



MASSEY UNIVERSITY

# Formaldehyde – friend or foe

AUSA Conference 2011

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# OEL Definition

Values for the maximum average atmospheric concentration of contaminants to which

- most workers may be exposed
- for an eight-hour working day without adverse injury to health.

(ACGIH TLV Booklet 1958).

ALRA introduced in 1996



# Synonyms

- Australia OES (Occupational exposure standard)
- France VME (Valeur Moyenne d'Exposition)  
VLE (Valeur Limite d'Exposition)
- Germany AGW (Arbeitsplatzgrenzwert)  
MAK (Maximale Arbeitsplatz-Konzentration)
- England OEL (Occupational exposure limit)
- Netherlands MAC (Maximaal Aanvaarde Concentratie)
- New Zealand WES (Workplace Exposure Standard)
- Malaysia PEL (Permissible exposure limit)
- Poland NDN (Najwyższe Dopuszczalne Natężenie)
- Russia ПДК (предельно допустимая концентрация)



# USA

- TLV (Threshold Limit Value) is a recommendation by ACGIH
- PEL (Permissible Exposure Level) regulatory level set by OSHA

Many USA Industrial hygienists think the PEL's do not provide sufficient protection – leads to:

- REL (Recommended Exposure levels) by NIOSH, or
- WEEL (Workplace environmental exposure level) by AIHA



For this presentation

OEEL

Unless referring to a specific country

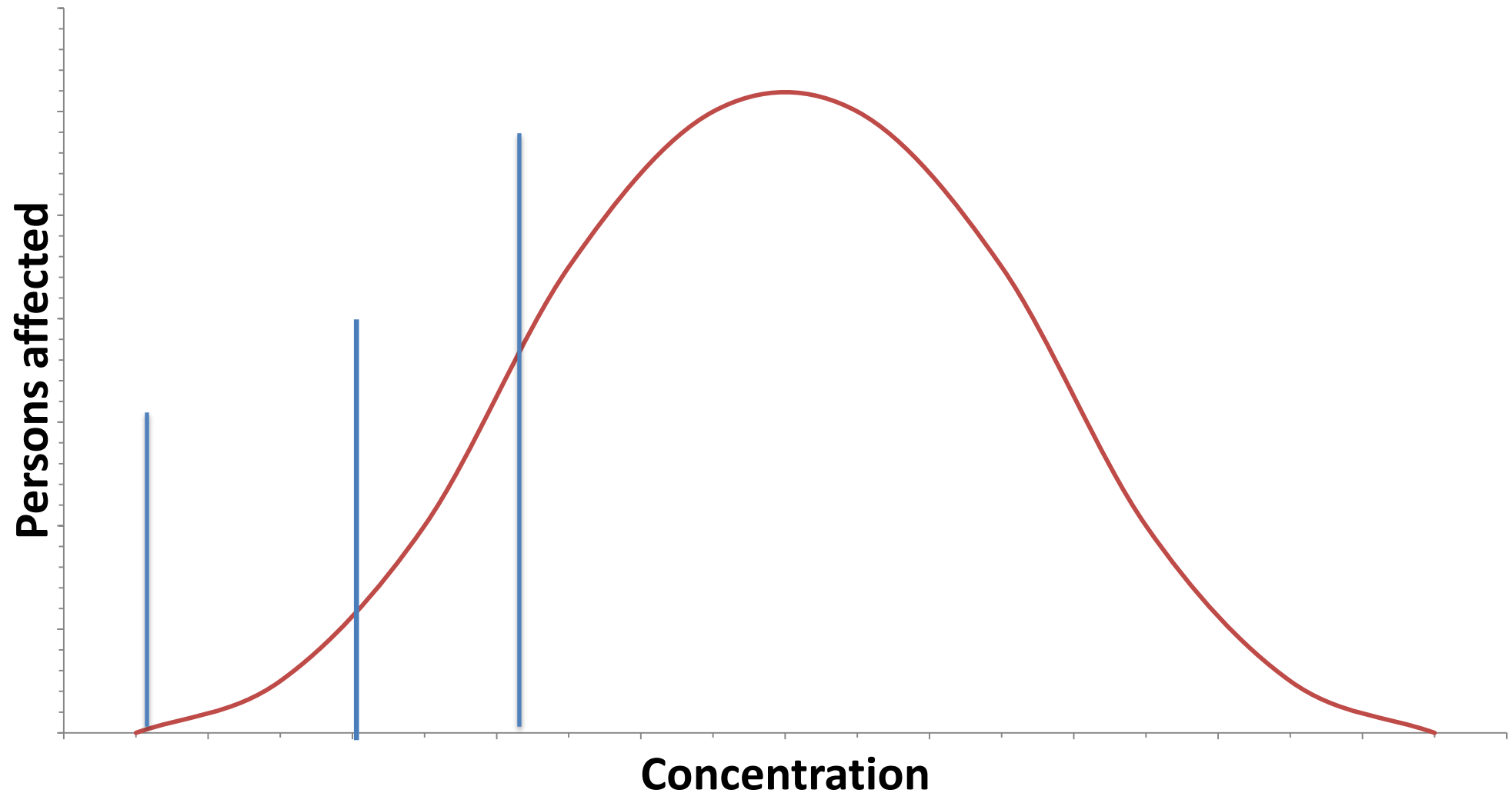


# Types of OEL

- TWA Time Weighted Average
- STEL Short-term exposure Limit
- C Ceiling Exposure Limit
- GEL General Excursion Limit



# Probability of persons affected by increasing concentration of toxic substance



# OEL History

- 1910 proposed as concept in UK
- 1912 Leege and Duckering set levels for lead and silica – inspectorate reject
- 1919 Sanitary engineers in USA (TB was main worry)  
> Sanitarians
- 1930's USA accept Sanitarians, IH profession develops  
UK follows
- 1912 German list by Kobert – not used
- 1946 First ACGIH list name changed from MAK to TLV



# Use of OEL's

## **Reference tool** for monitoring chemical risks

- larger organisations
- experience or contracted IH

## **Education and information**

- raising awareness on chemical risks.
- however considerable ignorance of meaning

## **Environmental legislation**

## **BUT wide spread ignorance prevails**

# International OEL lists

USA -ACGIH TLV's most influential OEL's in the world.

- used by most industrialised countries since 1950s
- large influence on other OEL setting committees  
(even when country purports to have its own OEL's)

Germany – MAK's developed separately to TLV's

- based exclusively on scientific information about health effect

Russia - ПДК calculated using computational techniques, informed by biological experiments, dynamic monitoring of the health of a person exposed , and USA EPA levels.

# Criteria in setting OEL's

- Irritant effects?
- Health effects?
- What can be achieved by controls?
- Impact on industry process?
- Cost benefit analysis?

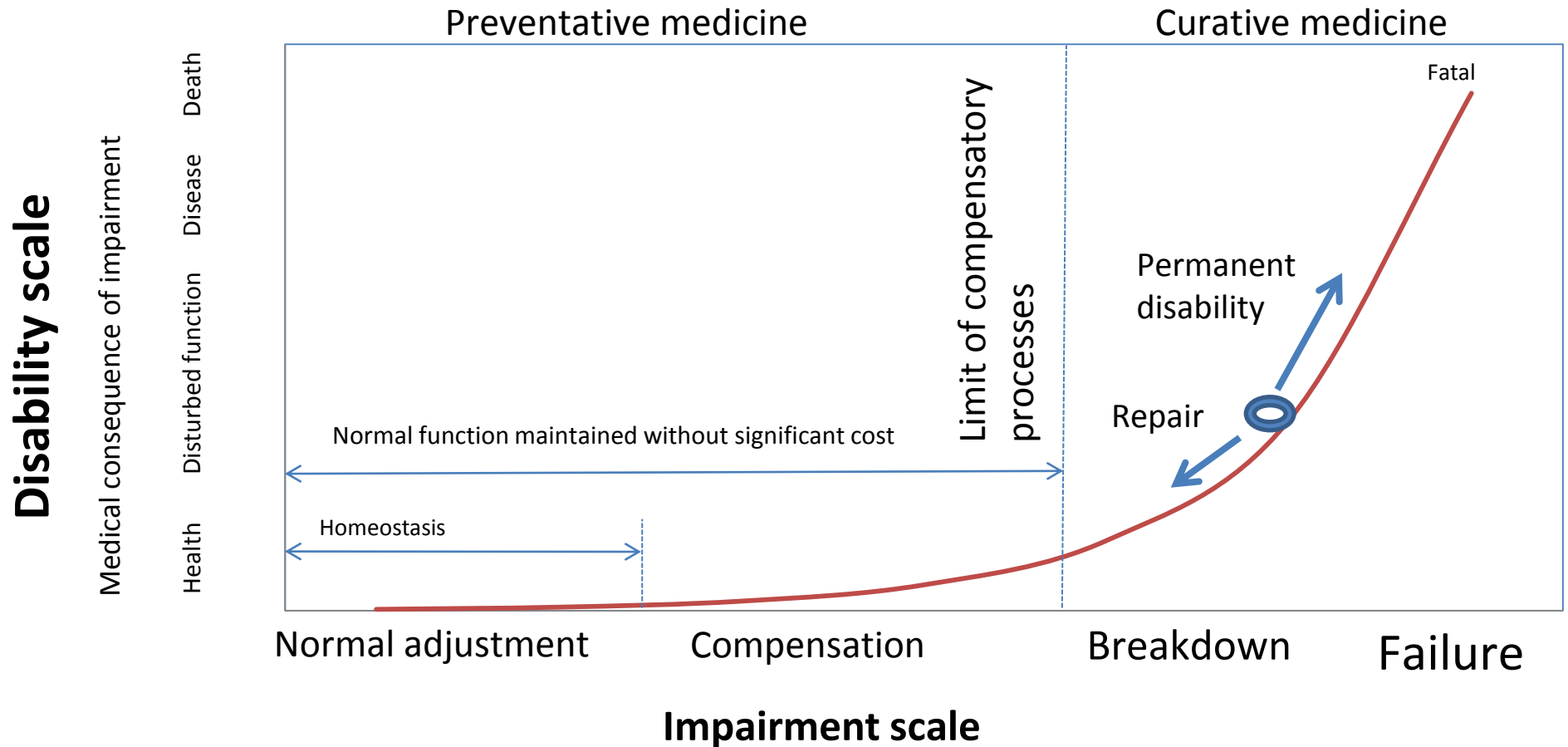


# Criteria has moved over time

- Most, TLVs have been set to take into account the practicability of the controls and to balance these against the evidence of harm (Piney)
- A necessary compromise (Winslow)
- Since mid 1980's health effects have tended to dominate in OEL setting process (Piney)

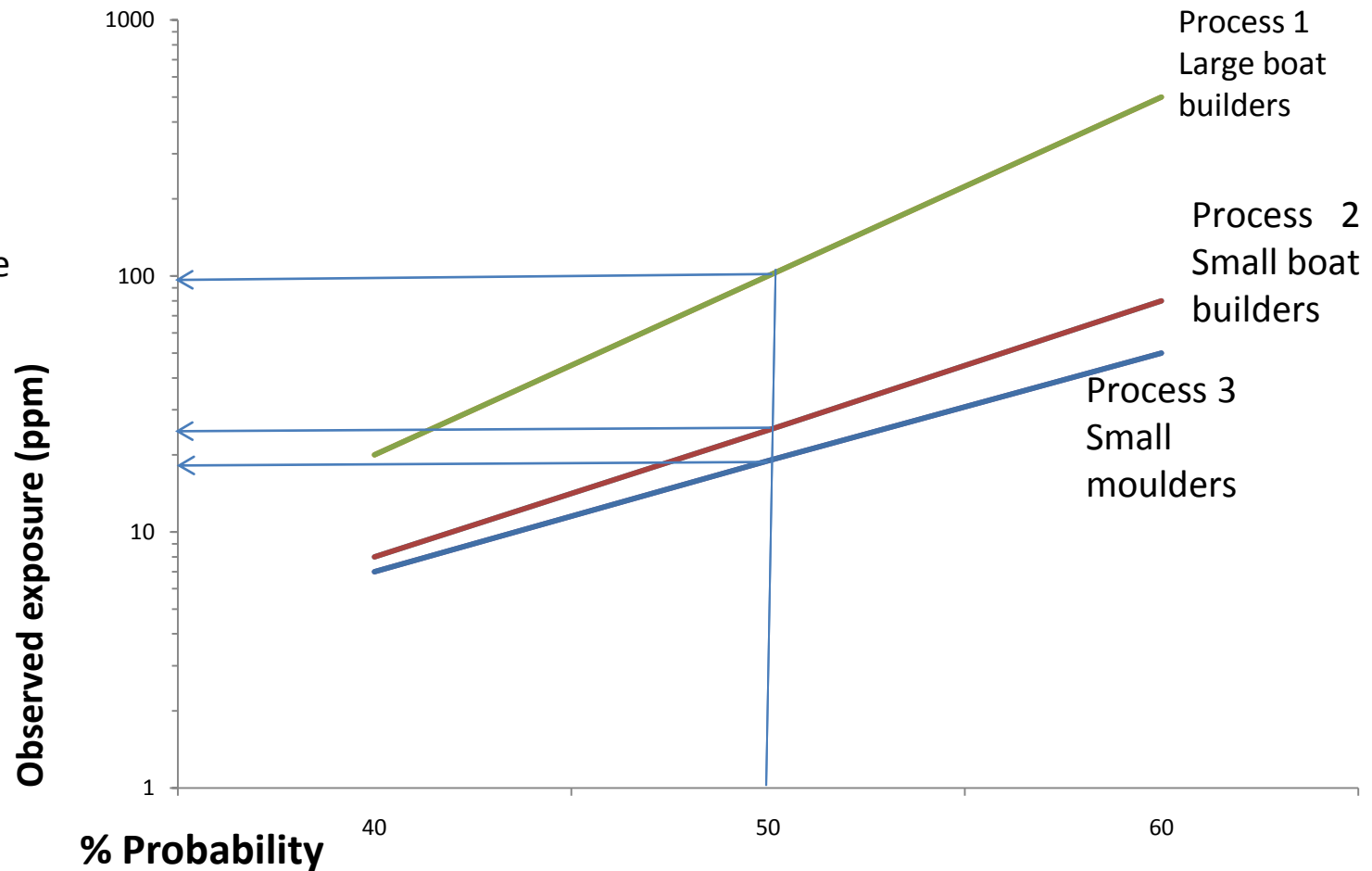


# The dilemma in using health effects



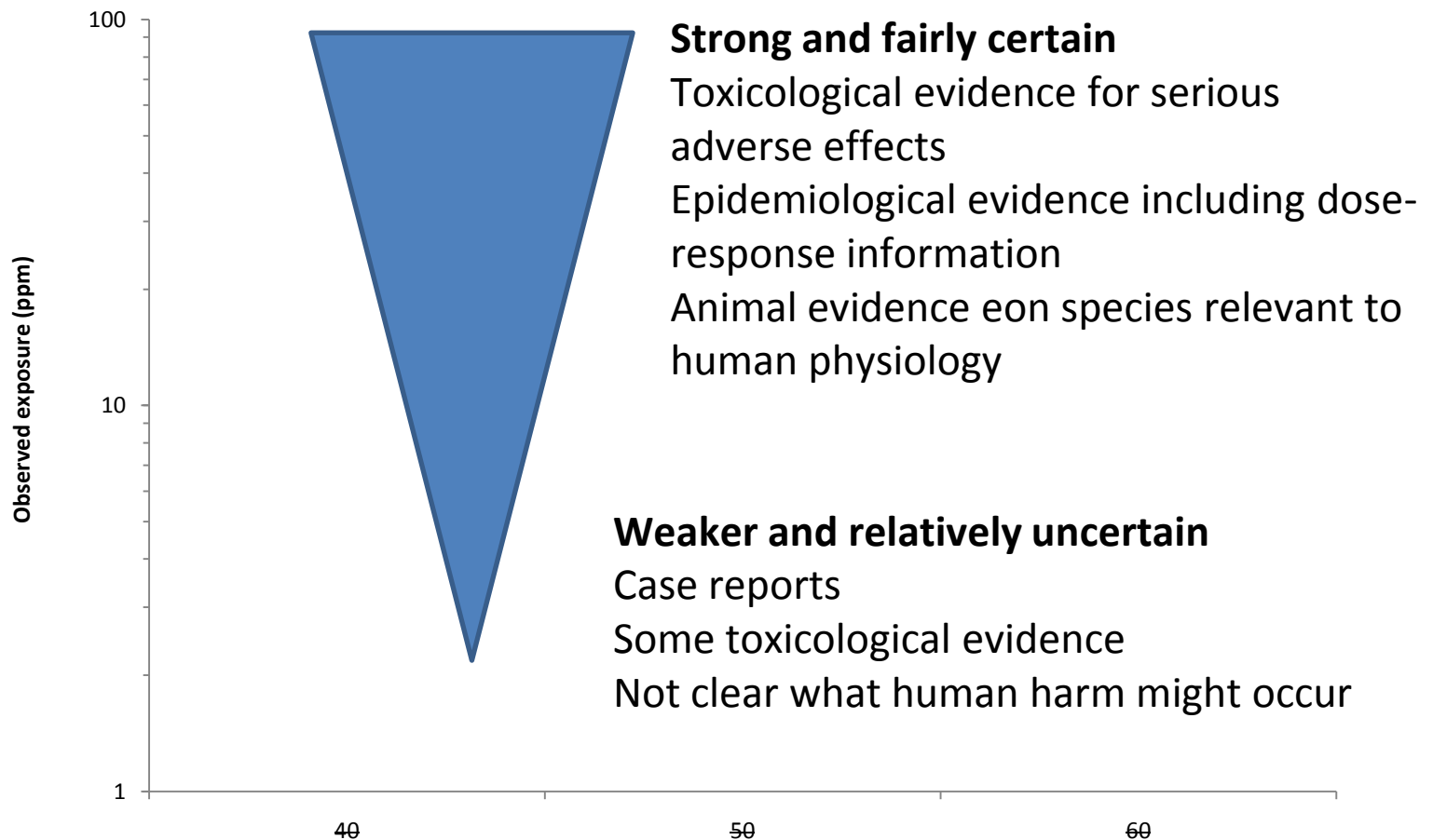
# What is reasonably practical?

Approximate average exposure for the three processes

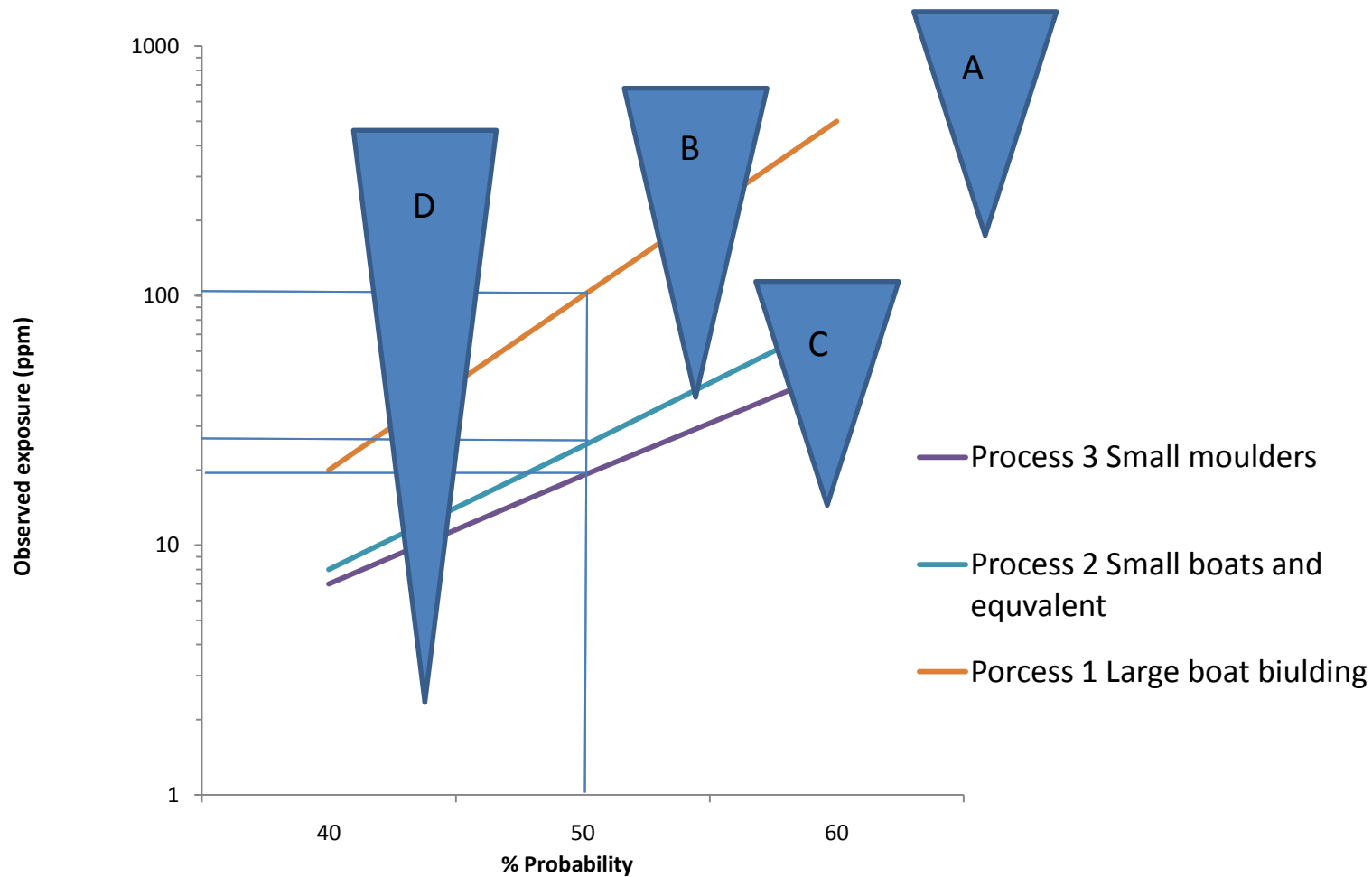


# Health evidence

does not come in a neat dose response curve



# Integrating health evidence and BPM



# What does all that look like in practice

- Tripartite models (employer, employee, regulator)
- Integrated with ‘independent’ expertise.
- Two stage determination
  1. Scientific/health-based ‘experts’ (sometimes representing economic interests sometimes not, and sometimes a mixture of both)
  2. Economic/technical issues of feasibility. Here economic interests and the social partners are represented
- Enforceability



# Formaldehyde

- Biocide: disinfectant; germicide, fungicide
- Manufacture of phenolic resins, artificial silk and cellulose esters, dyes, organic chemicals, glass mirrors, explosives; tanning and preserving hide
- Fabrics: mordanting (fastness of dyes on fabrics)waterproofing
- Latex: preserving and coagulating
- Embalming
- Photography
- Protein insolubility
- Human and Veterinary Medicine

**55,000 tonnes (at 100%) used in Australia pa**



# Formaldehyde – health effects

Acute health effects relate to formaldehyde's **irritative and inflammatory** properties. It readily reacts with biological tissues, particularly the mucous tissues lining the respiratory tract and the eyes

Chronic health effects include:

- May cause sensitisation by skin contact
- **Limited evidence of a carcinogenic effect.**
- Possible respiratory sensitiser (limited evidence).
- Cumulative effects may result following exposure

## Changes in formaldehyde WES over time in New Zealand

Year , publisher, edition	WES (ppm)
1986 (MoH)	2 (ceiling)
1992 (effective from 1992)	1 (TWA), 2 (STEL)
1994 (DoL from 1994)	1 (ceiling)
2002 (DoL from 2002)	1 ( ceiling)
2010 (DoL 5 <sup>th</sup> edition)	0.5 (TWA8), 0.33 (TWA12), 1 (ceiling)



# What is the problem for Universities?

## Typical formaldehyde exposure

gross anatomy teaching,	Embalsming >1 ppm Student labs worst case 0.5 ppm
post-mortem sample fixation	< 0.3 ppm in trimming and store rooms
laboratory use	Australian studies > 1ppm Mean 0.917, but surrounding offices 0.314 ppm! (Dingle et al)

**NZ Proposed WES 0.3 TWA, 0.6 STEL**

**Wet teaching, PM and labs become marginal**

# Change setting process

- **Initial announcement**
- **Written submissions**
- **Concern indentified**
  - Detailed consultation
    - Benchmarking to other jurisdictions
    - Decision justification in other jurisdictions
    - Health effects
- **Meeting of all parties**
- **Debate**
- **Final decision**



# Rationale for changing CH<sub>2</sub>O WES in NZ

Environmental Protection Authority.

- Positive approval regime
- Included classification as a 6.7A substance (known or presumed human carcinogen)

Placed Department of Labour as employment regulator on notice,

Other factors

- Sampling methodology for monitoring Ceiling problematic
- Overseas OEL changes
- Ongoing concern about sensory irritation, chiefly of the eye and upper respiratory tract.



# Benchmarking

Country	Eight hour exposure limit (ppm)	Short term limit (ppm)	Ceiling limit (ppm)
Australia	1	2	-
Argentina	-	-	0.3
Belgium	-	-	0.3
Brazil -	-	-	1.6
Canada - Alberta	0.75	-	2
Canada – British Columbia	0.3	-	1
Canada - Manitoba	-	-	0.3
Canada -Newfoundland	-	-	0.3
Canada – Nova Scotia	-	-	0.3
Canada – Ontario	-	1.0	1.5
Canada – Quebec	-	-	2
Denmark	-	-	0.3
Finland	0.3	-	1.0

# Health effects focus

- Acute health effect –irritant effects
- Chronic health effects – changes to nasal cells in animal studies cited
- Sensitisation –studies cited (NICNAS, 2006; DECOS, 2006; ACGIH, 2001) disproving any association
- Reproductive toxicity – unlikely to be factor given rapid processing by first tissues of contact
- Carcinogenicity and mutagenicity – pages of evidence indicating uncertainty of expert opinion.



# Decision process of other OEL committees

The rationale and determination of these other committees was cited in full

- ACGIH 2001
- German MAK 2002
- DECOS 2003
- NEG 2003
- WATCH 2005
- NICHAS 2006
- IRRST
- SCOEL 2008
- Worksafe BC 2009



# Meeting players

- **Formaldehyde Users –**
  - **Suppliers - Chemical Industry, Formaldehyde council of Australia and New Zealand**
  - **Users,**
    - **Wood product manufactures and processes,**
    - **Agricultural users**
    - **Teaching and research users**
    - **Embalmers**
  - **Unions**
- **Health specialists – Toxicologists, epidemiologists, health physicians**
- **Regulators – DoL, ERMA, ACC**



# Debate range

- Law and invocation of WES
- Health evidence and robustness of research
- Practicality of controls v health effects
- Union view
- Impossibility of monitoring large sites
- No controls applied to imported items

Setting process flawed? Minister drawn in



# Distillation of Views and final decision

2002	2008 proposed	2010 Decision
1 ppm (CEILING)	0.3 ppm (TWA <sub>8</sub> )	0.5 ppm(TWA <sub>8</sub> )
	0.6 ppm (STEL)	0.33 ppm(TWA <sub>12</sub> )
		1 ppm (CEILING)

Final process not transparent

# Conclusions – who knows what, who pays?

Expert opinion – public good health funding

Organisational users – monitoring results, no funding

Regulator – don't have monitoring data

## IMPLICATIONS

**Practitioners need to enter the debate**

**other wise health concerns will dominate**

**Possible closure of teaching and research, or  
considerable expense to continue**