

# DNELs: The Good, The Bad & The Ugly



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# Product Stewardship and OELs

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- One form of Product Stewardship is providing 'safe limits' for working with a product and communication of the 'hazards' and/or 'risks' of a product via 'Product Literature' and the Safety Data Sheet
- Presumed that compliance with OEL indicates lower 'risk' of injury or illness
- USA has not traditionally done a 'risk assessment' for products other than Pesticides, Biocides and PMNs

# Another Product Stewardship Tool?

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European Union's REACH regulation has driven the development of '*de facto*' exposure limits:

DERIVED NO EFFECT LEVEL

**“DNEL”**

# Product Stewardship in Europe: REACH

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- Registration, Evaluation, Authorization of Chemicals –  
**TSCA on Steroids!**
- Risk Characterization of all uses required of Manufacturers, Importers and Distributors for chemicals
- Risk Characterization for the leading health effect:
  - (i.e., the toxicological effect that results in the most critical [lowest] **DNEL**) for a given [human] exposure pattern associated with an exposure scenario (ES)

# DNEL Refresher

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- Derived No-Effect Level (DNEL): The level of exposure above which humans should not be exposed
  - Used in REACH quantitative risk characterization
  - Established for the substance based on:
    - ✦ Population: Workers, consumers and the general population (via environment)
    - ✦ Route: Inhalation, dermal and ingestion exposure
    - ✦ Duration: Acute (short-term) and chronic (long-term) exposure
    - ✦ Effect: Systemic or local
  - Derived for chemicals having a threshold mode of action
  - Potential for many different DNELs because of different combinations and exposures (also see next two slides)

# DNELs and Human Exposure Patterns

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- REACH requires a Risk Characterization for the leading health effect (*i.e.*, the toxicological effect that results in the most critical [*lowest*] DNEL) for a given [*human*] exposure pattern associated with an exposure scenario (ES)
- May have many human exposure patterns within a defined exposure scenario (examples):
  - Worker/Dermal/Short-term/Local Effect
  - Worker/Inhalation/Short-term/Local Effects
  - Worker/Dermal/Long-term/Systemic Effects

# Why Talk About DNELs?

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- Over 150,000 substances exist in commerce in EU
  - Only about 1,500 substances have OELs anywhere around the world
- Every substance in commerce in the EU (thus the Rest of World) will have a **DNEL**
- DNELs will be on every European SDS & used in exposure and risk assessment for REACH Registration!



# DNELs: eSDS Section 8.1

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DNELs are required to be **Section 8.1** of REACH-compliant eSDS<sup>1</sup>:

Where a Chemical Safety Report is required, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios set out in the annex to the Safety Data Sheet.

**MANY DNELs (DERMAL, INHALATION, ETC.) WILL NOW BE IN SECTION 8.1 OF eSDSs (ALONG WITH OELs) → BE READY !!!!**

<sup>1</sup>See: Commission Regulation (EU) No. 453/2010 amending Regulation (EC) No. 1907/2006 (REACH) – effective 12/1/2010.



# OELs in REACH SDSs (Section 8.1)

Material	Source	Type	ppm	mg/m3
	EH40 WEL	TWA	100 ppm	430 mg/m3
	EH40 WEL	STEL	250 ppm	1,080 mg/m3
	ACGIH	TWA	20 ppm	
	ACGIH	STEL	40 ppm	

## Derived No Effect Levels (DNEL)

Component	Exposure Route	Exposure Type (long/short)	Application Area	Value
	Inhalation	acute, systemic effects	Worker	289 mg/m3
	Inhalation	acute, local effects	Worker	306 mg/m3
	Inhalation	long term, systemic effects	Worker	85 mg/m3
	Inhalation	acute, systemic effects	Consumer	174.25 mg/m3
	Inhalation	acute, local effects	Consumer	182.75 mg/m3
	Inhalation	long term, systemic effects	Consumer	10.2 mg/m3

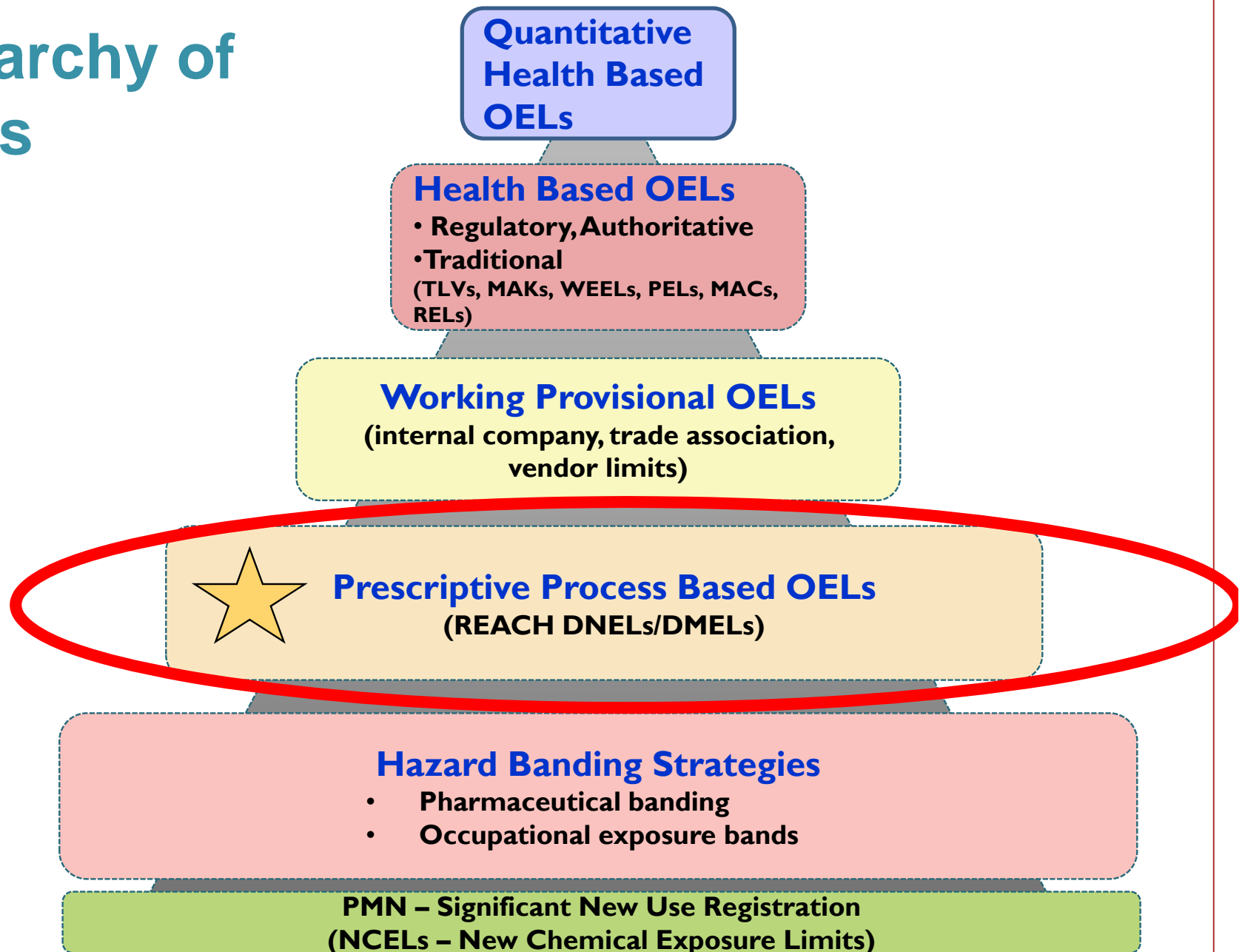
**Note:** All OELs and DNELs listed are for the **same chemical** (taken from section 8.1 of a REACH SDS)

# DNELs: Part of the Hierarchy of OELs

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- DNELs are a “Prescriptive” form of exposure limits
- Calculated / Derived values from limited toxicology data and specified methodology
- Original fear was that these limits would be “orders of magnitude lower than “Traditional Exposure Limits”
  - Some are much lower and some are actually higher!
- Industry experience has taught us something different!

# Hierarchy of OELs



**Hazard Banding + Exposure Banding → Control Banding**

# “The Bad”: Route to Becoming *de facto* OELs

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- In the absence of legitimate OELs:
  - Worker DNELs will become ‘*defacto OELs*’ for some companies and possibly some countries
  - Questions the validity of our historic TLVs, WELs, MAKs, WEELs, and other health-based guideline values
  - Which then sets up litigation against employers and the OEL-setting bodies
  - Once they are OELs in the USA, they will follow in ROW

# Simple Comparison

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- DNELs are:
  - Threshold-based non-cancer endpoints considered to be “No Effect Levels” for humans based on NOELs and AFs
- Worker DNELs are:
  - Calculated from Population DNELs
  - Prescriptive & Conservative – not based on judgment
- OELs are:
  - Levels of acceptable risk for workers based on NOAELs and LOAELs with SF (AF)  
\*\*We target 10 – 50% of the OEL for compliance
- OELs Utilize
  - Professional judgment and ‘weight of evidence’ with peer review by experts who draw comparative analogy between animal and human toxicology parameters

# DNELs Fill a Gap?

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- Why?

- Although DNEL<sub>w</sub> are established with the intent of risk assessment, in fact they are occupational exposure limits
- Thus, DNEL<sub>w</sub> are *de facto* OELs because they also provide the target concentrations for the proper control strategies to prevent worker injury and illness.

Yes!

- Why Not?

- Litigation in USA may drive employers to set and adopt OELs for everything they use rather than defer to the reference screening concentrations called DNELs

# Shortcut to Setting OELs?

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- Why?

- 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.

- Why Not?

- OSHA and most countries apply a socio-political process to setting compliance values when there is a chance of compliance fines and economic feasibility concerns
- Caveat: Could use DNELs as a starting point and use the data that is so hard to find!

Yes!

# Required vs. Desired

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- Why?

- DNELs are required to assess and ensure exposures can be controlled
- Exposure Scenarios describe risk management strategies – Easy Target

- Why Not?

- Employers don't necessarily look for the 'lowest' guidance value
- Very expensive strategies if not required

Yes!



# “No Effect Level”

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- Why?

- Risk Intolerance would select the ‘true threshold below effects’ as a derived No Effect Level’

Yes!

- Why Not?

- Some employers don’t know OELs exist, much less what to do with them; they are not likely to look for DNELs

# The Good: Hazard Index Needed

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- Why?

- The need for a 'safe limit' for the hazard index is strong and misunderstanding of the various 'routes of exposure' – they will use the worker inhalation DNELs

- Why Not?

- Registrants may derive different DNELs for a substance thus it will apply only to the specific scenarios of usage and will not apply across the board
  - ✦ Thus, the inclusion and confusion about OELs vs. DNELs just makes more guideline values available

Yes!

# REACH: Impact of DNELs

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- DNELs are developed independently by the manufacturer or importer
  - Some may come from SIEFs, but no obligation for that
- May or may not have used ECHA Guidance (Chapter R.8)
- May or may not have undergone peer-review
  - Scientific rigor and scientific defensibility
- May get different DNELs for the same chemical(s) from different manufacturers
  - Can lead to significant differences in RMMs and/or OCs for “safe” use

# DNELs and Health-Based OELs

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- The REACH regulation is clear that REACH “...should apply without prejudice to Community workplace and environment legislation.”
- In particular, the text of the REACH regulation goes on to say that the “Regulation shall apply without prejudice to a number of Directives including: “... Directive 98/24/EC....” [the EU Chemical Agents Directive; CAD]
  - CAD obligates employers to protect the health and safety of workers from risks of hazardous chemicals
  - CAD defines “Occupational Exposure Limit”

# DNELs and Health-Based OELs

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- Obligation under the CAD to monitor for compliance with the National (Member State) OEL
- No regulatory obligation to monitor to the DNEL after implementing any RMMs/OCs

Can DNELs provide workplace “exposure guidance”?  
→ Yes

DNELs do not displace OELs

DNELs  $\neq$  OELs

# Summary: DNELs & Product Stewardship

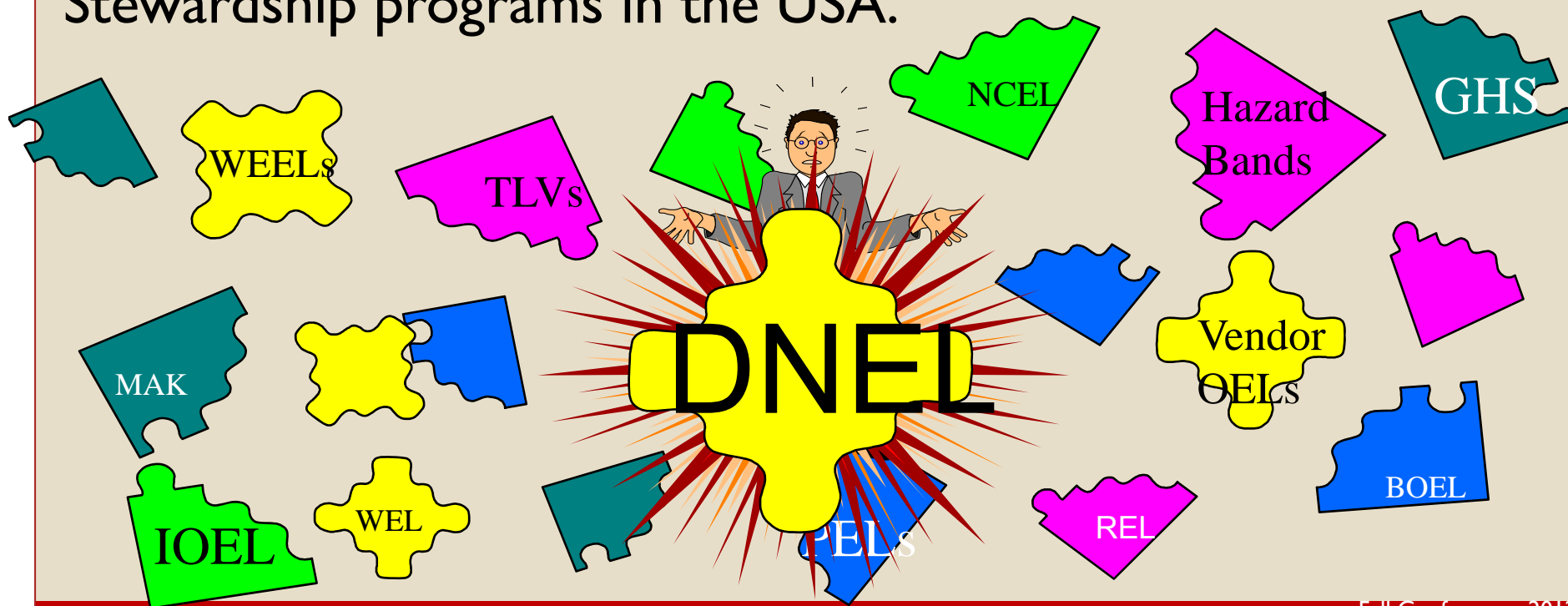
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# The Good ....

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We now have a starting point to capture the hazard data that we could not find, and can peer-review that data to develop meaningful OELs and develop more robust Product Stewardship programs in the USA.



# The Bad ....

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- If we do not recognize DNELs as '*de facto*' OELs and use them to 'inform' our setting of OELs and direction, we will miss an opportunity to perform the needed exposure assessments where OELs do not exist!



## and the Ugly!

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- If we don't recognize and address the use of DNELs in the USA, our litigation risks will rise because they will say “you knew better”!