

# Formaldehyde, friend or foe?

---

By Doug Pringle  
University Health and Safety Manager  
Massey University  
Palmerston North

Key Area: Health and Safety in Research

Paper for 2011 AUSA conference, Queensland University, July 2011

## Abstract:

This paper provides a commentary on the process of occupational exposure level (OEL) setting in New Zealand's regulatory environment, with reference to setting OEL process in other jurisdictions. The impacts of OEL's on teaching delivery and research methodology in Australasia of a substance ubiquitous to biological, veterinary and health sciences will be considered, along with evidence that all may not be well or compliant. The paper considers the dilemma of prioritising protection of; people, populations, research or teaching in an environment of academic freedom.

## Glossary

The term Occupational Exposure Level (OEL) may vary by jurisdiction and country, such terms are,

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)

There may be nuisances in how enforceable the set level might be. For example in the USA the;

- TLV (Threshold Limit Value) is a recommendation by ACGIH (American Conference of Governmental Industrial Hygienists), with only a guideline status.
- PEL (Permissible Exposure Level) regulatory level set by OSHA (Occupational Safety and Health Administration)

Many USA Industrial hygienists think the PEL's do not provide sufficient protection and so other levels are;

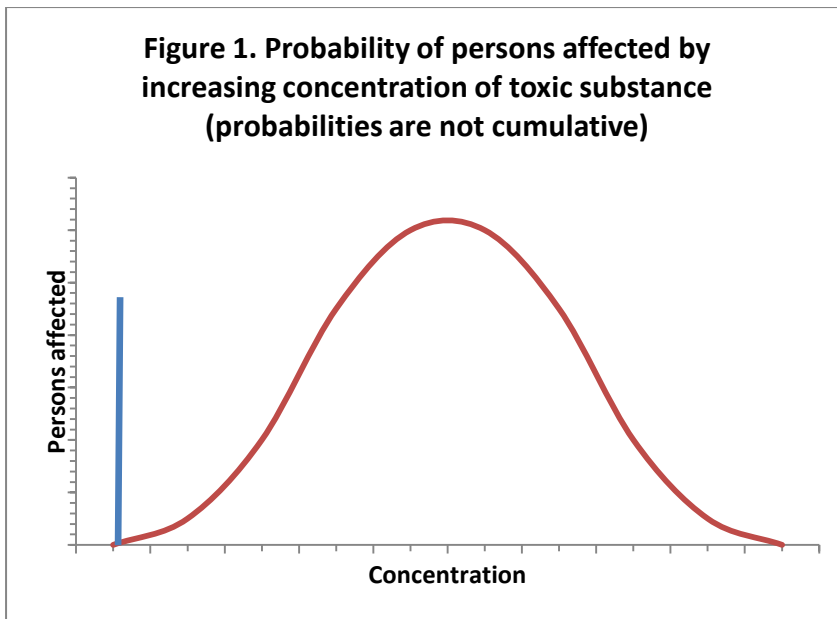
- REL (Recommended Exposure levels) by NIOSH (National Institute of Occupational Safety and Health), or
- WEEL (Workplace environmental exposure level) created by a committee of the AIHA (American Industrial Hygiene Association).

For the purposes of this presentation I will use the term OEL (Occupational exposure level) as encompassing term, unless discussing a specific jurisdiction when their term will be used.

## **OEL Definition**

They are 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. "They represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect" (ACGIH TLV Booklet 1958).

When considering value for an OEL , there is a need to determine where level is being set. For example the MAK is considered to protect most people, as per Figure 1 (taken from Elkins, 1948).



Subsequently the ALRA (As Low As Reasonably Achievable) principle emerged “In spite of the fact that serious adverse health effects are not believed likely as a result of exposure to the threshold limit concentrations, the best practice is to maintain concentrations of all atmospheric contaminants as low as is practical” (ACGIH TLV Booklet, 1996).

OEL’s may be expressed in four ways:

- TWA--Time weighted average, based on an allowable exposure averaged over a normal 8-hour workday or 40-hour work- week. A subscript may indicate the hours;
- STEL--Short-term exposure limit or maximum concentration for a brief specified period of time (usually 15 minutes), depending on a specific chemical (TWA must still be met);
- C—(Ceiling Exposure Limit) or maximum exposure concentration not to be exceeded under any circumstances. (TWA must still be met.)
- GEL – (General Excursion Limit). Often there is insufficient toxicological data available for the establishment of a Short Term Exposure Limit. Peak exposure should, however, still be controlled even in situations where the Time-Weighted Average level is not exceeded. A 15-minute exposure limit of three times the TWA is recommended. Where a STEL has been assigned, the STEL value takes precedence over the general excursion limit regardless of whether or not it is a stricter standard.

## History of OEL development (1)

Before OELs existed, 50 years before regulations, identified prescriptive methods were used to try to control exposure to hazardous substances. These were initially around lead exposure, but later silica.

---

<sup>1</sup> From Piney, HM HASE Principal Specialist Inspector (Occupational Hygiene)

OELs were first proposed by Elmhurst Duckering in the UK, as a way of limiting exposure to dust, in 1910. Elmhurst Duckering was, in effect, the first UK specialist occupational hygiene inspector. He and Thomas Legge the first Medical Inspector of Factories measured and qualified levels of lead that would cause poisoning. Legge combined Duckering's exposure measurements with his knowledge of the epidemiology of lead poisoning and symptoms and came to the following conclusion published in 1912: *"Somewhere about 2 milligrams, or 0.002 grams of lead we regard as the lowest daily dose which, inhaled as fumes or dust in the air, may, in the course of years, set up chronic plumbism."* This dose works out to be equivalent to 0.2 mg/m<sup>3</sup> lead-in-air, somewhat higher but pretty close to the current UK OEL for lead of 0.15 mg/m<sup>3</sup> (8-hour TWA).

However the inspectorate and legislature of the day had no appetite for such notions and specific solution based prescriptive regulations continued.

By 1919 the UK safety regulations attempted to control the worst excesses of exposure to toxic substances such as lead and silica. Both in the UK and USA the main threat to health was perceived to be infectious diseases such as TB. In the USA a specialist branch of the US Public Health Service developed, called "sanitary engineers". This group turned their attention to the workplace and started to apply the preventative approach used by industrial hygienists today. The term applied at the time to OELs was "Sanitarians". In parallel in the UK one of the earliest users of Sanitarians in assessment of dust exposure and control in polishing workshops was Winslow who stated: *"The only standard which can be altogether satisfactory for a sanitarian, is one that deals directly with the actual conditions of the air inhaled by the worker"* (Winslow 1919, quoted by Piney).

Once exposure measurements were made it was up to the hygiene engineers, employees and industry, to determine: 'What level of exposure is attainable or safe?' Practical answers were subsequently developed.

It wasn't till the 1930s and 1940s before the concept of Sanitarians became accepted in the USA, followed by UK. The acceptance coincided with toxicology developing as a branch of physiology and occupational hygiene. Subsequently OEL's were developed, applied and promulgated by industrial hygienists in the USA, the ACGIH TLVs being the most famous and influential of the standards.

### Early OEL lists

One of the first exposure limits lists was published by the German toxicologist Kobert in 1912 but, with no Industrial Hygiene profession to use and promulgate them, it appears that they were not widely used.

In the USA the nascent Industrial Hygiene profession grew and various lists of OEL's were published in the 1930s (Sayer and Dallavalle). No equivalent profession or OEL's were developed in the UK. In 1938, in the USA, the National Conference of Governmental Industrial Hygienists (NCGIH) was formed and a year later the American Industrial Hygiene Association (AIHA) was founded. In 1941 a "Threshold Limits" subcommittee of the NCGIH "Technical Standards" committee was created drawing on Warren Cook's compilation of OEL's (Cook). The committee presented the first list of 144 MACs (Maximum Allowable Concentrations) to the annual meeting of the Conference in 1946. It was published in the US PHS Newsletter the same year. Since then a steadily extended list of ACGIH limits have been published each year. In 1948, two years after the first list was compiled, MACs were renamed Threshold Limit Values or "TLVs". Early Industrial Hygienists in the USA needed OEL's, to work to and the ACGIH provided them.

## Limitations on using OELs

Prior to considering how OEL's are set the context for their use needs to be appreciated. They are a technical approach to managing contaminant hazards and not well understood in industry.

Their main uses are (adapted from Walters *et al*):

### As a reference tool

As a reference tools for monitoring systematic management of chemical risks in larger organisations, where there is experience and support for such a task either within the organisation or through the use of technical assistance from external prevention services/occupational hygiene consultants. This is important in sectors of industry where hazardous chemicals are in use, where substitution is not possible and specification standards for machinery and processes do not mitigate the need for monitoring performance standards. The use of OEL's in these situations may have some benchmarking value for other workplaces; however, strong evidence of widespread transfer of good practice is hard to find (Walters et al).

Their use as reference tools in monitoring workplace exposures in such firms is useful as an indicator of adequate risk assessment for regulatory agencies in enforcement practices in firms in which hazardous chemicals are in use and where it is suspected that exposure levels are high. The extent of use of OEL's in this respect is not pursued rigorously everywhere, but its existence is important and particularly useful in seeking improvements at the 'dirty end' of industrial activities. Compliance with standards for which OEL's are a reference point remains a useful indicator of good practice. It is rare in New Zealand for the inspectorate to

actually visit workplaces and when they do to have the expertise to undertake an industrial hygiene assessment.

From a scientific/technical perspective OEL's are also useful reference tools, for large scale surveillance of exposure such as has been studied in relation to various substances in Germany, and which has helped to contribute to understanding concerning the health effects of exposures.

### **Education and information**

OEL's provide an important informative and educative role in raising awareness on chemical risks. Even though there is considerable ignorance of their detailed meaning (and in some cases of their existence), they are nevertheless an important reference point and objective standard for informing discourse on prevention strategies.

They may also be useful 'norms' for larger employers to follow. While monitoring airborne exposures may prove difficult, the existence of OEL's creates an important pressure on suppliers to provide information about the safe use of hazardous chemical products. As such they have a role in several different loci in risk assessment cycles. Moreover, they are important in determining the approach to risk assessment and in alerting employers, workers and their representatives to the need to take seriously risk management issues involved in processes concerning the use or substitution of such substances. A caveat concerning their use in this respect however concerns the need for a proper understanding of their meaning. For example, if notions that they represent safe levels, or even values above or below which dramatically different effects occur are persistent, they undermine their role and contribute to their misuse.

Provided the caveat concerning proper understanding of their meaning applies, they may have a helpful role in defining specification standards that can be used in determining risk management issues concerning the purchase and installation of new plant. In some situations where monitoring is anyway extremely unlikely, such specification standards may obviate the need for its use.

### **BUT wide spread ignorance prevails**

While the above are all 'positive uses', they also need to be seen in the context of the enormous levels of ignorance about OEL's amongst users of chemical products (Olsen *et al*). This has been demonstrated particularly by the UK HSE research. This in turn has led to concepts in the COSSH essentials or control banding methodologies.

The ignorance is reinforced by the inspectorate with very few cases mounted for exceeding an OEL, certainly none in New Zealand (validated on Safeguard court base).

There seem to be several linked reasons for the lack of enforcement, most of which relate to the limited resources of both inspectors and inspected as well as a perception that there are frequently other, more appropriate means of achieving improved risk management of chemical hazards (usually substitution). Inspectors frequently do not have the capacity to do more than demand evidence of measurement. They are often neither equipped nor skilled sufficiently to be able to undertake such measurement themselves. It is widely understood to be the responsibility of duty-holders to undertake measurement. This may be reasonably well acted-upon in large companies that use hazardous chemicals, but is far more seldom exercised by the owner managers of small enterprises that are also substantial users of hazardous chemicals.

### ACGIH TLVs

The ACGIH TLV's have been, and still are, the most influential OEL's in the world. They were taken up by many industrialised countries in the 1950s and still have a large influence on other OEL setting committees.

While a lot of countries purport to have their own OEL's they are more often based on ACGIH TLV's, with some specific variation. Two notable exceptions to general international dependence on the ACGIH occur:

- (1) Germany's limits (Maximale Arbeitsplatz-Konzentrationen — MAKs) have developed separately from ACGIH and are said to be based exclusively on scientific information about health effects. The MAK documentation states that 'scientific criteria for the prevention of adverse effects on health are decisive, not technical or economical feasibility'. Carcinogens and genotoxic substances are given TRK values because it is accepted that such limits cannot be based exclusively on health considerations. There is no longer any explicit influence of the ACGIH on the development of exposure limits although they were used historically.
- (2) Russia limits appear to be based on a "probabilistic" approach, developed by EPA (the Office for the U.S. Environmental Protection Agency). Developed in the early 1980s, a risk assessment is used to take account the compatibility of action of harmful factors, in addition to weight ratio can vary, depending on symbatically (a measure similar relationships in mathematical analysis) or additive such factors. With such an approach is possible to use tightly fixed OEL they are replaced by specially studied risk assessments, more informative and reasonable. The OEL is reported to be calculated use computational techniques, the result of biological experiments, as well as material dynamic monitoring of the health of a person exposed to hazardous substances.

The paper now turns its attention to what factors or perspectives are used in setting an OEL.

### **Criteria in setting OEL's**

Different perspectives affect the setting of OEL's. How much weight should be given to:

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

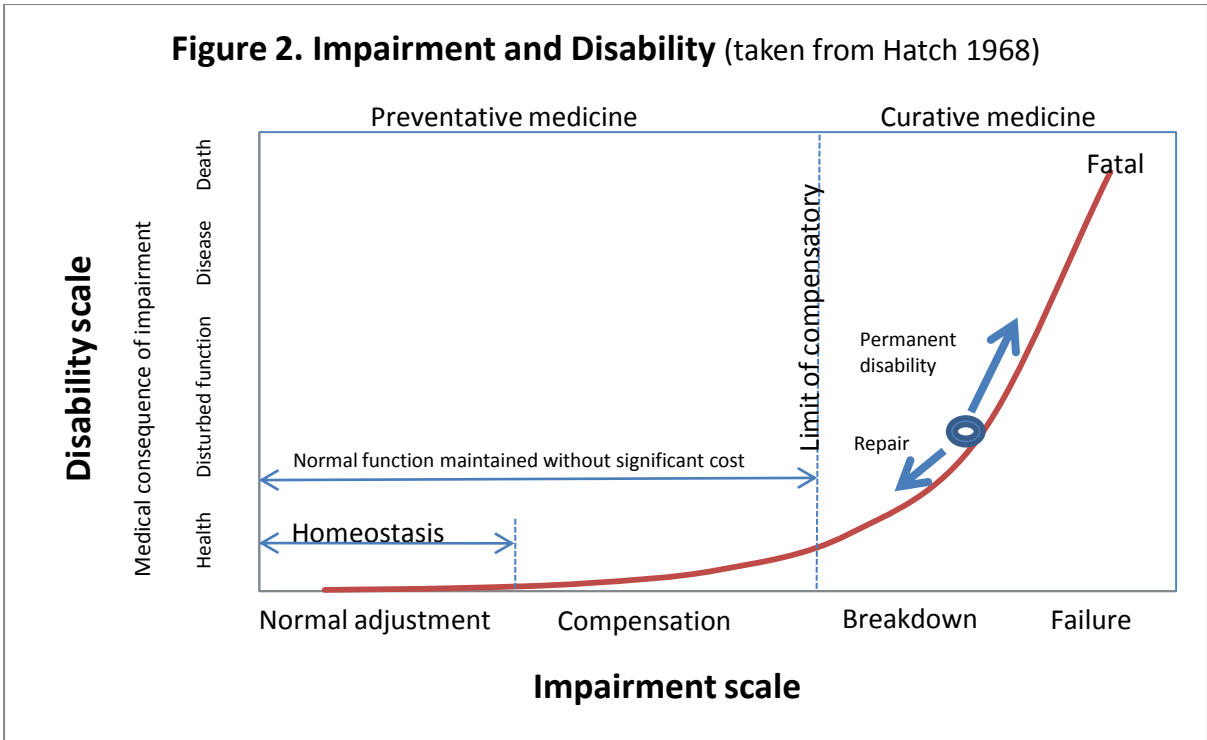
In reality most, TLVs have been set to take into account the practicability of the controls and to balance these against the evidence of harm. This doesn't mean that all TLVs are what might be called 'unsafe', but it does mean that many of them were and are based on a necessary compromise, one that Winslow would have recognised.

Initially, reasonably practicable approaches dominated the setting of OEL's. Since the mid 1980's health effects have tended to dominate in the OEL setting process (Piney)

### **What are health effects?**

Theoretical dose response dominated early thinking. For many substances there would be a threshold of effect, a point at which a person was exposed and absorbing material, but where there is no permanent toxic response; no harm. For some substances, primarily genotoxic carcinogens, it's probable that there will be some 'response' even down to low exposure (dose) levels. The classic sigmoid D-R curve is based on ideas of homeostasis, that the human body can cope naturally with a certain degree of repeated chemical exposure/insult. (ACGIH)

Put another way where on the diagram (Figure 2) by Hatch where do you set the threshold - in the normal adjustment zone, or in the compensation zone?



**Reasonably practical perspective (Industry view)**

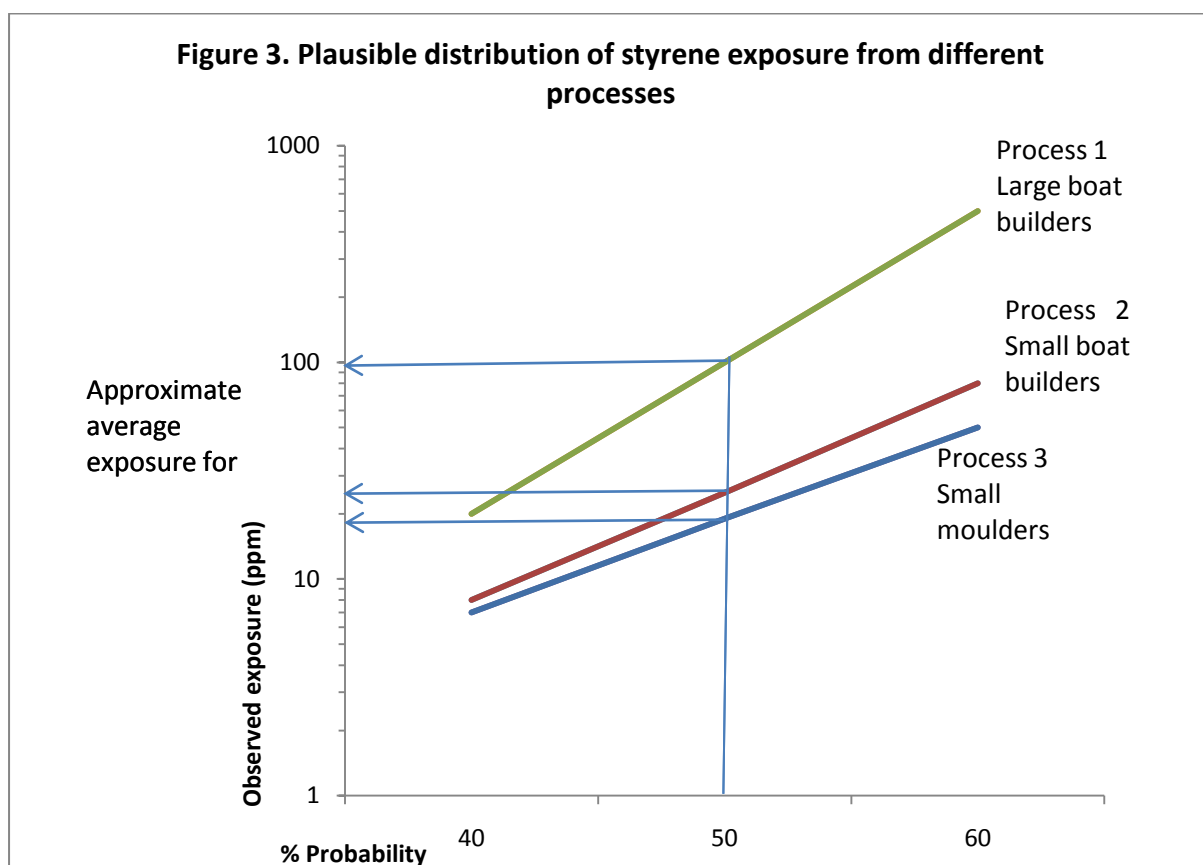
The incorporation of industrial views or reasonably practicable is illustrated using the setting for Styrene. In 1957 the ACGIH TLV Committee agreed a TLV for styrene of 100 ppm (8 hour TWA). In 1984, 27 years later, after three years deliberation, in the UK set a Control Limit for styrene of 100 ppm (8 Hour TWA). The evidence on health effects was similar for both committees. Neither committee placed much emphasis on health effects, as there is no strong evidence for dose-related health effects. As such, the committees focused on practicability of control and these issues hadn't changed much between 1957 and 1984.

Three industries used most of the styrene, large boat building, small boats or equivalent scale processes, and small moulding processes. The three processes can be generalised, and type of exposures and plotted as in Figure 3. The spectrum of practicability ranged from 25 ppm at the stringent end to 100 ppm at the more lenient end of the reasonably practicable spectrum.

The factors that then determined the OEL was the impact on industry which was determined by large boat builders using open moulding processes (process 1 on Figure 3). Exactly where the OEL is set will depend upon how the OEL setting committee balances its perception of the seriousness of health effects, the likelihood that the effect will occur at a certain level of exposure and its perception of how difficult it will be to control exposures within the spectrum of exposures defined by Process 1.

A reasonably practicable OEL is not necessarily the same value in every country. There is a spectrum of options implying relatively stringent or lenient controls on "Process 1" type activities. Whichever levels are chosen, they are all reasonably practicable with more or less effort and cost.

If an OEL value is set r lower than that which can be achieved by the best control methods, then that would place a number of organisations into non compliance, or out of business in that country if the OEL was enforced.

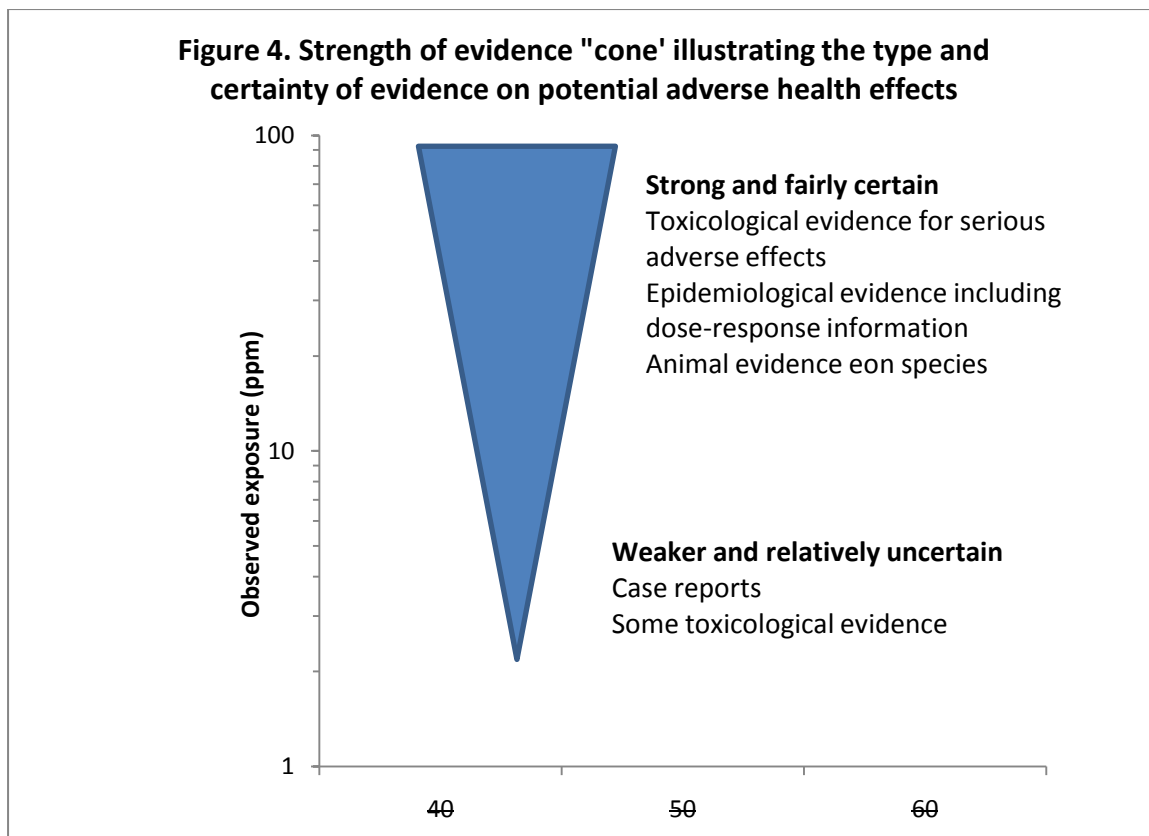


### Integrating health views and reasonable practicable

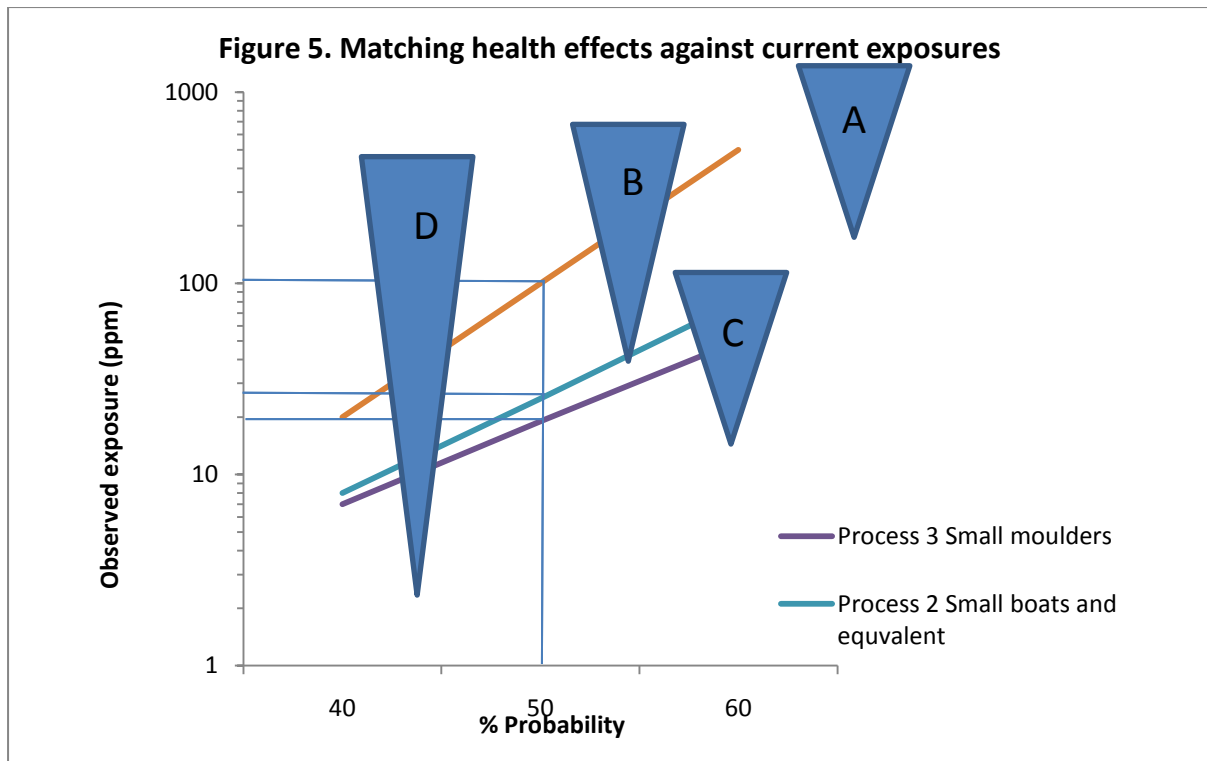
The types of health evidence used in setting an OEL is illustrated in an evidence 'cone' shown in Figure 4. The cone illustrates the strength of certainty of evidence about adverse health effects. The shape of the cone may vary; if the evidence is strong there may be little that is uncertain. Alternatively the evidence may be quite uncertain.

The position of the cone on the axis illustrates the observed concentrations of the containment at which the evidence is observed.

**Figure 4. Strength of evidence "cone" illustrating the type and certainty of evidence on potential adverse health effects**



The health evidence can then be overlaid on the distribution of measured environmental levels observed in industry process. The intersection of the health evidence (the cone) and controlled contaminant levels gives four possible intersections as shown in figure 5.



The four intersections of relationships shown in Figure 5 are:

- (A) Where all current processes are operating exposures are operating below where adverse health effects occur. This happens but is probably, relatively, unusual.
- (B) Where the strongest evidence of effects applies mainly to the exposures caused by “Process 1” -the Process causing the highest exposures. This puts pressure on process 1 to reduce exposure, and is the more typical intersection encountered in OEL determination.
- (C) Where the evidence is strong that potentially serious health effects are likely to occur across the range of Process 1 exposures and well into the exposures caused by several other Processes. This creates a dilemma for process organisations and puts pressure on process 2 and less on 3. This creates the most difficulty for the regulator’s, and employers’/employees’, in that all processes need to address the exposure, some more than others.
- (D) Where some evidence suggests possible health effects across the full exposure ranges of current Processes. This creates pressure on all processes to reduce exposure. This is less common, but can occur such as with carcinogens.

Probably intersection relationship (C) is easiest to spot and would require rapid action by the regulator and the industries running Process 1. Relationships (B) and (D) are more

typical and (D) invites the question - What are the reasonably practicable exposure levels for Processes 2 and 3?

## OEL determination

There is a strong similarity between countries in the way in which structures for setting or adopting OEL's allow for stakeholder participation. The setting determination is usually based on tripartite models, with the addition of 'independent' expertise. In countries in which OEL's are set there are also broad similarities in the procedures involved. Mostly there is a two stage determination process in which the scientific/health-based issues are dealt with, usually by 'experts' (sometimes representing economic interests sometimes not, and sometimes a mixture of both) and a second determination process in which economic/technical issues of feasibility are considered. Here economic interests and the social partners are represented.

The extent to which the above process is often an effect of country size. Larger countries or those with active Occupational Hygienists will engage in determination and establish OEL's for substances of significance for them. Smaller countries may be OEL "takers" and not engage so actively in setting OEL levels. Usually smaller countries will use the ACGIH recommendations (Walters et al).

From this theoretical back ground, the paper now considers the application of OEL setting in New Zealand context.

## Regulatory application of OEL's in NZ

The Department of Labour (DoL) is New Zealand's Labour inspectorate or regulator, and is responsible for enforcement of the Health and Safety in Employment Act. The DoL publishes OEL's which are based on ACGIH with some local (NZ) variation. The OEL'S "*are intended to be used as guideline for people qualified in occupational health practice*". As such they are not directly enforceable as standards per se, nor are they enforced.

Enforcement of OEL's comes from the Environmental Protection Authority (Formally known as Environmental Risk Management Authority). The Environmental Protection Authority takes a more concrete view of OEL's with statements from the Hazardous Substances and New Organisms Act of:

- The authority may at the time or after it approves a hazardous substance ... apply an applicable WES S:77B(1)
- A WES value can be applied by:
  - "Setting" a value –S:77B (10 (a)
  - "Arriving" at a value specified in regulation -R:30(10(b)

- “Adopting” a value proposed by DoL -R:30(1)(b)
- “Providing for” the setting of WES – S:77B(1)(b)
- Actual practice
  - “Adopting” a value proposed by DoL when approving the substance
  - “Notes” overseas OEL where no DoL WES is set.

Thus the Environmental Protection Authority OEL is far more binding. The Environmental Protection Authority however is a jurisdictional agency covering all phases of a hazardous substance and enforcement of the OEL in an occupational context is in turn delegated back to DoL.

It is much harder for DoL to gain a conviction under the Hazardous Substances and New Organisms Act as the defence options are more. The net result is there have been no DoL court cases where the WES have been used as supporting evidence of non compliance.

The above introduction sets out the background to OEL’s. The paper next considers how this applies to formaldehyde.

## Formaldehyde – a case study

### Health effects of formaldehyde

Formaldehyde is a powerful reducing agent that has ubiquitous use as:

- Disinfectant; germicide and fungicide for plants, vegetables, intensive animal industries
- Manufacture of phenolic resins, artificial silk and cellulose esters, dyes, organic chemicals, glass mirrors, explosives; tanning and preserving hide
- Improve the fastness of dyes on fabrics; mordanting and waterproofing fabrics; preserving and coagulating rubber latex; in embalming fluids
- Photography for hardening gelatin plates, papers, printing, developing
- Biocide to prevent mildew and spelt in wheat and rot in oats
- Render casein, albumin and gelatin insoluble
- Human and Veterinary Medicine

The Formaldehyde Council of Australia and New Zealand estimate 55,000 tonnes of Formaldehyde (at 100%) is manufactured In Australia for industrial use each year.

Formaldehyde is described as having acute health effects of:

- Causes burns; .Risk of serious damage to eyes.

- Toxic by inhalation, in contact with skin and if swallowed. Vapours may cause dizziness or suffocation. Vapours potentially cause drowsiness and dizziness (limited evidence).
- It is highly irritating with the predominant effect of short-term exposure in humans being sensory irritation experienced firstly in the eyes, followed by perception of the odour and then irritation of the nose and throat accompanied by discomfort, lachrymation, sneezing, coughing, nausea and dyspnoea (DECOS, 2003).

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

In New Zealand the exposure level for formaldehyde have been changed as shown in the table below

<b>Year , publisher, edition</b>	<b>WES (ppm)</b>
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)

Within Veterinary medicine there are three processes of interest to Universities which are considered in more detail. In some respects the three processes can be aligned to Pineys theoretical model shown in Figure 3 above. The processes are:

1. gross anatomy teaching,
2. post-mortem sample fixation, and
3. diagnostic laboratory use

## **Veterinary School Monitoring (observed levels – a process perspective)**

## 1. Gross anatomy teaching

Gross anatomy teaching to veterinary students is done using unwanted or ailing companion animal cadavers. The euthanasia process uses modern embalming techniques on unconscious animal to perfuse the tissue with preservative. The embalmers objective is balance the use of formaldehyde. If too much formalin is used the cadaver longevity is good, but student exposure will be higher. If too little formaldehyde is used the cadaver will not last the two required semesters with a loss of learning objectives by the students.

During the euthanasia process there can be leakage of the embalming fluid as the animal circulatory system fails. Thus personal protective equipment is clumsy in such a delicate procedure and table slot extraction is used to maintain contaminant concentrations below the 1 ppm WES.

Once cadavers are preserved they are stored in a chiller and systematically studied by student dissection. Teaching of gross anatomy takes place in a large teaching wet laboratory equipped with additional room extract. Observed formaldehyde levels during winter periods when the room is closed up to keep it warm have been of the order of 0.5 ppm. Exposure monitoring during summer months measured lower levels as windows can be opened to reduce aroma and exposure. Exposure is worse on opening the abdominal cavity.

The use of pre prepared cadavers for examination purposes also results in formaldehyde exposure. As the cadavers require extensive preparation by technicians they are retained for as long as possible. Storage is in large formaldehyde solution tanks. The evaporation from the tanks is such that the WES CEILING is reached within a few minutes of opening a tank. Prior to examination use the cadavers will be washed to reduce student exposure during the exam. The washing process while protecting the students produces extensive formaldehyde aerosol for the technicians. Locally extracted washing mechanism and air supplied respirators protect the staff involved in this process.

Anatomy teaching using *Squalus acanthias* (dog fish) is used for 100 level zoology. The fish are washed for a week prior to student dissection which takes place over two consecutive weeks. The fish are stored in water during the dissecting. While the preservation methods of formaldehyde solution tanks saturation are primitive, the washing brings the formaldehyde release to reasonable levels of less than 0.3 ppm. The in tank washing of a week prior to class use also reduces need for personal protective equipment for technicians.

## 2. Post-mortem Sample fixation

Post-mortem laboratories use prefilled containers of formaldehyde to fix sample specimens prior to histology laboratory analysis. Highest levels are observed when placing specimens,

but these are well below the WES CEILING of 1 ppm. Monitoring in trimming rooms and store rooms showed similar low results.

### **3. Diagnostic lab use**

Laboratory scale use of formaldehyde occurs in histology and biology laboratories for tissue fixation and anatomical specimen preservation. While the use of formaldehyde is small, its volatility means the laboratory spaces and surrounding rooms may contain high levels. However within the laboratory there are more solutions available for formaldehyde vapour control, by way of fume cupboards and local extract systems to bench mounted apparatus. As a result few complaints and monitoring for formaldehyde have been undertaken within Massey laboratories. Xylene irritation is of greater concern in histology laboratories. However Massey's experience is not shared by other Universities.

An Australian study of 5 laboratory and surrounding spaces in 2002 showed results of 0.14 to 3.013 ppm with a mean of 0.977ppm. Two laboratories ranged above Australian OES TWA of 1ppm. The survey of surrounding offices found 0.0314ppm to 0.548ppm with a mean of 0.314ppm. Fixed monitoring tended to over predict TWA, whereas personal badges reflected the movement of workers in and out of lab spaces. The infiltration of the contaminant into surrounding office spaces was of concern as users of these spaces did not take any precautions and period of exposure potentially for prolonged periods of time (Dingle et al, 2002). Unfortunately, the study did not distinguish the type of laboratories and if it included gross anatomy teaching with extended use of preserved cadavers then that would most likely account for the higher observed OEL's.

### **Industry dependence on formaldehyde**

What is clear is veterinary teaching depends on formaldehyde. A corollary is that the New Zealand bio security status is also dependent on the substance use. Given the production in Australia of 55,000 kg at 100% the substances is well established, ubiquitous internationally and no ready substitutes exist.

Given the narrow safety margin between the OEL and observed processes levels illustrated above, any proposal for change would likely to impact University veterinary teaching and research.

### **Proposal for change**

DoL as the regulator signalled a change in WES. Sentinel events over time included:

- November 2008 Notice of intended changes to 7 WES's, submissions invited

- August 2009 further consultation determined as necessary for wood dust and formaldehyde.
- December 2010 Final decision and announcement of new WES.

### Basis for change

The main basis for review of formaldehyde in New Zealand given where based on human studies on acute inhalation of formaldehyde indicate adverse health effects including: mucous membrane irritation, shortness of breath, upper airway irritation and sore throats, at concentrations below 1ppm (source ACGIH Formaldehyde TLV Chemical Substances Documentation 7th Edition).

The key catalyst for the change was the classification determination by the Environmental Protection Authority. The classified as a 6.7A substance (known or presumed human carcinogen) under the HSNO Act, effectively placed DoL on notice, requiring them to reconsider the WES for occupational application. DoL also noted monitoring against a Ceiling limit can be problematic in terms of sampling methodology and detection limits. As such they proposed an 8-hour WES-TWA of 0.3ppm and a WES-STEL of 0.6ppm. These levels are intended to minimise the potential for sensory irritation, chiefly of the eye and upper respiratory tract. However, even at these levels, some workers may be responsive to the irritant effects of formaldehyde due to increased sensitivity.

The detailed consultation included a comparison with other jurisdictions as shown below:

<b>Country</b>	<b>Eight hour exposure limit (ppm)</b>	<b>Short term limit (ppm)</b>	<b>Ceiling limit (ppm)</b>
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
France	0.5	1	-
Germany (MAK)	0.3	0.6	1
Italy	-	-	0.3
Japan	0.1	-	0.2

Netherlands	1	1.5	-
Norway	0.5	1.5	-
South Africa	2	2	-
Spain	-	0.3	-
Sweden	0.5	-	1
Switzerland	0.5	1	
United Kingdom (HSE)	2	2	-
USA (ACGIH)	-	-	0.3
USA - NIOSH	0.016	0.1	
USA - OSHA	0.75	2	

The detailed consultation document (2009) gave a fuller explanation under the following headings;

### Health effects

- Acute health effect – the focus was on 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 – 3 pages of evidence indicating uncertainty of expert opinion.

### Proposed WES

Based on the environmental classification, the DoL have been in effect forced to review the setting other jurisdictions. The other values considered in detail with full citation of decisions were:

- ACGIH 2001 Value set at 0.3 ppm CEILING for irritation of most people as a means of ALAP for suspicions of carcinogenicity
- German MAK 2002. The MAK set its value of 0.3 ppm TWA based on irritation effects to the eyes. Keep in mind the MAK seeks to set a “safe” value.
- DECOS (Dutch expert committee on Occupational Standards) and NEG (Nordic Expert Group) 2003 established Lowest observed adverse level was 0.25ppm, (suggesting a level of 0.125 with safety margin) but the documented levels in those countries remain much higher on basis of a lack of evidence for carcinogenicity at low concentrations.
- WATCH (Working group on action to control chemicals (UK) 2005 while acknowledging 0.3ppm at endpoint for irritation. The UK levels are set at moderate irritation to eyes, nose and throat.

- NICHAS 2006 (National Industrial Chemicals Notification and Assessment Scheme (Australia)) recommends 0.3 ppm TWA and 0.6 STEL, but required levels remain at 1ppm TWA and 2 ppm STEL.
- IRRST (Institute de Reserche Robert Sauvé en Santé et en Sécurité du Travail) Quebec indicated less than 0.75 ppm irritation was similar to that experienced by individuals without occupational exposure. They indicate proportion of population moderately affected by concentrations of 0.75ppm to 3ppm is 1.6 to 14.9%.
- SCOEL (European Union Scientific Committee on Occupational Exposure limit Values) 2008 regard formaldehyde as a genotoxic carcinogen and recommended a level to avoid cell proliferation (sensory irritant effect) at 0.2 ppm TWA.
- Worksafe BC 2009 set 0.3 ppm TWA and 1ppm CEILING on basis NOEAL (No observed adverse effects level ) at 1ppm.

It was against this back ground that consultative meeting was called by the regulator to endeavour to reach consensus for New Zealand. The meeting was confined to parties who had made submissions to the earlier notice to change formaldehyde WES levels.

### Formaldehyde WES meeting 2009

In contrast to the deliberate two processes observed in developed countries, both scientific/health-based issues are dealt with ‘experts’ along with economic/technical issues of feasibility where considered in a single public meeting. It is possible expert opinion had additional “inside” hearing but this was not openly disclosed.

Participant’s single concatenated tripartite and expert meeting composed of:

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

As a result of the curious meeting composition debate ranged from:

- Law and invocation of WES (HSNO v HASE)

- Highly technical health evidence and robustness of research (toxicologists v FCANZ<sup>2</sup>)
- Practicality of controls v health effects
- Consider health effects only (Unions)
- WES ceiling is sometime exceeded, impossibility of monitoring large sites, no controls applied to imported items (large users).

### Flawed WES setting process?

During discussion it became evident the regulator was inclined to place more weight on health effects as required by HASE, and not practical feasibility. As well as the single standards setting meeting, New Zealand doesn't have a two stage process such as the USA of an initial recommendation (e.g. ACGIH) and then permissible level considering cost benefit (OSHA).

The University responded by writing to the Minister of Labour pointing out flawed setting process (signed by VC). The Minister responded by detailing process and *the process will avoid closure of research facilities if industry provide monitoring results (paraphrased)*.

### Distillation of Views and final decision

The process for final decision was not transparent, but resultant level where lowered with the introduction of TWA levels as shown in Table 3. The TWA levels have a 12 month stay to December 2011 to allow processes to be modified.

Table 3. Existing WES, proposed and final levels		
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)

### Conclusions – who knows what, who pays?

In setting of OELs in New Zealand context there is a balancing of what is reasonably practical and health effects as demonstrated by this paper. However the balance is tenuous and not altogether transparent.

---

<sup>2</sup> FCANZ Formaldehyde Council of Australia and New Zealand

Objectives are to encourage accurate scientific evaluation of formaldehyde and formaldehyde based materials and to communicate sound scientific information relating to the uses, benefits and sustainability of these products to relevant regulatory and administrative bodies and the general public.

The impression is health effects tend to be weighted more heavily as “expert opinion” and access to such information. Research funding is available to understand toxicology and epidemiological effects, whereas there is not the same “public good funding” available to users to advance or apply control methodologies.

Users will hold monitoring information as they undertake day to day activities to protect the health of their staff. This is partly predicated by the performance based (Robens style) legislative environment which places a higher responsibility on employers to control hazards, whereas the inspectorate only has to undertake “reasonable” actions to ensure enforcement. In New Zealand with reduced funding of specialist roles within the inspectorate such as industrial hygiene, then what is practical field information will reside with employers.

As a result, is it up to practitioners as represented at this conference to:

- engage in the field of occupational hygiene and apply that science to teaching and research processes that use hazardous substances, and
- be prepared to enter the debate and share the results of monitoring. Without that information the regulator cannot make informed decisions.

One aspect of the New Zealand WES setting process of concern is the basis on which hygiene monitoring results are shared with the regulator. The regulator is responsible for enforcement. Within teaching and research practice situations of staff concern with exposure to hazardous substances routinely occur. Occupational hygiene monitoring is a way of placing empirical objectivity around the concern. Sometimes monitoring indicates staff concerns are unjustified. Other times the monitoring will identify substandard procedure, with resultant intervention needed. This takes place within an employment setting within organisations which have good access to internal expert resources, and a desire to protect staff. Sometimes the interventions are a balancing act of resources, availability and cost of solutions. Safety practitioners are all too aware of the safety tolerances that are accepted in such decisions.

It is uncertain if sharing such information with the regulator may result in focused targeted attention by the inspectorate. The process for WES setting in New Zealand could be improved if the context for sharing industry based hygiene monitoring results was done in a context of immunity from enforcement attention or via a party that was independent of the regulator.

## References

ACGIH 1958 TLV's Threshold Limit Values for Chemical Substances in the Work Environment Adopted by ACGIH for 1958.

Cook, W.A. 1945. 'Maximum allowable concentrations of industrial atmospheric contaminants', *Industrial Medicine* 14: 936-946.

DECOS 2003. (Dutch Expert Committee on Occupational Standards) *Formaldehyde – Health-based recommended occupational exposure limit*. Health Council of the Netherlands, The Hague. Publication No 2003/02OSH.

Dingle, P. Tan, R. Jones, J. and White, K. 2002. *Personal exposure to formaldehyde in laboratories*. *Australian New Zealand Journal Occupational Health and Safety*, 18(2):161-165.

Elkins, H.B. 1948. 'The case for Maximum Allowable Concentrations', *American Industrial Hygiene Association Quarterly* 9: 22-25.

Hatch, T. Drinker. and Choate S.P. 1930. *Control of the silicosis hazard in the hard rock industries*. *Journal of Industrial Hygiene* Volume 12. Number 3: 75 -91.

Olsen, K.B., Harris, L-A., Laird, I.S., Legg, S.J., Noble, A. and Perry, M. 2009. *Occupational health and safety management of chemicals in small businesses in three industries in New Zealand*. Proceedings of USE2009: Understanding Small Enterprises - a healthy working life in a healthy business, International Conference, Elsinor, Denmark, 20-23 October 2009: 626 – 645.

Piney, M, 2001. *OEL's and the effective control of exposure to substances hazardous to health in the UK (Version 3)*. HSE paper.

Sayers R.R. & J.N. Dallavalle 1935. 'Prevention of occupational diseases other than those caused by toxic dusts', *Mechanical Engineering* 57: 230-234.

Walters, D. Grodzki, K. Sarah Walters, S 2003. *The role of occupational exposure limits in the health and safety systems of EU Member States*. Prepared by South Bank University for the Health and Safety Executive 2003.