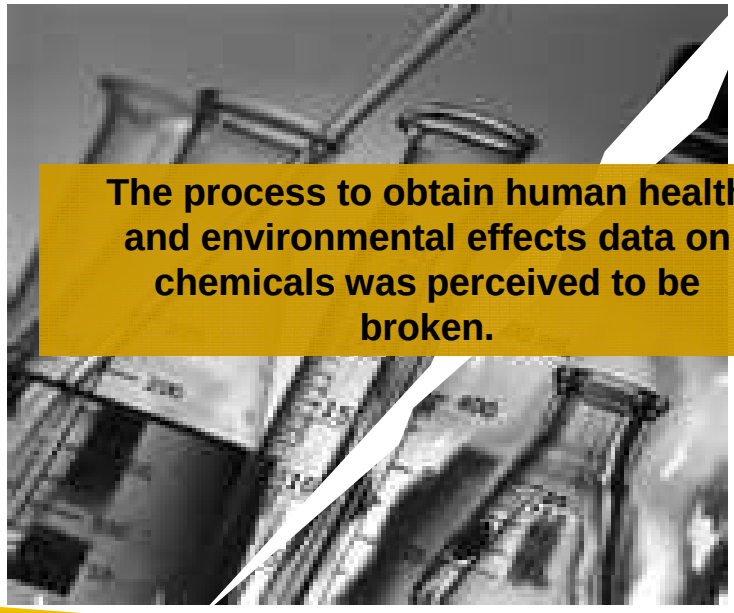
REGULATION (EC) No 1907/2006

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation

The result of several factors…

PERCEIVED FAILURE TO PROTECT SENSITIVE POPULATIONS

- Phthalates released from toys
- Pentabromo diphenyl ether in breast milk



The process to obtain human health and environmental effects data on chemicals was perceived to be broken.

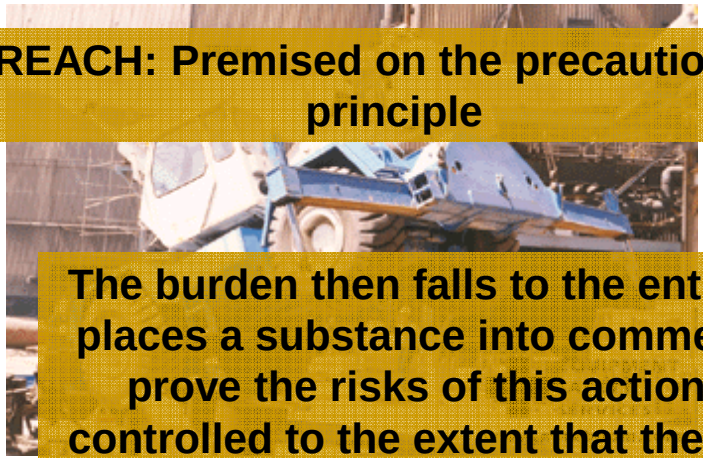
How Did We Get Here?

REACH: Premised on the precautionary principle

The precautionary principle presumes that placing chemical substances into commerce could harm the public and the environment if there is no evidence or scientific consensus that there would be no harm.

How Did We Get Here?

REACH: Premised on the precautionary principle



The burden then falls to the entity that places a substance into commerce to prove the risks of this action are controlled to the extent that the public and environment would not be harmed.

How Did We Get Here?

So how will we know whether risks are acceptably controlled?

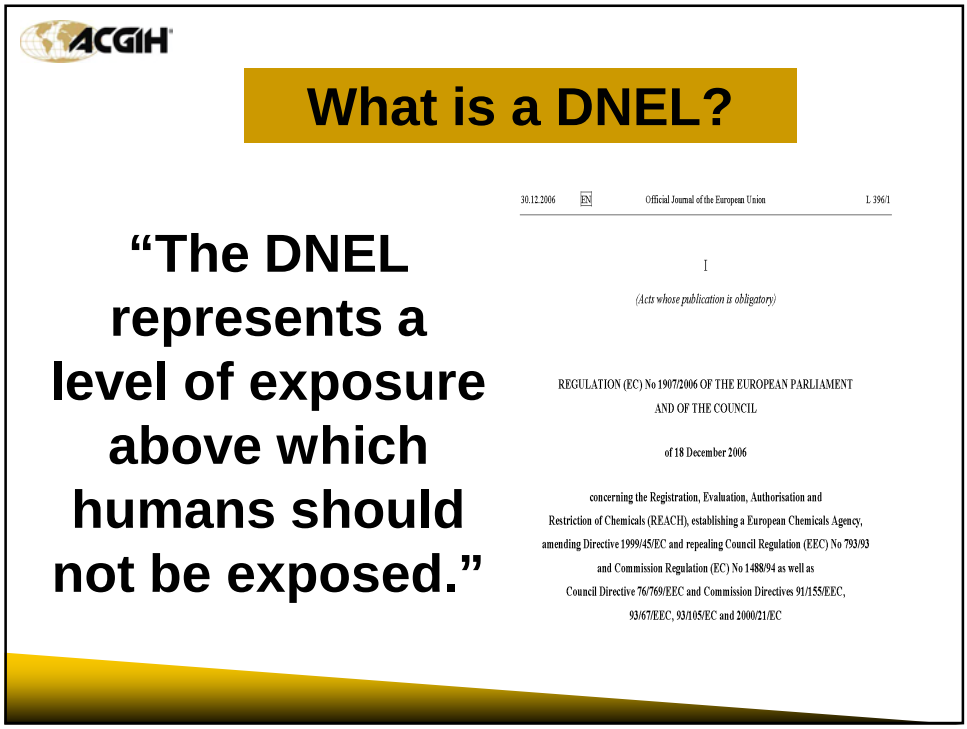
- ✓What standard / standards are to be used?
- ✓Upon what will the standard be based?

How Did We Get Here?

Given the burden of proof, to assess the potential for harm you should:

- ✓Be aware of what harm, if any, could result.
- ✓Know how, where and by whom used.
- ✓Understand the controls in place to prevent exposure.

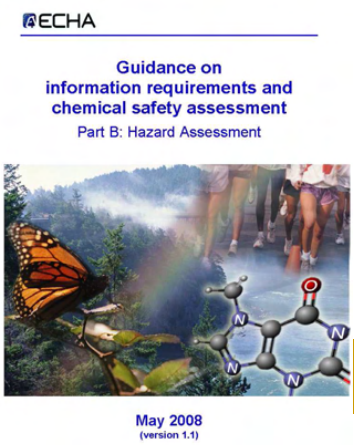

ACGIH
What is a DNEL?
What standard do you compare to?
THE STANDARDS:
Environment = PNECs
Human Health = DNELs


ACGIH
What is a DNEL?
"The DNEL represents a level of exposure above which humans should not be exposed."
30.12.2006 EN Official Journal of the European Union L 396/1
I
(Acts whose publication is obligatory)
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 December 2006
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

What is a DNEL?

Level of exposure not defined in the regulation.

What is a DNEL?



Have to go to the guidance documents

DNEL = NOAEL / AF

What is a DNEL?

Given the context of REACH and the precautionary principle …

The DNEL is a risk assessment tool…

Similar to an OEL

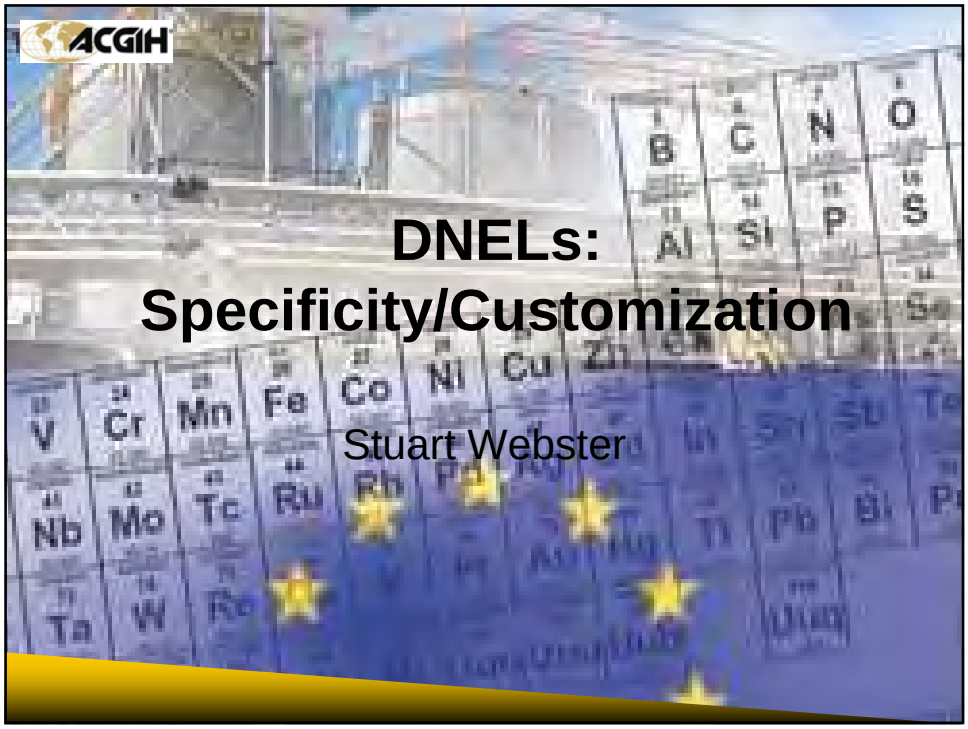
IN SUMMARY

Entities that place substances onto the EU market have the burden to prove use of their substances would not harm human health.

After gathering health effects information, the next step is to assess the risk of use.

The standard or bar to which the risk of use to human health is compared is the DNEL.

In an occupational context, the DNEL could be construed to be a de facto OEL.



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Intent of Presentation

Later on we will compare DNELs to OELs in the context of the concerns that have been voiced.

Intent with next sections is to lay the groundwork.

For some, information may seem basic or heard before.

For others, may be entirely new.

Intent of Presentation

With the next couple of sections we intend to cover the following:

- ✓DNELs in the context of their specificity
- ✓DNELs regarding their limitations/boundaries
- ✓How DNELs are derived
- ✓Aspects considered when deriving DNELs and their real-world application

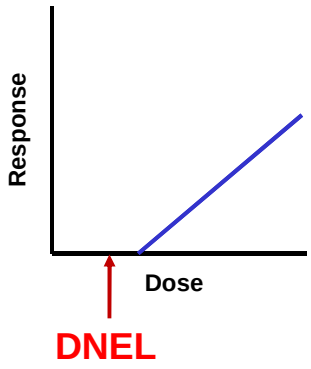
Limitations

The DNEL was not intended to be an OEL

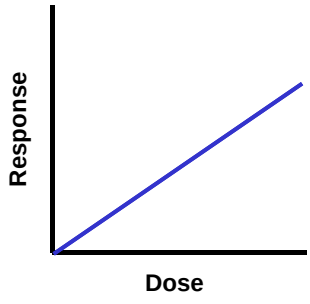
There is a different finish line than the OELs

Limitations

- The DNELs are for threshold effects.
- The assumption is exposure to the substance at that level would be below a no effect level.



Limitations



DNELs are not intended for non-threshold effects.

NO DNEL – Use the DMEL
(Derived Minimal Effect Level)

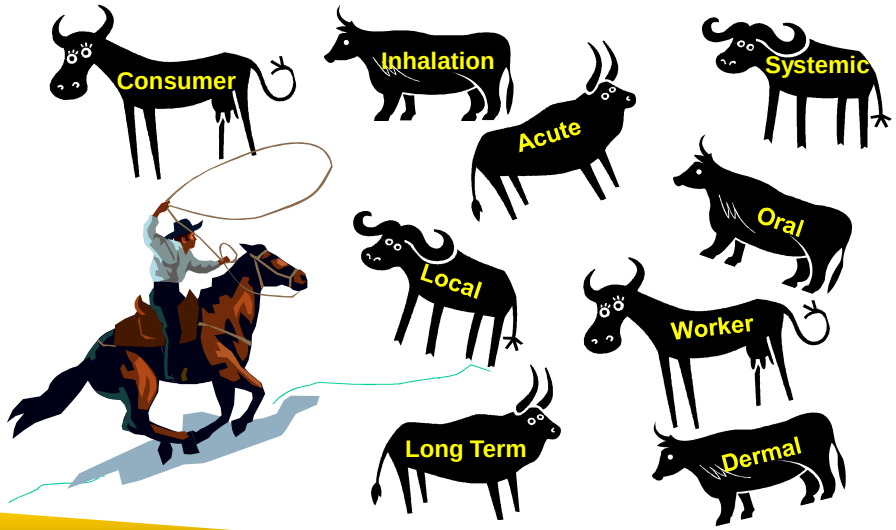
A Plethora of DNELs

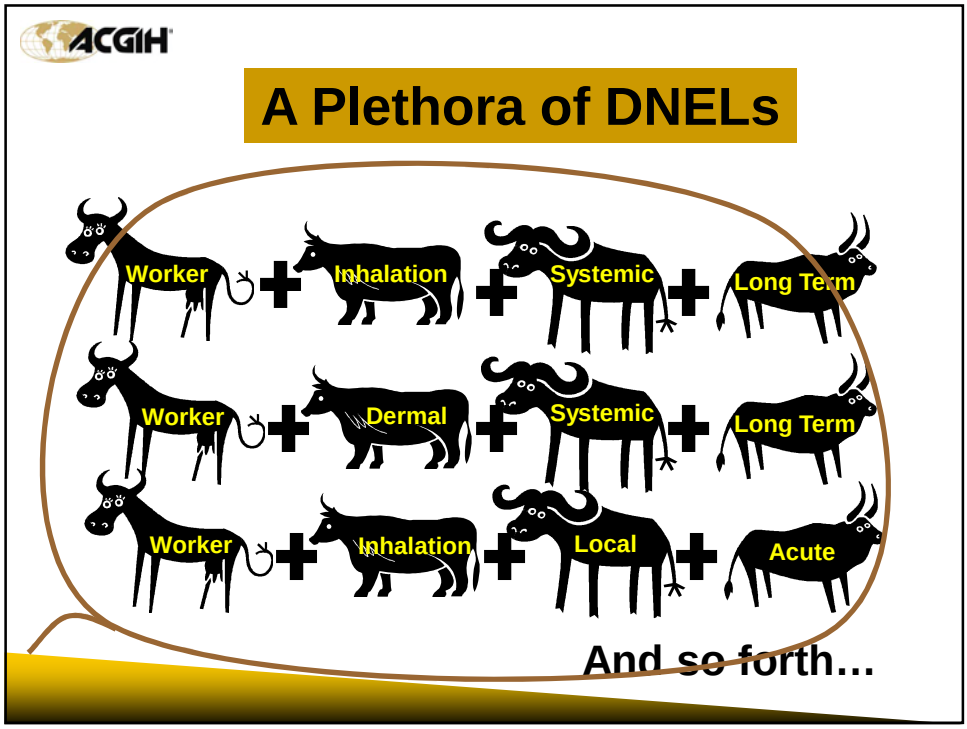
A concern expressed by many is that there could be many DNELs for a single substance.

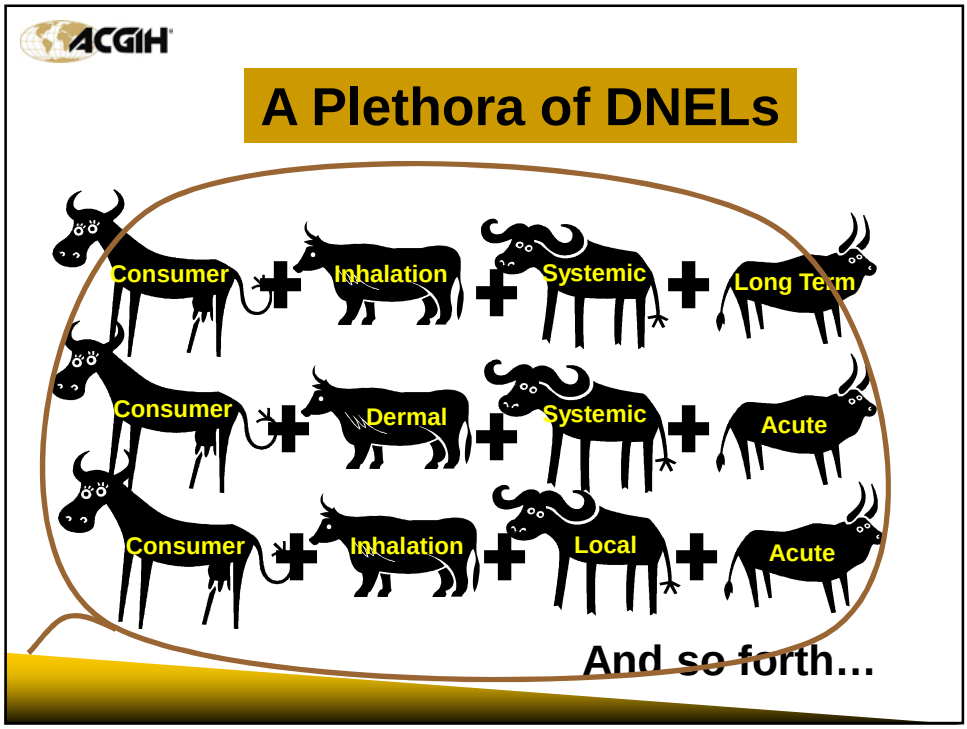
We are not going to directly address this concern but lay out the facts that have given rise to the concern.

The concern will be addressed later.

A Plethora of DNELs




ACGIH
A Plethora of DNELs
Worker
Inhalation
Systemic
Long Term
Worker
Dermal
Systemic
Long Term
Worker
Inhalation
Local
Acute
And so forth…


ACGIH
A Plethora of DNELs
Consumer
Inhalation
Systemic
Long Term
Consumer
Dermal
Systemic
Acute
Consumer
Inhalation
Local
Acute
And so forth…

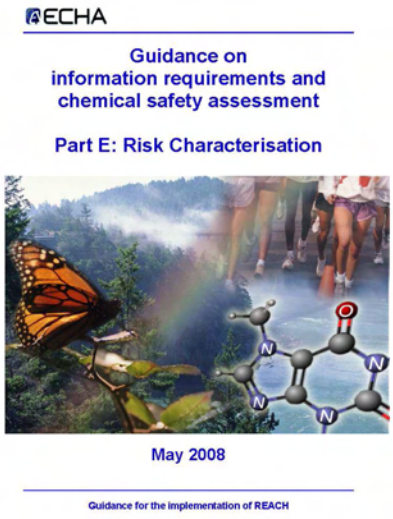
More Specificity

Sensitive Populations:

- **Children**
- **Pregnant Women**
- **Elderly**

Boundaries of Use

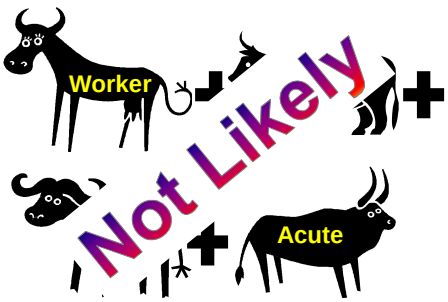
- No single document presents everything about DNELs.
- DNELs discussed under multiple contexts.
- However, summed up nicely in the Risk Characterization doc.



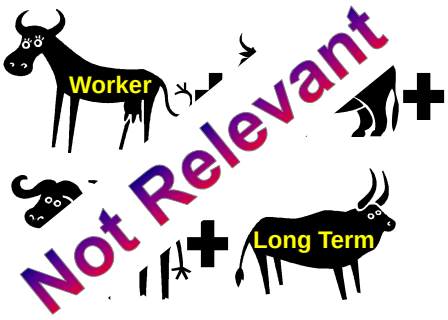
Possibilities: Workers, Systemic Effects

LONG-TERM, INHALATION DNEL	Repeated exposure ≥1 day mg substance / m^3
LONG-TERM, DERMAL DNEL	Repeated exposure ≥1 day mg / kg bw OR mg / cm^2
ACUTE, INHALATION DNEL	Peak Inhalation Exposure mg substance / m^3

Possibilities: Workers, Systemic Effects



Possibilities: Workers, Systemic Effects



Possibilities: Workers, Local Effects

LONG TERM, INHALATION DNEL	Repeated Inhalation Exposure mg substance / m^3
LONG TERM, DERMAL DNEL	Repeated Dermal Exposure mg / cm^2 OR parts per million
ACUTE, INHALATION DNEL	Inhalation Peak Exposure mg substance / m^3
ACUTE, DERMAL DNEL	Single Dermal Exposure mg / cm^2 OR parts per million

e.g., substances causing irritation, corrosion or sensitisation

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Possibilities: General Population, Systemic Effects

LONG-TERM, INHALATION DNEL	Repeated exposure mg substance / m^3
LONG-TERM, DERMAL DNEL	Repeated exposure mg / kg bw OR mg / cm^2
ACUTE, INHALATION DNEL	Occasional inhalation exposure mg / m^3
LONG-TERM, ORAL DNEL	Repeated exposure mg / kg bw

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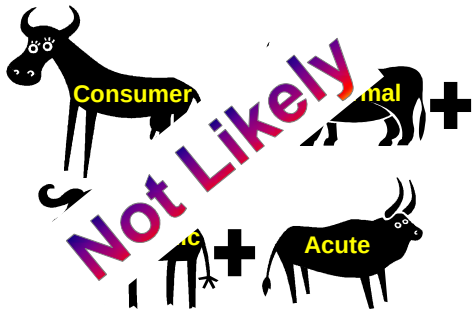
Possibilities – General Population, Local Effects

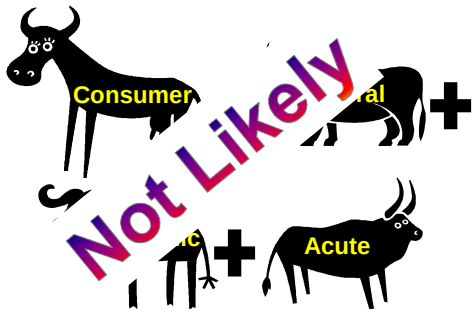
LONG TERM, INHALATION DNEL	Repeated Inhalation Exposure mg substance / m^3
LONG TERM, DERMAL DNEL	Repeated Dermal Exposure mg / cm^2 OR parts per million
ACUTE, INHALATION DNEL	Inhalation Peak Exposure mg substance / m^3
ACUTE, DERMAL DNEL	Single Dermal Exposure mg / cm^2 OR parts per million

e.g., substances causing irritation, corrosion or sensitisation

Possibilities: General Population, Systemic Effects



Possibilities: General Population, Systemic Effects

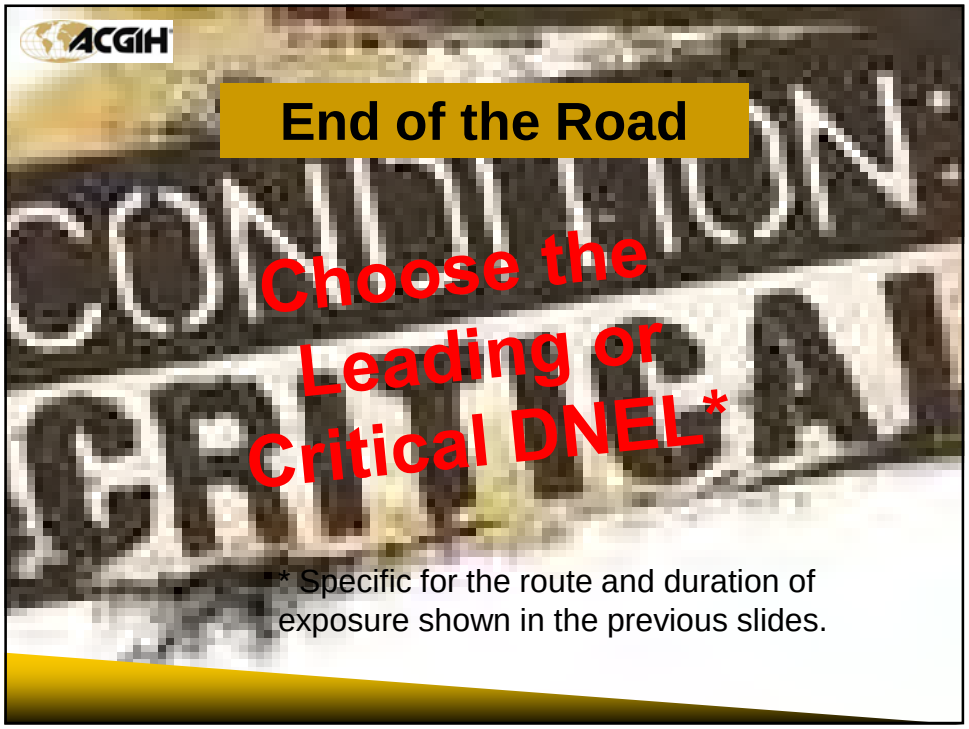


For Non-Threshold Effects:

Calculate the DMEL

(Derived Minimal Effect Level)

According to the same possibilities

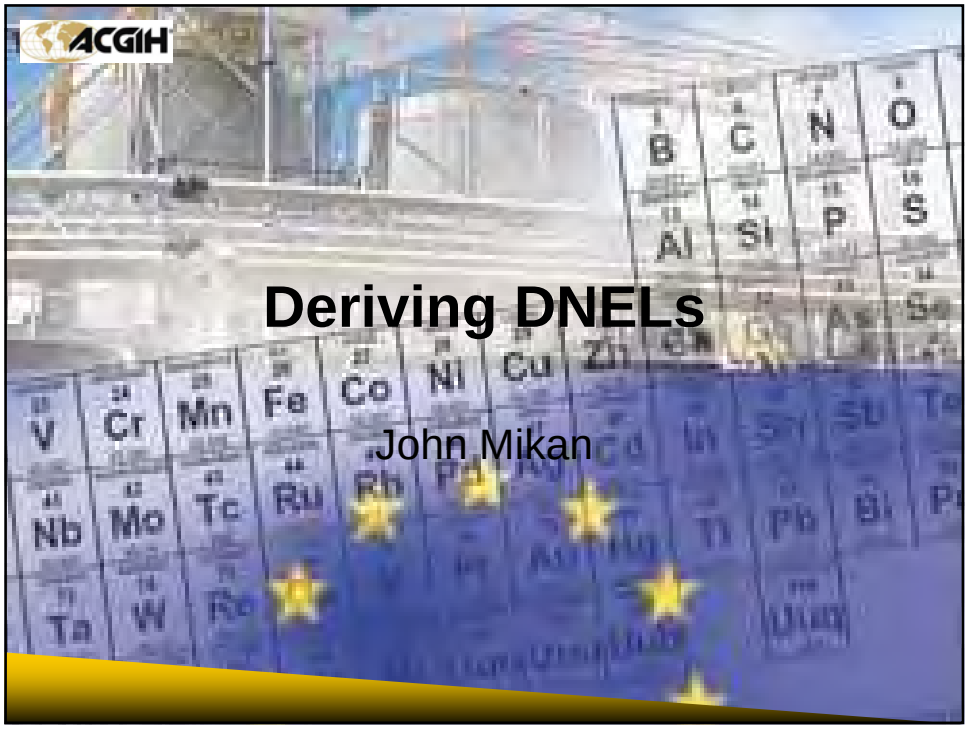


End of The Road

Use the DNELs to calculate the RCRs.

Bottom Line

- Not all exposure combinations relevant.
- Not all combinations are likely.
- Similar effects for different exposure routes will be combined into one DNEL.
- The purpose of the different DNELs is to find the leading or critical DNEL for the particular exposure route and duration.



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What's Required?

While manufacturers are required to derive DNELs, the "requirements" defining the derivation process are remarkably vague.

REGULATION (EC) No 1907/2006, Annex I – General Provisions for Assessing Substances and Preparing Chemical Safety Reports: "Step 4: Identification of DNEL(s)….When establishing the DNEL, the following factors shall, ***inter alia***, be taken into account:

a) The uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;

b) The nature and severity of the effect;

c) The sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies."

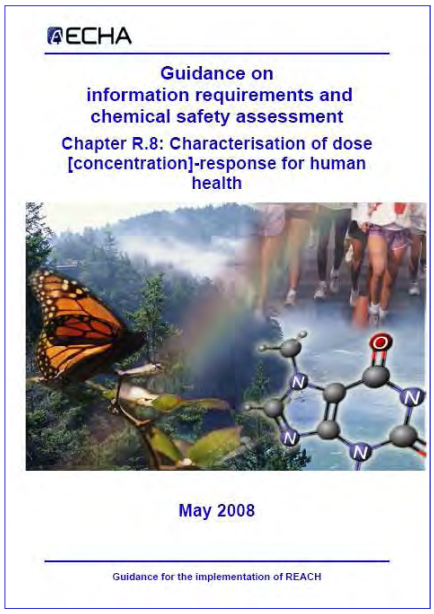
Inter alia – Latin for "among other things"

ECHA Guidance:

http://guidance.echa.europa.eu/

Legal Notice

"…users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this website does not constitute legal advice…"



Getting Started

Initial Considerations:

1. Segment(s) of the Population Exposed:
   a. Workers
   b. Consumers
   c. Children
2. Relevant Route(s) of Exposure
3. Relevant Duration(s) of Exposure
4. Type(s) of Effect(s): Local and/or Systemic?

The Basic Steps

Step 5 – Select the Critical DNEL(s)

Step 4 – Apply Assessment Factors

Step 3 – Modify the Starting Point

Step 2 – Decide on Mode of Action

Step 1 – Gather Relevant Dose Descriptors

Deriving DNELs

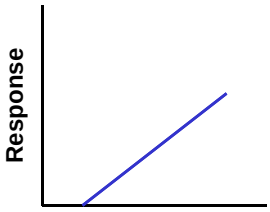
Step 1 - Gather Relevant Dose Descriptors:

- No Observable Adverse Effect Levels (NOAELs)
- Lowest Observable Adverse Effect Levels (LOAELs)
- Lethal Dose 50% (LD_{50})
  Lethal Conc. 50% (LC_{50})
- Benchmark Dose (BMD) Descriptors*

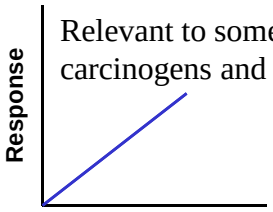
*More on this later

Deriving DNELs

Step 2 – Decide on Mode of Action:



Threshold Response



Relevant to some carcinogens and mutagens

Non-Threshold Response

CAUTION: The fact that a NOAEL has been observed in a study does not necessarily equate to a threshold response as the number of animals studied may have been too few to observe the response at low doses.

Deriving DNELs

Step 3 – Modify the Starting Point:

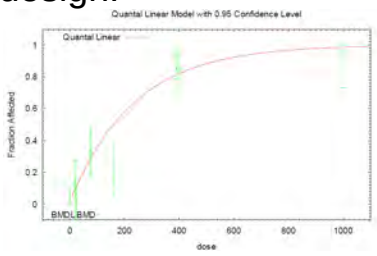
1. Body weight, if starting point is not already normalized
2. Converting units
   a. Oral to Inhalation (mg/kg-bw/day to mg/m^3/day)
   b. Oral to Dermal, local effects (mg/kg-bw/day to mg/cm^2/day)
3. Route of Exposure / Bioavailability:
   a. Oral to Inhalation, if known
   b. Oral to Dermal, if known
4. Inhalation Rate (e.g., resting rat to working human)

Default Physiological Scaling Factors

Species/ Physiological parameters	Rat	Human
Body weight	250 g	70 kg
Respiratory volume (standard; sRV)	0.2 l/min/rat = 0.8 l/min/kg bw (allometric scaling [a])	0.2 l/min/kg bw
for relevant duration:		
6 h exposure	0.29 m^3/kg bw	5 m^3/person
8 h exposure	0.38 m^3/kg bw	6.7 m^3/person
24 h exposure	1.15 m^3/kg bw	20 m^3/person
Respiratory volume light activity for worker (wRV)		
8 h exposure		10 m^3/person

The Benchmark Dose

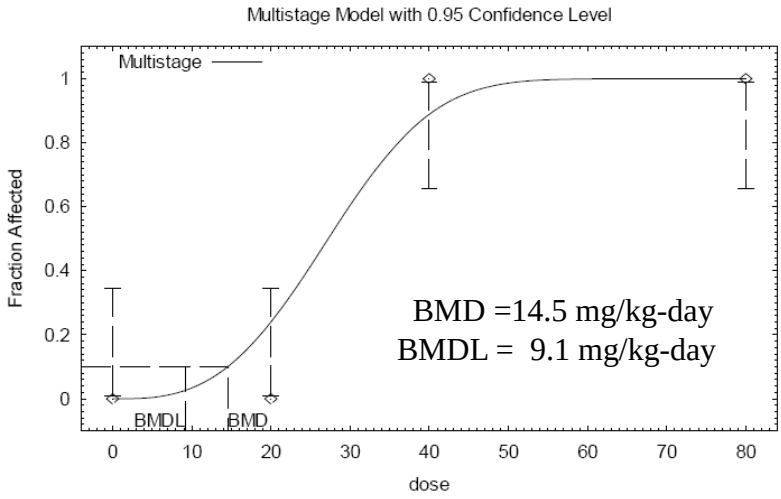
Utilizes standard statistical principles to predict the true no effect level and lowest effect level (1% increase in an observable effect), adjusting for study design.



The Benchmark Dose

- Based on approaches dating back to 1961.
- Formalized by U.S. EPA in 1995 to use for non-cancer risk assessments.
- BMD Software:
  http://www.epa.gov/ncea/bmds/index.html

Example BMD Output



Deriving DNELs

Step 4 – Apply Assessment Factors:

1. Exposure Duration:
   a. Subacute to chronic (28 days to lifetime)
   b. Subchronic to chronic (90 days to lifetime)
2. Interspecies (rat to human)
3. Intraspecies (variability among humans)
4. Quality of the Database

ECETOC vs ECHA Default Assessment Factors

ECETOC (from Tech Report No. 86)		ECHA (from Guidance Doc r8)	
• Establishment of NOAEL		• Establishment of NOAEL	
– LOAEL to NOAEL	3	– LOAEL to NOAEL	3-10
• Duration of exposure		• Duration of exposure	
– Subacute/chronic NOAEL	6	– Subacute/chronic NOAEL	6
– Subchronic/chronic NOAEL	2	– Subchronic/chronic NOAEL	2
– Local effects by inhalation	1	– Local effects by inhalation	1-2.5
• Route to route		• Route to route	
– Oral to inhalation	ND	– Oral to inhalation	2
– Oral to dermal	ND	– Oral to dermal	1
• Interspecies and Intraspecies		• Interspecies and Intraspecies	
– Mouse (scaling)	7	– Mouse (scaling)	7
– Rat (scaling)	4	– Rat (scaling)	4
– Monkey (scaling)	2	– Monkey (scaling)	2
– Dog (scaling)	2	– Dog (scaling)	1.4
– Interspecies (local eff. By inh)	1	– Interspecies (local eff. By inh)	1
– Intraspecies (local effects)		– Intraspecies (local effects)	
• Consumers	5	• Consumers	10
• Workers	3	• Workers	5

PBPK Modeling

Physiologically-based pharmacokinetic (PBPK) modeling can be used to adjust or deviate from the default assessment factors.

Example DNEL Derivation

Description	Value	Remark
Step 1) Relevant dose-descriptor	NOAEL: 250 mg/kg (oral; rat) 90-day study.	1000 mg/kg bwt/day: 10/10 males and 1/10 females died. 500 mg/kg bwt/day: males only had decreased mean body weight and body weight gain.
Step 2) Mode of Action	Threshold Effect	CNS depression with resulting body-weight reduction.
Step 3) Modification of the starting point	1/0.38	Oral to inhalation unit conversion (8h exposure)
	1	Route to route bioavailability extrapolation not appropriate.
	6.7 m^3/10 m^3	Inhalation Rate: Resting rate to light work
Step 4) Assessment factors		
Exposure duration	2	Sub chronic to chronic
Interspecies	1	No interspecies extrapolation for Inhal.
Intraspecies	3	Worker default AF
Quality of database	1	
DNEL (Chron. Inhl. Worker)	250 x 2.6 x 1 x 0.67 / (2 x 1 x 3 x 1) = **73 mg/m^3**	

Alternative to DNEL

Indicative
Occupational
Exposure
Limits (IOELs)

Currently 100 Substances

EU-adopted health-based, non-binding values, derived from the most recent scientific data available and taking into account the availability of measurement techniques.

Using an IOEL as a DNEL

CAUTION: When using an IOEL, the registrant must ensure that the IOEL is valid with respect to the toxicological data in the registrant's dossier.

What About Other OELs?

Binding
Occupational
Exposure
Limits (BOELs)

Currently 4 Substances

EU-adopted, binding limits, that reflect socio-economic and technical feasibility factors in addition to toxicological information taken into account when establishing IOELs.

What About Other OELs?

National
Occupational
Exposure
Limits (National OELs)

Adopted at the member-state level (e.g., German MAK).

What About Other OELs?

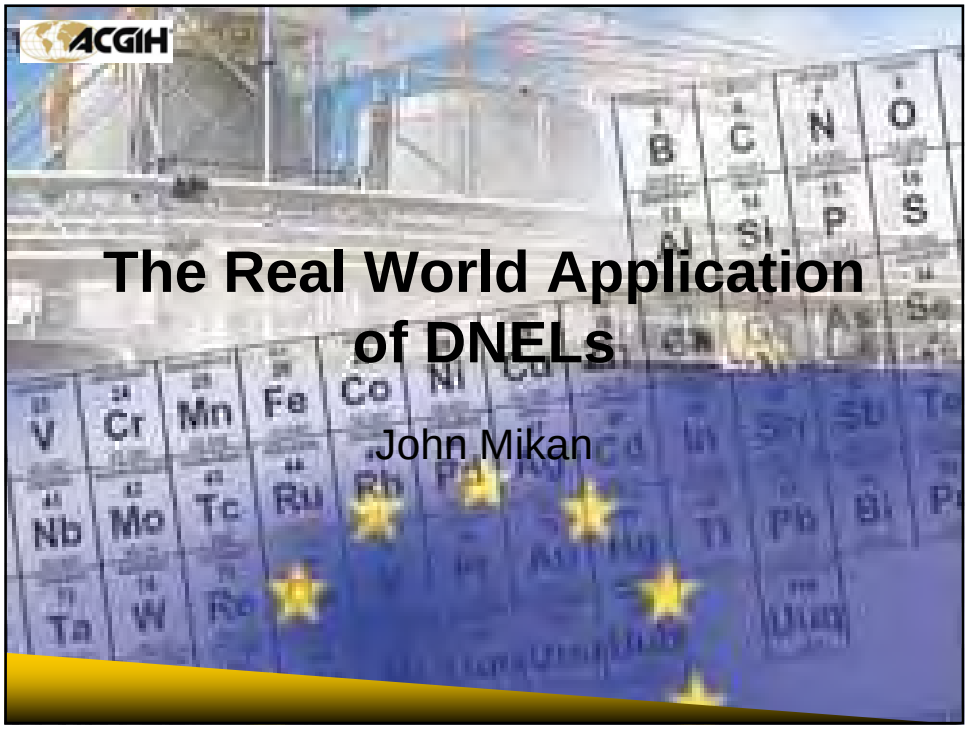
OSHA PELs
NIOSH RELs
ACGIH® TLVs®

What About Other OELs?

- BOELs, National OELs, TLVs®, PELs, etc. can't be used in place of deriving DNELs.
- A BOEL or National OEL that is lower than the derived DNEL may be used.
- The REACH regulation and guidance are silent on the topic of using a non-EU OEL that is lower than the derived DNEL.

What About Non-Threshold Effects?

A "Derived Minimal Effect Level" or DMEL is established using a "linearised" risk estimate or a "large assessment factor" approach.



We Have Our DNELs Now What?

As mentioned, DNELs are used much like an OEL, but are extended to include the general “consumer” population...

...And like an OEL, the DNEL is compared to information regarding exposure to characterize risk.

Risk Characterization

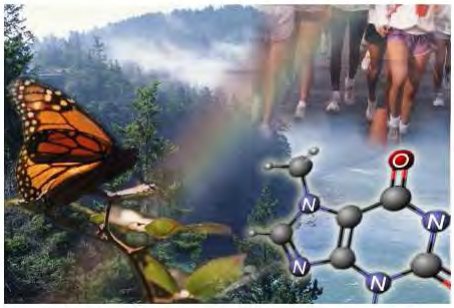
Risk
Characterisation
Ratio (RCR):

$$RCR = \frac{\text{Exposure}}{\text{DNEL}}$$

ECHA

Guidance on information requirements and chemical safety assessment

Part E: Risk Characterisation



May 2008

Guidance for the implementation of REACH

Risk
Characterisation
Ratio (RCR):

$$RCR = \frac{\text{Exposure}}{\text{DNEL}}$$

$$RCR_{Inhalation} + RCR_{Dermal} + RCR_{Oral} = RCR_{Total}$$

Risk Characterisation Ratio (RCR)

RCR < 1 →

← RCR ≥ 1

The Exposure Assessment

$$RCR = \frac{\text{Exposure}}{\text{DNEL}}$$

1. Exposure Scenarios
2. Estimation Models:
   a. EUSES/EASE
   b. ECETOC TRA
   c. Stoffenmanager
   d. ConsExpo
   e. RISKOFDERM
   f. Various EPA Models
3. Measured Data
   a. Published
   b. Unpublished

What If RCR ≥1?

1. Risk Management Measures (RMMs)*
   a. Ventilation
   b. PPE
   c. Training
   d. Limit Duration of Exposure
   e. Limit Concentration

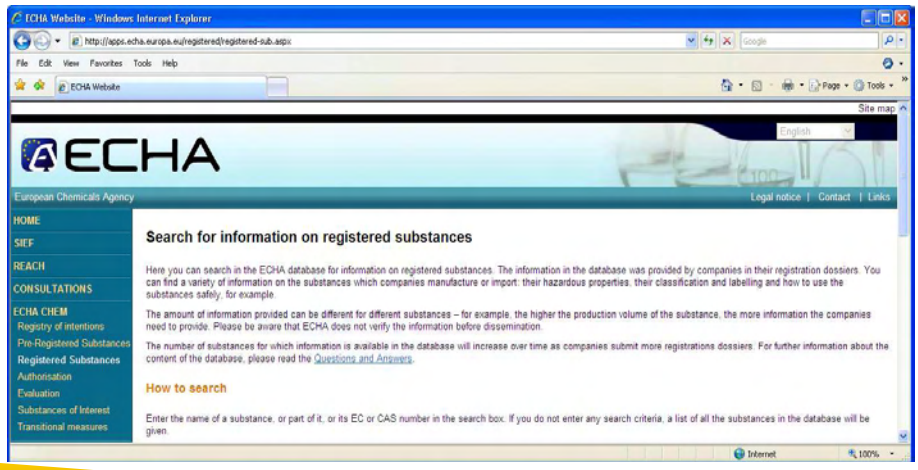
***Become mandatory on extended Safety Data Sheet**

Summary Risk Characterisation

Exposure Scenario	RCR (inhalation)	RCR (dermal)	RCR (all routes)
Exposure Scenario #1	0.01	0.10	0.11
Exposure Scenario #2	0.10	0.01	0.11
Exposure Scenario #3	0.20	0.00	0.20
Exposure Scenario #4	0.50	0.05*	0.55

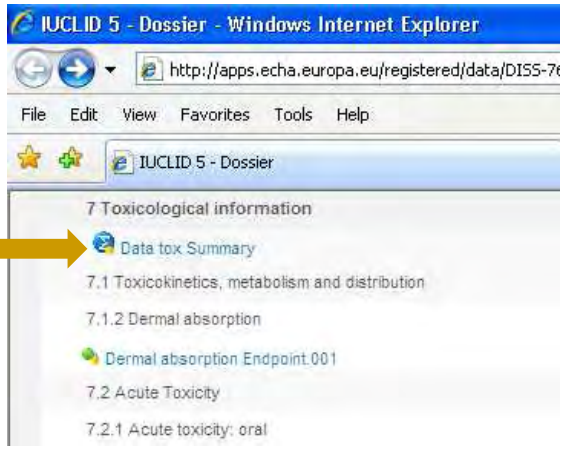
*Assumes proper selection and use of gloves

Availability of DNELs



Availability of DNELs

Search for substance, "view" dossier, click on Data tox Summary



DNELs will also be presented in Section 8 of the EU Safety Data Sheet…

…alongside other OELs

SAFETY DATA SHEET

Product XYZ

Date of Issue: February 3, 2010 Revision:2

7. HANDLING AND STORAGE

HANDLING — Wear protective equipment to comply with good occupational hygiene practice. Avoid contact with skin and eyes. Use only in well-ventilated areas. Avoid inhalation of vapours. Avoid inhalation of mists.

STORAGE — Keep container tightly closed. This product should be stored away from sources of strong heat or oxidising chemicals.Heating of containers may cause pressure rise, with risk of bursting.

Storage Temperature: Ambient.
Storage Life: Stable at ambient temperatures.
Specific use: Surface treatment preparation

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Industrial use only.

Respirators — Wear suitable respiratory protective equipment if exposure to levels above the occupational exposure limit is likely.

Eye Protection — Goggles giving complete protection to eyes.Safety spectacles. Have available eyewash bottle with clean water.

Gloves — Plastic or synthetic rubber gloves.

Other — Contaminated clothing should be discarded.

OCCUPATIONAL EXPOSURE LIMITS

Organochlorofluorosilane

Exposure limits	Type	Notes
None established		

Derived No Effect Levels (DNELs)	Type	Notes
10 ppm	Worker (Long-term, inhalation)	
20 ppm	Worker (Short-term, inhalation)	

What About Unintended Consequences?

Can regulators use DNELs to demonstrate non-compliance?

Will EU member-states abandon their current OEL processes and default to the DNELs?

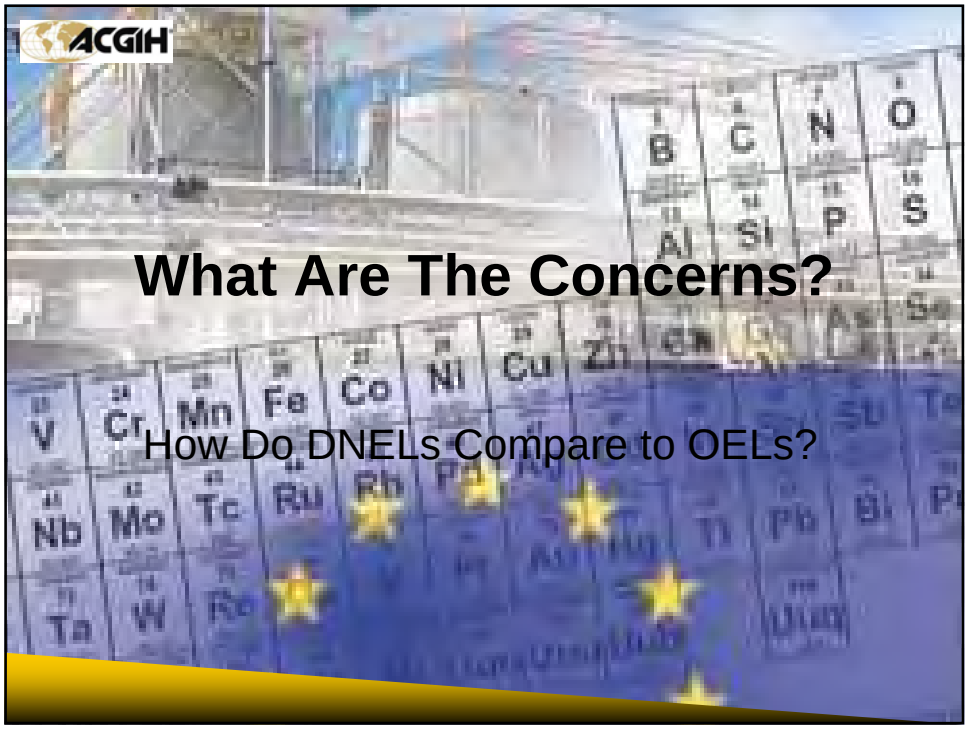
Will the EU grab hold of the DNELs and turn them into IOELs?

What About Unintended Consequences?

Will manufacturers derive overly conservative DNELs to shield themselves from liability?

Will manufacturers "adjust" their DNELs to achieve a favorable RCR?

Will we see multiple DNELs for the same substance when manufacturers can't agree?



Concerns

"The change associated with GHS and REACH that will cause the most confusion for workers will be the new "exposure limits" known as Derived No Effect Levels (DNELs)."

Skoglund, R. and D. Deeds, **Global Impact: GHS and REACH Will Transform Worker Safety and Health Programs.** The Synergist 20(8), September 2009.

Concerns

"A key feature of REACH is the Derived No Effect Levels (DNELs), a new health- and ecotoxicity-based exposure limit."

Rutkowski, E., **Updating PELs: Is Now the Time? AIHA Weighs Another Attempt at Changing OSHA.** The Synergist 20(9), October 2009.

Concerns

"…REACH also requires new extended safety data sheets for all the chemicals, and these will state the DNELs; so for the people in the workplace—employers or workers—these will surely become the numbers that count."

Ogden, T., **REACH-how is it going?** Annals of Occupational Hygiene 54(1), January 2010.

Concerns

"The calculation of DNELs follows a rule-based approach... This can result in a very conservative figure, perhaps two or three orders of magnitude lower than that from the traditional OEL setting process."

Adkins, C., L. Booher, et. al., **Occupational Exposure Limits-Do They Have A Future?** International Occupational Hygiene Association, August 20, 2009.

Concerns

Concerns that will be discussed:

- ✓ The DNEL derivation process will be "closed".
- ✓ The data relied upon to derive the DNEL will not be as robust as that of an OEL.
- ✓ Derivation of DNELs is a fixed, rigid process with little flexibility.

Concerns

Concerns that will be discussed:

- ✓ There will be many or different DNELs for a substance.
- ✓ If more conservative, will this doom the OEL?
- ✓ The DNELs will be unrealistically conservative.
- ✓ Once derived, are the DNELs set in stone?

The DNEL Derivation Process ...ed

AGREE: To A Point

Manufacturers and Importers (M/I) derive the DNELs.

✓There is no obligation to invite the public and stakeholders.

✓In that sense, the process is closed.

The DNEL Derivation Process Is Closed

However...

✓Collaborate within consortia and SIEFs

✓Will see the lead registrant DNELs and RMMs

✓In that sense, the process is open

The DNEL Derivation Process Is Closed

Generally With OELs

- ✓Collaborate upfront with stakeholders and public
- ✓Then some committee or entity weighs evidence & decides upon the value

With DNELs

- ✓No upfront collaboration
- ✓M/I set DNELs, publish in CSR and eSDS
- ✓Backend ECHA, public and NGO reviews

Perceived To Be As Robust

- ✓ Is data adequate for classification and labeling?
- ✓ Is data adequate for health / risk assessment?
- ✓ Does data fulfill expectations for tonnage band?

Data Adequacy Assessment Expectations

Perceived To Be As Robust

OEL

- Process to rate studies is rooted in judgment.
- Key studies are disclosed.
- Do not see studies that were not key studies.

DNEL

- Process to rate studies is based on Klimisch scoring system.
- Have to disclose the full literature search.
- Can see studies not chosen to be key study for endpoints.

Perceived To Be As Robust

Klimisch Scores

- Defined system for scoring reliability of data.
- Studies can be ranked.
- Cautiously consider 3 and 4 ranked data.

1 = Reliable w/out restrictions
2 = Reliable with restrictions
3 = Not reliable
4 = Not assignable

The DNEL Derivation Process = Rule Based Approach

OEL	DNEL
Derivation Processes (some) = rule based	Regulation = Not Rule Based
Derivation Processes (others) = no rules	Companies can choose approach
	Companies taking technically sound approach

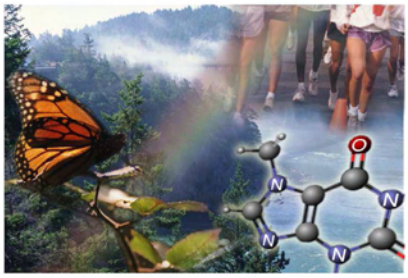
DISAGREE

The DNEL Derivation Process = Rule Based Approach

ECHA

Guidance on information requirements and chemical safety assessment

Part B: Hazard Assessment



May 2008
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Guidance Docs = Rule Based

Still: Flexibility in approach allowed

There Will Be Many DNELs for a Single Substance

OEL	DNEL
Full Shift TWA	Many DNELs
Short Term 15-min TWA	The RMMs are the important stuff
Ceiling or Peak Exposure	Could have many DNELs & ES but limited RMMs

AGREE

DNELs: Unrealistically Conservative

The concern is that the process will create DNELs that are well below OELs.

The exposure level a DNEL is intended to control to is different than an OEL.

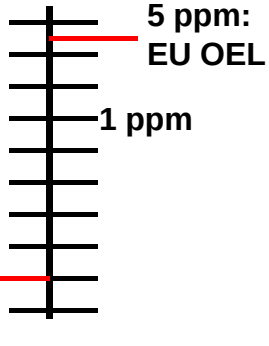
The exposure level is based on the precautionary principle = prove no harm.

DISAGREE

DNELs: Unrealistically Conservative

HYDROGEN SULFIDE

Based on Technical Guidance Document (TGD) and 10 ppm NOAEL

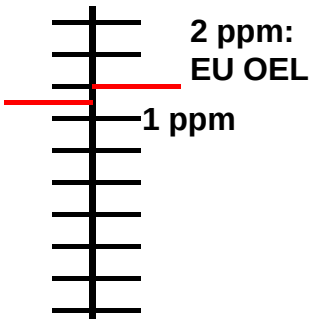


Money, C., **What are the Likely Impacts of REACH for Occupational Hygiene?** BOHS Conference, April 2007.

DNELs: Unrealistically Conservative

ETHOXYETHANOL

Based on TGD and 50 ppm NOAEL

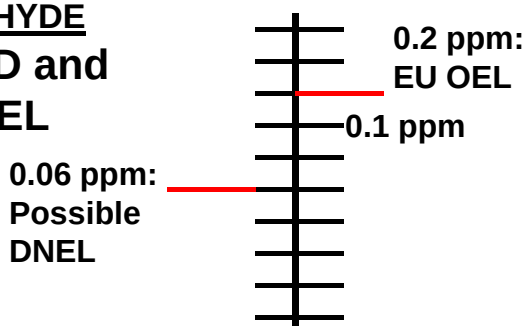


Money, C., **What are the Likely Impacts of REACH for Occupational Hygiene?** BOHS Conference, April 2007.

DNELs: Unrealistically Conservative

FORMALDEHYDE

Based on TGD and 0.3 ppm NOAEL

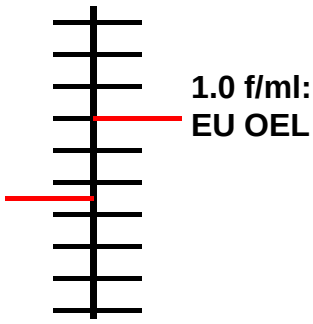


Money, C., **What are the Likely Impacts of REACH for Occupational Hygiene?** BOHS Conference, April 2007.

DNELs: Unrealistically Conservative

MAN MADE MINERAL FIBERS

Based on TGD and 25 fiber/ml LOAEL



Money, C., **What are the Likely Impacts of REACH for Occupational Hygiene?** BOHS Conference, April 2007.

DNELs: Unrealistically Conservative

With OELs there is some residual risk even if exposed to less than the OEL.

- ✓ **That risk typically not quantified, led to conservatism in IH practice.**
- ✓ **Along with statistical conservatism if exposures > 50% OEL.**
- ✓ **Embodied in the < 1/2 to 1/10 OEL concept.**

DNELs: Unrealistically Conservative

Thus, we have built into our approach to occupational exposures the precautionary principle.

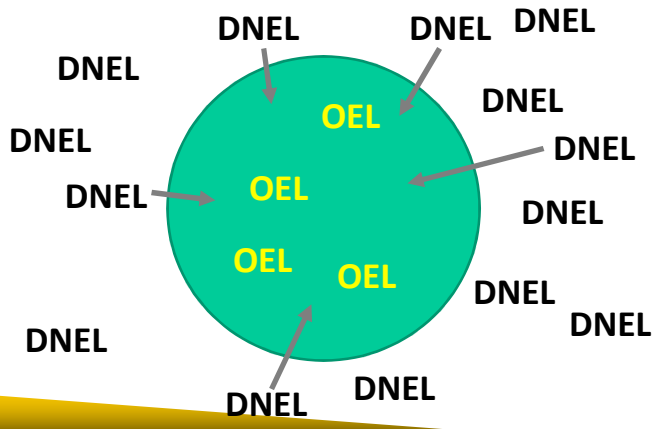
So why are we surprised or alarmed by the DNEL?

Concern: DNEL[illegible] be treated

AGREE

DNELs Treated As OELs

Nature abhors a vacuum



DNELs Treated As OELs

The belief is that DNELs will be treated as OELs.

Therefore, DNELs will be treated as OELs.

DNELs Treated As OELs

DNELs ≠ OELs

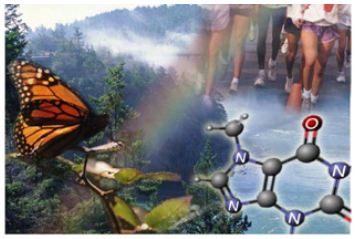
Educate, Educate, Educate

DNELs Treated As OELs

Develop IH Guidance

Your Organization Here

Guidance on DNELs and Application to Occupational Workplaces



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OELs Are Doomed?

OELs Are Not Doomed

- DNELs are M/I recommendations.
- There may be many values for each particular exposure route and duration for the same substance.
- Member States and NGOs will debate and have opportunity to present their views by a number of routes including legislation and harmonization efforts.

OELs Are Not Doomed

- One obstacle for OEL development was lack of data.
- REACH will greatly expand the dataset on substances and there will probably be subsequent testing and development of more data.
- Opportunity for advancement of OELs

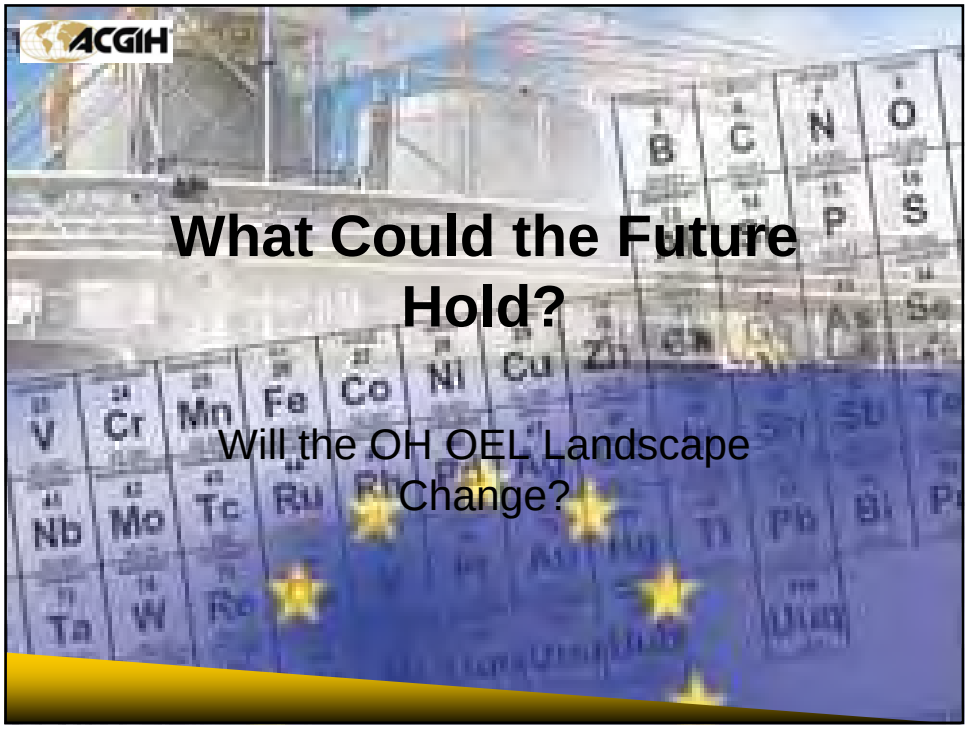
In Summary

In an occupational context, the DNEL could be construed to be a de facto OEL.

DNELs are different from OELs. Opportunity to embrace and educate.

There is an opportunity for OELs.

The DNEL is intended to be more conservative than the OEL. However, already matches our practice.



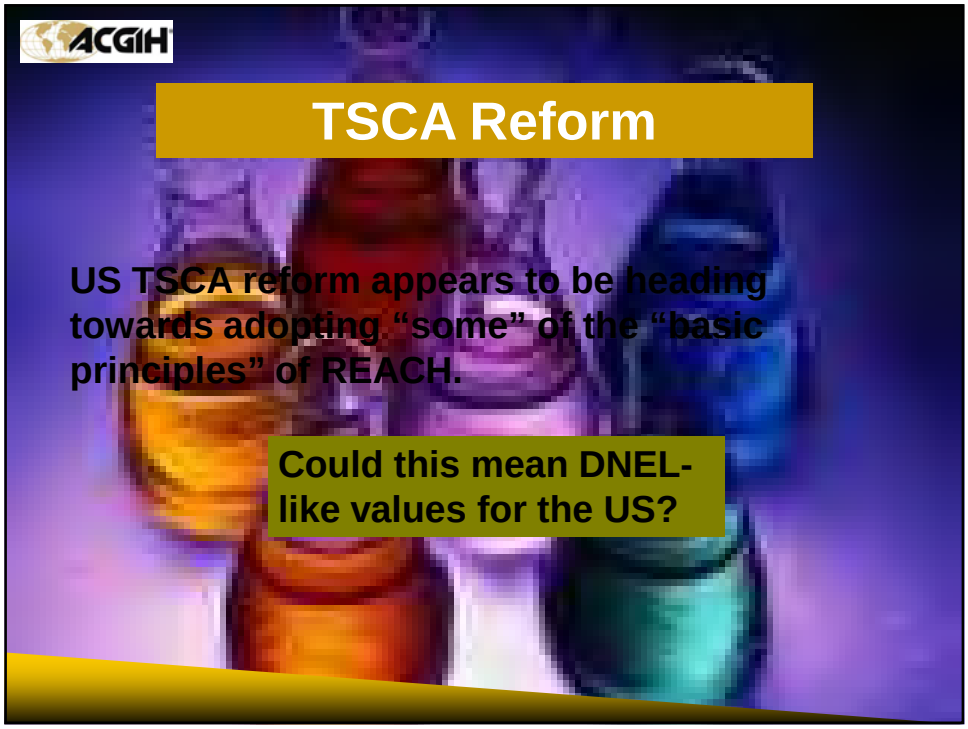
ACGIH

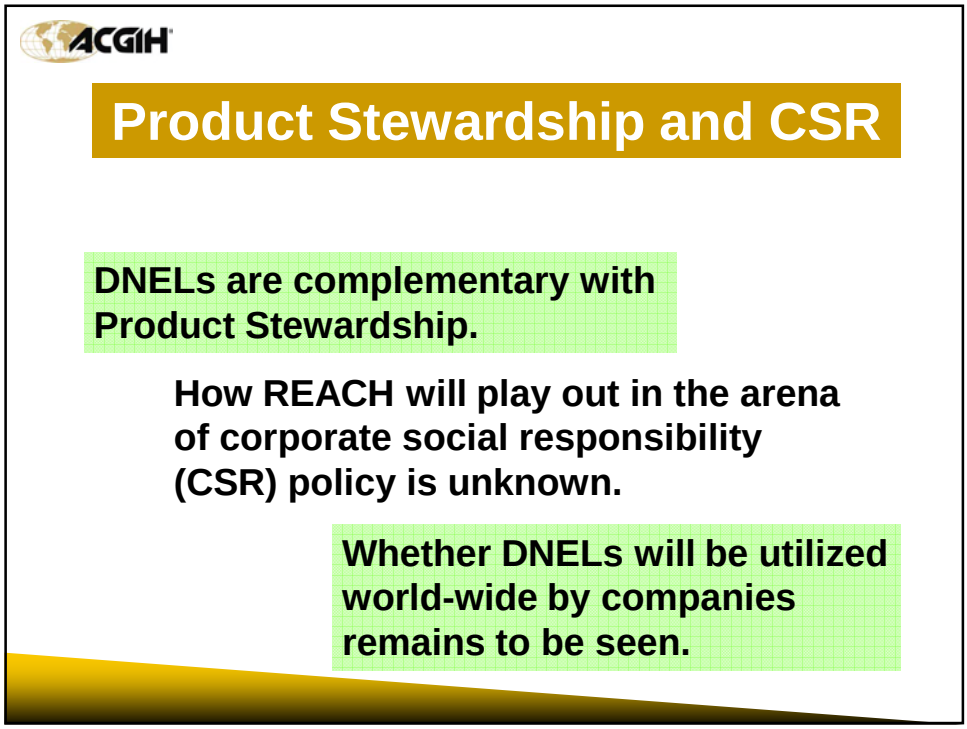
Updating of OSHA PELs

There continues to be a great deal of discussion on the need to update the OSHA PELs.

Some have argued, in response to OSHA's failed attempt to update the PELs in 1989, that manufacturers should be required to develop OELs for the substances they manufacture and to publish the limits on the MSDS.

Given the global nature of the chemical industry, REACH may have effectively accomplished what may have never been agreed to in the US.


ACGIH
TSCA Reform
US TSCA reform appears to be heading towards adopting "some" of the "basic principles" of REACH.
Could this mean DNEL-like values for the US?


ACGIH
Product Stewardship and CSR
DNELs are complementary with Product Stewardship.
How REACH will play out in the arena of corporate social responsibility (CSR) policy is unknown.
Whether DNELs will be utilized world-wide by companies remains to be seen.

Other Exposure Guidelines

General Population DNELs could impact other exposure guidelines:

- EPA AEGL
- EPA Reference Dose (RfD) and Reference Concentration (RfC)
- CDC ATSDR Minimum Risk Levels

Will the OEL Landscape Change?

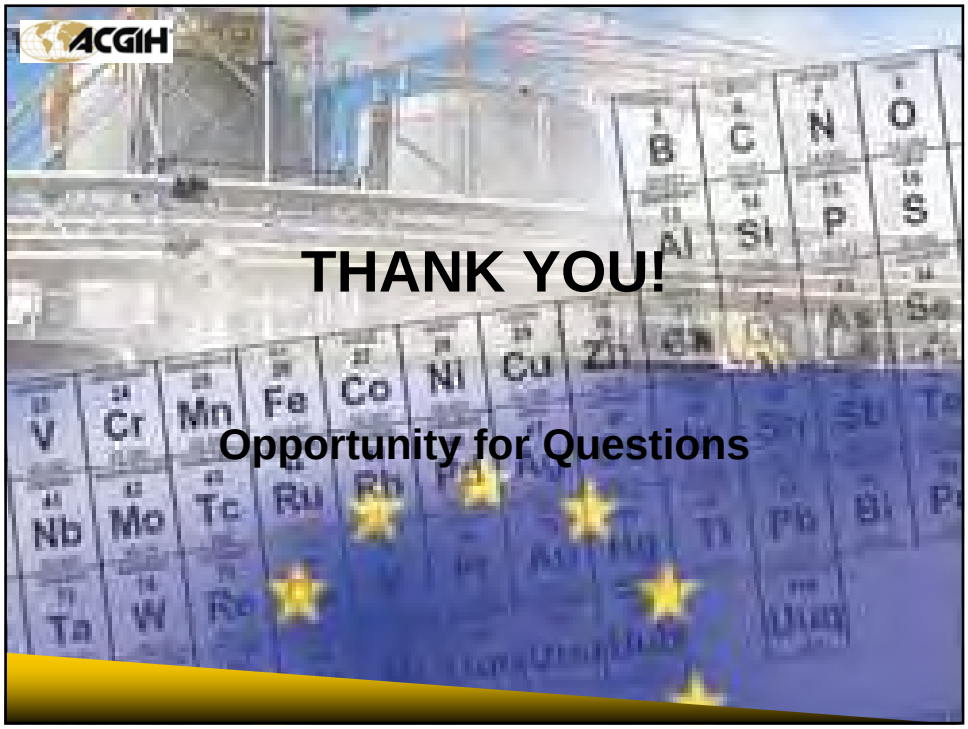
Definitely Yes

- ✓Not just an EU issue.
- ✓REACH: Reflection of changing values.
- ✓The amount of information available to the public about chemicals and exposure risks is about to exponentially increase.

DNELs: An Opportunity for the IH Profession?

The derivation of DNELs in the EU, published for the world to see, opens the door for new research in IH:

- Development of new air sampling methods
- Characterizing exposures against the DNELs
- Respirator cartridge breakthrough studies
- Glove permeation studies
- Biomonitoring



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