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PAPER

OELs and the effective control of exposure to substances hazardous to health in the UK (Version 3)

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OELs and the effective control of exposure to substances hazardous to health in the UK (V3)

1.0 Abstract Before OELs existed regulations, based on specification standards, were used to try to control exposure to hazardous substances. OELs were first proposed by Elmhurst Duckering in the UK, as a way of limiting exposure to dust, in 1910. But, in practice, OELs were developed, applied and promulgated by industrial hygienists in the USA, the ACGIH TLVs being the most famous and influential standards. This paper covers the early control of hazardous substances, the development of TLVs and UK OELs, how reasonably practicable OELs are set and discusses a range of issues raised by the development, definitions and use of OELs. There are no conclusions or recommendations as the paper is a contribution to the current debate on the UK OEL Framework.

2.0 Introduction If you know something of the early history of OELs and the development you may wish to skip the earlier subsections of this paper. I have illustrated various concepts with graphics which are integral to the arguments developed.

2.1 Background The work of the professional occupational hygienist involves anticipating, recognising, evaluating and controlling health hazards at work. In particular it involves understanding how work processes can cause exposure, how the exposure can cause harm and how such exposure can be controlled. All professional occupational hygienists use OELs, or some surrogate, when assessing whether overexposure is occurring or when deciding how much control measures should reduce exposure.

I have worked in HSE for over twelve years as a Specialist Inspector in what is now called the Field Operations Directorate (FOD) and I have been a practising OH for 23 years. From 1984 to 1989 I did research at Aston University into "*The development of chemical exposure limits for the workplace*" and obtained my PhD in 1990. I work with, use and interpret OELs as part of my day-to-day practice in field investigations and enforcement support. Because I have a good historical, theoretical and practical understanding of OELs I agreed with Robin Tarry (FOD Health Unit) that I would prepare a paper on the subject to assist the current debate. In this paper my overall purpose is to describe and explore how OELs and associated guidance have been, and can be, used to help to effectively control exposure to substances hazardous to health in the workplace. I have modified my first Drafts as a result of comments and would welcome further comments and suggestions.

3.0 Early UK control of substances hazardous to health The beginnings of governmental control of exposure to substances hazardous to health started, in the UK, in the late 19th Century with some basic regulations applied to specific processes. Fairly early on in the 20th Century a few UK pioneers put forward the idea of developing OELs but the idea in fact took off and was put into practice in the USA in the 1930s/1940s. The way regulations were developed and formulated to reduce exposure to toxic substances, and the early attempts at setting OELs, provide important lessons for current standard setters. In the early 20th Century, even though toxicology was a minor, underdeveloped branch of physiology and occupational hygiene, as such, did not formally exist as a profession the early pioneers wrestled with difficulties and dilemmas which modern-day WATCH and ACTS members would recognise.

3.1 Specifying standards for the ‘Dangerous Trades’

In the last quarter of the 19th Century the concerns of the UK Factory Inspectorate (FI) began to encompass acute occupational health issues such as lead poisoning. In 1878 the Factory Workshop Act, “*empowered Inspectors to require mechanical ventilation, whenever they saw fit in workrooms in which dust, gas, vapour or other impurities were generated*” (Djang 1942). Towards the end of the 19th Century certain industrial diseases, such as lead poisoning, became notifiable and a series of enquiries were held from which a variety of Regulations were developed. The regulations included fairly detailed specifications of how processes should be run, working arrangement and ventilation requirements. This specification approach to standards was also used in the USA and Europe.

Two people who made a very significant contribution in the UK were Thomas Legge and Elmhurst Duckering. Legge was the first Medical Inspector of Factories and Duckering was, in effect, the first UK specialist occupational hygiene inspector. Both men were involved in detailed studies of lead absorption and poisoning and silica dust exposure and silicosis. Earlier, in the 1880s, some use of air measurements was made by the UK FI Inspectors, who measured carbon dioxide concentrations to assess the adequacy of general ventilation in factory workshops, but Duckering took measurements observation and process understanding much further. Examining a number of dusty processes, mainly involving lead, he measured lead-in-air emissions and exposure and analysed the sources of dust emission in terms of their contributions to exposure. He also identified surface contamination as a source of potential absorption, via ingestion. From his work process analysis he was able to propose controls, based on changes of process and working methods and on the application of exhaust and general ventilation. His work, in my opinion, was exemplary.

3.2 Controlling the chronic health effects of lead

Thomas 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.” (Legge & Goadby 1912).

This dose works out to be equivalent to 0.2 mg/m³ lead-in-air, somewhat higher but pretty close to the current UK OEL for lead of 0.15 mg/m³ (8-hour TWA).

3.3 OELs first proposed as “*The most scientific way of regulating a dusty trade...*”

Having used air sampling and assessed emissions and exposure, Duckering could see a way forward to allow control of exposure in all ‘dusty trades’ whatever the processes causing exposure. There was no need to develop specification standards for each and every process and industry if performance standards could be developed. He summarised his solution:

“The most scientific way of regulating a dusty trade would be to impose a limit on the amount of dust which may be allowed to contaminate the air breathed by the workpeople and to leave the manufacturer a completely free choice of methods by which this result may be attained. If such a Regulation were to be adopted, the occupier of a factory would become liable to a penalty in such cases as it was found, experimentally, that the limit was exceeded. There is nothing inherently impossible in such a Regulation” (Duckering 1910, Author’s emphasis).

3.4 Specification and performance standards - first comments

Duckering and Legge's views were ahead of their time and not part of the regulatory ethos in the UK, or the rest of

Europe's, which was committed to specification standards for certain processes and regulations. Although air sampling was used, occasionally, to study some processes in some recognised "Dangerous Trades" these findings were invariably translated, summarised and transferred into Regulations - specification standards.

There are a number of advantages to specification standards especially for small companies and people auditing or inspecting controls. If the controls are clear, and known to all, whether or not a company is complying is a fairly straightforward matter both for the company and any external assessor to check. But the problem was then and still is now; **How does one know whether the controls specified are effective enough?** Without a meaningful health-related exposure target or standard to aim for no answer could be, or can be, given and this was the point that Duckering tried to get across in his 1910 report. But his idea fell on stony ground. In the UK the organisational and professional culture of the Civil Service and Factory Inspectorate (FI) meant that no "limit on the amount of dust" was set and used, in the UK, for many decades³.

3.5 Industrial Hygiene develops in the USA - the first OELs are developed and used

3.5.1 Sanitarians Even though attempts were made to control the worst excesses of exposure to toxic substances such as lead and silica, the main threat to public health was still perceived, at the turn of the 19th century, to be infectious diseases. National and local authorities and campaigners in both the UK and USA were mainly concerned with public health measures to control TB and other infectious diseases. In the USA sanitary engineering developed as a specialist subject committed to the prevention of infection and the conditions which brought about infection. It was a few of these engineers, mainly in the US Public Health Service (PHS), who turned their attention to the workplace and started to apply the "sanitary engineers" preventative approach. They were the pioneers that formed the nucleus from which a new science-based profession, industrial hygiene (IH), was to grow.

3.5.2 First OELs From the start, these "Sanitarians", as they were then called, were concerned with workplace processes and control and with the developing methods of workplace exposure measurement. Once exposure measurements were made it was completely natural for them, and industry, to ask the question: 'What level of exposure is attainable or safe?' and people wanted and subsequently developed practical answers. Winslow was one of the earliest Sanitarians/IHs and in an assessment of dust exposure and control in polishing workshops 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)

He was echoing Duckering's words of some 10 years earlier, but he went further. Rather than making a general recommendation to set limits he set a standard for polishing workshops of 200,000 particles per cubic foot (ppcf) on the basis that this could be attained in the better workshops.

Seven years later, in 1926, the final report of the National Safety Council (NSC) committee on benzol (benzene), chaired by Winslow, was published. His approach to benzene was very similar to his approach to dust in polishing shops. The process was investigated, the controls were examined

³ Apart from the asbestos "dust datum" which although used in developing control recommendations appears not to have been used that much to check on compliance. There were also real problem with the degree of protection offered by this standard (see Footnote 4).

and ranked in terms of effectiveness and air sampling was performed. By these measures Winslow was able to identify the most effective types of control and to state, with some certainty, what exposure levels would occur if the better controls were applied. But this time the medical evidence showed that over one fifth of people, even with the best controls, would be affected.

Winslow could not identify a benzene exposure level which was both safe and attainable, an age old dilemma. His committee emphasised that good controls could reduce exposure to 100ppm and this value became the *de facto* limit although it was clear, at the time, that this exposure level was by no means 'safe'⁴.

3.5.3 Early OEL lists One of the first lists of exposure limits was published by the German toxicologist Kobert in 1912 but, with no IH profession to use and promulgate them, it appears that they were not widely used. In the USA the nascent IH profession grew and various lists of OELs were published in the 1930s (see, for instance, Sayer and Dallavalle (1935)). No equivalent profession or OELs were developed in the UK. In 1938, in the USA, the National Conference of Governmental Industrial Hygienists (NCGIH⁵) 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 and, drawing on Warren Cook's compilation of OELs (see Cook (1945)), 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 IHs in the USA needed standards, OELs, to work to, and the ACGIH provided them.

4.0 ACGIH TLVs TLVs have been, and still are, the most influential OELs 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. The name given to these OELs, the way that they have been set and presented, and the way that they have been defined and defended from attack, all have current relevance to the OEL Framework debate in the UK.

4.1 TLVs in historical context The occupational hygiene profession started in the USA, taking organisational form as the ACGIH and AIHA in the late 1930s, but developing from small beginnings for at least two decades beforehand. In the 1930s industrial toxicology hardly existed and the main concerns substances wise were primarily their acute effects. It was the hygienists, assisted by a few early industrial toxicologists, who moved people's concern to encompass chronic effects caused by long-term exposures. And it was they who introduced, and more importantly, applied OELs as benchmarks of control success. The ACGIH TLV Committee evolved out of this period of innovation and it is important to understand the industrial world in which the Committee operated. Little systematic work had been done on measurement of exposure or on applying controls, such as local exhaust ventilation, to industrial processes. In the main,

⁴ In effect, a similar compromised occurred in the UK five years later, in one of the few instances where the UK Factory Inspectorate mentions and used a dust standard. In discussions surrounding the 1931 Asbestos Regulations there was reference to a "*Dust datum*", the relatively low level of dust generated by "fly spinning", and this was used by a committee on dust control as a benchmark. But, as the Chief Inspector of Factories wrote at the time, "*This opinion (that no dust control was needed for exposures below the "dust datum") is necessarily based on one important assumption, namely, the existence of a critical limit of dust concentration below which workers may be employed without injury to health*" (Bellhouse, 1931). As it turned out, in this case, the "...critical limit of dust" not only didn't protect people from the disease connected with asbestos exposure at the time i.e. asbestosis. But neither did it protect people from the various cancers induced by asbestos which were not recognised as being connected with asbestos exposure at the time. Bellhouse was right to be wary.

⁵ Later, in 1946, to be re-named the "American Conference of Governmental Industrial Hygienists" or ACGIH

where controls were applied, they were applied to prevent acute health effects. Chronic health effects caused by exposures to substances at work were hardly on anyone's radar. It was the US occupational hygienists, in the main, who publicised the issue and tried to develop and apply OELs which would protect against these effects. There were problems with what was actually done, as will be described, but it is important not to judge people working in the 1930s by the standards applied to chemical exposure nowadays. In the 1930s, the idea that it was possible to set standards which would protect against chronic health effects, and which should be applied, was new and the pioneering standard setters were feeling their way.

4.2 TLV definition The year after the first TLV list was published in 1946, Fairhall, the second chairman of the Committee on Threshold Limits (1947-1951), addressed the problem of defining the limits as follows:

“As I view the matter I would define the maximum allowable concentration value as that amount of gas, vapour, fume or dust which can be tolerated by man with no bodily discomfort nor impairment of bodily function, either immediately or after years of exposure” (ACGIH 1947).

Fairhall's definition is absolute; TLVs (or MACs as they were called in 1947) were health-based OELs which not only protect exposed individuals' health now, but also offer protection after many years of exposure. But these standards needed to be applied in practice, and Fairhall had to deal with the question of practicability, which he did later in his report:

There is also one further point I should mention, although it is rather obvious. That is the necessity for preserving a balance between a suitable maximum allowable concentration value and the effect of attaining this value upon the manufacturing operation or process itself (ACGIH 1947).

Fairhall's dilemma echoes that of Winslow but his views on the protective nature of TLVs were typical of the time. Elkins, who was a member the Committee in the early days and was to be the sixth Chair of the Threshold Limits Committee, summarised his early views on the level of risk at the MAC value in a figure reproduced here as Figure 1. His belief, and the explicit claim exemplified by Figure 1, was that MACs protected the health of **all** people exposed at the MAC level.

4.2.1 The TLV presentational message From 1946 to 1952 the TLV list was published, with no comment, as a simple table of numbers. Calling them “*threshold limit values*” and publishing them as a bald table of numbers conveyed a strong symbolic message. The title and the single numbers invited the reader to believe that the values were “thresholds” and that exposures below these values were safe. Almost immediately the ACGIH was criticised for conveying this impression (Yant 1948) and again a year later for using such words as ‘maximum’ and ‘allowable’ (Smyth 1950). Smyth made the same points again in the mid-1950s in a long paper with some very cogent criticisms of ACGIH TLVs. He objected to tables of figures with no information on how the Committee arrived at the numbers listed, saying that: “no oracular or *ex cathedra* statement on health deserves serious attention” (Smyth 1956).

4.2.2 The TLV Preface Seven years after the first table of limits was published a Preface was added in 1953, but this only served to reinforce the implicit message of the table. TLVs are described as levels to which workers could be exposed “*without injury to health*” (ACGIH 1953). The full Preface is reproduced in Appendix 1. It makes interesting reading and some of the phrases are used by other OEL setting committees to this day.

The wording of the Preface and the effect of single numbers meant that the user was almost bound to ascribe a magical quality to the numbers and to do just what the Committee warned against, and what Smyth feared was happening; most, if not all, people using TLVs believed that exposures below the TLV were safe and that exposures above them were dangerous.

Five years after the first Preface was published it was rewritten to cope with complaints and misunderstanding and with the “...*apparent confusion which has developed in respect of the interpretation of TLVs*” (ACGIH 1958). The new Preface tried to clear up this confusion by taking a sentence from the earlier Preface and making it the first sentence of the new Preface: “*Threshold limits should be used as guides in the control of health hazards and should not be regarded as fine lines between safe and dangerous concentrations*” (ACGIH 1958). And the next sentence, which has had very similar wordings since 1958 to the present day, and which words are often used by other OEL setting committees, defined the protection offered by TLVs:

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

Protection is not promised for all workers, as in the first Preface in 1953 but to “nearly” all workers. The one word, “nearly”, could be seen as an important shift in the TLV definition. This all depends upon how one defines the word “nearly”. It is suitably vague and, together with a tabular TLV list, probably did little at the time to change the message conveyed to most TLV users. After all, ‘nearly’ can mean ‘most’ and ‘most’ can soon come to mean ‘all’ apart from those that are, in some way, very “sensitive”. For the Committee itself, the phrase probably did not have any exact meaning at first except to say that ‘some people’ would be affected in some way when exposed at and below the TLV to some substances. As long as ‘nearly all’ was not defined, the Committee could rely upon most users interpreting the phrase as meaning small to vanishingly small and many did and still do so.

Apart from the ‘nearly all’ phrase and the almost obligatory ‘fine lines’ disclaimer, there was another significant addition to the second Preface and that was a sentence emphasising it was, “*enlightened industrial hygiene practice*” to work to below the TLV value (ACGIH 1958). Nowadays this general exhortation has been changed to:

“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)

It is not exactly the same as the UK phrase “*as far as is reasonably practicable*” but the message is similar.

4.3 What are TLVs?

In reality many, if not most, TLVs have been set to take into account the practicability of the controls and to balance these against the evidence of harm and there is a variety of evidence to support this claim, which is summarised in Appendix 2. 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.

4.4 That was then, this is now

The majority of TLVs were ‘reasonably practicable’ - the potential risks to health have been balanced against the practicabilities of control. However, the analysis outlined in Appendix 2 covers the first four decades of TLVs and since that time things

might have changed. Certainly since the mid-1980s, when the Committee came under severe criticism from people like Castleman and Ziem, the number of industry “Consultants” on the Committee decreased from 40% to <20% (mid-1980s). Also my impression is that several recent TLVs have been set towards the harder end of the reasonably practicable spectrum.

Originally the Committee acted almost as a surrogate Federal OEL setting committee. Many of its most active members were employees of the US Federal Public Health Service (which became NIOSH in 1970 under the OSHA Act) and it was openly and publicly lobbied by the industries using or involved with substances under consideration. In 1970, when OSHA was formed the majority of the 1968 TLV list was taken and converted, without change, into Federal government Permissible Exposure Limits (PELs).

Although OSHA has had, and still has, real problems getting additional PELs onto the statute book this is the official route, in the USA, to create Federal OELs and has been for three decades. There is a sense in which, perhaps, the TLV Committee now feels a bit freer to choose less easily achievable OELs and can be more concerned with focusing on health effects evidence. As a result some of the more recent TLVs are probably set at the more stringent end of the reasonably practicable spectrum (see subsection 5.0). Even so, the majority of TLV values were set many years ago. Many of these Limits will be reasonably practicable numbers and a significant number will be extremely practicable if not difficult to exceed. In these instances, in practice, in most workplaces, with even minimum controls the TLV will not be exceeded. This conclusion is born out by what has been, in effect, a review by WATCH of some of the older TLVs (see Maureen Meldrum’s paper “Proposals for a definition of a limit value...”, (2001)).

4.5 Reviews of TLVs

WATCH has reviewed ~100 OESs (TLVs) in the last 10 years	For 80 the limit was reviewed In 20 cases a change to a MEL was recommended There remain ~350 OESs to review
Dutch led group are reviewing 168 of the “older” TLVs	15 were referred because they are probably genotoxic carcinogens 62 were based on inadequate data 26 were based on inadequate data and needed to be lower 6 were based on inadequate data but were probably OK 1 was set too low

Even if WATCH does not completely agree with the findings of the Dutch led review group the preliminary findings strongly suggest that a significant proportion of the the current OES (TLVs) numerical values should be reduced.

5.0 Reasonably practicable OELs While the last subsection focused on TLVs the same logic and lessons apply to almost all, if not all, OEL-setting committees. The proof of the pudding is in the OEL numbers. Generally, until recently, OEL values have been the same or similar values whatever the make-up of a committee and however it defines its OELs. It is important to separate out the written definitions and claims for the OELs, set by the various committees, from what has actually been happening in practice. Central to an accurate understanding is an appreciation of just what reasonably practicable OELs really are and an identification of what are the key factors that all committees must consider and deal with.

The slow rate of change coupled with the relatively small reductions in numerical value of TLVs has been presented as evidence that the TLVs are close to the 'threshold of effect'. This has reinforced the image that TLVs are more or less health-based OELs. Viewed from the standpoint of reasonable practicability, however, there is an additional and dominant reason for the low rate of change: the difficulties of controlling exposure down to a particular level for certain key Processes (see Figures 2 and 3). The problem will be familiar to UK standard setters. There is an almost standard pattern to the deliberations of a committee setting a reasonably practicable OEL which the following examples illustrate.

5.1 Rubber fume MEL Most, if not all, substances are used in, or generated by, a variety of processes and operations. If exposures are examined by process/operation a pattern is often evident. Figure 2 shows the distribution of rubber fume exposures, by common rubber industry Processes, which were known to ACTS in the mid-1980s. Standard setters have to struggle with sets of processes causing different ranges of exposures and yet insist upon setting a single number limit. These different exposure distributions are labelled Processes 1 - 3 in both Figures 2 and 3. Inevitably, the range of achievable levels for the Process causing the highest exposures, "Process 1" in the Figures, defines the terms of the debate. In the case of rubber fume the process causing the highest exposures was "General Rubber Goods" curing involving manual press work. Excessive rubber fume exposure was known to increase the risk of lung (and possibly other) cancers but there were no dose-response data. In these circumstances the level to which General Rubber Goods rubber fume exposure could be reduced determined the "Control Limit" eventually set. The initial limit was 0.75 mg/m^3 , but it was agreed that this would fall to the current limit of 0.6 mg/m^3 some two years later giving the industry time to cope and apply controls to processes which had never had controls applied before. Will the present rubber fume MEL of 0.6 mg/m^3 prevent the lung cancer risk? Past exposures with no controls could exceed $3 - 4 \text{ mg/m}^3$. A MEL of 0.6 mg/m^3 , if complied with, represents a five fold drop in exposure and some companies work to half the MEL which would make the fall in exposure ten fold. This drop in exposure may be enough to reduce the risk to low levels but only further epidemiology will tell whether the risk has been adequately controlled.

5.2 Styrene MEL 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, ACTS 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 and none of the parties on ACTS made great play of styrene's health effects. With no strong evidence for dose-related health effects, ACTS, and ACGIH before it, was almost cut loose from considering risk - the evidence wasn't there. The committees focused on practicability of control and these issues hadn't changed that much between 1957 and 1984 - boat building was still "Process 1" (see 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 spectrum⁶. The factors which pinned ACTS and the ACGIH Committees to coming to the same decision and the same OEL number⁷ hadn't changed in 27 years. Unless large boat builders stop using open moulding processes the exposure range, from within which a reasonably practicable styrene OEL can be chosen, will continue to be determined by this Process.

⁶ Within-hull lamination, where people work, in effect, in enclosed spaces, can cause exposures of several hundred ppm and all committees accept that RPE/BA needs to worn. It was accepted that this category of work shouldn't determine the OEL number and it was put on one side and treated as a special case.

⁷ More recently the styrene TLV has been reduced to 50 ppm and the European styrenated resin manufacturers association accept that this is a feasible exposure level

5.3 Reasonably practicable OELs - some implications

5.3.1 Range of choice is limited Figures 2 and 3 represent the reality of the work environment facing any OEL Committee wishing to set reasonably practicable limits. The reason why certain processes or operations become the focus of attention is clear. "Process 1" in the Figures causes the highest exposures. Exactly where the OEL is set will depend upon how the OEL 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 number lower than that which can be achieved by the best control methods applied to Process 1 is set then, automatically, a proportion of companies undertaking Process 1 type production will not be in compliance with the standard. No standard setting committee sets OELs which are impossible to comply with. Unless the companies involved fundamentally change Process 1, or develop much more effective controls, they would, in this instance, always be out of compliance.

5.3.2 Measured exposures are usually below, and in compliance with, the OEL

The reasonably practicable nature of many OEL also explains why, when OELs are reduced, the reductions are rarely large (Mendeloff 1988) and when exposures are measured they rarely exceed OELs. The latter effect was noted by Senn in 1995 and has been found by HSE Specialist OH Inspectors using the National Exposure Database (NEDB). For many processes measured exposures are below published UK OELs whether MELs or OESs. This shouldn't be a surprise; by definition it has got to be the case if an OEL is to be "*...reasonably practicable for the whole spectrum of work activities in*". If an OEL (MEL or OES) is set to be achievable by the majority of companies using or generating a particular substance in the UK it follows that, when exposures are measured, most of the results are, indeed, found to be below the OEL. It is a form of tautology but it has more meaning and effect than simply being a circular argument. People use OELs as definitive benchmarks of risk - below the limit is "safe" and above it is "dangerous". More importantly, companies and HSE inspectors use OELs as standards to judge compliance - as performance standards.

5.3.3 Reasonably practicable OELs can be "technology (un)forcing" If people rely upon sampling results to indicate whether controls are adequate or not then, for all companies running processes other than "Process 1" type processes (Figures 2 and 3), the OELs will confirm, in most instances, that control, however minimal, is adequate. They will already be working at exposures well **below** the OEL. The Americans coined the idea of some standards being "technology forcing". Such standards are difficult to achieve because they are set at levels well below current achievable values. They result, if properly applied, in the development of new and innovative control solutions. In the main "reasonably practicable" OELs are what might be termed "technology unforcing" - they tend to inhibit and suck the momentum out of any attempt to reduce exposure and to develop more reliable and effective controls for exposures other than those defined by "Process 1" (Figures 2 and 3). This matters when the evidence suggests that there are potential and significant health effects at lower exposure levels than the OELs.

Some other effects of single number, reasonably practicable, OELs are summarised in Appendix 3. The tension between wanting to set a standard which protects health, which exercises some control over the highest exposures, and which, at the same time, can be complied with was evident in the early work of sanitary engineers in the United States. The same unresolved dilemma exists today.

6.0 OELs and control of exposure to substances hazardous to health in the UK

How did we get to where we are today? Figure 4 summarises some of the relevant events in the use and development of OELs in the UK.

6.1 Use of TLVs in the UK

In 1959 the ACGIH Committee received a “...request from the British Embassy to publish the (TLV) list in a table to be included in a new publication of the British Department of Safety, Health and Welfare”. ACGIH agreed as long as the TLV list was published in its entirety and the first set of TLVs was published in 1960 in a Ministry of Labour pamphlet entitled “*Toxic Substances in Factory Atmospheres*”. Apart from general advice on how air contaminants could be controlled the booklet contained a section on “*Permissible Concentrations*” which included the following:

“While systems of control should be as effective as it is practicable to make them, it is desirable to have some guide to which the efficiency of control can be related ... For each substance a figure of concentration in atmosphere is given. If this concentration is exceeded, further action is necessary to achieve satisfactory working conditions” (MoL, 1960) Author’s emphasis.

The Factory Acts, from 1947 onwards, contained a general regulation requiring employers to apply exhaust ventilation control as close as possible to the source where airborne concentrations of substances were judged to be “*injurious to health*” or were what was described as “*offensive*”. But, as with all specification type standards there was the problem of knowing whether the controls were effective enough. How would a designer or employer know? But this time, unlike in the early 1900s when Legge and Duckering worked, there was a ready made source of standards. The intention of the Factory Inspectorate in 1960 was to use the ACGIH TLVs as “*guide(s) to which the efficiency of control can be related*” - as the standards by which the effectiveness of air contaminant controls would be judged.

6.2 UK OEL lists

The TLV list was published each year by the Factory Inspectorate until 1969 when the first UK OEL was added in the form of the 2 fibre/ml chrysotile limit developed by the British Occupational Hygiene Society (BOHS). HSE came into being in 1974 and ACTS in 1977 and the number of additional OELs developed in the UK had increased to eleven by 1980. The ACGIH list and the additional UK OELs were published in Guidance Note EH15 but publication stopped in 1980 and there was a four year hiatus until 1984 when EH40 appeared. In the interim the names of the OELs had changed. The UK OELs had become “*Control Limits*” and the ACGIH list of TLVs had been renamed *Recommended Limits*”. The two types of limit had different definitions. Control Limits were judged to “*...be reasonably practicable for the whole spectrum of work activities in Great Britain...and should not normally be exceeded*”. Recommended Limits “*...are considered to represent good practice and realistic criteria for control of exposure, plant design (and) engineering controls...*”.

6.2.1 COSHH in the 1980s - in the balance

Throughout most of the 1980s the Control of Substances Hazardous to Health or COSHH Regulations were being developed. As part of the negotiations it was agreed that two types of OEL would be included in the Regulations; Maximum Exposure Limits (MELs) and Occupational Exposure Standards (OESs). The COSHH Regulations were finalised and agreed by Parliament in 1988 and came into force in 1989. Guidance Note EH40/89 lists the first MELs and OESs. By 1989 ACTS had agreed 29 Control Limits and these were converted directly into 29 MELs. The definitions of Control Limits and MELs were and are similar. Most of the Recommended Limits were converted into OESs but the

definition was also changed. OESs were defined as being limits for which “...*there is not evidence that it (the OES) is likely to be injurious...*”. Later, when the Indicative Criteria were published, the definition of OESs indicated that they were, in effect, ‘safe’ levels of exposure. But, borrowing an evocative phrase from the ACGIH TLV Preface, they were not safe for all people exposed but for “*nearly all*”, although what proportion would be affected and to what extent has never been defined.

6.3 The origin of MELs and OESs

6.3.1 Control Limits - the answer to the inspector’s prayer?

TLVs

were useful and were used by FI/HSE Chemical Inspectors and some of the larger companies but they had no force in law. Also, under the Factories Act 1961 (Section 63), the fact that exposure exceeded the TLV value was useful evidence but inspectors usually needed to prove to the court that the exposure measured was liable to be “*injurious to health*”. To do this he or she had to get a Employment Medical Advisory Service (EMAS) doctor to attend court as an expert witness. Quite a few doctors did not feel that they had the detailed expertise and knowledge to do this and courts, as I understand it, quite often asked whether the exposures on the day of measurement would cause harm which was a very difficult, if not impossible, question to answer unequivocally. The idea of sustained exposures and potential harm was difficult to get across.

The upshot of these evidence and enforcement problems was that very few Section 63 cases, whether citing TLVs or not, were taken. This was recognised as a problem by the Factory Inspectorate (FI) in HSE in the 1970s and inspectors wanted OELs which had greater status and force in law and were easier to present in court. When ACTS was formed in 1977 the HSE factory inspectorate got some of what it wanted - “Control Limits”. These were set by a tripartite system and were accepted by all sides of industry, there was an AFAIRP requirement and it had been agreed with EMAS that if exposures greater than the Control Limit could be demonstrated then EMAS doctors would support prosecution⁸. At last FI inspectors had a small number of OELs with teeth and some guidance levels, published in EH40 from 1984, in the form of Recommended Limits, (ex-TLVs). This wasn’t an ideal arrangement, because Recommended Limits had less status in law but it was better, from the inspectors viewpoint, than what they had had before. The arrangement was, initially, the product of a pragmatic compromise which may have made sense at the time. What happened next, in my opinion, did not make sense and has distorted the development of OELs, and public perception of chemical risk, ever since.

6.3.2 Redefined OELs - the price for COSHH?

The first draft of the COSHH

Regulations was written in the early 1980s. There was a lot of consultation and involved negotiations and it took until 1987 for the CBI and TUC to agree the Draft Regulations. They were far more comprehensive than anything that had gone before. Part of the price for the CBI to agree to the Regulations was the continuation of the two types of OEL system but with an important change: the definition of Control Limits and MELs was left more or less the same but Recommended Limits were to be renamed Occupational Exposure Standards (OESs) and were to be redefined as “no effect” ‘safe’ levels. Some in the CBI described them as “*walk-away*” limits - once you reached them you didn’t have to do anything more. By definition, although exposed at and, indeed, above the OES, people were “safe”. There was a lot of debate within HSE and between the tripartite partners and central to this was the status of TLVs as the proposal was, in effect, converting reasonably practicable TLVs into “health-based” OELs. For whatever reasons, and no doubt the arguments were finely balanced, it was decided that OESs were a price worth paying to get the COSHH Regulations. Initially, in my opinion, this was indeed the case. The

⁸ Whether this agreement was ever put to the test I don’t know

COSHH Regulations did make industry take exposure to and control of exposure to chemical substances far more seriously. But, as time has gone by, the MEL/OES system and particularly the definition and description of OESs has become less and less tenable and, potentially, more and more harmful to HSE's goal of obtaining effective control of exposure to substances hazardous to health.

7.0 The impact of MELs and OESs The MEL/OES system has had a range of impacts on the way people, including HSE staff, view toxic substances, the standard setting process and the control of people's exposure to substances hazardous to health.

7.1 The universe of toxic substances MELs are seen, by all parties, as reserved for substances which are more 'dangerous' and to which exposure is more serious, compared with substances with OESs. This perception shows itself in the priority inspectors and HSE Sectors give to substances with MELs; the way industries negotiate when a substance they use is likely to be assigned a MEL and the way some industry sectors (eg offshore companies) avoid substances with MELs. While it is easier, as an inspector, to obtain the attention of companies and get improvements in control for MEL substances the rather black and white world of toxic substances the MEL/OES system has created is, in my opinion, a distortion of reality. It is incorrect to view all chemicals as toxic and capable of causing significant harm, and it is important to relate risk to the degree of exposure which actually occurs. In reality, the universe of toxic substances will be populated by some substances which cause serious health effects at relatively low levels of exposure, some middling bad actors which can cause serious health effects at 'high' exposures and others with a range of effects grading down to more or less innocuous. MELs don't cover all substances causing significant and serious health effects and OES don't only cover what might be described as "low risk materials". The universe of chemicals is unlikely to be divided neatly into mainly innocuous substances with a few 'bad apples'. That view is too neat and too unlikely, but it is encouraged and reinforced by the current system to the detriment of a clear view and understanding of substances hazardous to health and of how to effectively control exposure to them.

7.2 The MEL-OES dilemma As time has gone by, and the idea that MELs are only set for substances which cause quite serious harm (however defined) has grown, WATCH has not been able to recommend MELs for an increasing number of substances. The No Observed Affect Exposure Level (NOAEL) could not be identified, often because the evidence was not available, and therefore an OES could not be set but the substance wasn't clearly 'nasty' enough to warrant a MEL. The operation of the MEL/OES system since 1989 has continually reinforced the "MELs are reserved for only really 'nasty' substances" view of the toxic substances world and this has fed back into WATCH's deliberations. It may be that WATCH has, with time, got more nervous about setting 'safe' exposure levels, but the fundamental problem is with the spurious dichotomy that the MEL-OES division creates.

7.3 "But we are below the limit" Exposure measurement is not done routinely, but when it is done the exposures, for many processes are found to be below the relevant OEL. This effect has been mentioned before but is a point worth emphasising. MELs and OESs are set to be reasonably practicable for the full spectrum of industries in the UK. By definition the majority of people's exposures will be below the MEL and the OES value (see Figures 2 and 3). With MELs there is always the AFAIRP requirement, although exactly what might be a reasonably practicable exposure level is usually difficult to pin down. For OESs, as long as the employer meets the OES, no further action is required. The definition of the OES means that the employer can argue, quite correctly, that as no health effects will occur at exposures below the Standard, why should more time and resource be spent on reducing exposure any further? The problem here is that OESs are, in the main, recycled TLVs and as many of these are reasonably practicable OELs then one would expect

to see health effects at exposures below some, possibly quite a few, of the OESs. Yet exposure measurement will show that exposure, in many instances, are below the OES.

7.4 Health effects at exposures below the OES - the implications

By

definition one would expect some people to suffer ill health at exposures below MELs, that's why there is an explicit requirement to reduce exposures below MELs. The review of TLVs, described in subsection 4.0, indicates that, for a significant minority of substances, health effects are likely to occur at exposures below the relevant TLV. The WATCH programme and the Dutch-led initiative also indicate that some TLVs (OESs) were not well founded and a significant number were set too high to protect health. This doesn't mean that all current OESs (TLVs) are what might be described as "unsafe", but it does suggest that some have been and still are "unsafe". People's health will have been affected but employers may have been misled by the description and definition of OESs. This is a serious state of affairs. While it might have been a price worth paying to get the COSHH Regulations on the statute book in the first place, it is not, in my opinion, a price that we and the people exposed to substances with OESs should still be paying over ten years later.

7.5 Inspection and enforcement

The MEL/OES system has probably been biased if not distorted HSE's inspection priorities. Sector and Operational inspectors, along with most other parties, have taken the 'MELs are for the really dangerous substances' message onboard. It shapes Sector thinking and priorities and this, in turn, shapes FOD (and other Directorate) plans. As was made clear in subsection 7.1, in the "Universe of toxic substances" this view is a distortion of the reality of toxic substances and their effects on health. As for enforcement (mainly Improvement Notices (INs)), inspectors follow FOD Sector guidance and focus on substances with, or processes involving, MELs. Robin Tarry's paper on the enforcement of OELs shows this to be the case. It occurs not so much because HSE inspectors arrange for lots of air sampling to be done but because the MEL is taken to be a signifier of seriousness. Within limits, given the requirement to reduce exposures below MELs AFAIRP, the inspector doesn't have to demonstrate exposures that are at or above the MEL. He or she knows the substance has a MEL and that means that serious health effects could occur and he or she makes a judgement on the adequacy of exposure controls. The judgement may be made based on the first principles of control e.g simple ways of getting better performance from an exhaust ventilation system. Or the judgement may be made against Sector/industry guidance on good practice for the particular process.

Both of these mechanisms, Sector priorities and guidance and relative ease of enforcement, mean that inspectors enforce far more often against substances with MELs. The converse applies to substances with OESs - they don't receive the same attention.

The OES definition together with the Indicative Criteria, taken at face value, promise that the OES number is a 'safe' level of exposure. In law, all that an employer has to do is reach the OES exposure level, there is no AFAIRP requirement. This tends to put the onus on the inspector to demonstrate that exposures exceed the OES. This is a time and resource consuming process and often, when attempted, undermines any push by the inspector to improve control standards. As the majority of OESs are old TLVs and a significant proportion of TLVs are reasonably practicable OELs "*for the whole spectrum of work activities in the (USA)*" most exposures are **below** the OES and this is what HSE Specialist OH Inspectors usually find. Depending on the process some of us strongly urge the operational inspectors **not** to ask for measurements of exposure when OES substances are involved, but to rely on bluff and persuasion. However, this is not a strong or satisfactory position to be in, especially as health effects are likely for a significant number of OES substances at levels below the OES values.

The messages and meaning that the OES definition generates, its description in law and the fact that most processes cause exposures below the OES all conspire to undermine the enforcement effort of HSE inspectors. OESs may not be quite “*walk away limits*”, but sometimes they are close and there are probably quite a few substances, and circumstances, that we shouldn’t be walking away from.

Experienced inspectors know the problems with OES substances and they tend to use persuasion and bluff to obtain control improvements but they are rarely able to take formal enforcement action.

8.0 Discussion

There are lessons to be learned from past OEL setting, regulatory approaches and attempts to control health effects arising from exposure to chemicals. I would like to start with some discussion of what the TLV Committee probably thought it was doing when it set TLVs. This shines a light on the status of TLVs and it’s probable, if other OEL committees have been thinking along similar lines, that the discussion will illuminate the thinking of all OEL-setting committees.

8.1 Health-based or health-related OELs

Figure 5 reproduces the classic dose-response curves which are used to describe the relationship between exposure (dose) and toxic effect. The Figure is taken from a paper by Stokinger⁹ in which he explains how the ACGIH TLV Committee works and what it aims to do. The Dose-Response (D-)R curves illustrate how Stokinger thought about the world of human health and toxic substances. 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. Hatch illustrated these ideas well in a lecture to a group of occupational physicians (Figure 6) in 1968. Neither of the models in Figures 5 and 6 show a population response, but others do. The Figures show us how Stokinger and Hatch thought about toxic substances and what they, especially Stokinger, thought that they were doing when TLVs were set. Elkins, who was involved from the early days of the TLV Committee, at the start of his TLV work appeared to think that the MACs (later renamed TLVs) selected would protect the health of all those exposed (see Figure 1). This probably explains the absolute wording of the first TLV Preface in 1953 (see Appendix 1). From Stokinger’s writings it is clear that he really did believe his Committee was setting TLVs at, or below, the “threshold dose”.

The problem that has bedevilled a clear understanding of what the TLV Committee (and other equivalent committees) have been doing is that there has been a mis-match between what they said they were doing, and believed they were doing, and what they actually did. There is a sense in which the D-R curve coming to the threshold dose, shown in Figure 5, is a model of what Stokinger, his Committee, and many other OELs committees would have **liked** to have been able to do. They would have liked to set OELs low enough so that there were no significant health effects amongst people exposed “*day after day*”, i.e. that their exposure would be below the threshold dose. In practice they had to face the actual exposures which were occurring and take advice on, or work out, how far exposures could be reduced for “Process 1” type processes. A compromise had to be made between the evidence of health effects and the practicability of control for many TLVs and other OELs. It is an old compromise (see subsection 3.5) and not something to be ashamed of, but it must be clearly described for what it is. Things become very confused and potentially dangerous

⁹ Stokinger was the longest serving and most productive Chair of the TLV Committee. He was also the Head of Toxicology for the US PHS during his entire tenure as TLV Committee Chair.

if committees set, in effect, reasonably practicable OELs which take into account health effects but do not protect all exposed, and then **subsequently claim**, either explicitly or implicitly, that they are solely health-based limits and offer complete protection. Or, the committee setting the standards allow others to see their OELs and to use them as if they were solely health-based. Whichever way it happens, the confusion causes people to walk away from exposures which will be causing harm to some, in some cases possibly many, people because the exposures are less than the OEL and yet the claim, or, at least the belief is that everyone's health is protected.

If OELs are health-related, in that they offer some protection, it would help if the committees setting them could comment on what degree of protection is offered against what health effects. In practice the information on which to make such statements is rarely available and there is significant uncertainty surrounding the amount of protection offered by a particular OEL. That's why the ACGIH TLV and other committees include warnings to the professionals using their OELs that "...the best practice is to maintain concentrations of all atmospheric contaminants as low as is practical..." (ACGIH 1996) or some similar wording. The professional occupational hygienist, or other person referring to the OEL, should understand the basis of the particular OEL he or she is applying or using¹⁰. In UK parlance it means that, in some way, the "reasonably practicable" balance has to be struck for many, if not most, substances and, in many cases it is a grave mistake to treat OELs as "*fine lines*" between 'safe' and 'dangerous' conditions. The \$64,000 question is how far below the OEL should exposure be reduced? The answer depends upon the patterns of exposure, the likely health outcomes and the strength of the evidence on health effects.

8.2 Names, definitions and messages - words matter All the early pioneers in occupational hygiene wanted health-related if not health-based OELs to work to and chose names that suggested that that's what had been delivered. The names chosen for the OELs included words such as "threshold" or "maximum". The OEL numbers were presented in tables without qualifications. When defined, certainly in the case of the TLVs, the definitions reinforced the name chosen for the standard - they were said to be set at the threshold of effect. They were safe exposure levels. The same powerful messages are projected by the words and definitions HSE uses in the UK for MELs and OESs.

The lessons I draw from history are that words and definitions have an important and deeply symbolic impact on all parties involved and they should be used very carefully and thoughtfully. In particular:

1 When health-related OELs are being set, which is most of the time, the name(s) chosen should be neutral and should not suggest that the OEL is solely health-based and "safe". Words such as "*Threshold*", "*Maximum*" or even "*Limit*" should be avoided and more neutral, even ambiguous, words used, for instance, "*Exposure value*".

2 Definitions should be clear, open and cautious and should not claim more for the OELs than can be truly asserted; i.e. we shouldn't put into the definitions what we would **like** to do, but in all honesty know isn't possible most of the time. We should learn the lessons of the analysis of the ACGIH TLV Committee's work.

8.3 Effective control of exposure and a role for OELs

¹⁰ Since 1958 the TLV Preface has emphasised that TLVs should only be used by those trained in the discipline of IH

8.3.1 Specification and performance standards re-visited Before OELs existed, standards for a process would, where they existed, be defined in terms of what controls and/or work practices needed to be applied. Such specification standards are easier to apply, audit or inspect than performance standards such as OELs. The problem is: how do you know whether the control arrangement specified is good enough? There is also the problem of specifying the controls for each and every process or operation involving hazardous substances. This was the attraction of an OEL performance standard for Duckering in the UK and the early industrial hygienists (IHs) in the USA. If the OEL was well founded, all that the regulator had to do was specify the standard (the OEL) and leave it to the employer to reach it by whatever control measures worked.

The problem is that employers don't use OELs and they don't often measure people's exposure and quite a few OELs will not normally be exceeded, even if employee exposure was measured. There is little pressure for improvement in the current system and not enough practical help for employers, especially small companies, trying to control employee exposure down to low risk levels.

8.3.2 Converting performance based OELs into specification control standards

What employers need is practical guidance on how to comply with OELs and what employees (and employers) need is confidence that the limits used as benchmarks of effective control really do protect health sufficiently. The trick, if there is one, is to convert the performance standards, the OELs, into specification standards in a similar way to COSHH Essentials operates (HSE, 1999). If the OEL is health-based and the evidence on which it is based is robust then it could be the exposure target to achieve. If the OEL is less securely based then some fraction of it could be used as the control exposure target to achieve. There are a number of historical examples to learn from, for instance, in the stone working and pottery industries. In both cases exhaust ventilation controls already existed, i.e. there were already specification standards in place, but people still contracted silicosis and that showed that the specified control measures were not good enough.

8.3.2.1 US granite workers In the USA, granite workers died of silicosis, and associated TB, despite the fact that LEV controls were applied. Hatch and Drinker first identified a *“threshold dose of permissible dustiness”* based on dose-response epidemiological studies done by the US PHS (Hatch et al, 1930). They examined the study and came to the conclusion that *“...it would appear that a safe limit lies somewhere between ...9 and 20 million particles per cubic foot of air”*- (mppcf) and chose 10 mppcf. The standard was used in two ways *“First, it helps to differentiate hazardous from safe processes; and second, it will serve as a criterion of operating efficiency in the development of the dust control system”*. They used the standard to identify the processes which could be ignored and those which caused the most significant exposures - pneumatic tools. They then went on to design and test improved LEV systems, using the 10 mppcf standard as the benchmark of effectiveness. They converted a performance standard into a set of exhaust ventilation design specifications.

8.3.2.2 UK pottery workers An even more sophisticated set of control measures were developed for pottery work in the UK in the 1960s. Again using the 10 mppcf standard as the benchmark of control success¹¹. Occupational hygienists employed by the British Ceramics Research Association (BCRA) were looking for controls which reliably reduced exposures to well below 10 mppcf. They developed effective sets of integrated controls for a range of standard pottery processes, which involved a range of innovative LEV designs coupled with defined working practices and the development of low dust retention/release workwear fabric. Once the control measures had been well proven and defined very little further air sampling was done by the pottery industry, or HSE, but checks were made on the control measures. These were codified in BCRA and HSE

¹¹ By this time Hatch's *“permissible dustiness”* level had become a TLV of 10 mppcf

publications and became industry (specification) standards. The 10 mppcf TLV enabled the BCRA to convert the OEL performance standard into a set of control based specification standards.

8.3.2.3 Developing standard solutions to standard problems On the face of it, it should be possible to develop standard sets of control solutions for standard industry processes and operations. In practice to do this well requires the right people with the right mix of skills, a committed industry (and HSE) and a clear and robust performance standard (OEL) to work to. Depending upon the substance, and the basis of the OEL, it may be necessary to work to some fraction of the OEL. Hatch et al knew that 20 mppcf would cause some silicosis and chose 10 mppcf as the control benchmark. Nowadays we know that sustained exposures at the respirable crystalline silica dust (RCSD) MEL of 0.3 mg/m³ (8-hour TWA) carry a significant risk of silicosis and HSE guidance recommends, because of this residual risk below the MEL, that people exposed above one-quarter of the MEL (0.075 mg/m³ (8-hour TWA)) should be under medical surveillance. The appropriate control benchmark for RCSD is 0.075 mg/m³. For other substances, choosing the appropriate control benchmark may not be so simple but, in my experience, it is not impossible and it certainly helps one in making essential judgements on the adequacy of control measures. Without a benchmark, or some other way of gauging the potential degree of risk, how does one know that control measures are good enough?

8.4 Good practice controls Is it possible to assess a set of control measures and know that exposures will have been brought well below the relevant OEL? For most Processes where exposures, in the main, are usually well below the “Process 1” spectrum (see Figures 2 and 3) the answer is “Yes, it is possible to say with some confidence that exposures will be well below the OEL”. The control measures applied to these Processes might be the appropriate “good practice controls” in the new proposed OEL Framework. The question of balancing knowledge of health effects and practicability is discussed further in Appendix 4 and will influence the degree of effort needed to achieve “good practice controls”.

8.5 Sliding definitions and hopeful perceptions One final point concerning risk from exposure at a standard which is judged to be “...*reasonably practicable for the whole spectrum of work activities...*”. And, in this instance, the standard is not for chemical exposure but for a physical hazard - noise. The 90 decibel (dB(A)) limit has a definition similar to that for any other reasonably practicable standard, such as Control Limits in the 1980s and MELs in the 1990s. Sustained exposures to 90 dB(A) are by no means risk free and >10% of people, so exposed, will suffer significant hearing loss - it’s not a “safe” exposure standard but we, and the people exposed, live with it. In practice, inspectors would be overjoyed if all of industry could get noise exposures down to 90 dB(A).

I believe that the ACGIH Threshold Limits Committee was in a similar position in the 1940s/50s. The Committee knew that TLVs would result in better controls being applied to the worst processes, but couldn’t resist the temptation to make exaggerated claims for their standards. The problem with the noise standard, in terms of awareness and presentation, is that many people including, I suspect, some inspectors, regard 90 dB(A) as, more or less, the safe noise exposure level. There is a behaviour pattern here. Once a ‘risky’ standard which is *reasonably practicable for the whole spectrum of work activities* is chosen people, after a while, forget the early caveats attached¹². They start to project what they **wish** was the case onto the standard and in the user’s mind’s-eye the definition changes from somewhat risky, to safe-enough and, ultimately, to safe.

¹² Another example of where this occurred was the BOHS asbestos “*hygiene standards*”. The standards were set to limit the risk of asbestosis and this was made clear in the documentation. But, after a while, some people used the limits as if they protected against both asbestosis and cancer.

This is a chronic problem with such standards and it is up to the regulatory authority in charge of the standard, and the professionals involved in applying it, to keep reminding people of the status of the standard and the need to work to achieve lower exposure levels. Not an easy, but a very essential, task.

8.6 Fear of femptograms and fibres

The fact that OELs which are set to be “...reasonably practicable for the whole spectrum of work activities...” does not automatically mean that significant health effects will occur at OEL exposure levels. See Appendix 4. The first vehement criticism of TLVs in the 1960s came from environmentalists and the tendency to claim that meaningful and real health effects can occur at very, very low exposures still tend to come from this quarter. Sometimes it seems as though people believe that a health effect will occur no matter how low the dose, whether it is one femptogram¹³ or one fibre. The relationship between dose and risk, according to this thinking, is completely lost and one is left in an almost magical, pre-scientific world, where real risk exists because the substance or element exists. While the new OEL-setting framework should not make unsustainable and overoptimistic claims it will be important, where the evidence is robust, to be clear about the likely dose-response relationships. It would also help, in my opinion, to produce a more reasoned and rational debate if HSE could move away from the current all-or-nothing classification of carcinogens. It is quite clear that not all carcinogens have the same mechanism of action and potency and similar arguments probably apply to sensitisers. The current all-or-nothing classifications reinforce the belief that toxic properties are inherent to the substance and not to the dose of the substance. While current regulations may require HSE to be rigid there’s nothing to stop the OEL setters, where they are able, being explicit on questions of potency, dose and risk.

8.7 Trust me, I’m a scientist/specialist

For the first couple of decades after the formation of the ACGIH TLV Committee it is probably fair to say that most people took the Committee’s pronouncements, uncritically, at face value. From the late 1960s onwards, when the environmental movement started in earnest, public trust in science and government policy makers has waned steadily and in the UK, after BSE and other events, there is far less trust in government pronouncements. This has come about for a variety of reasons, many of which have nothing to do with science, but we do now live in different times. In 2000 the Government’s then Chief Scientific Adviser (Sir Robert May) updated the Guidelines on “*Scientific Advice and Policy Making*” in his “Guidelines 2000”. What is different now from the ‘good old days’ when scientists were, apparently, implicitly trusted is that advice needs to be explicit and transparent and the public should be able to see the logic of the advisory committee’s thinking, including the areas where information is uncertain and the assumptions that have had to be made. One point that may be relevant to OEL setting that’s in the Guidelines, is the involvement of the right people including people from outside the Department, in preparing advice. This use of people from outside HSE is already practised and is one of the strengths of HSC’s tripartite system. There may be scope here to involve more appropriately qualified and experienced people from universities and other institutions and organisations with particular knowledge on specific issues/substances.

8.8 Audiences for OELs

Up until 1989 when the COSHH Regulations came into force the implicit assumption in the UK had been that OELs for use by health and safety professionals, primarily occupational hygienists. Since 1958 ACGIH has emphasised that people using TLVs should be trained in the discipline. It was only with coming into force of the COSHH Regulations that employers and employees, across the board, were supposed to understand and apply OELs. In retrospect this was an optimistic if not unnecessary, ambition. People do need to know about OELs but different groups need to know different things. The audiences for an OEL system, which is part

¹³ A millionth of a milligram

of a framework for effectively controlling exposure to substances hazardous to health, will want different things some of which are identifiable.

Possible needs of audiences	
Inspectors	<ul style="list-style-type: none"> • OELs which reliably reduce, but do not, necessarily, prevent all risk • OELs related to sets of control measures • OELs which are, where necessary, “technology forcing” • OELs which are enforceable due to their clear and careful definition and status in law
OH professionals	<ul style="list-style-type: none"> • An OEL system which is coherent and logical and (relatively) easy to follow and explain.
Large employers	<ul style="list-style-type: none"> • Something similar to the OH professionals
Small employers	<ul style="list-style-type: none"> • To know what control measures are needed
Employees	<ul style="list-style-type: none"> • Confidence that the OELs offer reasonable protection • A coherent and (relatively) easy to follow explanation of how the OEL system and associated guidance works • Knowledge of what control measures should be in place and that these will adequately protect their health

9.0 Final comment

There are no formal conclusions or recommendations in this paper. The ACTS is currently reviewing the UK OEL Framework and the exact details of any changes have yet to be decided. This paper provided some background information and is meant as a contribution to the debate.

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Appendix 1

The first TLV Preface

“Threshold Limit Values for 1953

*“Values are given in the following tabulation for the maximum average atmospheric concentration of contaminants to **which workers may be exposed for an eight-hour working day without injury to health.***

*These values are based on the best available information from industrial experience, from experimental studies, and, when possible, from a combination of the two. They are not fixed values but are reviewed annually by the Committee on Threshold Limits for changes, revisions or additions as further information becomes available. Threshold limits should be used as guides in the control of health hazards and should not be regarded as fine lines between safe and dangerous concentrations. **They represent conditions only within which it is felt that workers may be repeatedly exposed, day after day, without their health being adversely affected.** It is felt, at the present time, that workers should not be exposed to a working environment containing any of these substances in excess of the value indicated”. (Author’s emphasis)*

Published in “*Industrial Hygiene and Occupational Medicine*” (1953) Volume 4.
Pages 296 - 298

Appendix 2 What are TLVs?

1 Evidence used to set TLVs Through an analyses of the minutes of the TLV committee, it can be established that of the 354 TLVs set between 1962 and 1984, in about 40% of the cases industrial data was sought or supplied, and in 13% of cases the TLV was based mainly on data supplied by industry (Piney 1989: 151-2; 520-56). On the basis that no industry sets limits it cannot comply with, practicability will have been an important, if not a major, factor in the setting of between 13 and 40% of TLVs. This is a similar finding to that of Castleman & Ziem (1988).

2 Comparisons with other OELs Another way of getting some measure of how far TLVs are from being health-based is to compare the ACGIH list with the NIOSH Recommended Exposure Limits (RELs), which are supposed to be solely based on health risk assessment. A comparison of 86 pairs found the following:

REL > TLV 3

REL = TLV 33

REL < TLV 50

Not all NIOSH RELs are lower than ACGIH TLVs but the majority are. On average, RELs were 40% lower than TLVs (Piney 1989: 192-200).

A further way of assessing the status of TLVs is to compare them with standards which are highly likely to be achievable. A reasonably practicable OEL is a limit which has ostensibly been set by balancing risks to health against the perceived costs of control. Almost by definition, reasonably practicable OELs are standards which can be met by large swathes of industry. With such limits there may be significant residual risk at exposures below at least some of the limits. By 1956 the ACGIH had set 216 TLVs and Imperial Chemical Industries (ICI) in the UK had set 55 internal OELs from which 48 paired comparisons are possible. They break down as follows:

ICI OEL = TLV 15

ICI OEL > TLV 16

ICI OEL < TLV 17

There is considerable overlap between the two lists; roughly one-third of the TLVs are the same as ICI's internal OELs, one-third were lower and one-third were higher. Overall, TLVs were somewhat more stringent than ICI's in-house OELs, but the considerable overlap would indicate that, in 1956, TLVs were reasonably practicable OELs pitched towards the lower end of the spectrum of reasonable practicability.

4.2.3 Evidence of health effects at TLV level exposures Another way of discovering what type of OELs TLVs are is to systematically examine the evidence on which the Committee made its judgements. Smyth did this in 1956 and Henschler and co-workers did so as an internal exercise for the West German DFG Committee in 1984 (Henschler et al. 1984). Roach (1980); also Roach & Rappaport (1990) examined the Documentation of 612 substances with TLVs. One of his conclusions was:

“...that TLVs are generally higher than the no-effect threshold of many people and TLVs for irritant substances are particularly high.” (Roach 1980)

Appendix 3

Table 1 Some other effects of single number reasonable practicable OELs
<ul style="list-style-type: none"> • Facilitation Reasonably practicable OELs enable processes and industries to proceed or continue within certain constraints. They thus may facilitate the use of certain substances or processes.
<ul style="list-style-type: none"> • Safe-Dangerous They are part of a standard setting system which apparently controls risk adequately by means of single number limits. As such they limit debate to the discussion of single numbers and encourage the “fine lines” misconception - below the limit is ‘safe’ and above the limit is ‘dangerous’
<ul style="list-style-type: none"> • Inhibition Given their reasonably practicable nature, they: <ul style="list-style-type: none"> (a) inhibit the production of health-based OELs, and (b) conversely and perversely they inhibit the identification and promulgation of practically attainable exposure levels at processes and for uses which currently operate below the OEL (see Processes 2 and 3 in Figures 2 and 3). <p>Please note: The intention is not to imply that all current reasonably practicable OELs are above what one might describe as “health-based” or “safe enough” levels, but, for a significant proportion, there will be significant residual risk at exposure levels below current limits. If this is the case, and the evidence is strong that this is so, it means that exposures in a number of, possibly many, instances should be reduced to below, in some cases to well below, current OELs.</p>
<ul style="list-style-type: none"> • Restrict uncontrolled use They exert restrictions on the uncontrolled use of substances for those processes causing the highest exposures.
<ul style="list-style-type: none"> • Informal control They also probably induce a certain level of informal control, in that, simply by virtue of a substance having an OEL, especially if it is ‘low’, it tends to become regarded as ‘toxic’.
<ul style="list-style-type: none"> • Selective attention OELs concentrate attention on substances on OEL lists. Conversely, OEL lists deflect attention away from substances which are not listed. There is a tendency for people either to believe that a substance not on the list is not of concern or to be confused about its properties and potential health effects. Either way, there is a tendency not to take substances without OELs as seriously as those with OELs.

Appendix 4

Health effects evidence and practicability

Figure 7 shows a graphical way of describing the strength of evidence that health effects are likely. Figure 8 shows some of the relationships that might apply in practice where one wants to match the evidence on health effects against exposures caused by a variety of Processes. The Figure combines the “strength of evidence cone” from Figure 7 with the exposure models in Figures 2 and 3. Four relationships of strength of evidence against exposure (on the vertical axis) are shown and, undoubtedly there will be others. It would help OEL setting committees, in my opinion, if they could identify which relationship applies when setting an OEL for a particular substance.

The four relationships shown in Figure 8 are:

(A) Where all current Processes are causing exposures lower than any which should cause health effects. 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) is more typical.

(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 is the regulator’s, and employers’/employees’, nightmare.

(D) Where some evidence exists suggesting possible health effects across the full exposure ranges of current Processes. This is less common, but probably applies to some carcinogens.

Probably 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? Again one can probably apply the COSHH Essentials approach in some instances, but others will require more careful examination. It shouldn’t be assumed that the reasonably practicable exposures for Processes 2 and 3 are any fixed proportion of the current exposures. It may well be that the ranges found are the result of almost no controls being applied. Thus looking at the rubber fume and styrene examples in Figure 2 and 3, and assuming relationship (D) applied, it would probably be possible to run extrusion processes at below 0.1 mg/m^3 rubber fume and small mouldings at 10 ppm styrene. This isn’t to suggest that companies need to do lots of air sampling but it does indicate that relatively inexpensive control measures could reduce exposures to around these values. These are the sort of exposures which would occur by applying good practice controls.

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Figure 1

Taken from Elkins (1948)

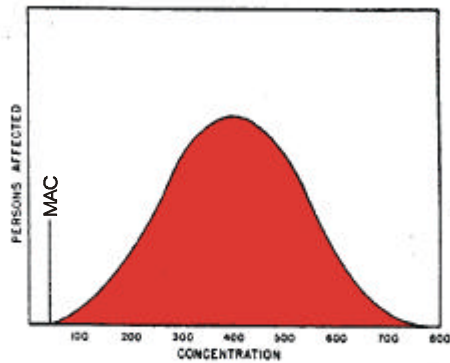


Fig. 1
Probability Curve of Percentage of Persons
Affected by Increasing Concentrations of Toxic
Substances. [Percentages not Cumulative]

The MACs (Maximum Allowable Concentrations),
apparently, protect **all** people exposed

Mark Pinye
Oct 2001

Figure 2

Rubber fume exposures in the
mid-1980s by process

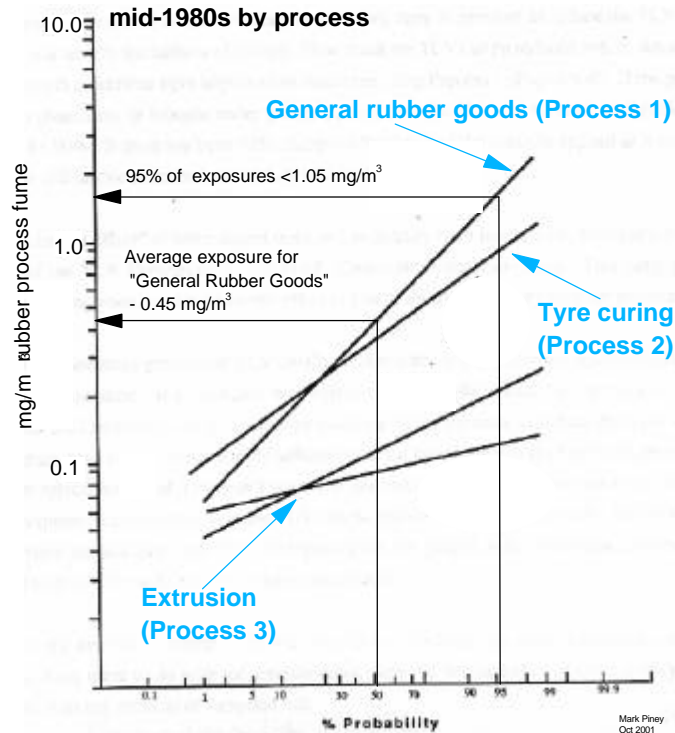


Figure 3

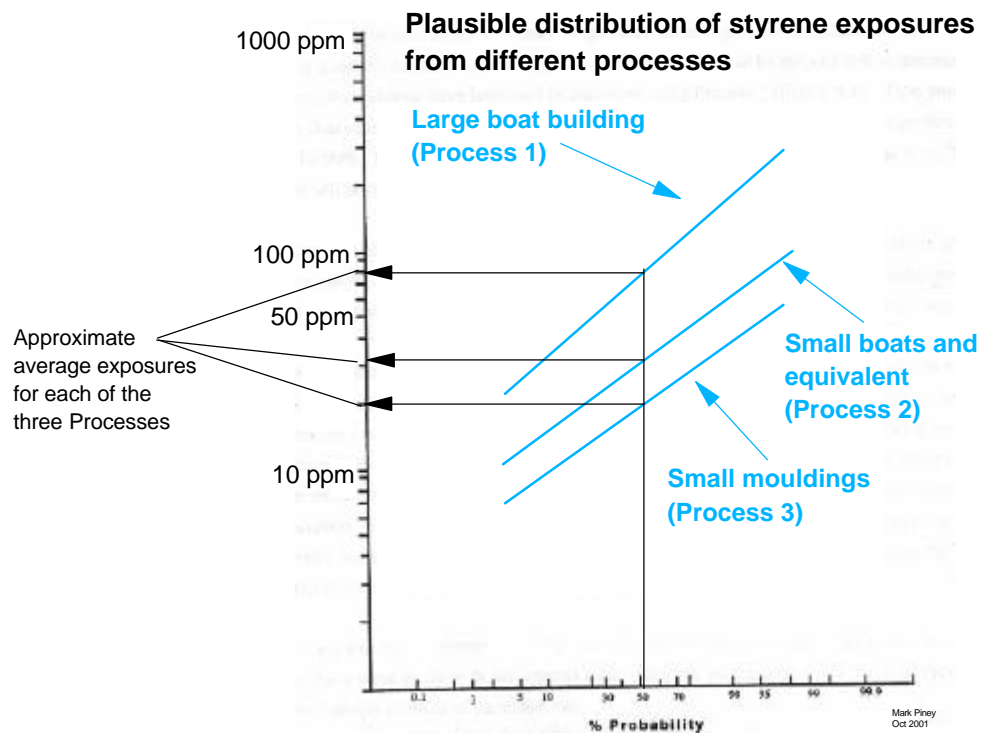


Figure 4 - OELs in the UK

- 1910** OELs first proposed in the UK by Duckering
- 1931** "Dust datum" standard used in development of Asbestos Regulations but not afterwards
- 1960** Ministry of Labour publishes ACGIH TLV list (initially in Safety Health and Welfare Series (No 8) and then in Technical Data Note (No 2))
- 1969** Asbestos Regulations refer to BOHS 2 fibre/ml chrysotile "Hygiene standard" published in 1968
- 1977** ACTS created. ACGIH TLV list, plus some UK OELs including some "Control Limits", published in Guidance Note EH15
- 1980** Last year that Guidance Note EH15 was published
- 1984** EH40 first published. Most TLVs are renamed "Recommended Limits" (definition "...good practice and realistic criteria")
"Control Limits" are listed separately (definition "...reasonably practicable for the whole spectrum of work activities in Great Britain")
- 1989** EH40 lists COSHH OELs
"Recommended Limits" redefined and renamed "Occupational Exposure Standards" (definition "...there is no evidence that it (the OES) is likely to be injurious")
"Control Limits" (X29) become "Maximum Exposure Limits" (MELs) (X29) with a similar definition to the originals

Figure 5

Theoretical dose-response curves

(amended slightly from Stokinger 1972)

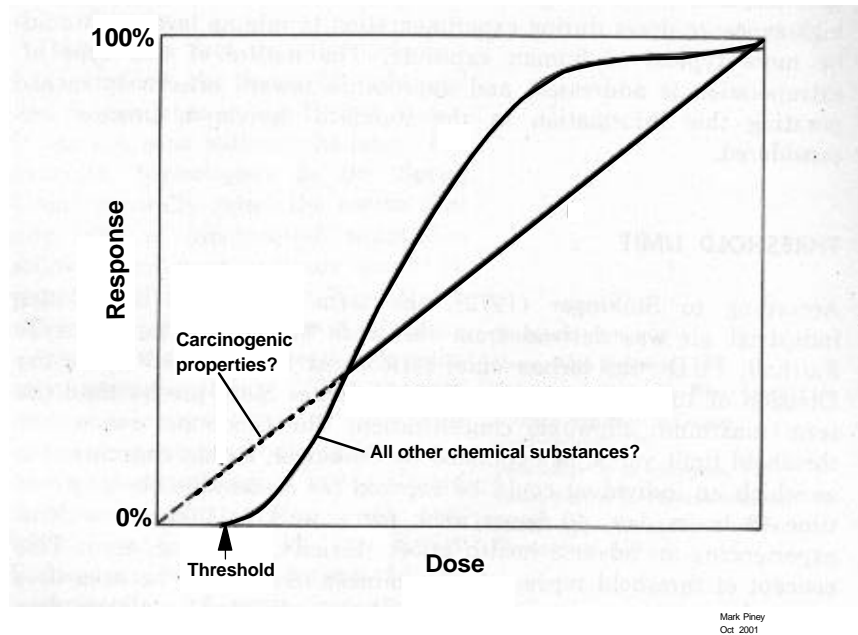


Figure 6 Impairment and disability

(taken from Hatch 1968)

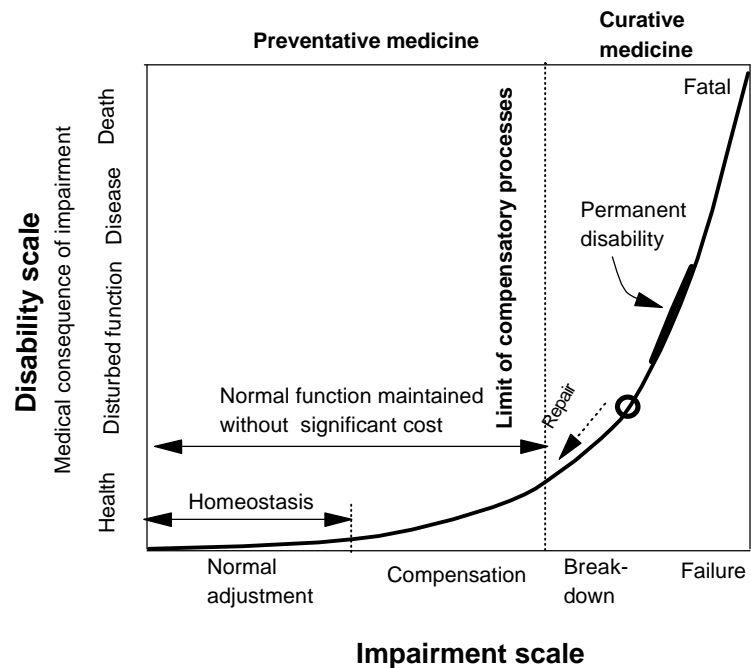
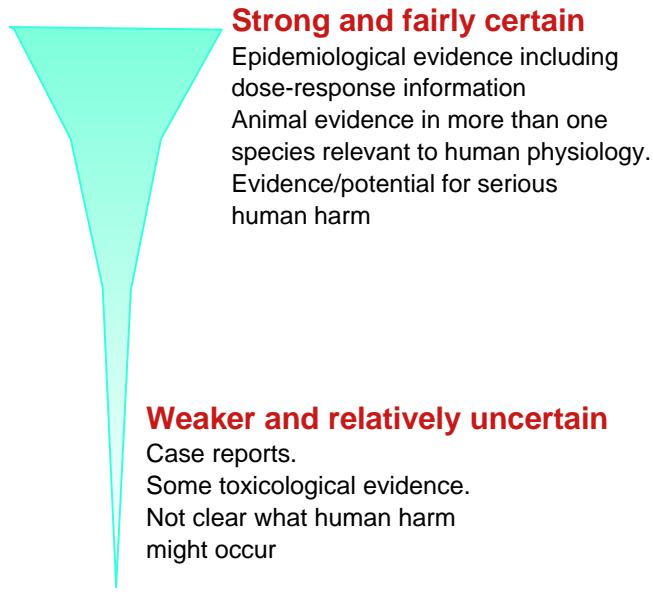
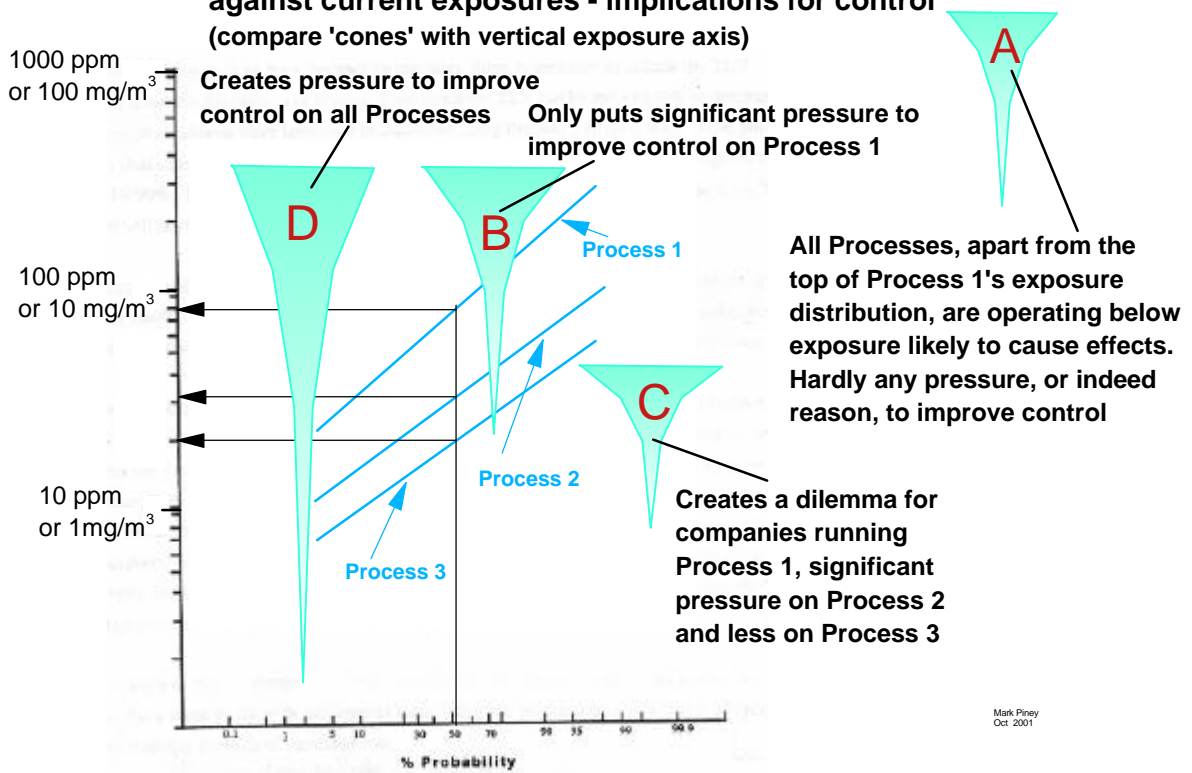


Figure 7 Strength of evidence 'cone' illustrating the type and certainty evidence on potential health effects



Mark Piney
 Oct 2001

Figure 8 Matching evidence of health effects/harm (see Fig 7) against current exposures - implications for control (compare 'cones' with vertical exposure axis)



Mark Piney
 Oct 2001